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RANDOMISED CLINICAL TRIAL OF FOUR DENTAL RESTORATIVE MATERIALS
[Silver Amalgam ‘Dispersalloy’, Compomer ‘Dyract AP’, Resin Modified Glass-Ionomer ‘Fuji II LC and Vitremer’]
PLACED IN CHILDREN

THESIS SUBMITTED FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN THE FACULTY OF MEDICINE
2005

Duaa E.I. Mustafa
BDS (Saudi Arabia), M.Clin.Dent (Eng)

EASTMAN DENTAL INSTITUTE AND HOSPITAL
FOR ORAL HEALTH CARE SCIENCES
UNIVERSITY OF LONDON
'Despite the great ease with which hard tooth tissue can be removed, an ideal material with which to restore this lost tissue has still to be discovered'

(Hollenback 1969).
Dedicated to the Children of the United Arab Emirates.
# Table of Contents

**TABLE OF CONTENTS** ........................................................................................................... 1

**LIST OF ABBREVIATIONS** ................................................................................................. 13

**LIST OF FIGURES** ............................................................................................................. 16

**LIST OF TABLES** ............................................................................................................... 18

**ABSTRACT** .......................................................................................................................... 21

**ACKNOWLEDGEMENTS** .................................................................................................... 23

**CHAPTER ONE. INTRODUCTION** .................................................................................... 24

Introduction ............................................................................................................................ 25

1.1. Aims of the Study ........................................................................................................... 29

**CHAPTER TWO. REVIEW OF THE LITERATURE: ASSESSMENT OF RESTORATIONS PLACED IN PRIMARY AND PERMANENT TEETH OF YOUNG PATIENTS** .......................................................................................................................... 30

Introduction ............................................................................................................................. 31

2.1. Tooth Morphology in Relation to Restorative Dentistry of the Young Patient ............ 32

2.2. Morphological Differences between Primary and Permanent Molars ................... 33

2.3. Dental Caries .................................................................................................................. 34

2.4. Caries in the Young Patient .......................................................................................... 38

2.5. Restorative Considerations in the Young Patient ....................................................... 40

2.6. Clinical Views on the Treatment of Approximal Caries ........................................... 41

2.7. Restorative Materials for the Young Patient ............................................................... 43

2.7.1. Dental Amalgam ........................................................................................................ 45
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7.1.1. History and Development</td>
<td>45</td>
</tr>
<tr>
<td>2.7.1.2. Composition</td>
<td>46</td>
</tr>
<tr>
<td>2.7.1.3. The Amalgam Restoration</td>
<td>47</td>
</tr>
<tr>
<td>2.7.1.4. Dental Amalgam and Primary Teeth</td>
<td>47</td>
</tr>
<tr>
<td>2.7.1.5. Fluoridated Dental Amalgam</td>
<td>48</td>
</tr>
<tr>
<td>2.7.1.6. Views on Dental Amalgam and Health</td>
<td>49</td>
</tr>
<tr>
<td>2.7.2. Tooth-coloured Restorations</td>
<td>50</td>
</tr>
<tr>
<td>2.7.2.1. Composite Resins</td>
<td>51</td>
</tr>
<tr>
<td>A. History and Development</td>
<td>51</td>
</tr>
<tr>
<td>B. Composition</td>
<td>52</td>
</tr>
<tr>
<td>2.7.2.2. Conventional Glass-Ionomer(s)</td>
<td>55</td>
</tr>
<tr>
<td>A. History and Development</td>
<td>55</td>
</tr>
<tr>
<td>B. Composition</td>
<td>57</td>
</tr>
<tr>
<td>C. Characteristics of Conventional Glass-Ionomer(s)</td>
<td>60</td>
</tr>
<tr>
<td>(i) Recharging GIC Restorations</td>
<td>60</td>
</tr>
<tr>
<td>(ii) Finishing of GIC Restorations</td>
<td>61</td>
</tr>
<tr>
<td>(iii) Summary of Conventional GIC Characteristics</td>
<td>62</td>
</tr>
<tr>
<td>2.7.2.3. Resin-Modified Glass-Ionomer(s) (RMGIC’s)</td>
<td>62</td>
</tr>
<tr>
<td>A. History and Development</td>
<td>62</td>
</tr>
<tr>
<td>B. Composition</td>
<td>63</td>
</tr>
<tr>
<td>2.7.2.4. Polyacid-Modified Resin Composites (PMRC’s) (Compomers)</td>
<td>65</td>
</tr>
<tr>
<td>A. History and Development</td>
<td>65</td>
</tr>
<tr>
<td>B. Composition</td>
<td>66</td>
</tr>
</tbody>
</table>
## Table of Contents

C. Summary of the Advantages and Disadvantages of Compomers ........................... 69
  (i) Advantages of Compomers .................................................................................. 69
  (ii) Disadvantages of Compomers ............................................................................ 69

2.7.2.5. Summary ......................................................................................................... 71

2.8. Assessment of Dental Restorations .................................................................... 72
  2.8.1. Direct Clinical Assessment of Dental Restorations ........................................... 74
  2.8.2. Indirect Assessment of Dental Restorations ..................................................... 77

2.8.2.1. Wear of Restorative Materials ....................................................................... 77
  A. Definition .................................................................................................................... 77
  B. The Wear Process ....................................................................................................... 77
  C. Common Types of Wear ............................................................................................ 78
    (i) Abrasive Wear ...................................................................................................... 78
    (ii) Erosive Wear ...................................................................................................... 78
    (iii) Fatigue Wear .................................................................................................... 78
  D. Pathological Consequences of Wear ...................................................................... 79
  E. Summary .................................................................................................................... 80

2.8.2.2. Methods for Indirect Assessment of Dental Restorations ............................... 81
  1. Rank Ordering System ............................................................................................. 81
    A. History and Development ....................................................................................... 81
    B. Other Indirect Standards ....................................................................................... 83
    C. Characteristics and Limitations of Indirect Assessment Standards ....................... 84
    D. Correlation between Direct Clinical and Indirect Assessment Methods ............... 86
  2. Photographic Assessment of Restorations ............................................................. 89
CHAPTER THREE. AIMS AND OBJECTIVES .............................................. 94

Introduction .......................................................................................................................... 95

3.1 Aims and Objectives of the Study ................................................................................. 95
A. Direct Assessment (in vivo) ............................................................................................. 95
B. Indirect Assessment (in vitro) .......................................................................................... 96

3.2. Null Hypotheses ............................................................................................................ 96
1. Direct Assessment (in vivo) ............................................................................................. 96
2. Indirect Assessment (in vitro) .......................................................................................... 96

CHAPTER FOUR. PATIENTS, MATERIALS AND METHODS ............................................ 97

4.1. Ethical Approval and Selection Criteria ..................................................................... 98

4.2. Subjects Taking Part in the Study ............................................................................... 98

4.3. Randomisation of Restorative Material ..................................................................... 101

4.4. Restorative Materials Evaluated in the Study ............................................................ 102

1. Dispersalloy ................................................................................................................. 102
2. Resin-Modified Glass-Ionomer(s) (RMGI’s) .............................................................. 102
3. Polyacid-Modified Resin Composites (PMRC’s) .......................................................... 102

4.5. Clinical Procedures ..................................................................................................... 105

4.5.1. Operators and Caries Diagnosis Reproducibility ..................................................... 105

4.5.2. Restorative Treatment and Cavity Design ............................................................ 105

4.5.2.1. Restorative Treatment Protocol ........................................................................ 105
4.5.2.2. Caries Removal and Cavity Design .................................................................. 107
# Table of Contents

A. Cavity Design for Amalgam Restorations ......................................................... 107
B. Cavity Design for Resin Restorations ............................................................ 108

4.6.3. Placement of Restorative Materials .......................................................... 109
A. Amalgam Restorations .................................................................................... 109
B. Resin Restorations ......................................................................................... 110
(i) Dyract AP ..................................................................................................... 110
(ii) Fuji II LC ...................................................................................................... 111
(iii) Vitremer ...................................................................................................... 111

4.7.4. Impression Taking of Completed Restorations .......................................... 115

4.7.5. Data Collection and Estimation of Sample Size ........................................... 116
3.7.5.1. Data Collection ..................................................................................... 116
3.7.5.2. Estimation of Sample Size ..................................................................... 116
3.7.5.3. Adjustments for Loss to Follow-Up ......................................................... 118

4.8. Assessment of Restorations ......................................................................... 119
4.8.1. Direct Clinical Assessment of Restorations *(in vivo)* .................................. 119

4.8.2. Statistical Evaluation .................................................................................. 122
3.8.2.1. Survival Analysis of Restorations ......................................................... 122
3.8.2.2. Life Table ............................................................................................. 122
   A. Cumulative Survival of Restorations ......................................................... 123
   B. Cumulative Survival of Restorations by Groups ........................................ 123

4.8.2.3. Cox Proportional Regression Analysis ............................................... 123

4.8.2.4. Assessment of Missing Data ............................................................... 124
   A. Sensitivity Analysis of Missing Data .......................................................... 124
B. Estimation of Numbers of Missing Data and Exfoliated Teeth ...................... 124

4.8.3. Indirect Assessment of Restorations (in vitro) ........................................ 125

4.8.3.1. Rank Ordering System ................................................................. 125
   A. Method .......................................................................................... 125
   B. Statistical Evaluation ..................................................................... 126

4.8.3.2. Factors Considered in Marginal Wear Assessments of Cast Replicas .... 130
   A. Method .......................................................................................... 130
   B. Statistical Evaluation ..................................................................... 131

4.8.3.3. Quantitative Measure of Wear ..................................................... 133
   A. Method .......................................................................................... 133
   B. Statistical Evaluation ..................................................................... 135

CHAPTER FIVE. RESULTS ........................................................................ 137

5.1. Subjects Taking Part in the Study ............................................................. 138

5.1.1. Number .......................................................................................... 138

5.1.2. Age and Gender ............................................................................ 138

5.2. Clinical Procedures ............................................................................ 141

5.2.1. Operators and Caries Reproducibility .............................................. 141

5.2.2. Restorations ................................................................................ 142

5.2.2.1. Number and Distribution ......................................................... 142

5.2.2.2. Cavity Design ......................................................................... 145

5.2.2.3. Cooperation of the Child Patient and Pain Control ....................... 146
   A. Patients' Cooperation and Restorations' Replacement Need .......... 146
   B. Pain Control and Restorations' Replacement Need ..................... 147
5.2.2.4. Moisture Control ................................................................. 148
5.2.3. Restorative Materials Used .................................................. 149
5.3. Restoration Follow-Up ............................................................ 149
  5.3.1. Number of Restorations at Follow-Up ................................. 149
  5.3.2. Restorations Replacement Need at Follow-Up ...................... 151
5.4. Survival Analysis of Restorations .......................................... 154
  5.4.1. Life Tables ........................................................................... 154
    5.4.1.1. Cumulative Survival of All Restorations ......................... 154
    5.4.1.2. Cumulative Survival for Each Restorative Material .......... 155
    5.4.1.3. Cumulative Survival of Restorations According to Anatomical Configuration ........................................................................ 156
    5.4.1.4. Cumulative Survival of Restorations According to Teeth Restored (Primary and Permanent) ........................................ 158
    5.4.1.5. Cumulative Survival of Restorations by Groups ................ 160
  5.4.2. Cox Survival Analysis ....................................................... 163
5.5. Results: Assessment of Restorations ...................................... 164
  5.5.1. Direct Clinical Evaluation of Restorations ......................... 164
    5.5.1.1. Assessment Criteria of the Direct Clinical Evaluation .......... 167
      A. Marginal Integrity ................................................................. 167
      B. Anatomical Form ................................................................. 168
      C. Marginal Discolouration ....................................................... 169
      D. Contact Point ..................................................................... 171
      E. Recurrent Caries ................................................................. 173
F. Replacement Need ..................................................................................................... 175
   (i) Amalgam ................................................................. 175
   (ii) Dyract AP ............................................................. 175
   (iii) Fuji II LC ............................................................ 175
   (iv) Vitremer ............................................................... 175

5.6. Assessment of Missing Data ......................................................................................... 181
   5.6.1. Sensitivity Analysis of Missing Data ................................................................. 181
       5.6.1.1. Assuming All Missing Data Were Failed Restorations ......................... 181
       5.6.1.2. Assuming All Missing Data Were Successful Restorations ................ 183
   5.6.2. Estimation of Numbers of Missing Data and Exfoliated Teeth .................... 185
       5.6.2.1. Lower Limits of Exfoliation Ages ............................................................ 186
       5.6.2.2. Upper Limits of Exfoliation Ages ............................................................ 187

5.7. Indirect Evaluation of Restorations .............................................................................. 188
   5.7.1. Rank Ordering System ....................................................................................... 188
       5.7.1.1. Calibration and Reproducibility of Rank Ordering System .................... 188
       5.7.1.2. Rank Ordering of Cast Replicas ............................................................... 191
       5.7.1.3. Wear Intervals and Replacement Need of Restorations ....................... 192
       5.7.1.4. Materials Marginal Wear Behaviour Over Time ..................................... 194
       5.7.1.5. Factors in Marginal Wear Assessments of Cast Replicas .................... 201
       5.7.1.6. Wear Behaviour of Each Restorative Material During the Study .......... 202
            (i) Amalgam ................................................................. 202
            (ii) Dyract AP ............................................................. 203
            (iii) Fuji II LC ............................................................ 204
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>(iv) Vitremer</td>
<td>205</td>
</tr>
<tr>
<td>4.5.2.2. Quantitative Measure of Wear</td>
<td>206</td>
</tr>
<tr>
<td>A. Data Analysis</td>
<td>206</td>
</tr>
<tr>
<td>B. Repeatability of Measurements</td>
<td>207</td>
</tr>
<tr>
<td>CHAPTER SIX. DISCUSSION</td>
<td>210</td>
</tr>
<tr>
<td>Introduction</td>
<td>211</td>
</tr>
<tr>
<td>6.1. Study Design</td>
<td>213</td>
</tr>
<tr>
<td>6.2. Restorative Treatment and Material Selection</td>
<td>217</td>
</tr>
<tr>
<td>6.2.1. Criteria for Restorative Treatment</td>
<td>217</td>
</tr>
<tr>
<td>6.2.2. Reasons for Materials' Selection</td>
<td>218</td>
</tr>
<tr>
<td>6.3. Subjects Taking Part in the Study</td>
<td>222</td>
</tr>
<tr>
<td>6.3.1. Number</td>
<td>222</td>
</tr>
<tr>
<td>6.3.2. Age</td>
<td>222</td>
</tr>
<tr>
<td>6.3.4. Gender</td>
<td>223</td>
</tr>
<tr>
<td>6.4. Clinical Procedures</td>
<td>224</td>
</tr>
<tr>
<td>6.4.1. Operators</td>
<td>224</td>
</tr>
<tr>
<td>6.4.2. Restorations</td>
<td>226</td>
</tr>
<tr>
<td>6.4.2.1. Cavity Design</td>
<td>226</td>
</tr>
<tr>
<td>6.4.2.2. Restorations for the Child Patient and Pain Control</td>
<td>227</td>
</tr>
<tr>
<td>A. Patient Cooperation and Restorations' Replacement Need</td>
<td>227</td>
</tr>
<tr>
<td>B. Pain Control and Restorations' Replacement Need</td>
<td>228</td>
</tr>
<tr>
<td>6.4.2.3. Moisture Control</td>
<td>228</td>
</tr>
<tr>
<td>6.4.2.4. Restorations and Primary Dentition</td>
<td>230</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>6.4.2.5. Restorations Follow-Up</td>
<td>231</td>
</tr>
<tr>
<td>6.4.3. Restorative Materials</td>
<td>232</td>
</tr>
<tr>
<td>6.4.3.1. Physical Properties</td>
<td>232</td>
</tr>
<tr>
<td>6.4.3.2. Handling of the Restorative Material</td>
<td>233</td>
</tr>
<tr>
<td>6.4.3.3. Protecting the Set Material</td>
<td>234</td>
</tr>
<tr>
<td>6.5. Survival Analysis</td>
<td>237</td>
</tr>
<tr>
<td>6.5.1. Life Table</td>
<td>237</td>
</tr>
<tr>
<td>6.5.2. Cox Survival Analysis</td>
<td>238</td>
</tr>
<tr>
<td>6.5.3. Assessment of Missing Data</td>
<td>239</td>
</tr>
<tr>
<td>6.6. Assessment of Dental Restorations</td>
<td>241</td>
</tr>
<tr>
<td>6.6.1. Direct Clinical Assessment of Dental Restorations</td>
<td>241</td>
</tr>
<tr>
<td>6.6.1.1. Limitations of Direct Clinical Assessment</td>
<td>242</td>
</tr>
<tr>
<td>6.6.1.2. Assessment Criteria of Direct Clinical Evaluation</td>
<td>243</td>
</tr>
<tr>
<td>A. Marginal Integrity</td>
<td>243</td>
</tr>
<tr>
<td>B. Anatomical Form</td>
<td>244</td>
</tr>
<tr>
<td>C. Marginal Discolouration</td>
<td>245</td>
</tr>
<tr>
<td>D. Contact Point</td>
<td>247</td>
</tr>
<tr>
<td>E. Recurrent Caries</td>
<td>249</td>
</tr>
<tr>
<td>F. Materials Replacement Need Over Time</td>
<td>251</td>
</tr>
<tr>
<td>(i) Amalgam</td>
<td>251</td>
</tr>
<tr>
<td>(ii) Dyract AP</td>
<td>252</td>
</tr>
<tr>
<td>(iii) Fuji II LC</td>
<td>254</td>
</tr>
<tr>
<td>(iv) Vitremer</td>
<td>254</td>
</tr>
</tbody>
</table>
6.6.2.2. Indirect Assessment of Dental Restorations ......................................................... 255

6.6.2.1. Rank Ordering System ........................................................................................... 255

A. Reproducibility of Rank Ordering System ............................................................. 256
B. Wear Intervals and Replacement Need of Restorations ........................................... 258
C. Materials' Marginal Wear Behaviour Over Time .................................................... 259
   (i) Amalgam ............................................................................................................ 260
   (ii) Resin-Based Restorative Materials .................................................................. 260
        Dyract AP ........................................................................................................ 260
   (iii) Resin-Modified Glass-Ionomer(s) (RMGICs) ............................................... 261
        Fuji II LC ........................................................................................................ 262
        Vitremer ......................................................................................................... 262

6.6.2.2. Quantitative Measure of Wear ..................................................................... 263

CHAPTER SEVEN. SUMMARY AND CONCLUSIONS .......................................................... 264

7.1. Summary and Conclusions ..................................................................................... 265
7.2 Assessment of Restorations ....................................................................................... 265
7.2.1. Direct Clinical Assessment of the Restorations (in vivo) ........................................ 265
7.2.2. Indirect Assessment of the Restorations (in vitro) ................................................ 266
7.2.3. Quantitative Measure of Wear ........................................................................... 266
7.3. Assessment of Missing Data .................................................................................... 267
7.3. Overall Conclusion ...................................................................................................... 268
7.3. Future Research ........................................................................................................ 268
REFERENCES.......................................................................................................................... 271

APPENDICES.......................................................................................................................... 303

Appendix I a. Ethical Approval from the Eastman Dental Institute in the UK .............. 304
Appendix I a. Research Protocol of the Eastman Dental Institute in the UK ............... 305
Appendix I b. Ethical Approval from the 'Ministry of Higher Education' and the 'Ministry
of Health', UAE ................................................................................................................ 313
Appendix I b. Research Protocol Presented to the 'Ministry of Higher Education’ of the
UAE ........................................................................................................................................ 314
Appendix II. Information Sheet and Consent Form UK .................................................. 320
Appendix III a. Database Collection Sheet (UK children) .............................................. 321
Appendix III b. Consent Form and Database Collection Sheet (UAE children) ............ 322
Appendix IV. Cast Rank Order Database (UK and UAE Restorations) ......................... 323
Appendix V. Primary School Dental Clinic, City of AbuDabi, UAE ......................... 326
Appendix VI Schools Visited for Data Collection, City of AbuDabi, UAE .................... 327
Appendix VII Clinical Pictures of Restorations (before and after treatment) ............. 328
Appendix VIII a: Retrospective / Survey Studies on Durability of Restorations in Primary
Molars ...................................................................................................................................... 330
Appendix VIII b: Prospective Studies on Durability of Restorations in Primary Molars . 338
## List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADA</td>
<td>American Dental Association</td>
</tr>
<tr>
<td>α</td>
<td>Alfa Rating (USPHS)</td>
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<tr>
<td>Anatfrm</td>
<td>Anatomical Form</td>
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<tr>
<td>Bis GMA</td>
<td>Bisphenol A-Glycidyl Methacrylate</td>
</tr>
<tr>
<td>B.S.CoeF</td>
<td>British Standard Institution Repeatability Coefficient</td>
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<tr>
<td>Contpt</td>
<td>Contact Point</td>
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<tr>
<td>COTE</td>
<td>Coefficient of Thermal Expansion</td>
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<tr>
<td>DCDMA</td>
<td>Di-Carboxy-Dimeth-Acrylate</td>
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<tr>
<td>df</td>
<td>Degrees of Freedom</td>
</tr>
<tr>
<td>dmfs</td>
<td>the number of decayed, missing and filled surfaces (deciduous dentition)</td>
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<tr>
<td>dmft</td>
<td>the number of decayed, missing and filled teeth (deciduous dentition)</td>
</tr>
<tr>
<td>DMFS</td>
<td>the number of Decayed, Missing and Filled Surfaces (permanent dentition)</td>
</tr>
<tr>
<td>DMFT</td>
<td>the number of Decayed, Missing and Filled Teeth (permanent dentition)</td>
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<td>EDH</td>
<td>Eastman Dental Hospital</td>
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<td>Ev</td>
<td>Evaluator</td>
</tr>
<tr>
<td>F</td>
<td>Failure</td>
</tr>
<tr>
<td>FDI</td>
<td>International Dental Federation (Fédération Dentaire Internationale)</td>
</tr>
<tr>
<td>FRR</td>
<td>Fluoride Releasing Resin</td>
</tr>
<tr>
<td>gi</td>
<td>gingivitis index (deciduous dentition)</td>
</tr>
<tr>
<td>GI</td>
<td>Gingivitis Index (permanent dentition)</td>
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<td>GIC’s</td>
<td>Glass-ionomer Cements</td>
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<td>HEMA</td>
<td>Hydroxyethylmethacrylate</td>
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<td>IS</td>
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<td>Ketac Silver</td>
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<td>μm</td>
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<td>Bacterial Plaque Index (permanent dentition)</td>
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<td>PMRC’s</td>
<td>Polyacid Modified Resin Composite (also known as Compomers)</td>
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<td>Stainless Steel Crown</td>
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<td>TCB</td>
<td>Tetracarboxybutyric acid</td>
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<td>United Arab Emirates</td>
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<td>UDMA</td>
<td>Urethane Dimethacrylate</td>
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<td>UK</td>
<td>United Kingdom</td>
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List of Figures

Fig 1: Essential Factors in the Aetiology of Caries ...............................................................36
Fig 2: Vivadent Model and Cast Replicas ............................................................................127
Fig 3: Cast Replicas and Rank Ordering Method ...............................................................128
Fig 4: Rank Ordering of Casts .........................................................................................129
Fig 5: Measurements of Protective Layer Coating ..............................................................132
Fig 6: Quantitative Measure of Wear ................................................................................135
Fig 7: Flow Diagram of Quantitative Measure of Wear ......................................................136
Fig 8: Direct Clinical Re-evaluation for Replacement Need ............................................151
Fig 9: Cumulative Survival of all Restorations ................................................................154
Fig 10: Cumulative Survival of Amalgam and Resin Restorations .....................................155
Fig 11: Cumulative Survival of Occlusal and Approximal Restorations .........................157
Fig 12: Cumulative Survival of Primary and Permanent Teeth Restorations ...................159
Fig 13: Cumulative Survival of Restorations by Groups ..................................................160
Fig 14: Direct Clinical Re-evaluation Using Modified Ryge Criteria .................................165
Fig 15: Marginal Integrity ..................................................................................................167
Fig 16: Anatomical Form ..................................................................................................168
Fig 17: Marginal Discolouration .......................................................................................170
Fig 18: Contact Point .......................................................................................................172
Fig 19: Recurrent Caries ..................................................................................................174
Fig 20: Clinical Follow-Up of Restorative Materials (Amalgam, Dyract AP) ....................177
Fig 21: Clinical Follow-Up of Restorative Materials (Fuji II LC, Vitremer) .....................178
Fig 22: Missing Data Assumption 1 ..................................................................................... 182
Fig 23: Missing Data Assumption 2 ..................................................................................... 184
Fig 24: Inter-evaluator Agreement ....................................................................................... 190
Fig 25: Median Marginal Wear Values for Each Restorative Material .............................. 197
Fig 26: Box plot of Marginal Wear of Materials at Baseline and Two years ..................... 200
Fig 27: Amalgam Cast-Order Wear Measures Over the 5 Visits ........................................ 202
Fig 28: Dyract AP Cast-Order Wear Measures Over the 5 Visits ....................................... 203
Fig 29: Fuji II LC Cast-Order Wear Measures Over the 5 Visits ....................................... 204
Fig 30: Vitremer Cast-Order Wear Measures Over the 5 Visits ........................................ 205
Fig 31: Checking for Funnelling Effect .............................................................................. 209
List of Tables

Table 1: Summary of Assessment Methods of Restorations ................................................. 88
Table 2: Observational Methods for the Loss of Substance of Dental Restoration .......... 91
Table 3: Quantitative Methods to Measure Loss of Substance of Dental Restoration ...... 92
Table 4: Patients Cooperation Level .................................................................................... 100
Table 5: Dental Disease Indices for Both Primary and Permanent Dentition ............... 100
Table 6a: Material Composition and Clinical Handling ...................................................... 103
Table 6b: List of Materials Used in the Study ..................................................................... 104
Table 7a: Placement Techniques of Restorations ................................................................. 113
Table 7b: Armamentarium ................................................................................................... 114
Table 8: Clinical Assessment Criteria for the Dental Restorations .................................... 120
Table 9: Age, Gender as well as Number of Restorations Per Child in both Groups (UK and UAE) .............................................................................................................. 140
Table 10: Caries Reproducibility ......................................................................................... 141
Table 11: Frequency and Percentage of Primary and Permanent Teeth, Occlusal and Proximal Restorations ......................................................................................... 143
Table 12: Frequency of Primary and Permanent Teeth Restored in the Study ................. 144
Table 13: Frequency and Percentage of Anatomical Configuration of Restorations ...... 145
Table 14: Frequency and Percentage of Restorations and Patients’ Cooperation .......... 146
Table 15: Number of Patients and Level of Cooperation at Each Group ........................... 146
Table 16: Type of Pain Control Used in Placement of Restorations ................................. 147
Table 17: Methods of Isolation Used in Placement of Restorations ................................. 148
Table 18: Frequency Distribution of Restorative Materials ................................................. 149
List of Tables

Table 19: Frequency of Restorations (UK and UAE) at Each Review Visit ...................... 150
Table 20: Reasons for Non-assessment of Restorations ...................................................... 150
Table 21: Frequency and Percentage of Failed Restorations According to Anatomical
   Configuration and Visit Number ......................................................................... 153
Table 22: Details on Restorations During Follow-up Visits .................................................. 162
Table 23: Frequencies of the Clinical Assessment of Restorations ..................................... 166
Table 24: Frequencies of Restorations and Type of Restorative Material at Each Review
   Visit ..................................................................................................................... 179
Table 25: Frequencies of Teeth (Primary and Permanent) Recorded as Failed Restorations
   .......................................................................................................................... 180
Table 26: Number of Restorations (Successful, Failed and Missing) According to Patients' Age (Lower Age Limits) ................................................................. 186
Table 27: Number of Restorations (Successful, Failed and Missing) According to Patients' Age (Upper Age Limit) ................................................................. 187
Table 28: Kappa Statistics and Initial Percentage of Agreement for Three Evaluators at the Start of the Inter-evaluator Agreement Evaluation Study .................................. 189
Table 29: Wear Intervals and Replacement Need Criteria using Vivadent Standard Model as Determined by 16 Paediatric Dentists ..................................................... 193
Table 30: Material Marginal Wear Behaviour Over Time (Cast Ordering Method)........... 196
Table 31: Adjusted P values and Median Differences of Material Wear Levels Compared with Baseline ................................................................................................. 198
Table 32: Median Changes in Wear and P Values from Baseline to Visit 5 ..................... 199
List of Tables

Table 33: Thickness of Protective Layer [difference in thickness before / after placement] for Each Resin Restoration ................................................................. 201

Table 34: Values of Weighed Impression Materials (1st and 2nd) Equivalent to Substance Loss .................................................................................................................... 206

Table 35: P Values of Paired Wear Measurement ........................................................................... 207

Table 36: B.S.Co. of Selected Wear Measurements ........................................................................ 207
Abstract

This study measures the one and two-year survival rates of restorations used to restore occlusal and approximal cavities of primary teeth, and occlusal cavities in the first permanent molars and premolars of children. Restorations were carried with / or without the use of local anaesthesia. The materials used were ‘Dispersalloy’, ‘Dyract AP’, ‘Fuji II LC’, and ‘Vitremer’. The unit of study was the individual tooth.

A total of 288 restorations were placed and the teeth were randomly allocated to one of the four restorative materials. Following a standardised inclusion criteria, two groups of children took part in the clinical trial.

In the first group, children and adolescents were recruited from the Caries Clinic of the Department of Paediatric Dentistry of the Eastman Dental Hospital. The mean age was 7.8 years. A total of 157 restorations were placed in 60 children.

In the second group, children and adolescents of the United Arab Emirates were recruited from their Primary School Dental Clinic. The mean age was 7.3 years and 131 restorations were placed in 92 children.

Caries diagnosis was carried out by both direct and tactile examination. Teeth with gross multi-surface caries and / or developmental enamel defects were excluded from the trial. All operative work was performed in a standard dental clinic environment. Rubber dam isolation was used whenever possible. High volume suction and a saliva ejector were used as an alternative. Cavity designs for both amalgam and resin restorations were based on a minimal intervention technique. Conventional high-speed and low-speed handpieces were used. The manufacturers’ instructions in the placement of resin restorations were followed.
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Abstract

Direct \textit{(in vivo)} clinical assessment of all restorations was carried out following the modified Ryge criteria at baseline and after 6, 12 and 24 months. Clinical Photographs were used whenever possible.

Indirect \textit{(in vitro)} assessment of all the restorations using stone cast replicas was carried out using a modification of the Leinfelder cast rank ordering method.

Restoration assessments and review appointments were made at 6, 12, 18 and 24 months from baseline respectively. Results showed that there was no significant difference between the four restorative materials tested over the 24 months trial period. Restoration failure was recorded in 10\% of the 288 originally placed restorations (10 Amalgam, 9 Dyract AP, 7 Fuji II LC, 4 Vitremer) and was primarily due to bulk fracture and recurrent caries during the 12-18 months' review period. Marginal discolouration was present in 52\% of the restorations by the end of the 18-month review period. After 2 years, 89\% of restorations appeared to be discoloured.

There was a significant difference between the UK group and UAE group in restoration survival. More restorations at the UAE needed replacement (P < 0.001) compared with those in the UK.

The \textit{in vitro} assessments of cast replicas showed evidence of marginal wear of the restorative material over time. The median wear change was 75\mu m - 125\mu m during the 18 - 24 months' review period. In an attempt to calculate the \textit{in vitro} volumetric (bulk) material loss, a pilot study was carried out using a light-body impression material and polyvinyl stent copings. The thickness of the impression material corresponded to the quantitative measure of over all material wear. The results of the pilot study were unsatisfactory, as reproducible values were only achieved at levels where the restoration was deemed to have failed.
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Lastly, I thank my parents and family for their unfailing support and kindness, particularly my father who has set me such a high academic standard which I only hope I have achieved.
Chapter One.

Introduction
Chapter 1

Introduction

The benefits of the scientific advances in dental materials' technology, which have taken such great strides in the last quarter of a century, are no more keenly appreciated than in the field of paediatric dentistry. A general shortcoming however, is the lack of adequate clinical investigation of materials that have been developed rapidly and subjected only to \textit{in vitro} studies. These developments include:

- The introduction of a number of modifications to glass ionomer cements (glass polyknoate) that were reported to improve the setting properties and moisture resistance. These changes include the addition of tartaric acid as well as the use of dried polymer powders. These modifications have not interfered with the ability to bond to enamel and dentine with sufficient strength to be useful clinically. One important advantage is a reduction in the need for extensive preparation.

- A further improvement in tooth-coloured filling materials has been the development of hybrid cements, also known as 'resin-modified glass ionomers'. These are based on the presence of a polymerising resin which is set 'on command' through a light-curing system. These developments have led to improved aesthetic and physical properties.

- The introduction of a polyacid-modified resin composite known as a 'compomer,' which is designed to combine the characteristics of both composite resins and glass ionomers, to achieve better physical, chemical, and mechanical properties compared with composite or glass ionomer alone. All adhesive materials rely on micro-mechanical retention or chemically bonding to enamel and / or dentine.
The use of adhesive materials represents a major advantage as there is minimal cavity preparation often without the need for local anaesthesia (Welbury et al 1991). A further advantage is that natural tooth tissue is preserved. Consequently, much of the innate strength of the tooth is maintained which renders it less likely to undergo pathological fracture (Bremer & Geurtsen 2001).

There is also the potential of fluoride-releasing properties of these tooth-coloured filling materials to prevent recurrent decay by remineralisation of the surrounding tooth tissue. This should allow localised repair of restorations instead of total replacement that would inevitably remove considerable amounts of sound tooth tissue.

All of these tooth-coloured restorative materials are used extensively by paediatric dentists, although clinical evidence for their use is lacking. Much of the so-called justification comes from the in vitro laboratory studies perhaps too distantly related from the day-to-day demands on restorations in the mouths of children.

The need and applicability of competently conducted clinical research to properly assess the suitability of tooth-coloured filling materials is the main theme of this dissertation.

This major concern has been summarised in a review published over ten years ago.

'The initially perfect resin treatments are simply not such a great success after a few years. The materials and techniques which appeared so promising in laboratory experiments, turned out difficult to apply clinically and were unable to withstand the varied exposures to which dental restorations are subjected. Frequently, both dentists and patients have had to
realise that the dream of the perfect and final treatment was just an illusion’ (Qvist 1993).

Although this statement was made ten years ago it is still true today.

The work presented here, along with its analysis and interpretation, will attempt to go some way to breaking down this illusion and providing paediatric dentists with robust data, enabling them to make an informed clinical decision on material selection.

Dental caries is one of the most common diseases affecting humanity with approximately 80% of the population in developed countries having had experience of the disease. Failure to restore carious teeth may result in considerable pain and suffering, and their eventual loss. Progression of caries into the pulp allows the micro-organisms within lesions to initiate an acute inflammatory response and cause severe toothache. Progression of this process may cause an abscess, and might be accompanied by facial swelling. Removal of diseased teeth may result in substantial aesthetic and functional problems for the individual including space loss and disturbance of the eruption process.

The aim of prevention and early restorative treatment of both primary and permanent dentitions is to maintain a functional and stable aesthetic arch configuration. Preventive measures can halt and even reverse the development of caries. This can be achieved by the regular use of topical and / or systemic fluoride, and the use of fissure sealants on the pits and fissures of permanent posterior teeth (Simonsen 1996). If decay has not been prevented or arrested, cavities and progression of caries into the dentine and pulp will occur. The decision to restore the affected teeth will depend on the rate of progression of caries and the age of the child. Studies in the UK suggest that much restorative dentistry comprises the replacement of existing restorations and accounts for 56% to 67% of all restorative work carried out (Nuttall 1985). Similar figures have been found in other parts
of Europe and in the USA (Klausner & Charbeneau 1985; Qvist et al 1986a; Qvist et al 1986b; Maryniuck & Caplan 2004).

The longevity of restorations is affected by factors such as the age of the patient, the properties of the filling material and the initiation and progression of caries in the filled tooth (Hunter 1985; Walls et al 1985; Holland et al 1986). Successive intra-coronal restorations tend to increase in size, leading to an increased risk of subsequent tooth fracture during function. Replacement restorations tend to be more complex than the initial restorations (Elderton & Nuttall 1983). They may have a shorter life span as the increased cavity size is more likely to involve the pulp (Wendt et al 1998).

In clinical practice, decisions are often made subjectively with a lack of standardisation, as there are no valid criteria used to decide when a restoration requires replacement (Elderton & Nuttall 1983). It is difficult to distinguish between subjective and objective factors in the decision making process and it is possible that this influence will have a greater impact on longevity than the physical properties and biocompatibility of a material (Elderton 1976b). The criteria used for the evaluation of restoration failure vary widely between dentists and may not be explicit. It is often difficult therefore to determine whether a restoration was replaced because the restoration actually failed, or whether the clinician subjectively deemed it to have failed (Elderton 1977; Elderton & Nuttall 1983).

For these reasons, the main objectives of the present study were to assess and evaluate the durability of restorations placed in the primary and permanent dentitions using standardised criteria for clinical assessment as well as indirect assessment of marginal wear that might result in a decision to repair or replace a restoration.
1.1. Aims of the Study

The aims of this study were to evaluate the two year clinical durability and survival rate, with particular reference to restoration marginal wear, of three hybrid tooth-coloured resin-based restorative systems ‘Dyract AP, Fuji II LC, Vitremer’. Silver amalgam in the form of ‘Dispersalloy’ was used as the main comparator in both primary and early mixed dentition.

The evaluation was carried out both direct (in vivo) and indirect (in vitro).
Chapter Two.

Review of the Literature:

Assessment of Restorations Placed in Primary and Permanent Teeth of Young Patients
Introduction

The restorative treatment of primary teeth is different from that of permanent teeth and most restorative materials tend to perform better in the permanent rather than in the primary dentition (Qvist et al. 1990a; Qvist et al. 1990b; Wendt et al. 1998). This difference in performance may be partly explained by differences in morphology, wear behaviour and dimensions of preparations of the primary teeth. Further, the conditions under which the restorations are placed will have an effect on their clinical outcome. Generally, the younger the child, the poorer the cooperation will be. Therefore, in young children the handling characteristics of restorative materials will have a greater effect on the clinical outcome than in the adult dentition (Fleming et al. 2001).

The survival rate of dental amalgam restorations in primary teeth was reported to be low when compared to stainless steel crowns, and is significantly related to the age of the child at the time of restorations placement (Holland et al. 1986; Roberts & Sherriff 1990). This is due primarily to the lack of adhesion to tooth substance, as well as being unable to reinforce tooth tissue (Fleming et al. 2001). While the use of resin composites with the acid-etch technique has shown promising results (Wucher et al. 2002), these materials -which require additional clinical stages- are more sensitive to variables occurring during manipulation than happens with amalgam alloys (Kilpatrick 1993b). Furthermore, the materials are less tolerant to misuse. Use of resin-based materials is difficult as they are required to be kept dry during placement.

Glass-ionomer cements have been used in primary teeth as another alternative to amalgam. The advantages of this type of material are that the adhesive properties, (they are self-adhesive and do not need the addition of an adhesive system) reduces the need for an extensive, mechanically-retained preparation. They also show a sustained fluoride release.
Clinical studies show that the survival rate of glass-ionomer restorations in the primary dentition is low - especially in proximal restorations - owing to the high number of fractures (Hickel & Voss 1988; Kilpatrick 1993b; Attwood et al 1994; Andersson-Wenckert et al 1995; Espelid et al 1999). The clinical and laboratory reports achieved with glass-ionomer cements containing silver sintered to the glass are even poorer (Thornton et al 1986; Croll & Phillips 1986; Chung 1993; Kilpatrick et al 1995). A list of clinical trials on durability of restorations in the primary teeth is given in Appendix VIII a,b.

2.1. Tooth Morphology in Relation to Restorative Dentistry of the Young Patient

This section covers the relationship between the morphology of the teeth and restorative considerations. Details of the anatomy of both primary and permanent molars are not given in this study, as such a task is considered beyond the scope of this thesis. Data is available in Wheeler’s Dental Anatomy Physiology and Occlusion (Ash 1993).

The crowns of primary molar teeth are more bulbous than the permanent successors, with a marked cervical constriction. The occlusal table is narrow in the bucco-lingual dimension owing to the occlusal convergence of the buccal and lingual walls (Curzon et al 1997).

The inter-proximal contact areas are broader, flatter and situated further gingivally than those between permanent molars (Berkovitz et al 1992). It has been reported that approximal caries of the mixed dentition usually does not occur until interproximal teeth contact develops, around the age of seven years (Dewar & Parfitt 1954). Also, it is claimed that proximal caries progresses more rapidly than occlusal caries causing a high percentage of pulp exposures (McDonald & Avery 1983).

The enamel of the primary teeth is 1-1.5mm thick, a value approximately half that found in the permanent dentition. The inclination of the enamel prisms in the cervical region of
primary teeth tends to be horizontal or slightly inclined towards the occlusal surface, whereas those of the permanent dentition are directed in a gingival direction (Mortimer 1970). This difference in the inclination of the enamel prisms may account for a more rapid spread of caries in the primary dentition (Mortimer 1970).

It has been suggested that the dentinal tubules of the primary teeth are smaller in diameter because of the peritubular dentine matrix is wider than that of permanent teeth (Hirayama et al 1985), hence the progression of the demineralization front of caries may progress more quickly, despite the density and the diameter of the dentinal tubules in the primary dentine being lower than in permanent successors (Koutsi et al 1994). Due to the morphology of primary molars, cavities tend to be too small to allow material bulk (amalgam in particular), thus compromising the durability of the restoration (Roberts & Sherriff 1990).

2.2. Morphological Differences between Primary and Permanent Molars

The crowns of the primary teeth are wider in the mesio-distal dimension compared with their crown height than are the permanent teeth.

The roots of the primary molars are relatively longer and more slender than the roots of the permanent teeth. There is also a greater extension of the primary roots mesio-distally. This flaring allows more room between the roots for the development of the premolar tooth crowns. The crown and roots of primary molars are more slender in mesio-distal dimensions at the cervical third than those of the permanent molars.

The cervical ridge on the buccal aspect of the primary molars is much more pronounced, particularly on the maxillary and mandibular first molars, compared with permanent molars.
The buccal and lingual surfaces of the primary molars are flatter above the cervical curvatures than those of the permanent molars, thus making the occlusal surface narrower compared with permanent teeth (McDonald & Avery 1983).

2.3. Dental Caries

Dental caries is a process of demineralization and remineralization of the hard tissues of the tooth (enamel, dentine and cementum) caused by the action of micro-organisms on fermentable carbohydrates.

This disturbance of the equilibrium between the tooth surface and the surrounding plaque fluid over time results in the loss of the mineral from the tooth surface (Fejerskov 1997). This has important implications (Ekstrand et al 2001):

- Plaque formation cannot be totally prevented by tooth brushing. These deposits are always metabolically active. Thus, plaque formation is a physiological phenomenon in an oral environment
- Lesion formation reflects the metabolic activity in the plaque
- At the crystallite level, the demineralization and remineralization resulting from pH fluctuations within the plaque cannot be prevented. The carious process itself cannot be prevented; it is a ubiquitous natural process
- The process can be active, rapidly progressing, slowly progressing or arrested
- The carious process is driven by the activity of the bacterial plaque and therefore modification of the plaque, can modify the caries process
- The disease can be controlled so that lesion progression to the stage of a white spot or a frank cavity can be prevented.
The aetiology of dental caries is multi-factorial and involves a dynamic inter-relationship between oral micro-organisms, dental plaque, ingestion of fermentable carbohydrates that provide bacteria with substrate for acid production, susceptibility of the teeth, salivary factors and temporal factors (van Houte 1994; Fejerskov & Thylstrup 1994; Ekstrand et al 2001).

The four factors described as essential in the aetiology of caries include (Keyes 1960; Keyes 1969). (Fig 1):

- A susceptible host
- Cariogenic microflora
- A suitable substrate
- Time.

All four factors must interact simultaneously for caries to occur and progress. The intake of cariogenic food is one of the important factors that will determine whether clinical caries will develop. The relative potential to initiate the caries process is known as the cariogenicity, or cariogenic potential of a given foodstuff. To date, no reliable method for determining the cariogenicity of foods has been found (Fejerskov 1997).
Fig 1: Essential Factors in Caries Aetiology

Keyes 1969
The carious lesion is characterized by sub-surface mineral loss beneath a relatively intact surface zone (Silverstone 1968; Larsen & Brunn 1994). The surface zone is believed to represent an area of re-precipitation of mineral derived from both the plaque and from deeper areas of the lesion (Silverstone 1977).

Dental caries is a globally prevalent disease of infectious bacteria transmitted in early childhood as soon as primary teeth start erupting, from parents or carers through an exchange of saliva (Svanberg & Westergren 1986). Historically, dental caries has been treated by surgical excision. Sound tooth structure was sacrificed to compensate for shortcomings in the physical properties of the various restorative materials available (Hollenback 1969).

There are particular sites on the tooth that favour plaque retention and are therefore prone to decay. These are enamel pits and fissures, approximal enamel surfaces, enamel at the cervical margin just coronal to the gingival margin (Dummer et al 1990; Ekstrand et al 2001).

Salivary factors play an important role in the protection against caries initiation and these include secretion rate, buffering capacity, electrolysis, protein secretion, immunological and bacterial agglutinating factors (Edgar & Hisham 1995; Hay 1995).

Demineralization of tooth tissues exposed to bacterial attack does not occur instantly. The variety of factors outlined above combine to substantially modify the progression of the carious process (Sutcliffe & Murray 1983; Ekstrand et al 2001).
2.4. Caries in the Young Patient

It is often said that occlusal pits, fissures, and interproximal surfaces are particularly susceptible to dental caries (Parfitt 1956; Dummer et al 1990). Although the caries experience of UK children aged 8-15 years has declined, studies have shown that occlusal caries still accounts for the majority of lesions in this age group (Parfitt 1955; Anderson 1982; Pitts & Davis 1992).

It is apparent that over the last two decades the prevalence and pattern of dental caries has changed in the UK and many other industrial nations. There has been a reduction in the prevalence of dental caries, a trend supported in the UK by the results of three surveys of Children’s Dental Health in the UK conducted in 1973, 1983 and 1993 (O'Brien 1994), yielding a mean dmft for 5 year old children of 4.0, 1.8, and 1.7 respectively. The mean DMFT for 12 years old was 4.8, 3.1, and 1.4 (Todd 1975; Todd & Dodd 1985; O'Brien 1994). Though this change in caries prevalence has reduced the caries attack rate on smooth surfaces, it has resulted in a larger proportion of carious lesions being found in the occlusal surfaces when radiographs were not used (Li et al 1993).

In the Middle East there have been only a few reports on dental caries experience in pre-school children. In the City of Abu Dhabi of the United Arab Emirates, there was a mean dmft of 5.1 reported in 1991 for 5-year-old schoolchildren. In 1998, the mean dmft for 5-year-old schoolchildren was 8.4 in the City of Abu Dhabi, 8.6 in Al Ain, and 5.7 in the Western Region giving caries prevalence of 93.8%. Few teeth were filled, with most carious teeth treated by extraction. There were no reports available for the 12 year old population (Al Mughery et al 1991; Al Hosani & Rugg-Gunn 1998).
In Saudi Arabia (Riyadh and Jeddah) and Oman, similar figures were reported for 5 and 6 year old children (Al Khateeb et al 1990; Al Shammery et al 1990; Al Ismaily et al 1997; Paul & Maktabi 1997), while for the 12 year old group a mean DMFT of 4 was reported (Magbool 1992).

This diversity in caries experience of the UK and the Middle Eastern children emphasizes the emerging difference in treatment philosophy. Treatment of caries should meet the needs of each particular patient, based on her / his caries experience.

In the UK, the original maxim of extension for prevention has been replaced by minimal intervention. This is most effective in early caries diagnosis and small occlusal lesions. In the Middle East, however, the high caries levels still demands treatment involving larger restorations and / or extractions.

The widely held belief is that early diagnosis of occlusal caries is therefore of particular importance in the primary dentition, as the rate of caries progression is more rapid than in the permanent dentition. This is thought to be related to the small dimensions of the primary teeth, where pulp involvement occurs more rapidly than in permanent teeth.
2.5. Restorative Considerations in the Young Patient

Restoration of the primary dentition is essential to maintain structure and function of the oral cavity. This, in turn, keeps the child pain free and avoids the need for early extraction. Therefore, restoration of primary teeth must not be neglected.

Apical infection may damage the underlying immature permanent premolar causing enamel hypoplasia, the so called ‘Turner teeth’ (Turner 1912; Welbury & Kilpatrick 1997).

Coronal breakdown and early extraction of primary teeth may result in crowding due to space loss leading to asymmetry of the permanent dentition.

It has been suggested that the quality and durability of restorative dental work depended on dentition, age of the patient, and type of restoration placed (Qvist et al 1990a). It has also been suggested that restorative treatment is palliative rather than remedial (Holloway 1975). It has also been concluded that it is wrong to assume that restorative treatment will be successful in the long term, and undoubtedly that some restorations will eventually fail (Elderton 1976a; Elderton 1976b). It is considered more accurate to assume that every restoration stands a significant chance of failure within a few years. The widely held view that conventional restorations in young ‘permanent’ teeth are permanent has been considered untenable (Hunter 1985).
The restoration of primary molars is influenced by many factors. These include:

- The age of the child
- The ability of the child to cooperate
- The acceptance of local anaesthetic
- Access
- Operator skill
- Behaviour management
- Speed.

The ideal restoration combines minimum treatment time with maximum durability and cost effectiveness. Most primary molars have a finite life expectancy, the maximum being around eight to ten years. A range of restorative materials are available for restoration of form and function of primary molars. These include:

- Amalgam
- Tooth-coloured restorations e.g. Glass-ionomer cements (GICs), Resin-modified Glass-Ionomer Cements (RMGICs), composites, and compomers (PMRCs)
- Pre-formed stainless steel crowns (SSC).

2.6. Clinical Views on the Treatment of Approximal Caries

The treatment approach of approximal dentine caries has changed substantially over the last decade. Preventive measures have gained a more prominent place since such procedures slow down or even arrest the progress of carious lesions, thus avoiding the invasive replacement of carious tissue (Mount 1991a). If prevention fails, restorative treatment may be necessary to eliminate the carious process. Historically, amalgam was the filling material of choice in primary molars, because satisfactory long-term results have been reported
(Welbury et al 1991; Kilpatrick 1993b). On the other hand, the durability of amalgam when used to restore multi-surface carious primary teeth is lower compared to that of preformed stainless steel crowns (Roberts & Sherriff 1990).

Amalgam is still the most frequently used restorative material for posterior teeth. Mass et al (1999) claim that no other restorative material has gained such an established position, based on laboratory studies and longitudinal clinical observation. However, the desire to preserve tooth structure, poor aesthetic appearance, and the rising public concern as to possible health hazards have encouraged health authorities and professionals to seek clinically appropriate alternative materials to amalgam. The most important examples of those materials - for restoration of primary as well as permanent teeth- are the adhesive materials (Forsten & Karjalainen 1990; Mount 1998; Marks et al 1999a,b; van Dijken et al 1999). The reported advantages of using adhesive materials compared with amalgam are the preservation of sound tooth tissue, the achievement of a marginal seal (Mertz-Fairhurst et al 1998; Banerjee et al 2001), and avoidance of the need for an isthmus, the well-known 'Achilles heel' of proximo-occlusal restoration (Marks et al 1999a). The main reasons for restoration failure in both primary and permanent dentition are isthmus fractures, marginal failure and recurrent caries (Welbury et al 1991; van Dijken 1995; Mjor 1997; Mjor & Qvist 1997; Wilson et al 1997; Wendt et al 1998). For the young patient a major advantage of a tooth-coloured material is patient motivation because of the greatly improved aesthetics compared with amalgam (Marks et al 1999a,b).
2.7. Restorative Materials for the Young Patient

Due to limited cooperation of the young patient and in order to reduce the risks of early failure\(^1\), the properties of materials should not be technique sensitive. Restorations must be durable and relatively long lasting (exfoliation is frequently not complete until approximately 12 years of age). They should be strong in thin section due to the relatively thin occlusal thickness of tooth tissue removed when compared with permanent teeth.

Traditionally amalgam and stainless steel crowns have been the mainstays of treatment for posterior primary teeth. Stainless steel crowns are the most effective method of restoration with survival rates in excess of 80% reported over an eight to nine year period (Roberts & Sherriff 1990; Einwag & Dunninger 1996). Stainless steel crowns (SSCs) last longer than Class II amalgam restorations (Messer & Levering 1988; Einwag & Dunninger 1996), as it is considered by some that amalgam has poor durability in primary teeth, especially when placed in proximo-occlusal cavities (Holland et al 1986; Levering & Messer 1988). This can be related partly to the differences in crown morphology of the primary molars resulting in minimal cavities that are too small to allow for amalgam bulk (Roberts & Sherriff 1990), and also to the limited access to the oral cavity with younger children, as higher failure rates were reported among Class II amalgams placed in children younger than 4 years (Levering & Messer 1988).

\(^1\) In this context, early failure defined as failure of the restoration within the 1st week post placement.
Throughout the past decade, adhesive materials are becoming more popular as they can be referred to as an all-purpose restorative material, allowing less destructive cavity preparation (Walls et al 1988b). This in turn reduces treatment time and, often, local anaesthesia is unnecessary (Welbury et al 1991).

A number of these adhesive systems including glass-ionomers, resin-modified glass-ionomer cements and poly acid modified resin composites have the ability to release fluoride, which is reported to have bactericidal effects (Ertugrul et al 2003). The restoration surface may be rechargeable by exposure to external fluoridated surrounding medium, as in solutions, gels and toothpaste (Hatibovic-Kofman & Koch 1991; Musa et al 1996; Rothwell et al 1998). This is perceived as useful since the ultimate intention of local fluoride release is to inhibit or reverse the carious process (Hicks et al 1986; Hicks 1986; Valk & Davidson 1987; Tsanidis & Koulourides 1992). No attempt, however, has been made to present a comprehensive review of the literature on the restorative options for the permanent dentition, as it is beyond the scope of this thesis, and only simple occlusal cavities were performed on permanent first molars and premolars¹.

¹ Common practice in clinical trials of this nature (Welbury 1989, Kilpatrick 1993a)
2.7.1. Dental Amalgam

2.7.1.1. History and Development

The most frequently used dental restorative material is dental amalgam. Amalgams are the reaction product of alloys of various metals with mercury. In the broadest sense, 'D. Arcets’ Mineral Cement,' the materials used in the early 1800s in France may be considered the first dental amalgam.

This alloy of bismuth, lead, tin and mercury was plasticized at 100°C then poured directly into the cavity. In 1818, Regnart moved a step closer to modern amalgam by increasing the amount of mercury used in preparing the ‘Mineral Cement,’ a modification that lowered the plasticizing temperature to 68°C.

The first uses of a room temperature mixed amalgam as a restorative material are attributed to Bell in England and Traveau in France in the early 19th century, the latter making a silver paste by combining filings from silver coinage with mercury (Frykholm 1957; Greener 1979). In the mid 19th century (1833), the amalgam war occurred in the USA with controversy over the risks of mercury use. Changes in the composition of the original amalgam to improve its properties were suggested during the latter half of the 1800’s by E. Townsend (Frykholm 1957; Greener 1979).

Subsequently F. Flagg defied authority by strongly advocating the use of the new material (Frykholm 1957; Greener 1979). The controversy finally ended in 1895 following systematic and scientific investigations by G.V. Black who published detailed results demonstrating amalgam to be a most promising material (Black 1895). It is interesting to note that some of the amalgam used today differs only slightly in composition from that advocated by Black (Frykholm 1957; Greener 1979).
2.7.1.2. Composition

Modern dental amalgams are prepared from two types of alloy. Conventional silver-tin amalgam is prepared from a silver-tin alloy containing small amounts of copper and zinc combined with mercury. Un-reacted alloy particles, called the gamma phase, are primarily a silver-tin complex. These particles react with mercury. The reaction occurs on the surface of the alloy particles to form a matrix consisting of gamma 1 and gamma 2 phases. The gamma 1 phase involves the binding of silver and mercury \((\text{Ag}_2\text{Hg}_3)\) and the gamma 2 phase involves the binding of tin and mercury \((\text{Sn}_7\text{Hg})\). The phases of amalgam are important as they represent the weakest portion of amalgam (Barber & Reisbick 1973).

With time the dental amalgam undergoes changes in its microstructure which potentially contributes to the early fracture and failure of amalgam restorations (Boyer & Edie 1990). Increasing copper concentration has prevented the formation of the gamma 2 phase, as the tin-mercury phase is replaced with a copper-tin phase \((\text{Cu}_3\text{Sn}_3)\). High-copper amalgams are prepared from either a mixture of silver-tin and silver-copper alloys (admixed alloys) or from a ternary silver-copper-tin alloy (single composition alloys). High copper amalgams have been reported to have superior clinical properties with a higher resistance to corrosion and marginal breakdown (Eley 1997), thereby improving its durability (Doglia et al 1986; Letzel et al 1989).
2.7.1.3. The Amalgam Restoration

The traditional treatment for carious lesions was outlined by G.V. Black in 1895. This consisted of the removal of the carious lesion, including soft demineralised dentine and unsupported enamel structure. Tooth preparation that follows these guidelines must also provide sufficient room for placement of a restorative material, based primarily on the physical properties of the material itself. Furthermore, the principle of extension for prevention was applied by extending preparations to include pits and fissures that may at some future time become carious.

Black’s cavity design requires the removal of tooth structure to prepare a specifically dictated outline form as well as an internal form that provides for mechanical retention of the restoration (Black 1908).

Adherence to these traditional guidelines results in removal of sound tooth structure. The net result is that the final preparation for a very limited carious lesion can involve extensive loss of healthy enamel and dentine (Robinson 1985).

2.7.1.4. Dental Amalgam and Primary Teeth

The use of dental amalgam to restore primary molars is common and its durability in occlusal cavity preparation is supported by clinical evidence (Hickel & Voss 1990; Welbury et al 1991). Studies have shown that longevity of an amalgam restoration is related to four major factors: the age of the child at the time of placement, tooth type restored, complexity of the restoration, and the number of occasions upon which one type of restoration is placed in a given tooth (Holland et al 1986; Levering & Messer 1988).
In the primary dentition, the survival rate of amalgam restorations has been reported to vary from 53-63% after 2 years (Qvist et al 1986a), to 38% in 1st primary molars to 48% in 2nd primary molar after 3 years (Holland et al 1986), and 73% in occlusal to 67% in proximal restorations after 5 years (Roberts & Sherriff 1990). The survival time has been shown to increase with the increasing age of the patient at time of placement of the restoration (Holland et al 1986; Roberts & Sherriff 1990). Restorations placed in children under 3 years old last on average less than a year (Holland et al 1986). It is therefore important to emphasize the need for caries prevention from a very early age, if only to delay the onset of caries, since any restoration will then be placed in an older child where it is likely to last longer.

Amalgam is a brittle material and thus needs to be placed in bulk, which necessitates larger cavity preparation (Robinson 1985; Kilpatrick 1993b), with the inherent risk of pulp exposure in primary molars when restoring a proximo-occlusal cavity. Failure of an amalgam restoration is usually related to new or recurrent caries (Lavelle 1976; Qvist et al 1986a). Fracture or total loss of amalgam restorations is generally related to variability in operator technical skills (Lavelle 1976; Lemmens et al 1988).

2.7.1.5. Fluoridated Dental Amalgam

The beneficial effect of fluoride as an anticariogenic agent is widely recognized (Lind et al 1976; Cawson & Stocker 1984; Hamilton 1990). There have been many attempts to incorporate fluoride salts into dental amalgam (Forsten 1976; Hurst & von Fraunhofer 1978) in order to maximize the benefits of the most commonly used restorative material. But it appears that the addition of fluoride to amalgam is a retrograde step in that corrosion
is enhanced. This leads to rapid surface breakdown and a marked reduction in strength (Hurst & von Fraunhofer 1978).

Recently, it was reported that the incorporation of an amalgam-bonding resin with fluoride releasing capability provides greater protection against a laboratory cariogenic attack than a conventional amalgam restoration (Hicks et al 2002).

2.7.1.6. Views on Dental Amalgam and Health

Silver amalgam has been used for restoring teeth for over 150 years and it is still used extensively in paediatric dentistry. It is easy to place, relatively inexpensive, and reliable. Until recently, amalgam was considered to be the most commonly used posterior tooth restorative material (Widstrom et al 1992). However, the improvement in the physical properties and clinical handling of the tooth-coloured materials, together with the continuing concerns over the toxicity of mercury, inhaled or ingested, has led to a debate questioning the desirability of continuing to use dental amalgam in children (Fuks 2002; Burke & Shortall 2001).

Major health care organizations such as the International Dental Federation, the American Dental Association, the United States. Department of Health and Human Services, Public Health Service, and the World Health Organization, have published policy statements confirming the safety of dental amalgam (FDI 1992). However, there is still concern about the safety as well as the environmental effects of mercury and there are debates on potential biohazards of amalgam affecting human health (ADA 1998). These concerns have led to a reduction in its use and increased efforts to find or develop acceptable alternatives to amalgam. In 1996 the international conference on Clinically Appropriate Alternatives to
Amalgam, held at the Academy of Dental Materials, in Munich, concluded that the alternatives are not necessarily better or safer (Olea et al 1996).

2.7.2. Tooth-coloured Restorations

Tooth-coloured restorations are commonly used in the restoration of anterior primary teeth or simple smooth surface cavities, as the indications for their use are similar to those for permanent teeth. Recently, newer materials have been advocated as all-purpose restorative materials in the deciduous dentition (Welbury et al 1991). The use of an adhesive material reduces the need for extensive preparation and potentially makes treatment easier for the child. Using an adhesive technique involving a resin composite is postulated to give very good results in the primary dentition. Silver amalgam use in primary teeth is waning, due not to fears about its mercury content but rather because suitable alternative materials have been developed. However, the number and detail of clinical trials on dental amalgam demonstrate that it is still the best documented restorative material. In many areas, performance is better than tooth-coloured filling materials. It has been the primary restorative material in dentistry for over a century (Fuks 2002). Definitive studies (Hickel & Voss 1990; Welbury et al 1991) have shown that dental amalgam in the primary dentition has a survival rate of 73% (occlusal restorations) to 67% (proximal restorations) after five years (Roberts & Sherriff 1990). In addition to being easy to use, it tolerates shortcomings in the clinical technique (see Appendix VIII a,b)
2.7.2.1. Composite Resins

A. History and Development

Composite resins were introduced to the dental profession more than 40 years ago. The initial bis-GMA based material, was developed by Dr. Bowen at the United States National Bureau of Standards, and the first commercial material known as ADDENT\(^1\) was marketed by the 3M company of St. Paul, Minnesota (Leinfelder & Vann 1982). Materials based on this resin were accepted enthusiastically by the dental profession. This was an improvement over the traditional silicate cement, which had been on the market for almost 85 years along with methyl-methacrylate based materials introduced in the 1940’s (Leinfelder 1976). Quartz filler particles were included in the resin to give better colour properties, as well as more durable wear characteristics. These resins demonstrated initial success, and several manufacturers believed that composite resins could serve as a viable substitute for dental amalgam. Results of a one year clinical trial conducted at the University of Indiana in 1971 demonstrated that composite resin (Adaptic\(^2\)) showed no significant difference in wear rate and marginal adaptability than amalgam restoration (Phillips et al 1971) in the first year after placement. Longer-term evaluation of composites showed less favourable results.

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\(^1\) Pearson, G. personal communications
\(^2\) J&J company, New Brunswick N.J.
Chapter 2
Lit. Review

(Phillips et al 1972; Leinfelder & Vann 1982). Problems noted with composite restorations were: loose or open inter-proximal contacts, voiding or porosity along the gingival floor, significant loss of anatomic form on the occlusal surface, as well as prolonged post-operative sensitivity in the permanent dentition (Phillips et al 1973; Leinfelder & Vann. 1982). First generation composites exhibited a number of problems. Most significant among these were inadequate shading, as colour alters over time, and wear on the posterior teeth exhibiting a disappointing outcome. Further problems were a variable setting-time, and solubility in organic solvents. Attempts to resolve these deficiencies were made by treating the filler particles with silane. The particles were actually bound within the resin matrix, causing less discolouration and degradation of the resin restorative materials. Filler particles were ground smaller compared with those utilized with the original resin-based composites. This allowed for more filler to be incorporated into the resin matrix (Ruyter 1988), with superior physical and mechanical properties and more promising results, particularly for minimal restorations of primary and early mixed dentition (Kilpatrick 1993b), and patients allergic to metals (Burke & Shortall 2001).

B. Composition

Composite resins are also referred to as composites or filled resins. As mentioned above, they consist of an inert glass or quartz filler in a resin matrix. Most filled restorative resins consist of three-dimensional combinations of a minimum of two chemically different materials with a surface interfacial phase. The three phases are:

- Matrix phase
- Surface interfacial phase
- Dispersed phase.
Composites set by a polymerisation reaction where monomers such as bis-GMA and urethane dimethacrylate (UDMA) are converted into cross-linked polymers. Each resin must include an accelerator-initiator system to begin and complete the setting of the material. For the chemically cured composite, the accelerator-initiator is usually an amine-peroxide system, whereas light-cured composites use a diketone-amine system, which is activated by intense blue light at a wavelength in the 460 - 470nm range. The resin matrix of all composites is based on dimethacrylate resins such as bis-GMA or UDMA, and its viscosity is reduced by a low molecular weight diacrylate.

The composite resin matrix is reinforced by glass filler particles, usually based on glass containing Barium or Strontium. These particles are of varying sizes between 0.5μ and 20μ and are of variable distribution to ensure good packing. Water absorbed into the resin matrix increases the risk of disruption of the bond between the resin matrix and the filler particles.

The clinical characteristics of composites are controlled by appropriate additions of accelerators and ultraviolet inhibitor containing materials. The surface interfacial phase consists of either a bipolar coupling agent (e.g. organosilane) to bind the organic resin matrix to the inorganic fillers, or a copolymetric or homopolymeric bond between the organic matrix and partial organic filler (Brauer 1975). The organosilane is prone to hydrolysis. Consequently, as these materials absorb water, they are thought to plasticize and become less durable.

The degree of interface adhesion between filler matrix and the micromorphological adaptation to enamel and dentin is similar for both primary and permanent teeth. This is critical for successful clinical use of any resin based restoration (Garcia-Godoy & Donly 2002). A number of reports (ADA 2003) supported the suitability of composite resins as
alternatives to amalgam for the restoration of primary (Mack 1970; Leinfelder & Vann 1982; Varpio 1993) and permanent molars (Phillips et al 1973; Osborne et al 1973) with longevity of 2-4 years in primary teeth (Nelson et al 1980; Oldenburg et al 1987; Tonn & Ryge 1988) and survival rates of 72.4% to 84% after 5 years in permanent teeth (El Mowafy et al 1994; Kohler et al 2000). Fractures within the body of restoration and at the margins as well as loose or open inter-proximal contacts, have been cited as a major problem regarding the failure of posterior composites as well as the materials being technique sensitive (Leinfelder & Vann 1982; Roulet 1988; Manhart et al 2000a; Manhart et al 2000b; Burgess et al 2002).
2.7.2.2. Conventional Glass-Ionomer(s)

A. History and Development

The development of amalgam, gold and porcelain restorative materials in the first half of
the 19th century stimulated the development of the dental cements as luting and lining
materials and more aesthetic restorative materials such as silicate cements and the acrylic
resins of the 1940’s. In the 1960’s, the idea of positive physico-chemical adhesion with
tooth tissue resulted in the invention of polyacrylic acid-based cements; first the
polycarboxylate and subsequently the glass-ionomer cements (Wilson & Kent 1971;
Wilson & Kent 1972). These materials were shown to undergo adhesion both to the
calcium in hydroxyapatite (Wilson et al 1983) and also to the organic phase of the dentine
(McLean 1994; Mount 1998). These proved to be satisfactory for a range of clinical
applications. The key properties of the glass-ionomer cements are adhesion to enamel and
dentine (McLean & Wilson 1977). These are related to their characteristics as aqueous
polyelectrolyte systems (Kent et al 1973).

The original glass-ionomer cements consisted of an aqueous solution of polyacrylic acid at
a concentration of about 45%, which reacted with powder consisting of calcium
fluoro-aluminosilicate glass (Kent et al 1973; Nicholson 1998). These early materials set
slowly, showed relatively prolonged sensitivity to moisture, and aesthetically were rather
opaque.
These properties have been steadily improved by incremental changes to the cement system, especially in the preparation of the basic glass powders. A number of modifications have become available:

- The addition of tartaric acid and acidic chelating agents to improve the setting properties (Wilson et al 1976; Crisp et al 1979)
- The use of alternative polymeric acids, such as acrylic / maleic, as the acid component (Crisp et al 1977)
- The use of dried polymer powders blended with the glass and activated by the addition of water (Prosser et al 1984)
- The development of metal ceramic containing cements (cermets) in which the filler consists of ceramic-metal hybrid (the most common being calcium fluorooaluminosilicate glass fused to silver) rather than a pure glass. These materials are used in situations where radio-opacity is required and for core build-up under crowns (McLean & Gasser 1985). Radio-opacity is also achieved by substituting strontium for calcium in the glass
- Metal–reinforced cements where a metal such as silver alloy (Simmons 1983; Swift 1988), or amalgam alloy (Beyls et al 1991) is added to an otherwise conventional glass-ionomer in an attempt to reinforce the set cement (Kramer & Frankenberger 2001)
- Reduction in glass particle size to accelerate setting reaction (Kaplan et al 2004).
B. Composition

Glass-ionomers cement (GIC) is a salt by chemical definition, which is formed by reaction between a polyalkenioc acid and fluro-aluminium silicate containing glass (Wilson & Kent 1972; Kent et al 1973).

**Glass:** This is an acid-decomposable glass usually ground to a fine powder, which on treatment with aqueous acid releases the cement-forming ions (typically Ca$^{2+}$, Al$^{3+}$, and possibly also Sr$^{2+}$, La$^{2+}$, or Zn$^{2+}$ depending on the composition). These latter ions provide radio-opacity.

**Acidic Polymer:** This is typically poly-acrylic acid, but may comprise polymers and copolymers of acrylic, itaconic, maleic, and vinyl phosphonic acids. Acidic functional groups are numerous along the polymer backbone, and the acids are water-soluble (McLean et al 1994).

**Acid-base Reaction:** This must take place as part of the cement-forming process. The cement forming is defined as the conversion of the initially viscous paste to a hard solid. In conventional glass-ionomer cement this reaction takes place within a clinically acceptable time, i.e. a few minutes. Glass-ionomers can be used as a liner, luting cement, or a base/core material. As a restorative material, glass-ionomer offers the advantage of being the only material with a true chemical bond to tooth structure (Mount 1993; Mount 1994). Glass-ionomers however, are brittle with low flexural and compressive strength (Berg 1998; Mass et al 1999). They are often aesthetically less satisfactory than other tooth-coloured restorations (Mount & Makinson 1982; Swift 1988; Mount 1998).
Clinical studies reported that GIC’s showed inadequate survival rates compared with that of amalgam when placed in primary teeth (Hickel & Voss 1990; Welbury et al 1991; Ostlund et al 1992) and permanent teeth (Hickel & Voss 1988; Mjor & Jokstad 1993; Mjor 1997).

Water is a necessary ingredient of the GIC, as an acid/base reaction can only occur in an aqueous medium. The fluoride in the glass is released over time (de Araujo et al 1996), with a very high fluoride washout phase occurring initially for a period of 7-10 days, depending on the rate of setting. The rate of fluoride release then slows and remains at a low level (Tay & Braden 1988). The fluoride release at this stage is diffusion controlled. Research has shown that GIC can also be recharged in the presence of ambient fluoride (such as that given during a professional fluoride administration), which can augment the fluoride in the surface material of the restoration (Forsten 1991).

The physical properties of traditional glass-ionomers have improved dramatically over the last 20 years aided by the introduction of higher powder-to-liquid ratio glass-ionomer materials and also provision of higher molecular weight poly acrylic acid (Berg 1998). These stiffer materials may be condensable, facilitating their use in posterior teeth, and allowing their application in larger occlusal restorations than previously possible (Berg 1998).

The Coefficient of Thermal Expansion (COTE) of glass-ionomer materials is similar to tooth structure, particularly to dentine. If there is a large disparity in the COTE of the material and the tooth structure, then temperature-related expansion / contraction can eventually lead to fracture or other failure of the restoration (McLean et al 1985; Berg 1998).
Traditional glass-ionomers are not command set materials. Although they bond chemically to tooth structure, they will fracture if subjected to strong opposing forces such as dysfunctional occlusion during excursive movements with a hard food substance.

Glass-ionomer restorative materials have been combined with silver or amalgam alloy to provide reinforcement (Swift 1988; Stratmann et al 1989). However, there has been a continuous debate about their use in restorative dentistry for children (Williams & Billington 1989; Forsten & Karjalainen 1990; Kilpatrick et al 1995; Holst 1996). Ketac-Silver (KS) for example, appears to have low compressive and flexural strength (Williams & Billington 1989; Beyls et al 1991; Pearson & Atkinson 1991) as well as poor marginal adhesive bonding properties (Billington et al 1996).

Glass-Ionomer systems currently available take too long for initial hardening and are susceptible to moisture and desiccation during the early setting phase. The hardened cement may show moderate to poor fracture strength and poor resistance to wear (Williams & Billington 1991). Although the adhesion and fluoride-releasing properties of the glass-ionomer materials are advantageous, the combination of difficult handling properties, extended setting time, and poor durability made these cements less satisfactory for routine use in children.

Since glass-ionomer cements were first developed in the 1970's, researchers and manufacturers have devoted their energies toward creating restorative materials that retain all the advantages of glass poly-alkenoate systems, but avoid the three chief limitations highlighted above: difficult handling properties, poor wear resistance, and poor fracture strength.
C. Characteristics of Conventional Glass-Ionomer(s)

Two improved conventional glass-ionomer restorative cements have been available for the last few years:

Ketac – Molar (ESPE)

- Fuji IX (GC).

They still only harden by the conventional acid-base neutralization reaction but have improved properties. The smaller particle size and distribution of glass powder have provided a rapid setting reaction leading to less sensitivity to moisture during the maturation phase, and low solubility in oral fluids after setting.

(i) Recharging GIC Restorations

To ensure a permanent anticariogenic effect, a dynamic situation is desirable. If there were only a one-way release of fluoride, there would be a danger of depleting the fluoride resources with time. If, on the other hand, ageing GIC materials are capable of both clinically binding and releasing fluoride, this would provide a permanent fluoride reservoir. Results of laboratory studies (Koch & Hatibovic-Koffnan 1990; Forsten 1991) suggest that this is possible. This has been referred to as recharging glass-ionomers or the reservoir effect (Rothwell et al 1998).

It is now considered that glass-ionomers release fluoride from a reservoir, which consists of both the unreacted glass-ionomer filler and the matrix (Forsten 1991). Once it has been depleted from a constant fluoride release, the reservoir can be replenished. The fluoride content in glass-ionomers is much higher than that of the tooth. With ion exchange over time, fluoride ions diffuse from the area of high concentration (in the GIC)
to the area of lower concentration (in the tooth). In this initial burst fluoride release process the hydroxyapatite in the tooth is permanently transformed into fluoroapatite. With time, a fluoride equilibrium between glass-ionomer cements and tooth is established (Forsten 1994; Forsten 1998).

Glass-ionomers will also generally release fluoride from the surface into the saliva, since a fluoride equilibrium between the GIC surface and the oral fluids occur. It is thus possible that the fluoride from the ionomer’s surface can be topped up from any source of fluoride ion in the oral fluids. There is evidence of fluoride release into saliva (Hatibovic-Kofman & Koch 1991). It has been suggested that protection afforded by the fluoride ions provides a zone of enamel around the restoration periphery, which is less prone to carious attack (Forsten 1998).

However, the long-term caries inhibition at the restoration margins will be less effective against new lesions that might develop. There is no conclusive evidence for or against a treatment effect of inhibition of recurrent (secondary) caries by glass-ionomers restoratives (Randall & Wilson 1999). This can be of concern in patients with high caries susceptibility (Dunne et al 1996). However, fluoride can be replenished in glass-ionomers with daily topical application in the form of toothpastes (Rothwell et al 1998).

(ii) Finishing of GIC Restorations

Glass-ionomers may be carved when the setting reaction has neared completion. This is may however stress the setting cement. It is better to delay contouring with abrasive stones until the material fully set. However, the final surface finish of any system is ultimately controlled by the size of the filler particles. Surface smoothness does not necessarily correlate with plaque retention and the chemical composition of the material is also important.
(III) SUMMARY OF CONVENTIONAL GIC CHARACTERISTICS

- Form a hard substance upon setting quickly (Crisp et al 1979)
- Minimal shrinkage, with good marginal integrity with reliable adaptation to tooth tissue (Mount 1989; Watson 1990)
- Coefficient of thermal expansion similar to tooth structure (Wilson & McLean 1988c)
- Adhere chemically to enamel and dentin in the presence of moisture (Wilson & McLean 1988b)
- Fluoride release (Forsten 1976; Forsten & Karjalainen 1990; Forsten 1994)
- Poor abrasion resistance and low tensile strength (Mount 1989)
- Bulk fracture (Qvist et al 2004a)
- Biocompatible
- Performs better when used to restore occlusal cavities of primary teeth (Qvist et al 2004b)
- Early moisture sensitivity requires protection (with varnish) immediately after placement (Earl et al 1989).

2.7.2.3. Resin-Modified Glass-Ionomer(s) (RMGIC’s)

A. History and Development

A variety of terms have been used for these hybrid cements. The term ‘resin-modified glass-ionomers’ implies that the characteristics of a glass-ionomer amine is maintained, but modified by the presence of a polymerizing resin (McCabe 1998).
This term was originally used by Antonucci in 1988. These materials set partly via acid-base reaction, and partly via photochemical polymerisation (McCabe 1998). Theoretically they should form an interpenetrating network.

B. Composition

RMGIC’s represent an attempt to overcome some problems with traditional glass-ionomers. These materials have improved aesthetics, with improved dimensional stability at high humidity (Kanchanavasita et al 1995), and improved initial physical properties (such as tensile strength and fracture toughness), accelerated curing by light and have fewer hydration problems (Kanchanavasita et al 1998).

To achieve the improved toughness, speed of setting and resistance to dehydration, the water present in the glass-ionomer system is replaced by water-soluble polymers or monomer systems capable of room temperature polymerisation. These were formulated in the late 1980’s (Antonucci et al 1988; Mitra 1991; Smith 1998).

These hybrid materials set in two ways; a GIC acid-base reaction and polymerisation of the resin component of the matrix. The resin component can be light-cured (Fuji II LC), dual-cured (Vitremer Restorative) or chemically cured (Vitremer Luting and Fuji Plus). The addition of a water-soluble monomer resin such as HEMA to the liquid system replaces some of the water in the system. This in fact slows down the acid-base reaction. A photo and/or chemical initiator determines the polymerizing setting reaction. Phase separation can occur, as light polymerisation is much faster than the acid-base reaction (McCabe 1998). The hoped for interpenetrating network does not form.

Although the setting process also involves the typical acid-base process between the filler and the polyacid matrix (Nicholson et al 1988), the polymerisation reaction is more rapid.
and is completed first (McCabe 1998). As these materials are somewhat opaque to light transmission, it is recommended by some clinicians that the initial layer, which can be considered to be the bonding layer, should be no more than a thin wash on the tooth surface.

This layer needs to be completely light-cured before adding more material. Light-curing the outer most layer gives the restoration improved resistance to hydration / dissection. Air inhibition of the surface requires overfilling. A thin coating of a resin adhesive can also reduce the risks of water imbibition (Mount 1993). Although these materials appear to be set after light-curing, the material is reported to become noticeably harder with time as a result of the acid/base setting reaction between the acidic polyacids in the material and the basic glass-ionomer filler particles (Nicholson 1998). A further disadvantage is that early finishing can damage the immature bonds to the tooth structure as well as weaken the material so that the incompletely reacted water-soluble components can wash out.

RMGI's are reported to have relatively poor colour stability; this is due to the reduced GIC setting rate, permitting the soluble components to leach out.

The structural integrity of RMGI's may be weakened by swelling, which occurs due to retained unreacted resin (primarily HEMA). This occurs mostly in the deeper areas of the restoration, where light polymerizable material is further away from the light source and attenuation occurs. Thus, these materials can be compromised unless a thin layer of the material is applied over the preparation (Kanchanavasita et al 1995), immediately cured, and followed by cured increments (Anstice et al 1992), since the depth of cure does matter (Nicholson 1998). The properties of resin-modified glass-ionomers cement materials make them ideal for use in many situations. The ease of placement, together with improved
aesthetics, makes their use a significant alternative to the conventional glass-ionomer materials (McCabe 1998).

Although their aesthetic qualities are better than those of conventional glass-ionomer materials, they are inferior in appearance to the resin composites due to the inherent opacity of glass-ionomer type glass used in these materials (Mount 1993).

The apparent ability to release fluoride makes them an attractive option with advantages over resin composites in approximal and smooth surface restorations, which are non-load bearing (McCabe 1998). They are useful as liners and bases. It has been suggested that RMGIC's are also useful in the restoration of primary teeth with minimal cavity designs for conservative treatment of occlusal and approximal lesions in non-stress bearing areas (Croll 1992; Croll & Killian 1993a; Croll & Killian 1993b; Croll & Helpin 1995). Due to the variety of polyacids used in both GIC and RMGIC's, it is frequently necessary to test a range of materials in the generic group since each manufactured material can behave in a different manner in the oral cavity (Wilson & McLean 1988a).

2.7.2.4. Polyacid-Modified Resin Composites (PMRC's) (Compomers)

A. History and Development

For several years manufacturers have used the term glass-ionomer to describe resin -based products, which bear only the vaguest resemblance to conventional glass-ionomers (McLean et al 1994).

Recent developments in dental materials technology offer a new category of light-cured resinous restorative; the polyacid-modified resin composites (PMRC). These are a sub-group of products, supposedly combining the characteristics of composites and glass-
ionomers (McLean et al 1994; Shaw et al 1998), with improved physical, chemical and mechanical properties (Kunzelmann 1996).

B. Composition

Polyacid-Modified Resin Composites (PMRC’s) are commonly referred to as Compomers, a name first used by the manufacturer Dentsply for its material Dyract. Significant confusion has been created concerning the very nature of compomers. The name ‘Compomer’ is a hybridization of COMPOsite and glass-ionoMER. However, these materials are not glass-ionomers (Berg 1998). These poly-acid-modified resin composites, consist of glass filler, which is based on a glass-ionomers glass component, and a polymerizable resin matrix. They do not contain water initially but absorb water from the mouth after the polymerisation reaction has taken place (Iazzetti et al 2001). Once set, fluid uptake may result in a further reaction between the glass and the un-reacted carboxylate group on the resin backbone (Burgess et al 1994; Burgess et al 2002). Compomers in their unpolymerised form are soft, non-sticky, pastes, presented in a unidose nozzled delivery device, and are easy to place. They were introduced in Europe in 1993-1994, and the first product available was Dyract (Mass et al 1999). An important claim was that the materials were reported to be developed as fluoride-releasing composites, providing a continuous low level of fluoride ions to the cavity margins (Berg 1998).

The formulation comprises resin composites with acid-modified monomers and basic glass filler particles (Burgess et al 2002). In an aqueous environment the material absorbs water and undergoes a slow rate diffusion-driven acid-base reaction, leading initially to a salt formation gradient at the uppermost material surface (Eliades et al 1998).
This results in fluoride ions being released to the surrounding medium soon after placement (Shen 2003). Dyract has undergone a number of formulation changes: these included the addition of an amine fluoride to the resin system to increase fluoride release, the use of smaller particle size to give a smoother surface finish, an increase in initiator systems to enhance the conversion, and the addition of cross-linking agents to improve wear resistance. The latest version is known as Dyract AP. Several manufacturers have followed this line of development. The restorations all have one factor in common, their requirement for water sorption after placement to achieve fluoride release via an acid-base reaction (Xu & Burgess 2003). This is reported to result in some expansion of the material (Burgess et al 2002). Compomers exhibit lower hardness values and lower flexural strength than composite resins (Chen et al 2003). As with composites, all compomers are used with an adhesive agent to bond to the tooth. This has the effect of reducing fluoride passage from the restoration into the cavity walls (Burgess et al 1993; Burkett et al 1993; Mass 1999; Burgess et al 2002). Almost all other physical properties of these materials are slightly less desirable than those of conventional composites (Burgess et al 2002; Chen et al 2003). Despite these differences the material is widely clinically accepted (Marks et al 1999b; Luo et al 2000).

Compomers differ from the GIC in at least two respects:

- First, the glass particles are partially silanized to provide a direct bond with the resin matrix
- Second, the matrix is formed during the light-activated free radical polymerisation reaction of monomers.
Those monomers are essentially modified methacrylates, (UDMA, BisGMA, etc) and new bi-functional monomers containing simultaneously two carboxylic groups and two double bond functions (TCB, DCDMA, etc). The bi-functional monomer is designed to react with the methacrylates by radical polymerisation. It also undergoes an acid-base neutralization reaction with the cations liberated from the glass particles when water is present. Theoretically, the three-dimensional network resulting from those two reactions should be formed both of covalent and ionic bonds (Meyer et al 1998). However, the absence of water in the composition of the polyacid modified composite resins prevents the neutralization reaction from commencing (Shaw et al 1998). Hence, those materials do not set in the absence of light, and are not glass-ionomer cements as previously defined (McLean et al 1994).

The PMRCs behave predominantly as composite resins, hardening with an initial photo-polymerisation, after which the material is completely set. Any acid-base reaction is produced only upon contact with saliva, which acts as the water component reaction (Cehreli & Altay 2000; Burgess et al 2002). In the presence of water from the oral environment, the acid functional groups, which are attached to the monomer units and are now part of the polymerised material, react with the glass (base) to initiate a glass-ionomer reaction. This theoretically provides fluoride release. The level of release declines sharply after 3 days (Xu & Burgess 2003). Some compomers may have fluoride salts in addition to the fluoride released from the latter GIC reaction. However, even taking account of this, additional fluoride released is significantly lower than that of traditional GIC or RMGI materials (Berg 1998; Meyer et al 1998; Xu & Burgess 2003).
Since compomers are essentially resin composites, they generally require the use of primers or adhesives prior to their placement (Berg 1998; Manhart et al 1999). The intermediary agents allow the compomer resin to adhere to the tooth structure (both enamel and dentine) of the preparation (Manhart et al 1999).

C. Summary of the Advantages and Disadvantages of Compomers

It is important to compare any new material such as compomers to existing materials that have been clinically successful for a number of years.

(I) ADVANTAGES OF COMPOMERS

• Ease of placement (Attin et al 1998; Attin et al 2001)
• No mixing, unidose dispensation
• Easy to polish (Burgess et al 2002)
• Good aesthetics (Garcia-Godoy 2000)
• Excellent handling (Peters et al 1996)
• Less susceptible to dehydration (Kanchanavasita et al 1995)
• Radio-opaque.

(II) DISADVANTAGES OF COMPOMERS

• Require a bonding agent like composites (Manhart et al 1999)
• More marginal staining and chipping (Attin et al 1998)
• Wears more than composites (Attin et al 1996, Burgess et al 2002)
• Enormous variation between manufacturers (Burgess et al 2002). This makes longevity difficult to predict
• Weaker physical properties than composites (Iazzetti et al 2001; Chen et al 2003)
• Significantly lower fluoride release than RMGICs (Meyer et al 1998)
• Common causes of restorations failure are bulk fracture and recurrent caries especially when used in primary teeth (Gross et al 2001)
2.7.2.5. Summary

It is apparent that tooth-coloured materials offer several advantages over amalgam, although these materials are still relatively untested in clinical use. Amalgam is still the most widely used and accepted material. On current knowledge, amalgam is the best documented restorative material and therefore, the most reliable comparator. Clinical evidence on RMGI’s and compomers is sparse. There is even less detailed clinical evaluation on their use in paediatric dentistry (Appendix VIII a,b).

In the light of the differing performance of restorative materials in the mixed dentition, it is essential that appropriate detailed clinical evaluation of these new materials be carried out under field conditions. Further, as the RMGIC’s, like conventional GIC’s, encompass varying formulations of polyacid which are known to have an influence on laboratory performance of conventional materials. Therefore, it is important to evaluate the clinical performance of the material with different chemical structures. This highlights the importance of carrying out the study outlined below.
2.8. Assessment of Dental Restorations

Investigation of the decision-making process involved in the placement and replacement of restorations in the everyday practice of paediatric dentistry may provide insight as to how to improve restorative materials and techniques.

Dental practitioners expect that the products they use will be appropriate for the purpose for which they have been advocated. With this in mind, there are number of questions that must be asked of any new or modified dental material:

- Does it possess physical properties sufficient for the intended purpose?
- Does it possess identifiable advantages over existing materials designed for the same purpose?
- Is it safe to use?
- Is it sufficiently easy to use?
- Will it perform well over an acceptable period of time?
- Is it cost effective?

These questions can only be answered to a limited degree by *in vitro* research methods currently available. Laboratory-based studies provide important data and help to provide information on the first three questions. Clinical studies complementing the laboratory studies are necessary to provide further information and address the remaining questions. Without adequate testing under field conditions, the reliability and usefulness of materials for conserving carious teeth in children cannot be adequately assessed.
Methodology for the clinical evaluation of dental restorations has not altered greatly in recent years. Studies need to extend over a suitable time period. Clinical evaluation is, therefore, a lengthy process.

Unfortunately, commercial pressures frequently cause manufacturers to rely on laboratory data with little support from clinical evaluation (Knibbs 1997). Correlation between laboratory and clinical performance is often difficult to determine (Taylor et al 1989; Taylor et al 1990). There is growing opinion that international standards should be agreed and enforced to encompass laboratory testing / indirect, as well as clinical / direct evaluations (Tyas 1991; Tyas & Wassenaar 1991). There are inherent difficulties in clinical evaluation of a material, since considerable reliance is placed on qualitative evaluations made, in most cases, by the operator who is assessing her/his own operative work.

Each time a dentist examines a dental restoration, a decision is made as to whether or not the restoration is clinically acceptable. The criteria used in reaching such a decision will vary depending on the teaching received as an undergraduate, on the age and experience of the dentist, current thinking in the profession, and the individual clinical history of the patient. It has been shown that dentists vary in their judgment as to when restorations need replacement (Elderton 1976b; Elderton 1977 Espelid et al 1985).

It is important when assessing the quality of the restorations, particularly in a comparative study of dental materials, that the criteria used are well defined and the clinical assessment made reproducible over a sufficient time span. The most widely used evaluation system is direct clinical observation as proposed by the Department of Health and Human Services, USPHS (Ryge & Snyder 1973; Taylor et al 1989).
2.8.1. Direct Clinical Assessment of Dental Restorations

This assessment method was developed in 1971 (Cvar & Ryge 1971). It is based upon direct clinical evaluation by two or more trained evaluators, and classification of the restorations into categories defined by standardized criteria. Depending upon the extent of the material loss, the restoration is classified as clinically acceptable, or unacceptable. It uses subjective, descriptive criteria defined by Ryge and Snyder in 1973. In order to satisfy the demands of reliability and consistency this method requires an 85% agreement for both inter / and intra examiner reproducibility. Below that level the results are considered to be unreliable. It is commonly used to assess amalgam and composite restorations. By custom and practice, 85% is the level of reproducibility commonly used giving ‘good’ agreement when using Cohen’s Kappa (Cohen 1968; Landis & Koch 1977).

‘The systematic checking of clinical quality will become the dental procedure that must be imposed on others to maintain the professional standards of his office’ (Ryge & Snyder 1973). The steps proposed are easy to use and have been employed in many studies (Phillips et al 1971; Mjor & Haugen 1976; Bryant et al 1979; Charbeneau & Bozell 1979; Hamilton et al 1983; Marks et al 1999b).

The clinical assessment of the ‘quality’ of an amalgam or resin restoration immediately post placement means checking the ‘degree of excellence’ or ‘degree of confidence’ against a standard. These concepts are difficult to define and it is important to note that the authors used only the criteria clearly defined by themselves (Ryge & Snyder 1973). Clinical assessment is the visual examination by a dentist, using a mouth mirror, an explorer, and supplementary lighting as needed. These provide controlled conditions for examination. When examining a restoration it is necessary to look at ‘surface and
colour, anatomic form, and marginal integrity'. These characteristics were chosen because they were considered the most important features that the dentist would evaluate to establish her/his treatment plan (Ryge & Snyder 1973).

The criteria for each characteristic focuses on important factors that the examining dentist must observe when rating the restoration in that category, and the one with the poorest rating determines the category (Ryge & Snyder 1973).

In this project, a modification and extension of the criteria have been developed for the direct clinical examination. The assessment evaluations are:

- **Marginal integrity**
  The restoration appears to adapt closely to the tooth along its periphery. An explorer does not catch when being drawn across the margins.

- **Anatomical form**
  Defined as the restoration being continuous with the existing anatomical form of the tooth.

- **Marginal discolouration**
  The degree of staining around the restoration when examining the enamel margin surrounding the restoration.

- **Recurrent caries**
  Described as caries underneath and/or around the margin of a restoration, also known as secondary caries (Kidd & Joyston-Bechal 1997), and occurring adjacent to a filling (Kidd 2001). In the present study, recurrent caries diagnosis was carried out by conventional visual and tactile examination for roughness and softening of decalcification after cleaning and drying the teeth undergoing examination (Konig 1966).
• Contact point
Assessed by passing a piece of un-waxed floss between the proximal contacts in an occluso-cervical direction, and out through the embrasure. This is carried out after the restorative materials have set to avoid disturbing the proximal contour.

• The need for replacement of the restoration
A failed restoration is indicated when there is loss of anatomical form with crevice formation, fracture of the restoration, post-operative sensitivity and / or recurrent caries.

Detailed assessment criteria is needed to establish what constitutes failures which call for replacement or repair of restorations (Mjor 1993). The Direct Clinical Assessment method provides valuable information regarding the loss of anatomic form over time of the study and correlates directly with the clinical action needed. A limitation is that it is not effective in evaluating small early changes and does not yield quantitative information about the actual loss of material (Leinfelder et al 1986b).
2.8.2. Indirect Assessment of Dental Restorations

The main characteristic to be evaluated by the indirect method is ‘wear’ which results in loss of marginal integrity as well as anatomical form affecting both tooth structure and the restorative material.

2.8.2.1. Wear of Restorative Materials

A. Definition

The definition provided by the Institution of Mechanical Engineers of the United Kingdom is ‘the progressive loss of substance from the surface of a body brought about by mechanical action’ (Sulong & Aziz 1990). Another definition of wear is ‘the progressive loss of material from its surface due to relative motion’ (Reid et al 1990).

B. The Wear Process

The main concern for the longevity of a posterior restoration continues to be resistance to wear in clinical or ‘everyday’ use. This is not surprising as restorative materials are in use continuously almost from the moment that they are placed.

Wear is a complex phenomenon and the relative lack of resistance to wear of resin-based materials compared with amalgam is the major problem associated with their use as a dental restorative material. Most of the work carried out on wear of dental restorative materials has involved resin-based composites. Unfortunately, to date there has not yet been an accurate way to estimate clinical longevity in laboratory studies, despite many efforts to develop laboratory simulations (De Gee et al 1986; Leinfelder et al 1989; De Gee et al 1989; Leinfelder & Suzuki 1999). Reliable and clinically useful wear information has come mainly from clinical research studies (Taylor et al 1994).
C. Common Types of Wear

(i) Abrasive Wear

This occurs when a rough, hard surface or loose, hard particles plough out softer materials. Abrasive wear may be described as 2-body wear (e.g. the action of a file over a material), or as 3-body abrasive wear when an intermediary abrasive medium comes between the two contacting subjects (e.g. toothpaste between a brush and a restoration. In practice the distinction between the two is often unclear.

(ii) Erosive Wear

This can be described as degradation of a material by the chemical environment. Erosive wear of both tooth tissue and restorative material may occur simultaneously in the mouth, although it is likely to contribute minimally to the overall pattern of wear of resin-and metal-based materials. It may well be significant in the wear of GIC’s. It is important to note in dentistry that the term erosion has also come to be associated with a chemical degradation effect of tooth tissue (Kidd & Smith 1996c).

(iii) Fatigue Wear

Under certain conditions a component in a structure may suffer a loss in strength over a period of time. The component is seen to weaken, probably as a result of cyclic loading. In the mouth this cyclic loading may be a combination of physical and erosive effects, thermal cycling and repeated stresses. Failure from fatigue results from a gradual build up of damage generated during function often leading to localized catastrophic failure. It is thought fatigue plays a very important role in durability of dental restorations (Braem et al 1994; Dewji et al 1998; Dietschi & Herzfeld 1998).
D. Pathological Consequences of Wear

There are several important clinical features that can result from wear (Kidd & Smith 1996c):

- Exposure of dentine on surfaces normally covered by enamel
- Notched cervical surfaces
- Sensitivity
- Pulpitis and/or loss of vitality.
E. Summary

Three main mechanisms are involved in the phenomenon of wear of dental restorative materials: abrasive, erosion, and fatigue. Different wear mechanisms produce different degrees of damage (Roberts et al. 1977; Swartz et al. 1982; Dewji et al. 1998). The wear is also related to the great variation in the nature and composition of the restorative materials tested. Every material must be considered individually and the results of wear from several different in vitro investigations should be considered in the light of quantitative and qualitative observations from in vivo studies. Clinically small restorations demonstrated less wear than larger restorations (Lutz et al. 1984; Sturdevant et al. 1986; Sturdevant et al. 1988). These studies were primarily on the permanent dentition, where cuspal morphology is more prominent, while the primary dentition shows a much flatter occlusal table, substantially reducing the degree of protection provided by the surrounding tooth structure (Berkovitz et al. 1992). Further work is needed to elucidate the possible protective influence provided by the surrounding cavity walls and tooth surface on the wear of restorative materials.
2.8.2.2. Methods for Indirect Assessment of Dental Restorations

1. Rank Ordering System

A. History and Development

The United States Public Health Service (USPHS) guidelines were developed for quality assessment of dental restorations (Ryge & Snyder 1973). Traditionally, the loss of anatomic form of dental materials has been evaluated by the procedure developed by Cvar and Ryge in 1971. However, the USPHS guidelines indicate that any method can be used that would provide a quantitative means of loss of material. It does specifically suggest that appropriate study casts be made of die stone developed from rubber base impressions. Casts should be made at the time of insertion and again at the recall visits. The die stone casts reflect the amount of material lost from the occlusal and the occlusal part of approximal restorations.

The American Dental Association Council on Dental Materials, Instruments, and Equipment (CDMIE) has selected such a method over the United States Public Health Service (USPHS) criteria or Ryge system because the latter cannot detect minor losses of materials. Essentially, the direct clinical evaluation method suffers from lack of sensitivity, and therefore is of limited application. Recent studies have shown that most clinical evaluators cannot detect the occlusal cavo-surface margin until 150μm to 175μm of material have been lost (Leinfelder et al 1986b; Taylor et al 1990).

Secondly, the data generated with the use of the USPHS system requires the use of non-parametric statistics because the data are from an ordinal scale. Recently, a number of alternative systems have been introduced for the measurement of material loss.
The first indirect method designed to quantify loss of material was developed in 1981 (Goldberg et al 1984). It consisted of a series of four die stone casts to serve as calibrated standards, against which casts of restored teeth could be compared. The standards were selected on the basis of wear exhibited at approximately one-fourth of the perimeter of the cavo-surface margin of mandibular molars. The exposed enamel wall at the occlusal-apical discrepancy between the restoration and the tooth was then measured with a travelling microscope at four sites in this area (Goldberg et al 1984; Leinfelder et al 1986a). These standards were subsequently modified in 1983 (Leinfelder et al 1983; Leinfelder & Roberson 1983), where the method consisted of a series of six die stone casts that involved the entire occlusal surface exhibiting differing levels of material loss at the cavo-surface margin (Leinfelder et al 1986b). The successive casts represent wear or material loss in increments of 100μm. The first cast, for example, represents a loss of 100μm; the second 200μm; and so forth. This then became known as the Leinfelder-Golderg standards [L-G system] (Gerbo et al 1990). Both of these systems resemble the system used for evaluation of amalgam restorations (Mahler et al 1970).

To use any of these systems, a cast of a tooth restored with a given material is compared against the standards. A match between the cast in question and one of the calibrated standards identifies the level of wear as that given by the standard cast, for example 100μm, 200μm, etc. Should the cast appear to fall between two levels, a value of 50μm would be recorded e.g. 150μm, 200μm, 250μm etc. In this regard, if the cast should approximate one of the standard casts but not match it, a value of 25μm at the higher end would be ascribed e.g. 175μm, 275μm (Leinfelder 1987). All these systems evaluate the condition of a restoration indirectly, that is by comparing a replica of the restoration to a standard, rather than directly evaluating the restoration itself. The
methods are essentially similar though the one designed for amalgam utilizes two-
dimensional photograph standards while the others utilize three-dimensional casts.

One significant difference between methods results from the use of calibrated standards
for the cast comparison method. This provides a means of making a scaling conversion,
which permits the development of indirect quantitative estimates of magnitude of
restoration wear (Leinfelder et al 1983; Leinfelder et al 1986a). This creates a pseudo-
numerical scale. This enables the use of summary statistics such as means and standard
development.

The evaluation of clinical restorations in this study was carried out by direct comparison
of the casts of the clinical restorations to the standard casts.

The casts are usually evaluated with the aid of a 2X magnifying lens and a high
intensity incandescent lamp. This is assumed to provide a consistent point source of
illumination. The lamp is positioned in front of the evaluator, and the casts are held so
that the light falls at a low angle to the surface and toward the evaluator (Leinfelder et al
1986a).

B. Other Indirect Standards

In an effort to improve the level of resolution associated with the indirect standards, a
modified system was developed (Moffa & Lugassy 1986). This method used a series of
cylindrical dies rather than replicas of restored teeth. The centre surface of these cylindrical
dies was offset by varying amounts and is known as the M-L scale (Gerbo et al 1990).
The basic difference between this system and the original optical standards is in the
number of reference points. Rather than 100μm differences between standards, the M-L
casts consist of references only 25μm apart. Consequently, it was theoretically possible
to determine loss of material on the occlusal surface at an appreciably higher level of resolution (Gerbo et al 1990).

More recently Vivadent has developed a further system of optical standards (Gerbo et al 1990; Taylor et al 1990). In principal this innovative system is a combination of the calibrated die stone standards and the M-L scale. Like the Moffa-Lugassy system the standards represent loss of material at 25μm levels. Unlike the M-L scale, however, each standard is in the shape of a posterior tooth. While the M-L scale contains standards, at 25μm levels only between 0 and 100, the Vivadent system contains 25μm standards over a range of 200μm. A comparison of all three standards [M-L scale, Vivadent and L-G standard] found that both M-L and Vivadent standards give essentially the same results, whereas L-G standards gave wear values which were twice as high (Gerbo et al 1990).

C. Characteristics and Limitations of Indirect Assessment Standards

The assessment systems of calibrated die stone casts lack the resolution of those involving computerized optical or mechanical probes. However, they offer the potential for rapid measurements of large sample sizes (Gerbo et al 1990; Tyas & Wassenaar 1990). While the more technical methods require two hours or more per sample, the standard cast systems can be assessed for an individual restoration in one minute or less. Furthermore, and importantly, the low cost of the die stone standards makes it possible for any investigator in any clinical setting to study oral wear assessment without the need for high technological and technique sensitive methods. These practical considerations have led to this type of system being more widely used for determining loss of anatomic form (Taylor et al 1990). The direct clinical evaluations based upon the USPHS method do use defined criteria for the classification of the degree of wear, but
are conceptual rather than physical and are designed more for the determination of appropriate clinical action than for the measurement of quantitative changes (Leinfelder 1987).

The indirect optical systems that are known are capable of determining the rate of changes only from one category to another e.g. 100μm to 200μm. Consequently they are insufficiently sensitive to quantify loss of material from the occlusal surface in the form of a continuous scale.

Rank ordering techniques are readily applied to casts and photographs, and can achieve high levels of inter-evaluator agreement (Leinfelder et al 1986a). In addition, rank ordering methods for indirect evaluation can show greater sensitivity than direct clinical evaluation (Taylor et al 1990), and may be capable of making consistent discrimination within groups, which would also receive the score rating using the USPHS methods. On the other hand, cast rank ordering systems show four major limitations (Leinfelder et al 1986a):

- They require the ability to make multiple direct comparisons between the objects studied
- They are suited only to indirect evaluation techniques
- The rankings are inherently valid only in comparison to the other study specimens using the same ranking procedure
- Rankings do not lead to quantitative results using a continuous scale
- In spite of these limitations, these ranking procedures will often identify earlier differences between the wear of restorative materials than the USPHS method (Taylor et al 1990).
D. Correlation between Direct Clinical and Indirect Assessment Methods

The USPHS method is based on direct clinical evaluation (Cvar & Ryge 1971), whereas the cast ranking methods L-G, M-L and Vivadent standards are based on evaluation of stone casts of restorations. Unfortunately, the results obtained with the indirect methods may not be comparable for specific criteria for example, recurrent caries, or marginal discolouration (Leinfelder & Roberson 1983; Leinfelder et al 1986a)

The direct method rates the wear of restorations in terms of specific categories of clinical acceptability, with the most commonly reported value being the 'A - B' transition corresponding to the onset of clinically detectable wear (Taylor et al 1989).

The indirect methods provide numerical estimates of wear by comparisons of casts of worn restorations with casts that serve as quantitative standards (Taylor et al 1990; Bayne et al 1994). Some important characteristics of dental restorations such as colour matching, recurrent (secondary) caries, and post-operative sensitivity, can only be measured effectively by direct clinical evaluation (Leinfelder et al 1986a). Other characteristics such as wear levels, anatomical form and marginal integrity, benefit from the use of indirect techniques using photos or casts. However, the validity of the Indirect Assessment depends on evaluators performing in an accurate, reliable, and consistent manner. For these reasons the inter-rater agreement both 'within' and 'between' evaluators was determined for the indirect method of assessment in this study (Altman 1991a). A summary of the common used methods for the assessment of posterior restorations (Direct and Indirect) are shown in Table 1.
The terms evaluators, intra-evaluator and inter-evaluators are commonly used at the
Eastman Dental Institute. In the literature the terms examiners, assessors, raters /
agreement, are all used in the same way. The term 'examiner' and its derivatives will be
used for the clinical part of the study that forms the main part of this thesis. While the
term 'evaluator' and its derivatives will be used for the indirect (experimental) part of
the study. The other terms were used where referring to the papers of cited authors.
Table 1: Summary of Assessment Methods of Restorations

<table>
<thead>
<tr>
<th>Methods of assessment</th>
<th>Procedures</th>
<th>Total time per restoration</th>
<th>Outcome measure</th>
<th>Expense</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Clinical</td>
<td></td>
<td></td>
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<tr>
<td>USPHS</td>
<td>Direct observation</td>
<td>1-2 min</td>
<td>Qualitative</td>
<td>Low</td>
<td>(Cvar &amp; Ryge 1971)</td>
</tr>
<tr>
<td>Modified Ryge</td>
<td>Direct observation</td>
<td>1-2 min</td>
<td>Qualitative</td>
<td>Low</td>
<td>(Dennison et al 1980a; Dennison et al 1980b)</td>
</tr>
<tr>
<td>Goldberg</td>
<td>Indirect Sectioned Impressions</td>
<td>30-60 min</td>
<td>5-10μm</td>
<td>Med</td>
<td>(Goldberg et al 1981)</td>
</tr>
<tr>
<td>Leinfelder</td>
<td>Indirect Cast Comparison</td>
<td>5 min</td>
<td>50μm</td>
<td>Low</td>
<td>(Leinfelder &amp; Roberson 1983; Leinfelder 1987)</td>
</tr>
<tr>
<td>M-L</td>
<td>Indirect Cast Comparison</td>
<td>5 min</td>
<td>50μm</td>
<td>Low</td>
<td>(Lugassy et al 1986)</td>
</tr>
<tr>
<td>Vivadent</td>
<td>Indirect Cast Comparison</td>
<td>5 min</td>
<td>25μm</td>
<td>Low</td>
<td>(Taylor et al 1990)</td>
</tr>
<tr>
<td>Mair</td>
<td>Indirect (Step-Wedge) Comparison</td>
<td>5 min</td>
<td>50μm</td>
<td>Low</td>
<td>(Mair et al 1990)</td>
</tr>
<tr>
<td>Winkler</td>
<td>Indirect (Step-Wedge) Comparison</td>
<td>5 min</td>
<td>25μm</td>
<td>Low</td>
<td>(Winkler et al 1991)</td>
</tr>
</tbody>
</table>
Chapter 2
Lit. Review

2. Photographic Assessment of Restorations

The photographic assessment involves using the same subjective Ryge criteria on viewing Ektachrome (Eastman Kodak Co., Rochester, N.Y.) colour transparencies with a 1:1 magnification taken at time of examination of the restorations (Johnson et al 1977). The transparencies are then examined using an x-ray viewer (Smales 1983). It is important to note that photographs should be taken as nearly as possible from the same position, and they should be all at right angles to the restored surface that is to be assessed (eg. occlusal, labial, and lingual), which might therefore limit the surfaces to be assessed. A further difficulty is the fact that it is impossible to take photographs reliably at 90° to the surface, especially when cooperation is limited. It is also important to note that, there are always some variations during photographic processing which affects the film image. These include:

- Processing technique
- Colour temperature of the film
- Storage conditions of the film prior and subsequent to its use.

One of the main advantages of using photographs or coloured slides in clinical research is that the material is available without the necessity of the patients’ presence. Thus different observers can make assessments independently without troubling the patient (Mezger et al 1985).

Coloured / or black and white transparencies or tracings can be used in another method where they are matched against two standard sets of enlarged (magnification X2, X3) colour transparencies. This method (Mahler et al 1970; Mathewson et al 1974; Sabott et al 1975; Mitchem & Gronas 1982) was used for assessing both amalgam and composite restorations to provide objective reference criteria (Smales 1983).
3. Quantitative Measure of Wear

One of the main shortcomings of any dental restoration, especially in the posterior region, is loss of material. This phenomenon influences the durability of the restoration.

Loss of material from dental restorations has been investigated extensively under laboratory conditions. Vrijhoef et al (1985a) suggested that in vitro wear resistance does not correlate, or correlates only weakly, with the wear resistance in vivo.

There is a need to develop reliable methods in which it is possible not only to assess qualitatively, but also quantitatively the extent of loss of surface material from dental restorations under oral conditions.

Several methods are now available to measure clinical wear. However, reliable wear information has come mainly from long-term clinical research studies of pooled data (Taylor et al 1994). Methods to determine material losses differ widely in the time and effort required to make the measurements, the cost of equipment and labour, and in their ability to generate quantitative wear values. In general, there appears to be an assumption that sophisticated, expensive and time consuming tests are in some way 'better'. However, information as to the sensitivity of such sophisticated tests is often lacking (Vrijhoef et al 1985a,b). A further problem is the limited availability of such materials because of the expense and ease of handling.
Wear measurement methods can be divided into three groups (Bayne et al 1994):

- Non-instrumental observational clinical evaluation methods
- Speciality methods
- Methods involving instrumental measurement of surface contours with computer assisted determination of wear values.

A number of tests on the clinical wear behaviour have been described in the dental literature. The most popular one is the USPHS-criteria as described earlier (Cvar & Ryge 1971), others are observational methods are listed in Table 2.

<table>
<thead>
<tr>
<th>Method</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>USPHS-criteria</td>
<td>(Cvar &amp; Ryge 1971)</td>
</tr>
<tr>
<td>Profilometer</td>
<td>(Meier &amp; Lutz 1978)</td>
</tr>
<tr>
<td>Extensometer</td>
<td>(Delong &amp; Douglas 1983)</td>
</tr>
<tr>
<td>Precision occlusal mapping</td>
<td>(Roulet et al 1983)</td>
</tr>
</tbody>
</table>

The need to quantify the loss of material helped to encourage the development of various methods. These have been described in the dental literature, for example, SEM-pictures (Kusy & Leinfelder 1977), weight loss of material (Handelman et al 1978), profilometry (Meier & Lutz 1979; Meier & Lutz 1980), and precision occlusal mapping (Roulet et al 1983) (Table 3).
Table 3: Quantitative Methods to Measure Loss of Substance of Dental Restoration

<table>
<thead>
<tr>
<th>Method</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEM-pictures</td>
<td>(Kusy &amp; Leinfelder 1977)</td>
</tr>
<tr>
<td>Weight of loss of material</td>
<td>(Handelman et al 1978)</td>
</tr>
<tr>
<td>3D Microscopy</td>
<td>(Mettler et al 1978; Roulet et al 1978)</td>
</tr>
<tr>
<td>Profilometer</td>
<td>(Meier &amp; Lutz 1979; Meier &amp; Lutz 1980)</td>
</tr>
<tr>
<td>Laser optical countering</td>
<td>(Atkinson et al 1982)</td>
</tr>
<tr>
<td>Moirée fringes</td>
<td>(Riethe 1981)</td>
</tr>
<tr>
<td>3D Microscopy + profilometer and computer</td>
<td>(Lambrechts &amp; Vanherle 1983)</td>
</tr>
<tr>
<td>MTS-Extensometer</td>
<td>(Delong &amp; Douglas 1983)</td>
</tr>
<tr>
<td>Weight of Material Loss with conversion of thickness</td>
<td>(van Groeningen &amp; Arends 1983)</td>
</tr>
</tbody>
</table>

The problem of any indirect method is that the measurements have to be made on models and not directly in the mouth of the patient. This introduces a source of variation as a result of model production.

In this study, the attempt to measure material wear was limited to non-instrumental observational clinical evaluation.
2.8.2.3. Summary

Laboratory-based studies provide important data and help to provide information on the durability of restorations.

It is recognised that when assessing the quality of the restorations, particularly in a comparative study of dental materials is subjected to operator variability (Nuttall & Elderton 1983; Espelid et al 1985; Mjor et al 1990). This indicates that the criteria used must be well defined and that the clinical assessment made reproducible over a sufficient time span.

Several methods are now available to measure clinical wear of restorative materials. For example, SEM-pictures, weight loss of material, and profilometry. However, reliable wear information has come only from long-term clinical research studies.

Rank ordering techniques are readily applied to casts or photographs, and can achieve high levels of inter-rater agreement. Rank ordering methods for indirect evaluation can show greater sensitivity than direct clinical evaluation, as multiple comparisons between the objects studied is possible. However, optical ranking methods do not lead to quantitative results using a continuous scale, but rather the imposition of a quasi continuous scale derived from categories representing decrements of wear.
Chapter Three.

Aims and Objectives
Introduction

Progress in materials' development can best be achieved by close study of both in vivo and in vitro test results. In vitro test methods may then be identified which may become valuable indicators of clinical performance of a restorative material. However, laboratory tests alone can never replace full clinical evaluation 'in the field'.

3.1 Aims and Objectives of the Study

To compare the survival rate of four restorative materials [Dispersalloy, Dyract AP, Fuji II LC, and Vitremer], placed under standard clinical operating conditions, in occlusal and proximal cavities in primary teeth and occlusal cavities in permanent first molars and premolars, using amalgam as the standard for comparison.

A. Direct Assessment (in vivo)

Assessment of restorations for durability and survival rate when placed under standard clinical operating conditions, in occlusal and proximo-occlusal cavity preparations of first and second primary molars. Restorations were also placed in occlusal preparations of first permanent molars and premolars. The direct assessment was carried out using modified USPHS criteria immediately after placement of restorations and at six-monthly intervals afterwards for a period of 24 months.
B. Indirect Assessment (*in vitro*)

Marginal wear levels for each of the four restorative materials / systems was carried out using a modification of the Leinfelder rank ordering method (Vivadent model Fig 2, page 127). This was by direct comparison of model replicas. These were a representation of the actual restorations placed in teeth of children and adolescents in this study. The indirect evaluation was carried out by three trained and calibrated evaluators.

A small study was carried out to measure the volumetric loss of restorative material over time.

3.2. Null Hypotheses

From the literature review, two null hypotheses were identified. These form the foundation for this study.

1. Direct Assessment (*in vivo*)

There is no significant difference in restoration survival between Dispersalloy, Dyract AP and Fuji II LC, and Vitremer. This was tested for the three following treatments:

- Occlusal (Class I) cavities in primary molars
- Approximal (Class II) cavities in primary molars
- Occlusal (Class I) cavities in permanent first molars and premolars.

2. Indirect Assessment (*in vitro*)

There is no significant difference in marginal wear between Dispersalloy, Dyract AP, Fuji II LC, and Vitremer. This was tested on cast replicas of the restorations assessed by the direct visual comparison method, which provide an accurate three-dimensional model of each tooth / restoration unit.
Chapter Four.

Patients, Materials and Methods
4.1. Ethical Approval and Selection Criteria

Ethical approval was obtained from the Research and Ethics Committees of the Eastman Dental Hospital (EDH) and the Ministry of Health of the United Arab Emirates (MOH-UAE) (Appendices Ia, Ib). The selection criteria for inclusion in the study were:

- Willingness of the child and parents to participate in the study, and to attend review visits at six-monthly intervals
- The presence of occlusal (Class I) and approximal (Class II) carious lesions in primary molars and occlusal (Class I) carious lesions in first permanent molars and premolars
- The ability of the child to cooperate for the dental treatment including the taking of an impression.

An information sheet was provided prior to obtaining written consent from the parents and verbal consent from each child (Appendices II, IIIb).

4.2. Subjects Taking Part in the Study

Two groups of children of similar age range, took part in the clinical trial:

- Group 1: Children and adolescents recruited from the Caries Clinic at the Department of Paediatric Dentistry of the Eastman Dental Hospital
- Group 2: UAE (City of Abu Dhabi) Children and adolescents recruited from their Primary School Dental Clinic (Appendix V). Ten randomly selected primary schools each with a dental clinic facility were selected for patients' recruitment (Appendix VI).
Each child recruited to the trial had a full dental examination to assess her/his suitability. This assessment was carried out in a standard clinical setting comprising a dental chair with standard dental lighting conditions, a dental mirror, and an explorer to remove any gross debris from the teeth. The teeth were visually examined for dental caries using internationally recognised diagnostic criteria (WHO 1987). Teeth visually diagnosed as carious were included in the study as radiographs were not available for the UAE group.

Gross multi-surfaced carious lesions exceeding one-third of the intercuspal width or teeth with enamel defects were excluded from the trial, as they would require more advanced restorative treatment that was beyond the scope of the study. Clearly, the treatment for such teeth was carried out to ensure that all children participating in the study were made dentally fit.

In order to meet the large sample size required, the unit of study was determined to be the individual tooth. A minimum of one / and a maximum of six restorations per child were planned for this study. All restorations were carried out in a standard dental clinic environment, using high and low-speed hand pieces as appropriate. Rubber dam isolation was used whenever possible. Alternatively, partial isolation with cotton rolls and high volume suction was used.

Pain control was achieved using local anaesthesia. Other methods such as Inhalation Sedation and non-pharmacological behaviour management techniques were used (e.g. Tell - Show- Do, Playful Humour, Distraction, Positive Reinforcement, Modelling and Behaviour Shaping) as the clinical circumstances required (Murphy et al 1984).
Patient behaviour and anxiety levels were recorded using the Frankl behaviour scale at baseline and review visits as shown in Table 4 (Frankl & Shiere 1962; Hosey 1995; Hosey & Blinkhorn 1995).

<table>
<thead>
<tr>
<th>Level of cooperation</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitely negative</td>
<td>1</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
</tr>
<tr>
<td>Positive</td>
<td>3</td>
</tr>
<tr>
<td>Definitely positive</td>
<td>4</td>
</tr>
</tbody>
</table>

An assessment of the overall status of the teeth and mouth was carried out using standard indices of dental health (Table 5) (Franco et al 1996).

<table>
<thead>
<tr>
<th>Primary (Deciduous) Dentition</th>
<th>Permanent Dentition</th>
</tr>
</thead>
<tbody>
<tr>
<td>dmfs the number of decayed, missing and filled surfaces</td>
<td>DMFS the number of Decayed, Missing and Filled Surfaces</td>
</tr>
<tr>
<td>dmt the number of decayed, missing and filled teeth</td>
<td>DMFT the number of Decayed, Missing and Filled Teeth</td>
</tr>
<tr>
<td>pi plaque index</td>
<td>PI Plaque Index</td>
</tr>
<tr>
<td>gi gingivitis index</td>
<td>GI Gingivitis Index</td>
</tr>
<tr>
<td>bi bleeding index</td>
<td>BI Bleeding Index</td>
</tr>
</tbody>
</table>
4.3. Randomisation of Restorative Material

Children taking part in the trial were randomly allocated to one of the four restorative materials. The unit of study was the individual tooth. To ensure equal number of samples in each group, the technique of 'minimisation' was adopted according to age and tooth-type. This was carried out by a computer software programme (StatMate 1995).

Minimisation is a method for random assignment that minimises the marginal imbalance in the numbers of patients allocated to different treatments by simple random numbers over several factors known to affect the outcome of the treatment (e.g. age) (Altman 1991c). A measure of imbalance is calculated over the set of prognostic factors describing the new patient, who is then most probably, but not invariably, assigned to the treatment that minimises the overall imbalance (White & Freedman 1978). This ensures that approximately equal numbers occur in each of the study groups to provide balanced or near balanced groups for statistical analysis.

In a few instances, during treatment it became apparent that the extent of the carious lesion did not conform to the inclusion criteria and the tooth required a different treatment approach to the planned restorative technique. The tooth was withdrawn from the trial. Patient recruitment continued until the numbers required were achieved.
4.4. Restorative Materials Evaluated in the Study

Dental amalgam was used as this provides the universally accepted standard with which other restorative materials can be compared. Three resin based restorative materials where limited clinical evaluation has been carried out under rigorous test conditions were selected (Sec.6.2.2). The materials were:

1. **Dispersalloy**
   - Conventional high-copper amalgam, used as the main comparator.

2. **Resin-Modified Glass-Ionomer(s) (RMGI’s)**
   - In this study 3M -Vitremer and GC Fuji II LC were selected from this category of restorative materials, since their chemistry is different. Vitremer was hand-mixed [powder and liquid], while Fuji II LC encapsulated [powder / liquid]. A cavity conditioner agent/ primer was provided for both materials.

3. **Polyacid-Modified Resin Composites (PMRC’s)**
   - These are commonly referred to as Compomers. Dyract AP. The most recent version of this type of material was selected and is a uni-dose syringable paste. Once set, water absorption is reported to cause a glass-ionomer reaction to take place (Young et al 2000), between un-reacted pendant carboxylate group on the resin and the surface of the glass filler.

   All three resin-based materials release fluoride (Creanor et al 1994; Forsten 1995; de Araujo et al 1996; Eliades et al 1998; Xu & Burgess 2003). For composition of materials used in the study, see Tables 6a, 6b.
# Table 6a: Material Composition and Clinical Handling

<table>
<thead>
<tr>
<th>Scientific name</th>
<th>Composition</th>
<th>Batch no.</th>
<th>Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Resin Restorative Materials</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dyract AP</strong> Polyacid-Modified Resin-based Composites (Compomer) (DENTSPLY DeTrey GmbH)</td>
<td><em>Prime &amp; Bond 2.1:</em> Dimethacrylate resins, PENTA (dipentaerythritol penta acrylate monophosphate), photo-initiators, stabilisers, Cetylamine hydrofluoride and acetone. <em>Dyract capsule:</em> Polymerisable resins, TCB resin, strontium-fluoro-silicate glass, strontium fluoride photo-initiators and stabilisers</td>
<td>980-6000488</td>
<td>Place directly into conditioned cavity</td>
</tr>
<tr>
<td><strong>Fuji II LC</strong> Resin Modified Glass ionomer (GC International)</td>
<td><em>Powder:</em> Fluoroaluminosilicate glass, peroxide/amine (micro-encapsulated) catalyst system, camphorquinone. <em>Liquid:</em> Co-polymer of maleic acid and acrylic acid, HEMA, water, activator</td>
<td>0302264</td>
<td>Activate capsule by depressing plunger then mix for 10 sec.</td>
</tr>
<tr>
<td><strong>Vitremer</strong> Resin Modified Glass Ionomer, Tri-Cure System (3M Dental Product)</td>
<td><em>Primer:</em> Consisting of Vitrebond co-polymer, HEMA (2- hydroxy-ethylmethacrylate), ethanol and photo-curing agents. Modifies the smear layer and completely wets the tooth structure to accommodate the glass polyalkenoate acid/base reaction. <em>Glass powder:</em> fluoroaluminosilicate glass particles. It also contains a proprietary reduction/oxidation system “microencapsulated”, potassium persulfate and ascorbic acid that catalyses a methacrylate “dark cure” of the cement. <em>Liquid:</em> an aqueous solution of polyacrylic acid modified with pendant methacrylate groups. In the liquid solution are Vitrebond co-polymer, HEMA, water and photo-initiators for visible-light curing.</td>
<td>19980507</td>
<td>Hand-mixing powder: liquid 2.5 : 1</td>
</tr>
<tr>
<td><strong>Amalgam Restorative Material</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dispersalloy</strong> Self activating capsules (DENTSPLY, Caulk)</td>
<td>Pre-encapsulated weight of alloy and mercury, self-activating. High copper amalgam. Single spill / or double.</td>
<td>941221F</td>
<td>Self activating capsules, just mix for 8-10 sec</td>
</tr>
</tbody>
</table>
# Table 6b: List of Materials Used in the Study

<table>
<thead>
<tr>
<th>Material</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispersalloy</td>
<td>Self-activating capsules. Caulk, Dentsply Int. P.O.Box 359, Milford, DE 19963-0359</td>
</tr>
<tr>
<td>Dycal</td>
<td>De Trey/ Dentsply, Konstaz, Germany.</td>
</tr>
<tr>
<td>Prime and Bond</td>
<td>Universal self-priming dental adhesive designed to bond composite and direct compomer materials to enamel and dentine. DENTSPLY DeTrey GmbH, de Tery-Straße 1, D-7867 Konstanz, Tel. +44(07531) 5830.</td>
</tr>
<tr>
<td>(DENTSPLY)</td>
<td></td>
</tr>
<tr>
<td>Fuji II LC</td>
<td>Light cured reinforced Glass-ionomer Restorative in capsules. Manufactured by GC Corporation, 76-1 Hasunuma-cho, Itabashi-ku, Tokyo 174-8585, Japan.</td>
</tr>
<tr>
<td>GC Conditioner</td>
<td>Poly acrylic acid cavity conditioner. GC CORPORATION. 76-1 Hasunuma-cho, Itabashi-ku, Tokyo 174-8585, Japan.</td>
</tr>
<tr>
<td>DELTON</td>
<td>Thin resin coating. Aromatic and aliphatic dimethacrylate monomers, light activated. DENTPLY Professional, DENTSPLY International. York, PA 17404. Tel. +44(1) 800 989 8826.</td>
</tr>
<tr>
<td>Vitremer Primer /liquid</td>
<td>3M Vitremer primer containing HEMA.</td>
</tr>
<tr>
<td>Vitremer Cavity Gloss</td>
<td>3M Vitremer finishing gloss, 6.5 ml/7.4g, Contains BIS-GMA and TEGDMA.</td>
</tr>
<tr>
<td>President</td>
<td>Additional silicone impression material.</td>
</tr>
</tbody>
</table>
4.5. Clinical Procedures

4.5.1. Operators and Caries Diagnosis Reproducibility

Two operators participated in the placement of the restorations. The author, Miss D. Mustafa and Ms. Doreen Matthew (Dental Therapist at the paediatric department, EDH). Restorative treatment allocation to either operators was randomly allocated according to study numbers generated by the ‘StatMate’ software. Both operators attended calibration sessions for intra and inter examiner reproducibility at six-monthly intervals. This was to standardise caries diagnosis, placement of the restorations as well as the assessment of the restorations. This technique was carried out using plastic and extracted primary and first permanent molar teeth. In this study, caries diagnosis was by visual inspection (WHO 1987), and only teeth diagnosed as carious in this way were included. This was because radiographic diagnosis was not available for the UAE group.

4.5.2. Restorative Treatment and Cavity Design

4.5.2.1. Restorative Treatment Protocol

All patients were treated as follows: Local anaesthetic and rubber dam isolation were used when possible, otherwise cotton rolls, dry guard, or high volume suction alone were used. A minimum of one restoration per child / mouth, and up to a maximum of 3
restorations within the same arch\(^1\) were completed at one visit. If the patient required any further fillings, these were performed at a subsequent visit.

\(^1\) Only one child (UAE gp) had six (the maximum permitted in the study) restorations placed (Table 9).
4.5.2.2. Caries Removal and Cavity Design

Cavity design was determined by the extent of the decay. Tooth preparations were made using a high-speed hand piece (300,000 rpm) with constant water spray. Removal of the minimal amount of enamel necessary to gain access to caries using a #330 carbide bur and #544 diamond bur under water coolant spray. A new bur was used for each patient. Soft demineralised dentine (often stained) was removed using either hand excavators (Kidd & Smith 1996a) or a round carbide bur in a slow-speed handpiece (25,000 rpm) with water spray (Andlaw & Rock 1996). In deep cavities spoon excavators were used for hand excavation of soft carious dentine.

High - and low - speed handpieces were used alternately so that the cavity was kept as small as possible commensurate with removing the soft dentine from the enamel-dentine junction such that it appeared hard when a probe was run along it (Kidd et al 2003b). Cavity design was achieved by adopting the minimally invasive technique (Sturdevant et al 1987; Garcia-Godoy & Hosoya 1998), and was limited to caries removal and/or existing restorations and recurrent caries. Sufficient enamel was removed to allow for excavation of any soft carious dentine. The inclusion of small to medium cavities with defective restorations is consistent with current practice in studies examining longevity of restorations (Holland et al 1986; Roeters et al 1998; Mass et al 1999; Wucher et al 2002). Details for cavity design are as follows:

A. CAVITY DESIGN FOR AMALGAM RESTORATIONS

Cavity preparation was according to modified Black’s principles criteria (Robinson 1985). Accepted minimal dimensions for amalgam are 2mm occlusally and 1mm elsewhere (Robinson 1985). In approximal cavities the proximal walls diverged towards the gingival, and the gingivo-buccal and gingivo-lingual line angles were rounded and
placed beneath the free gingivae. All line angles were rounded, and for both occlusal and approximal cavities, the buccal and lingual walls diverged slightly, to provide bulk. It was important to be conservative of tooth tissue so that the tooth remained as strong as possible and the occlusal forces placed on the amalgam kept as small as possible (Kidd et al. 2003b). However, if the tooth was caries free occlusally, it was not necessary to cut out the fissure. Mechanical retention was achieved by the addition of retentive grooves at the buccal and lingual walls of the proximal box as well as the addition of undercuts. Any carious or unsupported enamel were removed, using either the air turbine of a gingival marginal trimmer, using it as a hatchet with a cutting stroke to trim the buccal and lingual aspects of the approximal part of the cavity (Kidd et al. 2003b). This resulted in a rounded approximal outline facilitating thorough condensation of the amalgam in the gingival area.

B. CAVITY DESIGN FOR RESIN RESTORATIONS

Cavity preparation was limited to caries removal, and the orifice of the cavity was made wide enough bucco-lingually to obtain adequate visibility and access to the carious dentine beneath. Caries was removed from the enamel-dentine junction using a round bur. Additional retentive grooves were added at the buccal and lingual walls of the proximal box. No bevels were prepared and cavo-surface margins were 90°.

In a number of deep cavities (both amalgam and resin restorations) calcium hydroxide liner (Dycal) and/or glass-ionomer lining was applied for protective, and therapeutic reasons (Kidd & Smith 1996b), to the axial and/or pulpal cavity walls. In others no liner was used.

After cavity preparation, the cavities were rinsed with water (Kidd & Smith 1996b), and dried gently. For proximal cavities, a narrow contoured stainless steel matrix band,
coated with a thin layer of petroleum jelly, was adapted to the tooth and wedged using wooden wedges.

### 4.6.3. Placement of Restorative Materials

The manufacturer's instructions were followed carefully. Restorations were placed by both operators according to a strict protocol. For details on placement techniques and armamentarium see Tables 7a, 7b. Clinical Pictures are provided in Appendix VII.

#### A. AMALGAM RESTORATIONS

Amalgam (Dispersalloy, Densply Int. USA.) uni-dose capsule was mixed in the amalgamator for 10 seconds. The mixed alloy was then transferred to a suitable container (dappen dish) and a small amount was picked up in an amalgam carrier and transferred into the cavity. The first increment of amalgam was directed into the deepest part of the cavity. Great care was taken to condense the amalgam thoroughly at the gingival area, sliding the hand condenser from side to side to ensure adaptation of the material to the axial walls. Hand condensation then proceeded by pressure on the amalgam mass in the centre of the cavity, then stepping the condenser towards the walls of the cavity and the ends of the fissure. As the amalgam level reached to cavity margins, packing continued to allow an excess to build up over the ultimate level of the finished restoration. It was then burnished to ensure marginal adaptation. The amalgam alloy was carved when it was sufficiently hard using 'Hollenback' and 'Discoid-cleoid' carvers. The carvers were held so that the blades lay across the margin of the filling, half on tooth and half on amalgam, with a parallel movement carving back the amalgam defining the margin of the restoration. Finishing of the amalgam restoration was then completed using standard methods (Andlaw & Rock 1996). No cavity varnish was used
stroke of the carver. Once the amalgam had initially set, waxed dental floss was used in an occluso-gingival direction to clear the interproximal contact. Occlusion was then adjusted with the aid of articulating paper, after removing the rubber dam or cotton-wool rolls, and the patient was asked to place the teeth lightly together (Kidd et al 2003b).

Finishing of amalgam restorations was carried out using finishing burs and was limited to the elimination of surface roughness around the edges when reported by the patient. No polishing of amalgam restorations was carried out.

B. RESIN RESTORATIONS

Resin restorative materials are very susceptible to blood or saliva contamination, Rubber dam isolation was used whenever possible; otherwise cotton rolls, dry guard, or high volume suction alone were used. All resin-based materials were placed in increments to minimise polymerisation shrinkage.

(i) DYRACT AP

The primer liquid was applied (prime and bond system) in ample amounts to wet and saturate the cavity surface and then left undisturbed for thirty seconds. Removal of excess solvent and spreading of the resin layer evenly was achieved by gently blowing air for three to five seconds, and light-curing for ten seconds.

A second layer of the primer was applied and immediately cured. Dyract AP, a uni-dose compule system, was deposited directly into the cavity. Dyract AP was applied in layers up to a thickness of 2mm in order to enable full light polymerisation time of at least 30 seconds. For proximal cavities, after removal of the matrix bands, the restorations were cured through the lingual and buccal enamel walls and excess material trimmed with a No. C17 Carver (Deubert & Jenkins 1982).
Restorations were contoured with aluminium oxide polishing discs (Soflex discs), or composite finishing stones (Andlaw & Rock 1996). The occlusal surface of the restoration was then protected by applying a low viscosity lightly filled resin (DELTON, light-cured pit and fissure sealant) as advised by the manufacturers.

(ii) Fuji II LC

The GC conditioning liquid (mild polyacrylic acid) was applied, following the manufacturer’s instructions, to wet and saturate the cavity surface and then left undisturbed for thirty seconds. Removal of excess solvent and spreading of the liquid layer evenly was achieved by air thinning for three to five seconds, and curing for ten seconds.

Each Fuji II LC capsule was activated then placed in a mechanical mixer for nine seconds before injecting the contents into the cavity. The material was light-cured for 40 seconds. For approximal (Class II) cavities, after removal of the matrix bands, the restorations were cured through the lingual and buccal enamel walls and excess material trimmed with a No. C17 Carver. Restorations were contoured with aluminium oxide polishing discs (Soflex discs) (Andlaw & Rock 1996).

The surface of the restoration was then protected by applying a low viscosity lightly filled resin (DELTON, light-cured pit and fissure sealant) as advised by the manufacturers (Sidhu & Watson 1995; Sidhu et al 1995).

(iii) Vitremer

3M Vitremer conditioning liquid was applied, following the manufacturer’s instructions, to wet and saturate the cavity surface and then left undisturbed for thirty seconds. Removal of excess solvent and spreading of the resin layer evenly was achieved by air thinning for three to five seconds, and curing for ten seconds.
Vitremer powder and liquid (the fluoro-aluminosilicate glass with the modified poly­
acrylic acid) were hand-mixed according to manufacturer's instructions, then placed in a 
syringe, injected into the cavity and light-cured for 40 seconds for initial 
polymerisation.
For class II cavities, after removal of the matrix bands, the restorations were cured 
through the lingual and buccal enamel walls and excess material trimmed with a No. 
C17 Carver.
Restorations were trimmed and polished with aluminium oxide polishing discs (Soflex 
discs). The occlusal surface of the restoration was then protected by applying a thin 
layer of cavity gloss (3M Vitremer gloss, as per manufacturers' instruction). This 
protects against moisture contamination until the retarded GIC reaction is completed 
(Garcia-Godoy 1986; Garcia-Godoy 1988; Henry & Jerrell 1989; Croll 1992; Croll & 
Cavanaugh 1997).
<table>
<thead>
<tr>
<th>Resin Based Restoration</th>
<th>Cavity Conditioning</th>
<th>Mixing</th>
<th>Placement Technique</th>
<th>Finishing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyreact AP</td>
<td>Prime &amp; Bond was applied in 2 layers: ample amounts applied to thoroughly wet and saturate cavity surface. Then dried using air syringe, excess removed and spread evenly, cured for 10 sec.</td>
<td>Uni-dose compute for immediate injection.</td>
<td>Compute tip inserted into notched opening of applicator gun barrel. Dyreact AP dispensed directly into cavity. Material packed using a condenser. In deep cavities incremental placement of 2mm was carried out. This was to minimise polymerisation shrinkage. Excess material removed using a flat plastic instrument. Material cured for at least 40 sec. To ensure polymerisation each area of the entire restoration was exposed to light cure.</td>
<td>Immediately after curing, gross excess removed with fluted finishing burs or diamond. Inter-proximal area finished and polished. Outer Dyreact AP surface protected with a thin coat of Delton fissure sealant.</td>
</tr>
<tr>
<td>Fuji II LC</td>
<td>Washed and excess water removed. GI Cavity conditioner applied for 20 sec to remove smear layer.</td>
<td>Before activation, capsule tapped on a hard surface to loosen powder, then activated by pushing the plunger until it was flush with the main body. Mechanically mixed for 10 sec.</td>
<td>Using capsule applicator, the Fuji II LC was injected directly into the cavity. The material was contoured using a plastic instrument. Light cured for 20 sec using visible light. For cavities deeper than 2 mm, layering technique was used.</td>
<td>Under water spray using superfine diamond bur, silicone point and polishing strips. Outer surface protected with a thin coat of Delton fissure sealant.</td>
</tr>
<tr>
<td>Vitremer</td>
<td>Primer applied for 30 sec to enamel and dentine surfaces, dried using air syringe for 15 sec, then light cured for 20 sec.</td>
<td>Powder mixed into the liquid (using 2 scoops of powder to 2 drops of liquid, ratio 2.5/1). All of the powder was incorporated into liquid in 45 sec.</td>
<td>The mixed Vitremer was syringed into the cavity keeping the syringe tip immersed in the material to minimise air entrapment. The restoration was contoured using a plastic instrument. Light cured for 40 sec, exposing the entire surface area to visible light.</td>
<td>Carried out immediately using conventional rotary instruments. Soflex discs recommended. Vitremer 3M finishing gloss is applied to restoration to protect it.</td>
</tr>
<tr>
<td>Cavity Preparation</td>
<td>Conventional cavity design following modified Black's principles (minimal destruction technique). Undercuts and/or retention grooves were added for mechanical retention. Contoured stainless steel matrix bands and wooden wedges for class II restorations. Cavity varnish was not used.</td>
<td>Vivadent Silamat was used to triturate the amalgam for 4 to 6 sec with Silamat set at M2 speed (4500μm).</td>
<td>Hand condensation technique used immediately after mixing was completed. Cavity angles and undercuts were packed using a small-faced plugger. Sufficient pressure applied to ensure marginal adaptation. Any mercury-rich amalgam was removed from surface with a small cotton pledget. Carving began immediately after condensation, using either discoid-cleoid or (C17) carver. Before removal of matrix band in class II cavities, marginal ridge area was carved carefully, on removal of the matrix band; gingival margins were smoothed and burnished using a beaver tail burnisher.</td>
<td>Occlusion was adjusted using articulating paper at placement visit. Finishing of restorations was carried out using finishing burs to eliminate surface roughness of the restorations reported by the patient. No polishing of amalgam restorations was carried out during this trial.</td>
</tr>
</tbody>
</table>

Table 7a: Placement Techniques of Restorations
### Table 7b: Armamentarium

<table>
<thead>
<tr>
<th>Instruments used in cavity preparation and placement of the restorative materials</th>
</tr>
</thead>
</table>
| **Basic tray set up** | • Tray 1: explorer, mirror, tweezers  
• Rubber dam kit: clamp holder, punch, clamps (W2A, W7, DW, 14A)  
• Cotton rolls  
• Articulating paper  
• Widgets  
• Light cure kit DENTSPLY QHL 75 curing light. Model No.503, serial no.503-0546. |
| **Cavity preparation** | • High speed hand piece (300,000 rpm)  
• Conventional speed contra-angle hand piece (25,000 rpm)  
• High speed burs: No.330, diamond burs No.544  
• Slow speed burs: large rose head round bur (sizes 5 or 8), inverted cone  
• Gingival marginal trimmer  
• Spoon excavator (large and small)  
• Dycal(Ca(OH)\_2) cavity liner. |
| **Condensation and carving** | • Amalgam carrier or amalgam gun  
• Dappen dish  
• Round condenser  
• Hollenback carver  
• Discoid-cleiod carver  
• C-17 carver  
• Flat plastic  
• Ball burnisher  
• Beaver-tail burnisher  
• Spatula  
• Glass slab  
• Matrix retainer: Tofflemire matrix band/or auto-matrix  
• Universal matrix band (regular and conventional) and auto lock loop  
• Wooden wedges  
• Dental floss (waxed and un-waxed). |
| **Finishing and polishing** | • Pear shaped finishing bur  
• Composite finishing kit (high speed)  
• Soflex-discs  
• Finishing strips. |
4.7.4. Impression Taking of Completed Restorations

Immediately after the restoration had been placed, completed and in the case of resin restorations protected by a cavity gloss or low viscosity fissure sealant (Sec. 4.6.3.B), an impression was made using a silicone-based impression material (President) in a rigid plastic sectional tray (Fig 3, page 128). This created a baseline record of the intact restorations and to enable the Indirect Assessment of materials over the period of study.

Each impression was poured using die stone ‘Crystacal R’. The impressions were taken at baseline and at each recall visit afterwards, and poured within two days using the same technique. The stone models were trimmed and stored carefully to enable indirect evaluation of the marginal wear levels of the restorations at a later date.
4.7.5. Data Collection and Estimation of Sample Size

4.7.5.1. Data Collection

Data was collected for each restoration at the time of placement (baseline), and at six-monthly intervals for two years. At each review, the patients had a routine dental examination including a check-up of the teeth, periodontium, and related oral structures. The surface quality and contact points of the restored teeth were assessed macroscopically. The data items were collected in standard format as shown in Appendix III a,b. Every effort was made to ensure that follow-up occurred as closely as possible to six-monthly intervals. If patients (and their parents) failed to attend for the review visit further attempts were made to contact them either by letter or by phone. All review appointments were completed within one month of the scheduled date.

4.7.5.2. Estimation of Sample Size

The aim of the study was to assess the clinical durability of four restorative materials when placed under standard conditions in young patients. In order to estimate the size of the sample required to identify changes of clinical significance, it was desirable to carry out sample size calculations for several different scenarios, not just one (Kirkwood & Sterne 2003b).

There are many variations reported on the success rate of resin restorations in the literature. These vary from 81% (Folwaczny et al 2001), 78% (Andersson-Wenckert et al 1997), 74% (Luo et al 2002), 60% (Kilpatrick et al 1995) and 50% (Ostlund et al 1992). To take account of these variations two sample size estimates were calculated.
These were based on the proportion of each filling material surviving two years; the proportions (expressed as percentages) were calculated as follows:

1. It was considered that a 20% difference in survival rates would be of sufficient clinical importance to substantially influence the clinical choice of material for clinical practice. As Dispersalloy has been reported to have a survival proportion of 90% (El Mowafy et al 1994), it is thus appropriate to seek a 70% survival proportion for each of the resin-based restorative materials.

The sample size needed to estimate a 20% difference in survival, with a power of 75% at a 5% level of significance is given by the formulae below:

\[
\frac{u \sqrt{\left[ \pi_1 (1 - \pi_1) + \pi_2 (1 - \pi_2) \right]}}{\left( \pi_2 - \pi_1 \right)} + \sqrt{2 \pi (1 - \pi)}
\]

\[
\pi_1 = \text{Survival percentage of amalgam restorations} \quad (\pi_1 = 90%)
\]

\[
\pi_2 = \text{Survival percentage of resin restorations} \quad (\pi_2 = 70\% \text{ for } 20\% \text{ difference})
\]

\[
u = \text{One-sided percentage point of the Normal distribution corresponding for given power; if power} = 75\% , u=0.67
\]

\[
v = \text{Percentage point of the Normal distribution corresponding to the (two-sided) significance level; if significance level} = 5\% , v = 1.96
\]

(Kirkwood & Sterne 2003b)

This resulted in a sample size of 65 restorations in each group giving a total of 260 required for the whole study.

2. A sample size estimate based on a more pessimistic survival rate would involve a difference of 25% between Dispersalloy [with a survival proportion of 90% (El Mowafy et al 1994)] and 65% each of the resin based restorative materials. This alternate sample size was calculated with a power of 90% at a 5% level of significance, using the same formulae. This also resulted in a total of 260 restorations for the study.
4.7.5.3. Adjustments for Loss to Follow-Up

In addition, the calculated sample size should be increased to allow for possible non-response or loss to follow-up (Kirkwood & Sterne 2003b). An adjustment was made to allow for 10% loss to follow up (Welbury et al 2000); this was calculated using the formulae below:

\[
\text{Adjustment factor for } x \text{ % loss} = \frac{100}{100 - x}
\]

\[
x = 10
\]

(Kirkwood & Sterne 2003b)

Multiplying the adjusted factor by the unadjusted sample size estimate of 260 gave a total of 288 restorations to be placed, allowing for 10% loss to follow up.
4.8. Assessment of Restorations

4.8.1. Direct Clinical Assessment of Restorations (*in vivo*)

The previously described subjective, descriptive clinical criteria were followed for Direct Clinical Assessment of restorations (Ryge & Snyder 1973; Ryge 1980). This was carried out by visual examination by the dentist, using a mouth mirror, and an explorer to gently remove debris from the fissure system. This approach was used as a sharp probe can cause cavitation and/or damage an incipient carious lesion (Bergman & Linden 1969; Kidd 1984).

The assessment evaluations comprised

- Marginal Integrity
- Anatomical Form
- Marginal Discolouration
- Recurrent Caries
- Contact Points
- Need for Replacement of the Restoration.

The restorations were checked clinically and scored following the criteria shown in Table 8, the database form was completed accordingly (Appendix IIIa,b).
Table 8: Clinical Assessment Criteria for the Dental Restorations

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Marginal Integrity</strong></td>
<td></td>
</tr>
<tr>
<td>The restoration appears to adapt closely to the tooth along its periphery, with no crevice formation. An explorer (dental probe) does not catch on being drawn across the margin or only does so in one direction.</td>
<td>1</td>
</tr>
<tr>
<td>An explorer will catch in either direction at some point around the margins and there is visible evidence of early crevice formation into which the explorer will penetrate. Dentine and lining are not visible.</td>
<td>2</td>
</tr>
<tr>
<td>Explorer will penetrate into the crevice to sufficient depth that the dentine or lining is exposed. The restoration is loose or requires replacement.</td>
<td>3</td>
</tr>
<tr>
<td>The restoration is fractured or lost and needs replacement.</td>
<td>4</td>
</tr>
<tr>
<td><strong>B. Anatomical Form</strong></td>
<td></td>
</tr>
<tr>
<td>The restoration is continuous with the existing anatomical form of the tooth.</td>
<td>5</td>
</tr>
<tr>
<td>The restoration is discontinuous with the existing anatomical form of the tooth but the discontinuity is insufficient to expose dentine or lining material and hence the restoration is clinically acceptable.</td>
<td>6</td>
</tr>
<tr>
<td>The restoration is not in continuity with the existing anatomy of the tooth, or is loose; the discontinuity is sufficient to expose dentine or lining, hence the restoration requires replacement.</td>
<td>7</td>
</tr>
<tr>
<td>Chapter 4</td>
<td>Patients, Materials and Methods</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>The restoration is fractured or lost and therefore needs replacement.</td>
<td>8</td>
</tr>
<tr>
<td>For proximal cavities only, fracture of the isthmus.</td>
<td>9</td>
</tr>
<tr>
<td><strong>C. Marginal Discolouration</strong></td>
<td></td>
</tr>
<tr>
<td>Not present / no marginal staining.</td>
<td>10</td>
</tr>
<tr>
<td>Discolouration (marginal staining) less than one third of circumference of restoration.</td>
<td>11</td>
</tr>
<tr>
<td>Discolouration (marginal staining) more than one third and less than two thirds of circumference of restoration.</td>
<td>12</td>
</tr>
<tr>
<td>Discolouration (marginal staining) around whole of the circumference of the restoration.</td>
<td>13</td>
</tr>
<tr>
<td><strong>D. Recurrent Caries</strong></td>
<td></td>
</tr>
<tr>
<td>No recurrent decay.</td>
<td>14</td>
</tr>
<tr>
<td>Recurrent decay detected (Direct by visual examination and use of blunt probe).</td>
<td>15</td>
</tr>
<tr>
<td><strong>E. Contact Point</strong></td>
<td></td>
</tr>
<tr>
<td>Contact point present, assessed by passing a piece of un-waxed floss.</td>
<td>16</td>
</tr>
<tr>
<td>Loss of contact point, no resistance when passing dental floss.</td>
<td>17</td>
</tr>
<tr>
<td><strong>F. Need for Replacement</strong></td>
<td></td>
</tr>
<tr>
<td>Replacement not needed [1,2,5,6,10,11,12,13,14,16,17].</td>
<td>18</td>
</tr>
<tr>
<td>Replace restoration [3,4,7,8,9,or 15].</td>
<td>19</td>
</tr>
</tbody>
</table>
4.8.2. Statistical Evaluation

4.8.2.1. Survival Analysis of Restorations

The results are presented using survival analysis techniques. This analysis is especially useful where there are losses to follow up. It is important to note that, in cases of missing data, the life table data was censored as these considered losses to follow up\(^1\) (Altman 1991b). Failure of the restoration in this study was defined as the need for replacement. This could be due to one or more of the following:

- Loss of anatomical form with crevice formation
- Fracture of the restoration
- Postoperative sensitivity
- Recurrent caries.

4.8.2.2. Life Table

Curves for ‘Replacement of restoration needed’ were presented using the Berkson Gage life-table approach for cumulative survival of restorations over the 2-year trial period, using computer software (SPSS 2000). This approach is appropriate for interval data, in contrast to recoding exact survival times.

---

\(^1\) When the period of observation was cut-off before failure, such data was censored.
The survival analysis was carried out for:

A. **Cumulative Survival of Restorations**

- Evaluation of the cumulative survival of all restorations placed
- Evaluation of the cumulative survival of restorations according to restorative materials used (Amalgam and Resin restorations)
- Evaluation of the cumulative survival of restorations according to anatomical configuration (Occlusal and Approximal)
- Evaluation of the cumulative survival of restorations according to teeth restored (Primary and Permanent).

B. **Cumulative Survival of Restorations by Groups**

Two groups of patients participated in the trial: one from the UK and one from the UAE. The survival curves in the two groups were compared using the Log Rank test\(^1\).

**4.8.2.3. Cox Proportional Regression Analysis**

Multilevel Cox proportional hazard regression analysis was used to take into account the clustering of the data, which utilized robust standard errors to account for the clustering of data (having multiple restorations per child), and which used the restorations (teeth) at level -1 and subjects (child) at level -2. This was performed using computer software (Stata 2000).

\[^1\] Long Rank test is a non-parametric approach to comparing survival curves.
4.8.2.4. Assessment of Missing Data

This was carried out to check the extent to which conclusions based on the observed data would be affected by the outcome of missing data. In order to assess the effect of missing data two analyses were considered:

A. Sensitivity Analysis of Missing Data
   - Assuming all missing data as failed restorations
   - Assuming all missing data as successful restorations.

B. Estimation of Numbers of Missing Data and Exfoliated Teeth
   - Lower limits of exfoliation ages
   - Upper limits of exfoliation ages.
4.8.3. Indirect Assessment of Restorations (*in vitro*)

4.8.3.1. Rank Ordering System

A. METHOD

For this part of evaluation the Vivadent scale\(^1\) system was used for the indirect *in vitro* evaluation. Assessments were made by three clinicians (evaluators) who ranked the casts. Impressions of the restored teeth were taken at baseline and at the review appointments after 6, 12, 18 and 24 months. Using an addition silicone material ‘President’. Impressions were cast with ‘Crystacal’ stone material, and subjected to an assessment of wear by the three evaluators.

The marginal wear was measured using the ‘Williams Dental Scale’ (Ivoclar-Vivadent) (Leinfelder 1987). This scale has 18 moulds of restored molar teeth placed on a platform. All restorations in the model had a degree of wear ranging from 25μm to 1000μm (Fig 2) [giving semi-quantitative estimates from an ordinal scale].

Using the same lighting and a periodontal probe to outline the cavity margins, with the aid of a magnifying glass if required, each examiner visually assessed the models independently, and gave a rank score to conform to wear score on the scale. Two of the evaluators ranked the cast replica without any knowledge of the materials used or time passed since placement (visit number). In this way, the additional evaluators were

---

double blind. The third evaluator, (the author) was aware of the materials used in the
restored teeth.

The replicas of the restored teeth created from the rubber base impressions were used to
assess and evaluate the condition of the restoration, by comparing the replica of the
restoration with a laboratory standard (Vivadent model), allowing a quantitative
estimate of magnitude of restoration wear.

Rank scores were compared. If there was a difference of opinion, all three examiners
reviewed the model together and agreed on a rank. Only agreed rank orders of the three
evaluators were used for statistical analysis (Fig 3).

Each cast was given a score for the occlusal margins, as well as the occlusal part of
proximal restorations, in total two assessments were made, 'restoration margin of
occluso-buccal and occluso-lingual' (Fig 4).

In each case the evaluators were instructed to rank score the casts according to the
maximum marginal wear detected. In cases where there was a greater amount of wear
on one aspect of the cavity than the other, the closest average reading was taken and
recorded. The rank orders were initially recorded on paper, the data was then entered in
the computer for statistical analysis at a later date (Appendix IV).

B. Statistical Evaluation

Distribution and analysis of wear changes was carried out for each of the four
restorative materials from baseline to end (visit 5) using the Kruskal-Wallis non-
parametric one way analysis of variance, and at each review visit using the Friedman
test. This was performed using SPSS statistical package (SPSS 2000).
Fig 2: Vivadent Model and Cast Replicas

Occlusal table showing varying levels of wear

Vivadent model

Williams Dental Scale Vivadent model
Fig 3: Cast Replicas and Rank Ordering Method

Impression and Cast replica

Rank Order of Casts
Fig 4: Rank Ordering of Casts

Occluso-buccal

Occluso-lingual
4.8.3.2. Factors Considered in Marginal Wear Assessments of Cast Replicas

A. Method

To investigate the effects of the protective layer [added immediately after placement of the resin-based materials] on the marginal wear behaviour of the restorative system on the Indirect Assessment of the cast replicas, the following limited experiment was conducted (Fig 5):

- For each resin restorative material a small cylinder of the material was prepared using a contouring mold (Dentsply), the material was placed in the mold and a glass slide applied to the surface to provide a smooth finish. The material was then light-cured through the glass slide (using Dentsply QHL 75 curing lite). Ten specimens were made for each material in the trial.

- The cylinder was removed from the mold and the thickness of this cylinder was measured using an electronic micrometer\(^1\), to an accuracy of 1\(\mu\)m.

- A thin layer of a protective material, in the case of both Dyract AP and Fuji II LC restorations Delton was used, while 3M finishing gloss was used for Vitremer restorations. The protective layer was applied using a brush provided by the manufacturers; the protective layer was applied to one 'end' surface for each of the cylinders. A second measurement of the specimens' thickness was carried out.

---

\(^1\) Electronic micrometer 0-25mm: Mitotoyo (U.K.) Ltd, model CD-6 No. 002903.
B. Statistical Evaluation

A total of 30 measures, one for each of the 10 cylinders for each material, was measured before and after applying the coating layer. The difference before and after applying the protective layer was calculated. The Kruskal-Wallis non-parametric one way analysis of variance test was used for all three resin based materials to determine any variation in thickness when using the protective outer layer.
Fig 5: Measurements of Protective Layer Coating

DENTSPLY Contouring molds

Specimens ready to be coated with protective layer

Specimens of resin-based materials

Electronic micrometer 0-25mm, to measure specimens’ thickness
4.8.3.3. Quantitative Measure of Wear

The limitations of the rank ordering method led to an attempt to calculate volume loss and measure overall surface wear. The same Vivadent model was used for this preliminary *in vitro* experiment.

A. Method

- The plastic teeth selected for this measure were the models showing 25μm, 100μm, 200μm, and 700μm. The 25μm was chosen as the 'baseline' as the Vivadent model does not provide a replica with no wear levels. This was used to produce a total of 10 suck-down polyvinyl stents made to fit over the occlusal table. As the tooth model is parallel sided, the vinyl stents extended down to the base of the tooth (Fig 6)
- Each of the polyvinyl stents were cut free at the base, and gently removed from the tooth model. It was then trimmed so that its peripheral extent was approximately 4mm beyond the tips of the cusps. This ensured that the baseline coping was tightly seated, covering both occlusal, buccal and lingual surfaces
- A small vent was made occlusally on the vinyl stent to allow excess impression material to flow out during seating of the polyvinyl stent
- For each of the previously mentioned plastic teeth showing different levels of wear (100μm, 200μm, and 700μm) a duplicate stone model copings were created which were then used for this experiment
- Each of the copings were sprayed with Stone Die and Plaster Hardener Resin as a separator
• The copings were then filled with a silicone impression material (President microSystem light body surface activated) placed on the baseline model and held with light finger pressure [finger pressure was measured on an electric scale for consistency at each time] for 5 minutes. The light bodied rubber base impression material filled the space created by the simulated wear on the model.

• The vinyl stents were removed from the model and the excess impression material was removed with a wax knife.

• The thickness of the impression material (corresponding to the wear) was then measured.

• The fully hardened material was weighed on an electronic scale\(^1\).

• For each coping this procedure was carried out twice to check accuracy and repeatability, without distorting the polyvinyl stent.

• The impression and weight procedure was repeated 10 times, resulting in 10 pairs of weights of enclosed pieces of impression material.

• Data was analysed to determine if there was a true continuous variable.

The step-by-step procedure is shown on the flow diagram Fig 7.

\(^1\) (Mettler Toledo 0.001 gm).
Fig 6: Quantitative Measure of Wear

Polyvinyl stent placed on tooth representation of the Vivadent model

B. STATISTICAL EVALUATION

A model showing 25µm of wear was used as the baseline from which the polyvinyl stents were prepared. Further models showing 100µm, 200µm, 400µm, 700µm wear, were used to estimate the amount of material loss over time (see page 206). The aim was to identify a single measure of repeatability, that would encompass the British Standard Institution repeatability coefficient (B.S.Co) (Petrie & Sabin 2000).
A small study carried out on teeth copings of the Vivadent model.

Baseline model, polyvinyl stent coping filled with silicone impression material and fitted on the model, and pressed gently into place for 5 minutes.

Fully set impression material carefully removed from the coping, and the ‘flash’ trimmed with a sharp wax carver.

Impression material weighed on an electronic scale (Mettler Toledo 0.001 gm).

A total of 10 pairs of impressions were made using each vinyl stent only twice.
Chapter Five.

Results
5.1. Subjects Taking Part in the Study

5.1.1. Number

A total of 152 children were recruited to the trial. Consent was obtained from parents at a diagnostic clinic. Permission was also obtained from each child where appropriate, as some patients signed their own consents (six UK patients, and five UAE patients). Only three parents refused permission for their children to take part in the trial. Two groups of children participated in the clinical part:

- Group 1: 60 children and adolescents were recruited from the Caries Clinic at the Department of Paediatric Dentistry of the Eastman Dental Hospital
- Group 2: 92 children and adolescents were recruited from the Primary School Dental Clinics, City of Abu Dhabi, UAE. A total of ten primary schools with dental clinic facilities were visited by the author. Trips to the UAE were made every six months for the patient recruitment and subsequent follow-up visits. Details on field trips to the UAE are provided in Appendices Ic and V.

5.1.2. Age and Gender

The mean age of the UK group at the start of the trial was 7.8 yrs (sd 2.2 yrs), while the mean age of the UAE group at the start of the trial was 7.3 yrs (sd 1.1 yrs). After 24 months (by the end of the trial), the mean age of the UK group, was 9.8 yrs (sd 2.2 yrs), while in the UAE group was 9.3 yrs (sd 1.2 yrs).

Most of the patients were aged 6-10 years, a total of 101 in which 229 restorations were placed. For the 3-5 year age group there were 38 children with 45 restorations and for the 11-15 year old children there 13 in which only 14 restorations were placed.
There were 33 males and 27 females in the UK group, and 85 males and 7 females in the UAE group. By the end of the trial, there were 15 males and 21 females in the UK group, and 27 males and 3 females in the UAE group. Out of the 157 restorations placed in the UK, 13 (18%) children had a single restoration placed, while out of the 131 restorations placed in the UAE a total of 74 (56%) children had a single restoration placed. Only one child (UAE group) had a total of six restorations placed. The distribution of children between the UK and the UAE by age and gender as well as the number of restorations per child is shown in Table 9.
<table>
<thead>
<tr>
<th>Age at start (yrs)</th>
<th>Number of patients</th>
<th>Mean</th>
<th>sd</th>
<th>Min</th>
<th>Max.</th>
<th>Age at end (yrs)</th>
<th>Number of patients</th>
<th>Mean</th>
<th>sd</th>
<th>Min</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.K.</td>
<td>60</td>
<td>7.8</td>
<td>2.2</td>
<td>4.2</td>
<td>15.4</td>
<td>U.K.</td>
<td>36</td>
<td>9.8</td>
<td>2.2</td>
<td>6.26</td>
<td>17.43</td>
</tr>
<tr>
<td>U.A.E.</td>
<td>92</td>
<td>7.3</td>
<td>1.1</td>
<td>6.0</td>
<td>14.0</td>
<td>U.A.E.</td>
<td>30</td>
<td>9.3</td>
<td>1.2</td>
<td>8.04</td>
<td>16.03</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender start</th>
<th>Male frequency (%)</th>
<th>Female frequency (%)</th>
<th>Total (%)</th>
<th>Gender end</th>
<th>Male frequency (%)</th>
<th>Female frequency (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.K.</td>
<td>33</td>
<td>28%</td>
<td>60 39%</td>
<td>U.K.</td>
<td>15</td>
<td>36%</td>
<td>36 54.5%</td>
</tr>
<tr>
<td>U.A.E.</td>
<td>85</td>
<td>72%</td>
<td>92 60%</td>
<td>U.A.E.</td>
<td>27</td>
<td>64%</td>
<td>30 45.4%</td>
</tr>
<tr>
<td>Total</td>
<td>118</td>
<td>34</td>
<td>152</td>
<td>Total</td>
<td>42</td>
<td>24</td>
<td>66</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of restorations per child</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Total Restorations</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.K. (n=60)</td>
<td>13</td>
<td>18%</td>
<td>16</td>
<td>10%</td>
<td>18</td>
<td>11%</td>
<td>7</td>
</tr>
<tr>
<td>U.A.E. (n=92)</td>
<td>74</td>
<td>56%</td>
<td>7</td>
<td>5%</td>
<td>5</td>
<td>4%</td>
<td>3</td>
</tr>
<tr>
<td>Total Restorations</td>
<td>87</td>
<td>46</td>
<td>69</td>
<td>40</td>
<td>40</td>
<td>6</td>
<td>288</td>
</tr>
</tbody>
</table>
5.2. Clinical Procedures

5.2.1. Operators and Caries Reproducibility

Two operators participated in placement of the restorations. To assess examiner reproducibility for recording dental caries, and assessment of restorations, ten full arch tooth blocks were examined by both operators for inter-examiner variability (Fleiss et al 1979). The tooth blocks were re-examined one week later by the primary investigator for intra-examiner variability. The technique for placement of the restorations was standardised using plastic and extracted primary and first permanent molar teeth.

Cohen’s Kappa (Cohen 1968) was calculated and this gave good agreement (Landis & Koch 1977), as shown in Table 10.

Reproducibility studies were performed every six months to ensure maintenance of consistency between the two investigators throughout the trial. Calibration sessions for both inter/intra examiner reproducibility were repeated three times during the first 18 months of trial and on each occasion good agreement was achieved. This demonstrates consistency in the clinical assessment.

<table>
<thead>
<tr>
<th>Table 10: Caries Reproducibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inter-examiner agreement</td>
</tr>
<tr>
<td>Intra-examiner agreement</td>
</tr>
</tbody>
</table>

This is considered good agreement (Landis & Koch 1977)

Restorative treatment allocation to either operators was randomly allocated according to study numbers generated by the ‘StatMate’ software.
5.2.2. Restorations

5.2.2.1. Number and Distribution

A total of 288 restorations were placed; 54.5% (n=157) of the restorations were placed in the UK group [76% (n=120) of these by the primary operator and 23.5% (n=37) by the therapist], while the primary operator placed 45% (n= 131) of the total restorations in the UAE. The distribution of restorations is illustrated in Table 11. There were 224 restorations placed in primary first and second molars, 61 restorations in permanent first molars and three restorations in premolars. There were a total of 156 occlusal restorations and 132 proximal restorations.

Details on teeth (primary and permanent) restored in the study are shown in Table 12 using both the BDJ and FDI tooth notation. By the end of 24 months the difference in the success rates of the restorations according to tooth type (primary or permanent) was non-significant (P value = 0.24). The success rate for both primary first and second molars was 86.5% [with 95% C.I. 80.3% to 92.6%], and for the permanent first molars and premolars it was 86.7% [with 95% C.I. 77% to 96.4%].
Table 11: Frequency and Percentage of Primary and Permanent Teeth, Occlusal and Proximal Restorations.

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Primary Molars</th>
<th>Permanent Molars</th>
<th>Premolars</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.K.</strong></td>
<td>157 (54.5%)</td>
<td>121 (77%)</td>
<td>35 (22%)</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td><strong>U.A.E.</strong></td>
<td>131 (45.4%)</td>
<td>103 (77%)</td>
<td>26 (22%)</td>
<td>2 (0.6%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>288 (100%)</td>
<td>224 (77%)</td>
<td>61 (22%)</td>
<td>3 (1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Occlusal (%)</th>
<th>Proximal (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.K.</strong></td>
<td>157 (54.5%)</td>
<td>93 (60%)</td>
<td>64 (48%)</td>
</tr>
<tr>
<td><strong>U.A.E.</strong></td>
<td>131 (45.4%)</td>
<td>63 (40%)</td>
<td>68 (51%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>288 (100%)</td>
<td>156 (54%)</td>
<td>132 (46%)</td>
</tr>
</tbody>
</table>
Table 12: Frequency of Primary and Permanent Teeth Restored in the Study.

<table>
<thead>
<tr>
<th>Upper Right</th>
<th>Upper Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>UR 6</td>
<td>UL D</td>
</tr>
<tr>
<td>16</td>
<td>64</td>
</tr>
<tr>
<td>17</td>
<td>21</td>
</tr>
<tr>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>46</td>
<td>74</td>
</tr>
<tr>
<td>LR 6</td>
<td>LL D</td>
</tr>
<tr>
<td>44</td>
<td>75</td>
</tr>
<tr>
<td>LR 4</td>
<td>LL E</td>
</tr>
<tr>
<td>85</td>
<td>34</td>
</tr>
<tr>
<td>LR E</td>
<td>LL 4</td>
</tr>
<tr>
<td>84</td>
<td>36</td>
</tr>
<tr>
<td>LR D</td>
<td>LL 6</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

| UR 4        | UL E       |
| 14          | 65         |
| 0           | 45         |
| 2           | 25         |
| 46          | 16         |
| LR 4        | LL E       |
| 14          | 36         |

| UR E        | UL 4       |
| 55          | 24         |
| 46          | 16         |
| 24          | 36         |
| LR E        | LL 6       |
| 54          | 36         |
| LR D        |            |
| 26          |            |
| LR D        |            |
| 26          |            |

| UR D        | UL 6       |
| 54          | 26         |
| 24          | 16         |
| 17          | 20         |
| LR 6        | 24         |
| LR 4        | 16         |
| LR E        | 36         |
| LR D        | 36         |
| LL D        | 16         |
| LL E        | 36         |
| LL 4        | 36         |
| LL 6        | 36         |
5.2.2.2. Cavity Design

The anatomical configuration form of all the restorations is shown in Table 13.

<table>
<thead>
<tr>
<th>Anatomical configuration of restorations</th>
<th>Number and percentage of restorations in the U.K.</th>
<th>Number and percentage of restorations in the U.A.E.</th>
<th>Total number and percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occlusal (Class I)</td>
<td>93 (56.5%)</td>
<td>63 (41%)</td>
<td>156 (54%)</td>
</tr>
<tr>
<td>Occlusal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesial</td>
<td>4 (3%)</td>
<td>1 (0.7%)</td>
<td>5 (1.7%)</td>
</tr>
<tr>
<td>Distal</td>
<td>0 (0%)</td>
<td>5 (4%)</td>
<td>5 (1.7%)</td>
</tr>
<tr>
<td>Occluso-mesial</td>
<td>39 (29.5%)</td>
<td>32 (24.3%)</td>
<td>71 (25%)</td>
</tr>
<tr>
<td>Occluso-distal</td>
<td>21 (16%)</td>
<td>22 (17%)</td>
<td>43 (15%)</td>
</tr>
<tr>
<td>Occluso-mesial-buccal</td>
<td>0 (0%)</td>
<td>2 (1.5%)</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>Occluso-distal-lingual</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>MOD¹</td>
<td>0 (0%)</td>
<td>6 (4.5%)</td>
<td>6 (2%)</td>
</tr>
<tr>
<td>Total</td>
<td>n = 288</td>
<td></td>
<td>(100%)</td>
</tr>
</tbody>
</table>

During the 24 month study period, the need for replacement of restorations according to anatomical configuration (occlusal or approximal) was marginally significant with more proximal restorations needing replacement (P value = 0.045) [Sec 5.4.1.4, page 160].

The success rate for occlusal (Class I) restorations was 90.5% [with 95% C.I. 85% to 96%] and for proximal (Class II) restorations was 81% [with 95% C.I. 72% to 90%].

¹ (MOD): Mesio-Occluso-Distal., narrow not exceeding one third of the intercuspal width of primary molars.
5.2.2.3. Cooperation of the Child Patient and Pain Control

A. Patients' Cooperation and Restorations' Replacement Need

Patient behaviour and anxiety levels were recorded using the Frankl behaviour scale at baseline and review visits [Sec.4.2. materials and methods]. The number of restorations and the patient's cooperation levels are shown in Table 14.

| Table 14: Frequency and Percentage of Restorations and Patients' Cooperation |
|-----------------|------------------|-------------------|
| Patient cooperation level Category | Number and percentage of restorations | Number and percentage of patients |
| Rating code | | |
| Definitely negative | 17 (6.0%) | 8 (5.3%) |
| Negative | 42 (14.5%) | 14 (9.2%) |
| Positive | 168 (58.3%) | 110 (72.3%) |
| Definitely positive | 61 (21%) | 20 (13%) |
| Total | 288 (100%) | 152 (100%) |

There were more cooperative patients from the UAE group when compared with the UK group although this was not statistically significant. This is illustrated in Table 15.

| Table 15: Number of Patients and Level of Cooperation at Each Group |
|-----------------|------------------|-----------------|
| Patient cooperation level Category | UK Group | UAE Group |
| Rating code | | |
| Definitely negative | 5 (8.3%) | 3 (3.2%) |
| Negative | 5 (8.3%) | 9 (10%) |
| Positive | 42 (70%) | 68 (74%) |
| Definitely positive | 8 (13.3%) | 12 (13%) |
The need for replacement of restorations according to patient behaviour was non-significant (P value = 0.832, Chi-Square value = 0.045, df = 1). Of the restorations that needed replacement during the period of the study (in total n=30) 13 were placed in patients with cooperation levels of 1 and 2 combined, and 21 were placed in patients with cooperation levels of 3 and 4 combined.

B. PAIN CONTROL AND RESTORATIONS’ REPLACEMENT NEED

A total of 267 restorations were placed using local anaesthesia while only 21 restorations were placed with no local anaesthetic. The type of pain control used and number of restorations are set out in Table 16.

<table>
<thead>
<tr>
<th>Pain Control used</th>
<th>Number and percentage of restorations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infiltration</td>
<td>185 (64%)</td>
</tr>
<tr>
<td>Inferior alveolar block (ID block)</td>
<td>68 (24%)</td>
</tr>
<tr>
<td>Inhalation-Sedation + Infiltration</td>
<td>7 (2.4%)</td>
</tr>
<tr>
<td>Inhalation-Sedation + ID block</td>
<td>6 (2%)</td>
</tr>
<tr>
<td>Inhalation-Sedation alone</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Behaviour Management alone (no LA or IS)</td>
<td>21 (7%)</td>
</tr>
<tr>
<td><strong>Total number of restorations</strong></td>
<td><strong>288 (100%)</strong></td>
</tr>
</tbody>
</table>

Due to the small numbers (Table 15), the association between replacement need of restorations during the 24 months study period, and pain control methods was carried out by comparing the replacement need when using local anaesthesia [infiltration and ID block] with the replacement need without the use of local anaesthesia [IS and behaviour management alone]. This was non-significant using Fisher’s Exact Probability test (P value = 0.70).
5.2.2.4. Moisture Control

Isolation with rubber dam was used when possible, otherwise cotton rolls, dry guard, or high volume suction alone were used. The methods of isolation and the number of restorations illustrated in Table 17.

Table 17: Methods of Isolation Used in Placement of Restorations

<table>
<thead>
<tr>
<th>Method of isolation</th>
<th>Number and percentage of restorations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubber Dam+ suction</td>
<td>161 (56%)</td>
</tr>
<tr>
<td>Cotton rolls + suction</td>
<td>125 (43.4%)</td>
</tr>
<tr>
<td>Dry-guard + suction</td>
<td>1 (0.35%)</td>
</tr>
<tr>
<td>Suction alone</td>
<td>1 (0.35%)</td>
</tr>
<tr>
<td><strong>Total number of restorations</strong></td>
<td><strong>288 (100%)</strong></td>
</tr>
</tbody>
</table>

There was no significant difference in replacement need (failure rate) between the use of rubber dam as a method of isolation of the restorations when compared with the other methods combined (P = 0.85, Chi-Square = 0.033, df = 1).
5.2.3. Restorative Materials Used

The randomisation of the restorative materials was achieved using ‘StatMate’ software, which uses the method of minimisation for materials allocation. The distribution of restorative materials used is shown in Table 18.

<table>
<thead>
<tr>
<th>Restorative material</th>
<th>Amalgam</th>
<th>Dyract AP</th>
<th>Fuji II LC</th>
<th>Vitremer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.K. n = 157</td>
<td>33</td>
<td>43</td>
<td>37</td>
<td>44</td>
<td>157</td>
</tr>
<tr>
<td>U.A.E. n = 131</td>
<td>37</td>
<td>30</td>
<td>34</td>
<td>30</td>
<td>131</td>
</tr>
<tr>
<td>Total</td>
<td>70</td>
<td>73</td>
<td>71</td>
<td>74</td>
<td>288</td>
</tr>
</tbody>
</table>

During the study (24 months), of the 30 restorations failed, the replacement need for each restorative material was as follows:

- 23% for both Amalgam (n= 10) and Dyract AP (n=9) restorations
- 17% for Fuji II LC (n= 7) restorations
- 10% for Vitremer (n= 4) restorations.

From this, the need for replacement of restorations was statistically non-significant and was not associated with the restorative material (type) used (P value = 0.236, Chi-Square = 4.24, df = 3).

5.3. Restoration Follow-Up

5.3.1. Number of Restorations at Follow-Up

The status of all restorations was reviewed at approximately six-monthly intervals over a period of up to 24 months, until January 2003. The maximum number of review visits was four. Direct clinical evaluation of 288 restorations was carried out at baseline, 99% (n= 286) after 6 months, 90% (n= 259) after 1 year and 30% (n= 85) by the end of 2
The USPHS assessment criteria were applied to restorations seen at the review visits.

Table 19 illustrates the number of restorations at each review visit for both UK and UAE groups.

**Table 19: Frequency of Restorations (UK and UAE) at Each Review**

<table>
<thead>
<tr>
<th>Visit</th>
<th>UK Group</th>
<th></th>
<th>UAE Group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success</td>
<td>Failures</td>
<td>Missing</td>
<td>Success</td>
</tr>
<tr>
<td>Visit 1</td>
<td>157</td>
<td>0</td>
<td>0</td>
<td>131</td>
</tr>
<tr>
<td>Visit 2</td>
<td>155</td>
<td>2</td>
<td>2</td>
<td>129</td>
</tr>
<tr>
<td>Visit 3</td>
<td>135</td>
<td>3</td>
<td>19</td>
<td>113</td>
</tr>
<tr>
<td>Visit 4</td>
<td>90</td>
<td>2</td>
<td>65</td>
<td>74</td>
</tr>
<tr>
<td>Visit 5</td>
<td>42</td>
<td>1</td>
<td>114</td>
<td>38</td>
</tr>
</tbody>
</table>

The numbers and reasons for inability to assess the restorations are given in Table 20.

**Table 20: Reasons for Non-assessment of Restorations**

<table>
<thead>
<tr>
<th>Visit</th>
<th>Missing for a known reason</th>
<th>Missing for unknown reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Visit 2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Visit 3</td>
<td>16 (GA=2, Withd =9, Exf=5)</td>
<td>13</td>
</tr>
<tr>
<td>Visit 4</td>
<td>47 (GA=6, Withd = 20, Exf = 21)</td>
<td>65</td>
</tr>
<tr>
<td>Visit 5</td>
<td>26 (GA=2, Withd = 15, Exf = 9)</td>
<td>177</td>
</tr>
</tbody>
</table>

GA General anaesthesia (patient was referred for treatment under GA)
Withd Withdrew from the trial
Exf Exfoliated (tooth naturally exfoliated)
Only two restorations failed during the first 6-month period. By the end of the trial (24 months) the total number of failed restorations was 30, [15 restorations had recurrent caries (10 of these had also loss of contact point), 9 restorations showed bulk fracture, and 6 had loss of marginal integrity].

Of the 30 restorations that failed, six failed twice. These were two amalgam [failure was due to bulk fracture], two Dyract AP [one failed due to bulk fracture while the other was due to recurrent caries], and two Fuji II LC restorations [one due to bulk fracture while the other was due to recurrent caries]. On each replacement, some modifications of the cavity outline form were made, to aid retention of the restoration. All replacements were performed under rubber dam isolation. For amalgam restorations, additional attention was given to the undercuts to ensure retention, while for the resin restorations; placement procedures were conducted carefully to avoid moisture contamination to the conditioned enamel and dentine walls. The replacement was with the same restorative material that the tooth was randomly allocated to receive when entered into the study.

Of the 30 failed restorations, 36% (n=11) had occluso-mesial anatomical configuration. There was no pulpal involvement over the total observation time. The total number of failed restorations with their anatomical configuration and visit number are shown in Table 21.
Table 21: Frequency and Percentage of Failed Restorations
According to Anatomical Configuration and Visit Number

<table>
<thead>
<tr>
<th>Anatomical configuration</th>
<th>Number restored</th>
<th>Number and % failed</th>
<th>% failed as proportion of failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>156</td>
<td>8 (5.1%)</td>
<td>(27%)</td>
</tr>
<tr>
<td>Occluso-Mesial</td>
<td>71</td>
<td>11 (8.3%)</td>
<td>(37%)</td>
</tr>
<tr>
<td>Occluso-distal</td>
<td>43</td>
<td>6 (4.5%)</td>
<td>(20%)</td>
</tr>
<tr>
<td>Occluso-Buccal</td>
<td>6</td>
<td>1 (0.7%)</td>
<td>(3.3%)</td>
</tr>
<tr>
<td>Occluso-Lingual</td>
<td>5</td>
<td>2 (1.5%)</td>
<td>(6.6%)</td>
</tr>
<tr>
<td>Mesial</td>
<td>2</td>
<td>1 (0.7%)</td>
<td>(3.3%)</td>
</tr>
<tr>
<td>MOD</td>
<td>2</td>
<td>1 (0.7%)</td>
<td>(3.3%)</td>
</tr>
<tr>
<td>Total failed restorations</td>
<td>30</td>
<td></td>
<td>(10%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visit number</th>
<th>Number restored</th>
<th>Number and % failed</th>
<th>% failed as proportion of failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd</td>
<td>286</td>
<td>2 (0.7%)</td>
<td>(7%)</td>
</tr>
<tr>
<td>3rd</td>
<td>259</td>
<td>11 (4.2%)</td>
<td>(37%)</td>
</tr>
<tr>
<td>4th</td>
<td>176</td>
<td>12 (7%)</td>
<td>(40%)</td>
</tr>
<tr>
<td>5th</td>
<td>85</td>
<td>5 (6%)</td>
<td>(17%)</td>
</tr>
</tbody>
</table>

Chapter 5
Results
5.4. Survival Analysis of Restorations

5.4.1. Life Tables

5.4.1.1. Cumulative Survival of All Restorations

The data obtained during the review period were analysed using survival analysis techniques. The cumulative survival curve (showing the proportion of all restorations surviving to the end of each interval) for the 288 restorations placed was determined by the Berkson Gage life table approach. This was used because it is tolerant of variations in the actual dates of assessment, which in reality varies around the predetermined time interval of 6 months, 1 year, etc. This is shown in Fig 9.

Fig 9: Cumulative Survival of all Restorations

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>Exposed to Risk</th>
<th>Hazard Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5.9</td>
<td>288</td>
<td>.0000</td>
</tr>
<tr>
<td>6-11.9</td>
<td>286</td>
<td>.0000</td>
</tr>
<tr>
<td>12-17.9</td>
<td>259</td>
<td>.0058</td>
</tr>
<tr>
<td>18-23.9</td>
<td>173.0</td>
<td>.0058</td>
</tr>
<tr>
<td>24</td>
<td>94.0</td>
<td>.2222</td>
</tr>
</tbody>
</table>

n = 288 restorations
5.4.1.2. Cumulative Survival for Each Restorative Material

The cumulative survival curves of each of the three resin restorations (Dyract AP, Fuji II LC, and Vitremer) could not be distinguished. For this reason, the survival experience of the three resin materials was combined. Fig 10 shows the cumulative survival curves of amalgam and resin restorations. There was no significant difference in the rate of replacement need for amalgam and resin restorative materials over the 2-year trial period, as indicated by the Log Rank test (P value = 0.32).

**Fig 10: Cumulative Survival of Amalgam and Resin Restorations.**

<table>
<thead>
<tr>
<th>Amalgam Restorations</th>
<th>Time (months)</th>
<th>0-5.9</th>
<th>6-11.9</th>
<th>12-17.9</th>
<th>18-23.9</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed to Risk</td>
<td></td>
<td>70</td>
<td>69</td>
<td>60</td>
<td>41.0</td>
<td>22.5</td>
</tr>
<tr>
<td>Hazard Rate</td>
<td></td>
<td>.0000</td>
<td>.0000</td>
<td>.0241</td>
<td>.0247</td>
<td>.2500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resin Restorations</th>
<th>Time (months)</th>
<th>0-5.9</th>
<th>6-11.9</th>
<th>12-17.9</th>
<th>18-23.9</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed to Risk</td>
<td></td>
<td>218</td>
<td>215</td>
<td>188</td>
<td>131.0</td>
<td>72.5</td>
</tr>
<tr>
<td>Hazard Rate</td>
<td></td>
<td>.0000</td>
<td>.0000</td>
<td>.0000</td>
<td>.0000</td>
<td>.2137</td>
</tr>
</tbody>
</table>
5.4.1.3. Cumulative Survival of Restorations According to Anatomical Configuration

The cumulative survival curve (showing the proportion of all restorations surviving to the end of each interval) for all of the 288 restorations placed according to their anatomical configuration (Occlusal and Approximal) is shown in Fig 11.

During the 24 months study period the need for replacement of restorations according to anatomical configuration (Occlusal and Approximal) was marginally significant showing more proximal restorations needed replacement. This was determined using the Log Rank test (P value = 0.045) [see page 145].
Fig 11: Cumulative Survival of Occlusal and Approximal Restorations

Chapter 5
Results

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>Occlusal Restorations</th>
<th>Approximal Restorations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (months)</td>
<td>Exposed to Risk</td>
<td>Hazard Rate</td>
</tr>
<tr>
<td>0-5.9</td>
<td>156</td>
<td>.0000</td>
</tr>
<tr>
<td>6-11.9</td>
<td>156</td>
<td>.0000</td>
</tr>
<tr>
<td>12-17.9</td>
<td>155</td>
<td>.0000</td>
</tr>
<tr>
<td>18-23.9</td>
<td>93.0</td>
<td>.0000</td>
</tr>
<tr>
<td>24</td>
<td>50.0</td>
<td>.1505</td>
</tr>
</tbody>
</table>
5.4.1.4. Cumulative Survival of Restorations According to Teeth Restored
(Primary and Permanent)

The cumulative survival curve (showing the proportion of all restorations surviving to
the end of each interval) for all of the 288 restorations placed according to teeth restored
(Primary and Permanent) is shown in Fig 12. During the 24 months study period the
need for replacement of restorations according to teeth restored (Primary and
Permanent) was non significant .This was determined using the Log Rank test
(P value = 0.73).
Fig 12: Cumulative Survival of Primary and Permanent Teeth Restorations

Primary molars

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>0-5.9</th>
<th>6-11.9</th>
<th>12-17.9</th>
<th>18-23.9</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed to Risk</td>
<td>224</td>
<td>222</td>
<td>200</td>
<td>126</td>
<td>60</td>
</tr>
<tr>
<td>Hazard Rate</td>
<td>.0000</td>
<td>.0000</td>
<td>.0079</td>
<td>.0080</td>
<td>.2240</td>
</tr>
</tbody>
</table>

Permanent molars and premolars

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>0-5.9</th>
<th>6-11.9</th>
<th>12-17.9</th>
<th>18-23.9</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed to Risk</td>
<td>64</td>
<td>63</td>
<td>57</td>
<td>46</td>
<td>36</td>
</tr>
<tr>
<td>Hazard Rate</td>
<td>.0000</td>
<td>.0000</td>
<td>.0000</td>
<td>.0000</td>
<td>.2174</td>
</tr>
</tbody>
</table>
5.4.1.5. Cumulative Survival of Restorations by Groups

The cumulative survival of restorations for each group (UK and UAE) shown in Fig 13. The Log Rank test showed that there was a significant difference between the two groups (P value < 0.001), with a better survival experience of the restorations in the UK group.

Fig 13: Cumulative Survival of Restorations by Groups
The graph (Fig 13) illustrates the difference in survival between the restorations placed in the UK and those placed in the UAE. There were six restorations from the UK group recorded as failed restorations while 24 restorations were recorded as failed from the UAE group. This produced failure rates of 0.0007 and 0.0082 per child month of study in both the UK and UAE respectively.

The large difference occurred because the restorations were not equally available for re-evaluation from both groups. Out of the 157 restorations originally placed in the UK, 28 restorations (18%) belonged to patients who withdrew from the trial. In addition, nine teeth (6%) were extracted under GA and six teeth (4%) had exfoliated in the UK.

When looking at restorations placed in the UAE, out of the 131 originally placed, 24 teeth (40%) exfoliated, 9 restorations (8%) belonged to patients who withdrew from the trial and only one restoration was extracted under GA.

Details on restorations during follow-up are shown in Table 22. This is a reworking of the data previously shown on Tables 19 and 20.
Table 22: Details on Restorations During Follow-up Visits

<table>
<thead>
<tr>
<th>Details on restorations outcome and missing data at 12 months review</th>
<th>Outcome</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success</td>
<td>Failure</td>
</tr>
<tr>
<td>Gp 1 (UK)</td>
<td>135</td>
<td>3</td>
</tr>
<tr>
<td>Gp 2 (UAE)</td>
<td>113</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details on restorations outcome and missing data at 18 months review</th>
<th>Outcome</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success</td>
<td>Failure</td>
</tr>
<tr>
<td>Gp 1 (UK)</td>
<td>90</td>
<td>2</td>
</tr>
<tr>
<td>Gp 2 (UAE)</td>
<td>74</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details on restorations outcome and missing data at 24 months review</th>
<th>Outcome</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success</td>
<td>Failure</td>
</tr>
<tr>
<td>Gp 1 (UK)</td>
<td>42</td>
<td>1</td>
</tr>
<tr>
<td>Gp 2 (UAE)</td>
<td>38</td>
<td>4</td>
</tr>
</tbody>
</table>
5.4.2. Cox Survival Analysis

The data were also analysed using a multilevel Cox proportional hazard regression analysis, which utilized robust standard errors to account for the clustering of data (having multiple restorations per child), and which used the restorations (teeth) at level - 1, and subjects (child) at level - 2 (Kirkwood & Sterne 2003a).

The Cox regression analysis was also repeated ignoring the clustering and the two results compared in order to assess the effect of clustering. It should be noted that Cox regression does not regard the failure times\(^1\) as interval data (which it is), but assumes that failure at the visit is the actual time of failure. The Cox regression analysis incorporating clustering showed a highly significant effect of groups (\(P= 0.001\)), with a hazard ratio of 11.23 with a [95% confidence interval of 2.62 to 48.0]. This indicated that Group 2 individuals (UAE children) were 11 times more prone to have a failed restoration when compared with Group 1 individuals (UK children)\(^2\). The Cox survival analysis, ignoring clustering, produced virtually identical results with a Hazard ratio of (11.23) [95% confidence interval was 2.61 to 48.21], indicating that the effect of clustering was minimal.

---

\(^1\) The visit at which the failure first recorded.

\(^2\) Apparent reasons for the difference explained on previous page (Sec.5.4.1.4).
5.5. Results: Assessment of Restorations

5.5.1. Direct Clinical Evaluation of Restorations

Of the 288 restorations placed, 259 (90%) were retained and were still in function after one year, while by the end of the two years only 85 (29.5%) of the restorations were retained and available for clinical re-evaluation. Bulk fractures at the isthmus occurred in 13 (4.5%) of the 288 restorations originally placed.

Secondary caries were evident in 15 (5%) of the 288 restorations placed. Nine (64%) were detected in proximal (Class II) restorations while five (36%) were detected in occlusal (Class I) restorations. This was diagnosed only by clinical examination. None of the patients complained of post-operative sensitivity.

Patients who failed to attend their review visit were recorded as missing data [Table 22 page 16]. The reasons for failure to attend the review visit were:

- Patients withdrawing from the trial (n = 44)
- Patients referred for General Anaesthesia. When cooperation deteriorated necessitating referral for treatment under G.A. (n = 10)
- Exfoliated primary teeth (n = 35)
- Patients failing the review visit for an unknown reason (n = 177).

The overall results of the direct clinical review of the restorations using the modified Ryge criteria are shown in Fig. 14. The numerical data on results of the scores on the restorations are in Table 23.
Fig 14: Direct Clinical Re-evaluation Using Modified Ryge Criteria

Overall Direct Clinical Re-evaluation of Restorations Using Modified Ryge Criteria

Visit No. | Frequency of Restorations
--- | ---
Visit 1 (n=288) | 25
Visit 2 (n=286) | 25
Visit 3 (n=259) | 75
Visit 4 (n=176) | 150
Visit 5 (n=85) | 175

Assessment Codes (Table 8 pages 120-121)
- Marginal integrity
- Recurrent caries
- Anatomical form
- Contact point
- Replacement need
- MD 1
- MD 2
- Marginal discoloration

Details on missing data (table 22 page 162)
Table 23. Frequencies of the Clinical Assessment of Restorations

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Baseline (visit 1)</th>
<th>6-months (visit 2)</th>
<th>12-months (visit 3)</th>
<th>18-months (visit 4)</th>
<th>24-months (visit 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing data</td>
<td>0</td>
<td>2</td>
<td>29</td>
<td>112</td>
<td>203</td>
</tr>
<tr>
<td>Code</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Marginal Integrity</td>
<td>288 0 0 0</td>
<td>286 0 0 0</td>
<td>244 9 5 1</td>
<td>166 7 1 2</td>
<td>49 29 5 2</td>
</tr>
<tr>
<td>Code</td>
<td>5 6 7 8 9</td>
<td>5 6 7 8 9</td>
<td>5 6 7 8 9</td>
<td>5 6 7 8 9</td>
<td>5 6 7 8 9</td>
</tr>
<tr>
<td>Anatomical Form</td>
<td>288 0 0 0</td>
<td>286 0 0 0</td>
<td>245 6 3 1 4</td>
<td>169 2 2 1 2</td>
<td>60 10 14 2 6</td>
</tr>
<tr>
<td>Marginal Discoloration</td>
<td>288 0 0 0</td>
<td>284 2 0 0</td>
<td>207 46 4 2</td>
<td>82 59 30 5</td>
<td>9 22 44 10</td>
</tr>
<tr>
<td>Code</td>
<td>14 15</td>
<td>14 15</td>
<td>14 15</td>
<td>14 15</td>
<td>14 15</td>
</tr>
<tr>
<td>Récurrent caries</td>
<td>288 0</td>
<td>286 0</td>
<td>257 2</td>
<td>166 10</td>
<td>70 15</td>
</tr>
<tr>
<td>Code</td>
<td>16 17</td>
<td>16 17</td>
<td>16 17</td>
<td>16 17</td>
<td>16 17</td>
</tr>
<tr>
<td>Contact Point</td>
<td>283 5</td>
<td>280 6</td>
<td>242 17</td>
<td>168 7</td>
<td>74 11</td>
</tr>
<tr>
<td>Code</td>
<td>18 19</td>
<td>18 19</td>
<td>18 19</td>
<td>18 19</td>
<td>18 19</td>
</tr>
<tr>
<td>Replacement Need</td>
<td>288 0</td>
<td>284 2</td>
<td>248 11</td>
<td>164 12</td>
<td>80 5</td>
</tr>
</tbody>
</table>

For assessment codes Table 8 pages 120-121.
5.5.1.1. Assessment Criteria of the Direct Clinical Evaluation

A. Marginal Integrity

During the first six months [visits 1 and 2] all 288 restorations were coded 1 as they all appeared to adapt closely to the tooth along its periphery with no crevice formation, and upon clinical examination the explorer did not catch on the restoration margin. Between the periods of 12-18 months [visits 3, 4] there was evidence of marginal integrity change in 22 (31%) of the 176 restorations re-evaluated. Six restorations out of the original 288 demonstrated crevice formation and required replacement [codes 3, 4]. These were; two Amalgams, one Dyract AP, two Fuji II LC and one Vitremer. The marginal integrity history is shown in Fig.15. Only 85 restorations were available for re-evaluation by visit 5.

Fig 15: Marginal Integrity

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>Frequency of Restorations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>n=288</td>
</tr>
<tr>
<td>Visit 2</td>
<td>n=286</td>
</tr>
<tr>
<td>Visit 3</td>
<td>n=254</td>
</tr>
<tr>
<td>Visit 4</td>
<td>n=176</td>
</tr>
<tr>
<td>Visit 5</td>
<td>n=85</td>
</tr>
</tbody>
</table>

Assessment Codes (Table 8 pages 120-121)

1. Restoration adapt closely to tooth periphery, explorer does not catch.
2. Explorer will catch at some point around the margins. Dentine not exposed.
3. Explorer penetrates into crevice. Dentine exposed.
4. Restoration fractured and need replacement.

Code 1
Code 2
Code 3
Code 4
B. Anatomical Form

On placement of the 288 restorations, there was continuity with the existing anatomical form of the tooth [codes 5 and 6]. By 12 months [visit 3], eight (3%) of the 259 restorations demonstrated changes in anatomical form [code 8]. By the end of 24 months [visit 5] anatomical form demonstrated change in 10 (12%) of the 85 restorations examined. Of the 288 restorations originally placed, eight (3%) restorations demonstrated bulk fracture at the isthmus [code 9] by visits (3 and 4). Five of them were in Amalgam restoration, three in Dyract AP and one in Fuji II LC. Anatomical Form change over time is illustrated in the Fig 16. Only 85 restorations were available for re-evaluation by visit 5.

Fig 16: Anatomical Form

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>Assessment Codes (Table 8 pages 120-121)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Code 5</td>
</tr>
<tr>
<td>n=288</td>
<td>Restoration continuous with anatomical form of the tooth.</td>
</tr>
<tr>
<td>n=286</td>
<td>Restoration discontinuous with tooth anatomy, Dentine not exposed.</td>
</tr>
<tr>
<td>n=259</td>
<td>Restoration discontinuous with tooth anatomy, Dentine exposed, restoration needs replacement.</td>
</tr>
<tr>
<td>n=176</td>
<td>Restoration fractured and needs replacement.</td>
</tr>
<tr>
<td>n=85</td>
<td>For class II cavities, fractured isthmus.</td>
</tr>
</tbody>
</table>

Visit 1
Visit 2
Visit 3
Visit 4
Visit 5
C. Marginal Discolouration

Marginal discolouration indicates marginal staining and/or mismatch of the colour of the restoration next to the enamel surrounding the restoration (Ryge & Snyder 1973; Ryge 1980).

During the study, marginal discolouration was evident from the first six months [Visit 2]. At 18 months, 92 (52%) restorations out of 176 showed marginal discolouration. By the end of 24 months [Visit 5, n = 85], 63 (74%) restorations were significantly discoloured [codes 12 and 13]. Enamel margins around amalgam restorations did not demonstrate as much marginal discolouration when compared with the three resin restorations.

At 18 months [Visit 4, n=176] only 1% of amalgam restorations demonstrated discolouration around their enamel margins, covering more than one third of the restoration circumference [code 12]. While for Dyract AP, Fuji II LC and Vitremer, there were 24 (14%) restorations with discolouration code 12, and 4 (2.2%) restorations that showed discolouration around the entire circumference of the restoration [code 13]. By 24 months [visit 5, n=85], amalgam restorations had four (5%) restorations with code 12, and only one with code 13, whilst Dyract AP restorations had 12 (14%) restorations with code 12, and three restorations with code 13. Fuji II LC restorations had 12 (14%) restorations with code 12, and two (3%) restorations with code 13. Vitremer restorations demonstrated discolouration in 16 (19%) restorations with code 12, and four (5%) restorations with code 13. The marginal discolouration history is illustrated in Fig 17. Only 85 restorations were available for re-evaluation by visit 5.
Fig 17: Marginal Discolouration

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>n</th>
<th>Marginal Discolouration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>288</td>
<td></td>
</tr>
<tr>
<td>Visit 2</td>
<td>286</td>
<td></td>
</tr>
<tr>
<td>Visit 3</td>
<td>259</td>
<td></td>
</tr>
<tr>
<td>Visit 4</td>
<td>176</td>
<td></td>
</tr>
<tr>
<td>Visit 5</td>
<td>85</td>
<td></td>
</tr>
</tbody>
</table>

Assessment Codes (Table 8 pages 120-121)

- Code 10: No marginal discolouration.
- Code 11: Discolouration less than 1/3 of restoration circumference.
- Code 12: Discolouration more than 1/3 and less than 2/3 of restoration.
- Code 13: Discolouration around the whole restoration circumference.
- Missing Data
D. Contact Point

Passing a piece of un-waxed floss between teeth contacts usually assesses contact point quality. Depending on the clinical situation and patient cooperation, establishing a smooth contact point can be difficult.

Of the 288 restorations placed 132 (45%) were approximal (Class II) restorations. The contact point was not present in 3 (2%) proximal restorations at visit 1, mainly due to difficulty in handling of the restorative material (two Dyract AP and one Fuji II LC restorations). At six months [visit 2], the contact point was 'lost' in 4 (3%) proximal restorations out of 130 re-evaluated. By the end of the first year [Visit 3], the contact point was lost in 11 (9.4%) out of 117 proximal restorations re-evaluated. Those included four Amalgam restorations, two Dyract AP, three in Fuji II LC and two Vitremer.

At the end of 12 months [Visit 4], the contact point was lost in seven (10%) of the 70 proximal restorations re-evaluated. These were two in Dyract AP, two Fuji II LC, two Vitremer and one Amalgam restoration. At 24 months [visit 5], the contact point was lost in six (15%) proximal restorations out of 40 restorations re-evaluated. Those were two Dyract AP, three Fuji II LC and one Vitremer restoration. The contact point history is shown in Fig 18.

---

1 Chances for disturbing the proximal contact are minimal; it is usually carried out after the restorative, material has set, passing the floss in an occluso-cervical direction then taken out through the embrasure.
Fig 18: Contact point

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>132</td>
</tr>
<tr>
<td>Visit 2</td>
<td>130</td>
</tr>
<tr>
<td>Visit 3</td>
<td>117</td>
</tr>
<tr>
<td>Visit 4</td>
<td>70</td>
</tr>
<tr>
<td>Visit 5</td>
<td>40</td>
</tr>
</tbody>
</table>

Assessment Codes (Table 8 pages 120-121)

- **16**: Contact point present, assessed by passing un-waxed floss.
- **17**: Loss of contact point, no resistance when passing dental floss.
- **Missing Data**

<table>
<thead>
<tr>
<th>Code 16</th>
<th>Code 17</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Frequency of Restorations

- 150
- 125
- 100
- 75
- 50
- 25
- 0
E. Recurrent Caries

Detection of recurrent caries in this study was performed clinically by direct visual examination and an explorer, after cleaning and air-drying the tooth.

Of the original 288 restorations placed, recurrent caries was recorded in 15 (5%) teeth over the 24-month period of the trial. These were seven occlusal restorations and nine proximal [five MO, two DO, and two MOD\(^1\)] restorations. Of the six Dyract AP restorations with recurrent caries, five were detected at visit 4 [18 months] and one at visit 5 [24 months]. Fuji II LC demonstrated six restorations with recurrent caries. One was detected at visit 3 [1 year], four at visit 4 [18 months] and one at visit 5 [24 months]. Vitremer demonstrated recurrent caries in three of its restorations. One was detected at visit 3 [1 year] while two at visit 5 [24 months]. No recurrent caries was detected in any of the 70 amalgam restorations. Despite this there was no statistically significant difference demonstrated between materials. Restorations with recurrent caries were recorded as failures, hence replaced. Recurrent caries history is demonstrated in Fig 19.

---

\(^1\)Anatomical configuration of proximal restorations include occluso-mesial (MO), occluso-distal (DO) and mesio-occluso-distal (MOD).
Fig 19: Recurrent caries

Recurrent Caries

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>288</td>
<td>286</td>
<td>259</td>
<td>176</td>
<td>85</td>
</tr>
</tbody>
</table>

Assessment Codes (Table 8 pages 120-121)
- Code 14: No recurrent decay
- Code 15: Recurrent Decay detected
- Missing Data

Chapter 5
Results
F. Replacement Need

The replacement need for each restorative material can be seen in Figs 20 and 21.

(i) AMALGAM

During the 2-year re-evaluation period, ten amalgam restorations failed, all having been placed in primary molars [5 D’s and 5 E’s]. Of these, five restorations failed due to bulk fracture at the isthmus, three restorations failed due to loss of contact point and the remaining two were due to loss of marginal integrity (adaptation). None of the restorations re-evaluated demonstrated recurrent caries.

(ii) Dyract AP

During the 2-year re-evaluation period, nine Dyract AP restorations failed. seven restorations were placed in primary molars [2 D’s and 5 E’s] and two were placed in first permanent molars. Of the nine restorations that failed, three were due to bulk fracture at the isthmus and loss of marginal integrity while the remaining six failed due to recurrent caries only.

(iii) Fuji II LC

During the 2-year re-evaluation period, a total of seven Fuji II LC restorations failed. four were placed in primary molars [1 D and 3 E’s] and three were in first permanent molars. Of the seven restorations that failed, five were due to bulk fracture with recurrent caries and loss of marginal integrity, and one failed due to bulk fracture alone, whilst the remaining one had recurrent caries.

(iv) Vitremer

During the 2-year re-evaluation period, four Vitremer restorations failed. three were placed in primary molars [1 D and 2 E’s] and one placed in first permanent molar.
Three restorations failed due to recurrent caries while the remaining restoration had loss of contact point and loss of marginal integrity.

There was no significant difference between the four restorative materials\(^1\) in replacement need over the 24-month study period (P value = 0.236, Chi-square = 4.24, df = 3). The success rate for both Amalgam and for Dyract AP was 85\% [with 95\% C.I. 69\% to 93\%]. Fuji II LC demonstrated 88\% success rate [with 95\% C.I. 75\% to 96\%], while Vitremer demonstrated a 92\% success rate [with 95\% C.I. 85.2\% to 99.5\%]. Details on the number of restorations at each review visit is demonstrated in Table 24. Details on teeth (primary and permanent) that were recorded with failed restorations is in Table 25, using both the British Dental Journal and FDI tooth notation.

\(^1\) Not including the missing data.
Fig. 20: Clinical Follow-Up of Restorative Materials (Amalgam, Dyract AP)

- **Amalgam Restorations**
  - Visit No. 1: S=70, F=0
  - Visit No. 2: S=69, F=1
  - Visit No. 3: S=60, F=5
  - Visit No. 4: S=41, F=2
  - Visit No. 5: S=19, F=2

- **Dyract AP Restorations**
  - Visit No. 1: S=73, F=0
  - Visit No. 2: S=73, F=0
  - Visit No. 3: S=61, F=43
  - Visit No. 4: S=40, F=5
  - Visit No. 5: S=15, F=1
Fig. 20: Clinical Follow-Up of Restorative Materials (Amalgam, Dyract AP)

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>S</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>69</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>60</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>41</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>19</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>S</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>73</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>73</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>61</td>
<td>43</td>
</tr>
<tr>
<td>4</td>
<td>40</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>15</td>
<td>1</td>
</tr>
</tbody>
</table>

Amalgam Restorations

Dyract AP Restorations
Table 24: Frequencies of Restorations and Type of Restorative Material at Each Review Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Number of Restorations</th>
<th>Amalgam</th>
<th>Dyract AP</th>
<th>Fuji II LC</th>
<th>Vitremer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 1</td>
<td>Total Success</td>
<td>288</td>
<td>70</td>
<td>73</td>
<td>71</td>
</tr>
<tr>
<td></td>
<td>Total Failure</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total Missing</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Visit 2</td>
<td>Total Success</td>
<td>286</td>
<td>69</td>
<td>73</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>Total Failure</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Total Missing</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Visit 3</td>
<td>Total Success</td>
<td>259</td>
<td>60</td>
<td>61</td>
<td>61</td>
</tr>
<tr>
<td></td>
<td>Total Failure</td>
<td>11</td>
<td>5</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Total Missing</td>
<td>29</td>
<td>7</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Visit 4</td>
<td>Total Success</td>
<td>176</td>
<td>41</td>
<td>40</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>Total Failure</td>
<td>12</td>
<td>2</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Total Missing</td>
<td>112</td>
<td>31</td>
<td>27</td>
<td>28</td>
</tr>
<tr>
<td>Visit 5</td>
<td>Total Success</td>
<td>85</td>
<td>19</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>Total Failure</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Total Missing</td>
<td>203</td>
<td>50</td>
<td>52</td>
<td>50</td>
</tr>
</tbody>
</table>
Table 25: Frequencies of Teeth (Primary and Permanent) Recorded as Failed Restorations

<table>
<thead>
<tr>
<th>Upper Right</th>
<th>Upper Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>UR 6</td>
<td>UR 4</td>
</tr>
<tr>
<td>16</td>
<td>14</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>46</td>
<td>44</td>
</tr>
<tr>
<td>LR 6</td>
<td>LR 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lower Right</th>
<th>Lower Left</th>
</tr>
</thead>
</table>

5.6. Assessment of Missing Data

5.6.1. Sensitivity Analysis of Missing Data

Often in randomised clinical trials, there are missing data, and it is well known that analyses based only on the observed results can be biased unless it can be assumed that the probability that an outcome is 'missing', is unrelated to the value of the missing outcome (i.e. data missing at random). Unfortunately, the validity of this assumption cannot be assessed since the missing outcomes, by definition, were not observed. One approach to this problem is to perform a sensitivity analysis (Magder 2003; Baker & Freedman 2003) to see the extent to which conclusions based on the observed data would be affected, given various degrees of departure from the 'missing at random' assumption. The sensitivity analyses used here were based on two possibilities:

- Assuming all missing data are failed restorations
- Assuming all missing data are successful restorations.

5.6.1.1. Assuming All Missing Data Were Failed Restorations

In order to assess the impact on survival of the assumption that all missing data were failed restorations, the same survival analysis (life table approach) used as before was performed but, in this instance, all missing data were recorded as failed restorations. The cumulative survival of restorations for each group (UK and UAE), is shown in Fig 22, recoding all the missing data as failed restorations.
From the graph (Fig 22), the difference in survival between the restorations placed in the UK and those placed in UAE is similar to that seen in the original cumulative survival graph which treated missing data as censored data (Fig 13 page 160), although the difference is more pronounced in the latter case (Fig 22). Furthermore, the Log Rank test for the data in Fig 22 showed that there was a significant difference in survival experience between the two groups (P value = 0.03), leading to same conclusion as when missing data was censored. Hence assuming all the missing data are failures does
not modify the earlier findings (page 159), in relation to survival experience of restorations placed in the UK and UAE.

5.6.1.2. Assuming All Missing Data Were Successful Restorations

In order to assess the impact on survival of the assumption that all missing data were successful restorations, the same survival analysis (life table approach) as used before was performed but in this instance all missing data were recorded as successful restorations. The cumulative survival of restorations for each group (UK and UAE), is shown in Fig 23, recoding all the missing data as successful restorations.
Fig 23: Missing Data Assumption 2

Assuming Missing Data as Successful Restorations

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>Group 1 (UK)</th>
<th>Group 2 (UAE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time (months)</td>
<td>Exposed to</td>
</tr>
<tr>
<td></td>
<td>0-5.9</td>
<td>157.0</td>
</tr>
<tr>
<td></td>
<td>6-11.9</td>
<td>157.0</td>
</tr>
<tr>
<td></td>
<td>12-17.9</td>
<td>157.0</td>
</tr>
<tr>
<td></td>
<td>18-23.9</td>
<td>157</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>140</td>
</tr>
</tbody>
</table>

|           | Time (months)| Exposed to    | Risk            | Hazard Rate  |
|-----------|--------------|---------------|-----------------|
|           | 0-5.9        | 131           | .0000           | .0000        |
|           | 6-11.9       | 131           | .0075           | .0080        |
|           | 12-17.9      | 131           |                 | .2881        |
|           | 18-23.9      | 131           |                 |              |
|           | 24           | 118           |                 |              |
From Fig 23, the difference in survival rate between the restorations placed in the UK and those placed in UAE is again similar to that noted in the original cumulative survival graph which treated missing data as censored data (Fig 13 page 160), although here (Fig 23) the difference is more pronounced. Furthermore, the Log Rank test for the data shows that there was a significant difference in survival experience between the two groups (P value < 0.001). This was similar to the result obtained when missing data was censored in the analysis. This demonstrated that the two assumptions for missing data produced similar conclusions to the original study results.

5.6.2. Estimation of Numbers of Missing Data and Exfoliated Teeth

Since the sensitivity analyses which assumed two extremes for the missing data [i.e. that missing data were (1) all failed restorations, and (2) all successful restorations] produced results which were similar to the analysis which ignored the missing data, it is inappropriate to perform a sensitivity analysis which assumes that the missing data fall somewhere between 'all failures' and 'all successes'. It is however important to determine how many of the missing observations might have been attributed to exfoliation of teeth. Of the original 288 restorations, 224 were restorations placed in primary molars. Of these, 102 were reported missing (Table 11 page 143). In order to estimate how many of these 102 restorations were missing due to exfoliation, considerations were given to patients' ages.

Previously in sections 5.6.1.1 and 5.6.1.2, the assumption relating to 'all failures' or 'all successes' was applied to this data taking account of two extreme situations. Therefore, in this section, patients' ages were considered twice, looking at both the lower limit and the upper limit of reported exfoliation ages in relation to both gender and ethnicity in separate analyses (Infante 1974).
5.6.2.1. Lower Limits of Exfoliation Ages

It is assumed that 30% (boys) to 41% (girls) of the children who were over 9.5 years of age would have exfoliated their teeth and so 9.5 years was taken as the cut-off age point for the determination of the number of missing restorations due to exfoliation (Miller et al 1965). It is recognised that this is a very approximate cut-off as exfoliation varies with a child's gender and ethnicity (Infante 1974). It was felt that the age of 9.5 years of age was a pragmatic limit and, if anything, would lead to an overestimation of the numbers of teeth that exfoliated. Table 26 shows the number of missing restorations as well as the numbers of failed and successful restorations in those children either over, under or exactly equal to 9.5 years old.

<table>
<thead>
<tr>
<th>Replacement Need (visit 5)</th>
<th>Patients Age</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 9.5 yrs</td>
<td>≥ 9.5 yrs.</td>
</tr>
<tr>
<td>Successful</td>
<td>15</td>
<td>65</td>
</tr>
<tr>
<td>Failed</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Missing data</td>
<td>123</td>
<td>80</td>
</tr>
<tr>
<td>Total</td>
<td>142</td>
<td>146</td>
</tr>
</tbody>
</table>

There were a total of 203 missing restorations at 24 months. 26 teeth were missing for a known reason [two referred to GA, 15 teeth of patients who withdrew from the trial, and nine teeth exfoliated (see Table 22 page 162)]. From Table 25, it can be seen that, of the remaining 177 missing teeth, 45% [80/177] of them belonged to patients > 9.5 of age when their primary molars (n=67) were at the lower limit of exfoliation age. It is assumed, as an approximation, that these numbers were missing because of exfoliation.
5.6.2.2. Upper Limits of Exfoliation Ages

It is reported that the upper age limit of exfoliation of primary molars is 11 years (Miller et al 1965). Similar calculations as in 5.6.2.1 were carried out taking 11 years as the cut-off age point for the determination of the number of missing restorations due to exfoliation. If anything, would lead to an underestimation of the numbers of teeth that exfoliated.

Table 27 shows the number of missing restorations as well as the numbers of failed and successful restorations in those children who were under, over or equal to 11 years of age.

<table>
<thead>
<tr>
<th>Replacement Need (visit 5)</th>
<th>Patients Age</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 11 yrs</td>
<td>≥ 11 yrs.</td>
</tr>
<tr>
<td>Successful</td>
<td>69</td>
<td>11</td>
</tr>
<tr>
<td>Failed</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Missing data</td>
<td>166</td>
<td>37</td>
</tr>
<tr>
<td>Total</td>
<td>239</td>
<td>49</td>
</tr>
</tbody>
</table>

As reported previously, there were a total of 203 missing restorations at 24 months. There were 26 teeth accounted for as described previously in Table 22 page 162. From Table 26, it can be seen that, of the remaining 177 missing teeth, 21% \([37/177]\) of them belonged to patients > 11 of age when their primary molars (n= 26) were at exfoliation age. It is assumed that these 37 restored teeth were missing because of exfoliation. The impact of missing outcome, for whatever reason will be covered further in the discussion.
5.7. Indirect Evaluation of Restorations

5.7.1. Rank Ordering System

For the indirect evaluation of restorations, impressions were taken from all restorations at baseline, 6, 12 and 24 months using silicone-based putty impression material (President) on a sectional tray (see materials and methods). Cast replicas were produced using die stone material (Fig.2, page 127). The occlusal surfaces of the stone replicas were subjected to qualitative examination [semi-quantitative estimates from an ordinal scale] to evaluate restorations' marginal wear and marginal integrity using the Williams Dental Scale template, and the collaboration of a team of two evaluators working with the primary operator.

The study was performed to evaluate the inter-evaluator agreement using this method (Altman 1991a). It was intended to test both the ability of individual evaluators to obtain similar results on repeated evaluations of the same casts, and the degree of agreement using kappa scores attained when comparing separate evaluators.

5.7.1.1. Calibration and Reproducibility of Rank Ordering System

Calibration training for all three evaluators was performed before the formal evaluation of the casts. Eight sets of casts (within the study) were allocated randomly to each evaluator to rank order each restoration. In order to assess intra-evaluator agreement reproducibility throughout the study, the training exercise was repeated every 4 weeks using casts the evaluators had previously rank ordered. This was carried out without knowledge of the earlier assessment. The casts were examined one week later by all three evaluators for inter-evaluator agreement.
Assessment of reproducibility was repeated every 4 weeks to ensure consistency and the Kappa statistic was calculated for each occasion (Table 28).

<table>
<thead>
<tr>
<th>Intra-evaluator agreement</th>
<th>Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ev 1</td>
<td>.658</td>
</tr>
<tr>
<td>Ev 2</td>
<td>.848</td>
</tr>
<tr>
<td>Ev 3</td>
<td>.862</td>
</tr>
</tbody>
</table>

Table 28: Kappa Statistics and Initial Percentage of Agreement for Three Evaluators at the Start of the Inter-evaluator Agreement Evaluation Study

<table>
<thead>
<tr>
<th>Inter-evaluator agreement</th>
<th>Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ev 1 and Ev 2</td>
<td>.455</td>
</tr>
<tr>
<td>Ev 1 and Ev 3</td>
<td>.235</td>
</tr>
<tr>
<td>Ev 2 and Ev 3</td>
<td>.407</td>
</tr>
</tbody>
</table>

The rank ordering of the cast replicas from the five visits of the 24 months trial took place over a period of eight months. With time, the degree of agreement between the evaluators improved as they became more familiar with the rank ordering system.

Inter-evaluator agreement of the material from the five visits of the 24 months trial took 32 weeks to rank order all 1087 cast replicas. This is demonstrated in Fig 24.
Fig 24: Inter-evaluator Agreement

Assessment of Inter-evaluator Agreement Between Evaluators

<table>
<thead>
<tr>
<th>Rank Ordering (1 month)</th>
<th>Kappa</th>
<th>Level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ev 1 and 2</td>
<td>0.455</td>
<td>moderate</td>
</tr>
<tr>
<td>Ev 1 and 3</td>
<td>0.235</td>
<td>fair</td>
</tr>
<tr>
<td>Ev 2 and 3</td>
<td>0.387</td>
<td>fair</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rank Ordering (2 &amp; 3 months)</th>
<th>Kappa</th>
<th>Level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ev 1 and 2</td>
<td>0.479</td>
<td>moderate</td>
</tr>
<tr>
<td>Ev 1 and 3</td>
<td>0.545</td>
<td>moderate</td>
</tr>
<tr>
<td>Ev 2 and 3</td>
<td>0.507</td>
<td>moderate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rank Ordering (4 &amp; 5 months)</th>
<th>Kappa</th>
<th>Level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ev 1 and 2</td>
<td>0.316</td>
<td>fair</td>
</tr>
<tr>
<td>Ev 1 and 3</td>
<td>0.832</td>
<td>very good</td>
</tr>
<tr>
<td>Ev 2 and 3</td>
<td>0.851</td>
<td>very good</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rank Ordering (6 &amp; 7 months)</th>
<th>Kappa</th>
<th>Level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ev 1 and 2</td>
<td>0.822</td>
<td>very good</td>
</tr>
<tr>
<td>Ev 1 and 3</td>
<td>0.837</td>
<td>very good</td>
</tr>
<tr>
<td>Ev 2 and 3</td>
<td>0.889</td>
<td>very good</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rank Ordering (8 months)</th>
<th>Kappa</th>
<th>Level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ev 1 and 2</td>
<td>0.928</td>
<td>almost perfect</td>
</tr>
<tr>
<td>Ev 1 and 3</td>
<td>0.870</td>
<td>almost perfect</td>
</tr>
<tr>
<td>Ev 2 and 3</td>
<td>1.000</td>
<td>perfect agreement</td>
</tr>
</tbody>
</table>

Ev = evaluator
5.7.1.2. Rank Ordering of Cast Replicas

A total set of 1087 casts were evaluated (rank ordered), representing the restorations involved in the 2-year clinical trial using the four restorative materials. Only replicas for which there was a 'before' and 'after' specimens were used for the rank order assessment. This was to ensure that all data was based on both 'within subject' and 'within tooth' (i.e. material type) assessment.

Stone casts were obtained of the 288 restorations at baseline; 286 restorations after six months, 259 after 12 months [1st year], 169 after 18 months and 85 at the end of 24 months [2nd year].

Each cast was evaluated separately three times by each of the three evaluators. Two evaluators involved in ranking were blind both to the material and the visit number. The primary operator was, however, aware of the material used and visit number (materials and methods page 126).

Cast replicas were compared with the calibrated standard casts using the Vivadent rank ordering model [modification of Leinfelder Standard Cast Method, Sec 4.8.3.1]. This is based on a comparison with 18 calibrated standard replicas of occlusal surfaces, with marginal wear ranging from 25μm - 200μm by 25μm, 250μm - 400μm by 50μm, and from 500μm - 1000μm by 100μm (Table 28).

To prevent bias, the casts for assessment were arranged in a randomised order. When the evaluators' scores did not agree, the cast replica was re-evaluated and a joint score agreed. Only the agreed score was used for statistical analysis.
5.7.1.3. Wear Intervals and Replacement Need of Restorations

For each wear interval of the standard cast Vivadent Model, codes (criterion) were made to categorise wear levels and the need for replacement of restorations (Table 29). The standards were created by giving a questionnaire to a total of 16 dental surgeons compromising of four consultants, four specialists and eight MSc students at the Department of Paediatric Dentistry of the Eastman Dental Institute.

Each of these 16 investigators was asked to examine the standard cast Viva-Dent model and note the level of marginal wear that would indicate need for replacement of the restoration. All investigators agreed that minimal marginal wear was represented by casts demonstrating 25μm – 200μm of marginal wear, and was given code 1. Codes 2 and 3 were given to casts showing marginal wear of 250μm – 400μm. Of these investigators 12 (75%) considered this amount of wear to be moderate. In addition it was agreed that a cast showing an marginal wear of 500μm or more was indicative of the need to replace the restoration, and was given code 4.

It would appear that the decision to replace a restoration is made when the marginal wear is 500μm or greater. In the moderate marginal wear group of 250μm – 400μm, the decision to replace a restoration was made only if there was additional clinical criteria such as post-operative sensitivity, recurrent caries, line fracture of the isthmus etc.
Table 29: Wear Intervals and Replacement Need Criteria using
Vivadent Standard Model as Determined by 16 Paediatric
Dentists

<table>
<thead>
<tr>
<th>Standard Score</th>
<th>Distance (µm)</th>
<th>Code and Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td></td>
<td>Code 1 Minimal occlusal wear</td>
</tr>
<tr>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>Every 25µm</td>
<td></td>
</tr>
<tr>
<td>125</td>
<td></td>
<td>Code 2 Moderate occlusal wear</td>
</tr>
<tr>
<td>150</td>
<td></td>
<td></td>
</tr>
<tr>
<td>175</td>
<td></td>
<td></td>
</tr>
<tr>
<td>200</td>
<td></td>
<td></td>
</tr>
<tr>
<td>250</td>
<td></td>
<td>Code 3 Occlusal wear is evident.</td>
</tr>
<tr>
<td>300</td>
<td></td>
<td>Restoration under observation and/or</td>
</tr>
<tr>
<td>350</td>
<td>Every 50µm</td>
<td>replaced</td>
</tr>
<tr>
<td>400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>500</td>
<td></td>
<td>Code 4 Crevice formation. Restoration</td>
</tr>
<tr>
<td>600</td>
<td></td>
<td>needs replacement</td>
</tr>
<tr>
<td>700</td>
<td>Every 100µm</td>
<td></td>
</tr>
<tr>
<td>800</td>
<td></td>
<td></td>
</tr>
<tr>
<td>900</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The categories were developed in order to re-evaluate the rank ordering system, correlating it with Direct Clinical Assessment of restorations.
5.7.1.4. Materials Marginal Wear Behaviour Over Time

The indirect wear evaluation data using the Vivadent Standard model demonstrated the six monthly and total wear of the restorations as evaluated independently by the team of three evaluators. The data represents categories of wear and is not measured on a linear scale, thus the median was deemed a better summary measure to describe the central tendency than the mean. When plotted, the changes of wear (base line-V\textsuperscript{1}) were skewed to the right, further justifying the use of median as a summary measure.

The median loss of the four restorative materials over the first 6 months was 125-150\(\mu\)m. It appeared that 243 (94\%) of the restorations by 12 months \([n=259]\) showed a median wear of 175\(\mu\)m or less. The amounts of wear increased 100\(\mu\)m by the end of 24 months to give a median wear of 200\(\mu\)m - 250\(\mu\)m \([n = 85]\). There were five cases (one amalgam and three Dyract AP restorations) of wear values reaching 700-800\(\mu\)m when the restorative material showed maximum marginal wear. The frequency distribution of material wear over time is presented in Table 30.

In a few cases where the restorative material was completely lost (one amalgam and two Dyract AP) it was recorded as a failed restoration, rather than material wear. The restoration was replaced immediately, another impression was taken and its cast replica was recorded as re-treatment and the new restoration considered to be a new visit 1 for assessment purposes.

\textsuperscript{1}V = visit No. 2, 3, 4 or 5.
There was a clear difference between amounts of wear for each of the restorative materials during each of the five visits.

This is shown in Fig 25. The Friedman test demonstrated a significant difference between the median amounts of wear in the five visits as follows:

\[ \text{Amalgam } P = .013, \text{ Dyract AP } P < .001, \text{ Fuji II LC } P < .001, \text{ Vitremer } P = .002. \]

Since the Friedman test was significant, in order to determine at which visit there was a significant loss of material compared with baseline, the Wilcoxon Sign Rank test was used, and the Bonferroni correction applied by multiplying the P-value by 4 to adjust for multiple testing. The median changes of wear and P values obtained for all four restorative materials compared with baseline are presented in Table 31. The maximum median wear occurred primarily between visits 4 and 5 [18 -23.9 months] and the median amount of material loss overall was 75μm -125μm.
Table 30: Material Wear Behaviour Over Time (Cast Ordering Method)

<table>
<thead>
<tr>
<th>Material</th>
<th>Baseline n = 70</th>
<th>6 months n = 69</th>
<th>12 months n = 60</th>
<th>18 months n = 41</th>
<th>24 months n = 19</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cast score in µm</td>
<td>Cast score in µm</td>
<td>Cast score in µm</td>
<td>Cast score in µm</td>
<td>Cast score in µm</td>
</tr>
<tr>
<td>Amalgam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>125</td>
<td>167</td>
<td>175</td>
<td>250</td>
<td>300</td>
</tr>
<tr>
<td>Median</td>
<td>100</td>
<td>150</td>
<td>175</td>
<td>175</td>
<td>200</td>
</tr>
<tr>
<td>Mode</td>
<td>75</td>
<td>150</td>
<td>200</td>
<td>150</td>
<td>200</td>
</tr>
<tr>
<td>Min</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>75</td>
<td>50</td>
</tr>
<tr>
<td>Max</td>
<td>300</td>
<td>300</td>
<td>300</td>
<td>600</td>
<td>700</td>
</tr>
<tr>
<td>Percentiles</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>100</td>
<td>250</td>
<td>175</td>
<td>175</td>
<td>200</td>
</tr>
<tr>
<td>70</td>
<td>175</td>
<td>200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyract</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>100</td>
<td>125</td>
<td>175</td>
<td>250</td>
<td>150</td>
</tr>
<tr>
<td>Median</td>
<td>75</td>
<td>125</td>
<td>175</td>
<td>175</td>
<td>250</td>
</tr>
<tr>
<td>Mode</td>
<td>50</td>
<td>150</td>
<td>200</td>
<td>175</td>
<td>200</td>
</tr>
<tr>
<td>Min</td>
<td>0</td>
<td>25</td>
<td>50</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>Max</td>
<td>300</td>
<td>300</td>
<td>500</td>
<td>775</td>
<td>800</td>
</tr>
<tr>
<td>Percentiles</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>100</td>
<td>125</td>
<td>175</td>
<td>175</td>
<td>150</td>
</tr>
<tr>
<td>70</td>
<td>125</td>
<td>150</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuji II LC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>100</td>
<td>125</td>
<td>175</td>
<td>200</td>
<td>150</td>
</tr>
<tr>
<td>Median</td>
<td>75</td>
<td>125</td>
<td>150</td>
<td>175</td>
<td>175</td>
</tr>
<tr>
<td>Mode</td>
<td>25</td>
<td>100</td>
<td>150</td>
<td>175</td>
<td>100</td>
</tr>
<tr>
<td>Min</td>
<td>0</td>
<td>25</td>
<td>50</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Max</td>
<td>225</td>
<td>300</td>
<td>300</td>
<td>300</td>
<td>350</td>
</tr>
<tr>
<td>Percentiles</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>75</td>
<td>125</td>
<td>150</td>
<td>175</td>
<td>125</td>
</tr>
<tr>
<td>70</td>
<td>125</td>
<td>175</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitremer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>75</td>
<td>175</td>
<td>175</td>
<td>200</td>
<td>175</td>
</tr>
<tr>
<td>Median</td>
<td>75</td>
<td>150</td>
<td>175</td>
<td>175</td>
<td>175</td>
</tr>
<tr>
<td>Mode</td>
<td>25</td>
<td>175</td>
<td>175</td>
<td>200</td>
<td>175</td>
</tr>
<tr>
<td>Min</td>
<td>0</td>
<td>75</td>
<td>75</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Max</td>
<td>300</td>
<td>450</td>
<td>450</td>
<td>400</td>
<td>500</td>
</tr>
<tr>
<td>Percentiles</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>75</td>
<td>175</td>
<td>175</td>
<td>175</td>
<td>175</td>
</tr>
<tr>
<td>70</td>
<td>125</td>
<td>175</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Wear values are in µm
Missing data not included
Fig 25: Median Marginal Wear Values for Each Restorative Material
<table>
<thead>
<tr>
<th>Material</th>
<th>Visits (1 &amp; 2)</th>
<th>Visits (1 &amp; 3)</th>
<th>Visits (1 &amp; 4)</th>
<th>Visits (1 &amp; 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amalgam</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted P Value</td>
<td>.004</td>
<td>50</td>
<td>25</td>
<td>250</td>
</tr>
<tr>
<td>Dyract</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P &lt; .001</td>
<td>25</td>
<td>.00</td>
<td>300</td>
<td>P &lt; .001</td>
</tr>
<tr>
<td>Fuji II LC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P &lt; .001</td>
<td>75</td>
<td>.00</td>
<td>225</td>
<td>P &lt; .001</td>
</tr>
<tr>
<td>Vitromer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P &lt; .001</td>
<td>75</td>
<td>.00</td>
<td>300</td>
<td>P &lt; .001</td>
</tr>
</tbody>
</table>

All p values are adjusted for multiple testing (x 4)
The Kruskal-Wallis one-way analysis of variance test indicated that there was no significant difference between the median changes in wear (from baseline through each visit and including visit 5) between any of the four restorative materials (Table 32).

<table>
<thead>
<tr>
<th>Material</th>
<th>Median wear μm</th>
<th>P value</th>
<th>Min μm</th>
<th>Max μm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amalgam</td>
<td>100μm</td>
<td>0.417</td>
<td>25μm</td>
<td>700μm</td>
</tr>
<tr>
<td>Dyract AP</td>
<td>75μm</td>
<td>0.421</td>
<td>50μm</td>
<td>800μm</td>
</tr>
<tr>
<td>Fuji II LC</td>
<td>100μm</td>
<td>0.283</td>
<td>.00μm</td>
<td>350μm</td>
</tr>
<tr>
<td>Vitremer</td>
<td>112.5μm</td>
<td>0.554</td>
<td>.00μm</td>
<td>500μm</td>
</tr>
</tbody>
</table>

This shows that there was no significant difference 'between the materials' in marginal wear levels over the two year period of the study.
This is also presented in box plot chart Fig 26, demonstrating the distribution of material loss from baseline to the end of the study [visit 5].

**Fig 26: Box plot of Marginal Wear of Materials at Baseline and Two years.**

- **Marginal Wear of Materials at Baseline and two years for Each Material**

<table>
<thead>
<tr>
<th>Materials</th>
<th>Baseline</th>
<th>24 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amalgam</td>
<td>70</td>
<td>18</td>
</tr>
<tr>
<td>Dyract AP</td>
<td>75</td>
<td>21</td>
</tr>
<tr>
<td>Fuji II LC</td>
<td>69</td>
<td>15</td>
</tr>
<tr>
<td>Vitremer</td>
<td>74</td>
<td>17</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td><strong>Min</strong></td>
<td>25</td>
<td>50</td>
</tr>
<tr>
<td><strong>Max Percentile</strong></td>
<td>300</td>
<td>700</td>
</tr>
</tbody>
</table>

Note: The baseline values for marginal wear were based on the Indirect Assessment by the 'trained / calibrated' evaluators assessing new restorations as exhibiting a small amount of marginal wear (Discussion page 259).
5.7.1.5. Factors in Marginal Wear Assessments of Cast Replicas

Following a limited experiment (Sec 4.8.3.2, page 130) on the influence of the protective layer added to the resin restorations on marginal wear assessment, the results of the thickness of the protective layer [difference in thickness before and after its placement] are shown in Table 33. The median value is a better measure here since the data was not normally distributed.

<table>
<thead>
<tr>
<th>Table 33: Thickness of Protective Layer [difference in thickness before / after placement] for Each Resin Restoration</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Dyract AP</td>
</tr>
<tr>
<td>Fuji II LC</td>
</tr>
<tr>
<td>Vitremer</td>
</tr>
</tbody>
</table>

The Kruskal-Wallis one-way analysis of variance test indicated that there was no significant difference between the median changes in thickness of the specimens before and after placement of the protective layer on the three resin restorative materials (P = 0.12). Although the exact thickness of the protective layer when placed on teeth in vivo could not be measured, from the data presented above it is concluded that the measurement effect of the protective layer on the wear behaviour of the three resin restorative systems was clinically non-significant.
5.7.1.6. Wear Behaviour of Each Restorative Material During the Study

An analysis of the degree of wear for each restorative material demonstrated the following:

(i) **Amalgam**

The median baseline value was 100µm, six months (visit 2) it was 150µm, at 12-18 months [visits 3,4] the median wear was 175µm and by two years it reached 200µm. There was additional material loss of 50µm - 75µm at each review visit. The minimum loss was about 25µm while the maximum material loss was 600µm - 700µm. This is illustrated in Fig 27 below.

**Fig 27: Amalgam Cast-Order Wear Measures Over the 5 Visits**

![Amalgam Indirect Cast-Score Wear Measure](image)

Missing data not included
(ii) **DYRAC TP**

The median baseline value was 75μm. The median reached 125μm at six months, and by 12-18 months it reached 175μm. At 24 months it had reached 250μm. The median loss of the material was 50μm -75μm at each review visit. The minimum loss was 0μm, while the maximum material loss was 775μm -800μm. This is illustrated Fig 28 below.

**Fig 28: Dyract AP Cast-Order Wear Measures Over the 5 Visits**

![Dyract Indirect Cast-Score Wear Measure](chart.png)

- **Visit 1**: n = 73
- **Visit 2**: n = 73
- **Visit 3**: n = 61
- **Visit 4**: n = 40
- **Visit 5**: n = 15

Missing data not included
(iii) **FUJI II LC**

The median baseline value was 75µm, by six months [visit 2] the median was 125µm, at one year [visit 3] it was 150µm, and by 18-24 months it reached 175µm. There was 75µm of median material loss at each review visit. The minimum loss was 0µm, while the maximum material loss was 350µm. This is illustrated in Fig 29 below.

**Fig 29: FUJI II LC Cast-Order Wear Measures Over the 5 Visits**

![Box plot](image-url)
(iv) **VITREMER**

The median baseline wear was 75μm. The median reached 150 at six months [visit 2], at one year it reached 175μm, and at 18-24 months it was still 175μm. There was a median material loss of 75μm at the first six months, then an additional loss of 25μm at every subsequent review visit. The minimum loss was 0μm, while the maximum material loss was 500μm at visit 3. This is illustrated in Fig. 30 below.

**Fig 30: Vitremer Cast-Order Wear Measures Over the 5 Visits**

![Box plot showing wear measures over 5 visits](image-url)
4.5.2.2. Quantitative Measure of Wear

A preliminary study was carried out to attempt the calculations of volumetric loss and measure overall surface wear.

A. Data Analysis

Weights of impression materials are presented in Table 34, where two sets of measurements were performed for each model wear value included in this part.

<table>
<thead>
<tr>
<th>Table 34: Values of Weighed Impression Materials (1st and 2nd) Equivalent to Substance Loss.</th>
<th>weight of material in grams, for selected standards of wear</th>
</tr>
</thead>
<tbody>
<tr>
<td>25μm</td>
<td>100μm</td>
</tr>
<tr>
<td>1st</td>
<td>2nd</td>
</tr>
<tr>
<td>0.0183</td>
<td>0.0239</td>
</tr>
<tr>
<td>0.0193</td>
<td>0.0238</td>
</tr>
<tr>
<td>0.0249</td>
<td>0.2439</td>
</tr>
<tr>
<td>0.0194</td>
<td>0.0239</td>
</tr>
<tr>
<td>0.0179</td>
<td>0.0248</td>
</tr>
<tr>
<td>0.0243</td>
<td>0.0184</td>
</tr>
<tr>
<td>0.0237</td>
<td>0.0247</td>
</tr>
<tr>
<td>0.2453</td>
<td>0.0239</td>
</tr>
<tr>
<td>0.0249</td>
<td>0.0247</td>
</tr>
</tbody>
</table>

For each category of wear, the difference between the 1st and 2nd measurements was plotted against the mean of these two measurements (Petrie and Sabin, 2000). In order to determine if the system provided repeatable values, the data was checked for a funnelling effect. This is the appearance when data is plotted on a graph; if this looks like a funnel this is interpreted to mean that a single measure is likely to be unreliable; as a result the repeatability varies according to the magnitude of the measurement, and a single measure is not acceptable. For the data presented above, funnelling occurred for both the 25 μm and 100μm wear levels. This indicates that the British Standard Institution Repeatability Coefficient could not be calculated. When wear levels were greater (200μm, 400μm and 700μm) the data was not funnelled and the British Standard
coefficient was calculated (Table 36). Fig 31 illustrates a graph of 25μm with funnelling effect, and 700 μm without funnelling effect. Paired t-tests were performed to check for bias, and all were non-significant (Table 35).

### Table 35: P Values of Paired Wear Measurement

<table>
<thead>
<tr>
<th>Paired measurements of wear values</th>
<th>P values</th>
<th>Mean of difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st / 25 and 2nd / 25</td>
<td>0.967</td>
<td>-.00155</td>
</tr>
<tr>
<td>1st / 100 and 2nd / 100</td>
<td>0.898</td>
<td>.00517</td>
</tr>
<tr>
<td>1st / 200 and 2nd / 200</td>
<td>0.240</td>
<td>.00158</td>
</tr>
<tr>
<td>1st / 400 and 2nd / 400</td>
<td>0.829</td>
<td>.00027</td>
</tr>
<tr>
<td>1st / 700 and 2nd / 700</td>
<td>0.909</td>
<td>.00031</td>
</tr>
</tbody>
</table>

### B. Repeatability of Measurements

The British Standards Institution Repeatability Coefficient provides a measure of the maximum likely difference between any two readings.

The British Standard Institution Repeatability Coefficient (B.S.Co) = \(1.96 \times \text{Sd of difference}\)

\[
\text{Sd} = \text{standard deviation of differences}
\]

(Petrie and Sabin, 2000)

In this pilot study, the B.S.Co was calculated for the amounts of wear and did not demonstrate a funnelling effect for 200μm, 400μm, and 700μm of wear models.

### Table 36: B.S.Co. of Selected Wear Measurements

<table>
<thead>
<tr>
<th>Amount of wear μm</th>
<th>B.S. Coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>200μm</td>
<td>.007252</td>
</tr>
<tr>
<td>400μm</td>
<td>.007310</td>
</tr>
<tr>
<td>700μm</td>
<td>.015484</td>
</tr>
</tbody>
</table>
From Table 36, it is apparent that if there is an amount of material loss of about 200μm, the maximum likely difference between any two measurements when weighing the impression material, 'which corresponds to the amount of material loss', is not more than 0.01gm. This is clinically undetectable and similarly applies to the other measurements. Therefore, the preliminary study using this method of measurement can be regarded as repeatable when the amount of material wear [material loss] is 700μm or more. Clinically, this is when replacement of the restoration most likely indicated.
Fig 31: Checking for Funnelling Effect

Difference between first and second measurement values against their mean

Difference between first and second measurement values plotted against their mean for 25μm of wear, demonstrating funnel effect.

Mean of 1st and 2nd values

Mean of 1st and 2nd values

Difference between first and second measurement values plotted against their mean for 700μm of wear, appeared to be more reproducible.

(Petrie & Sabin, 2000)
Chapter Six.

Discussion
Introduction

The oral cavity is a complex environment from both chemical and technological points of view. Consequently, *in vitro* experiments cannot mimic every detail of *in vivo* conditions. Although important and clinically relevant information can be obtained from *in vitro* experiments, a fully formed view about the clinical use of a particular dental material or technique can only be retrieved from suitably planned *in vivo* studies.

To do this properly it is necessary to apply the rigour of a randomised clinical trial. This is the only method of obtaining meaningful information on the durability of 'restorative systems.' In this context, the restorative system is a combination of the cavity preparation by the operator, restorative material used, method of preparing the material immediately before placement, placement of the restorative material, and any additional procedures after placement. Each of the elements plays a crucial role in the success or failure of the restoration.

Simonsen has stated that 'without clinical trials we are simply believing and this is not good enough for human subject treatment' (Simonsen 1992). Furthermore, clinical trials of new techniques and materials for the restoration of primary molars have to be compared with the benchmarks set by high quality studies on the durability of materials particularly those that have been in use for some time with a known performance profiles. Of the materials currently available, the amalgam restoration is widely regarded as the standard, since it has been in use for over a century of clinical dental practice (Mjor & Haugen 1976; Mjor & Qvist 1997). The amount of information available on its performance is substantially greater than any other restorative material.
Results of clinical trials are difficult to compare due to their heterogenicity. Factors such as difference in caries risk, operator skills, study duration, patient age, or evaluation criteria make comparison of different studies difficult. This reflects problems of any patient-based research. Attempts to standardise for all these factors may limit the flow of patient admission to the trial to an unacceptably low level. Patient groups which are too carefully defined render the findings inapplicable to the general population. The further difficulty of research workers developing their own criteria for evaluation, might also limit the value of most of the results. The development of assessment methods used by a range of operators working in different environments has been a major advance (Cvar & Ryge 1971). However, even with such well-established criteria it is important to recognise that a significant element of subjectivity enters into the assessment process.
6.1. Study Design

The present investigation was designed as a field trial, using four different restorative materials [amalgam, compomer, and two different formulations of resin-modified glass-ionomers].

The use of the term ‘field trial’ draws attention to the fact that the patients from the UAE enrolled in the trial were drawn from a typical community dental practice. This potentially permits the results to be related to the general child population. This is important because many reports of research into durability of restorations use patient groups for which general applicability does not apply e.g. dental students (Norman et al 1988; Lundin & Koch 1989; Wilson & Norman 1991). While selection of a specific patient group has the advantage of artificially low drop out rates, the consequence of this is that the results, perhaps, present a more biased view. This would be influenced by the high level of knowledge of preventive dental health, which is unlikely to occur in patients drawn from the general population.

In this study, each tooth was randomly allocated to one of the four restorative materials in the two different children populations. All restorations were tested for durability using a standard clinical setting similar for the UAE and the UK subjects. The central question addressed was whether there was a difference in the survival rates of the restorations using the different materials.

To meet the large sample size (n=288), with a limited time span available (24 months) the unit of study was determined to be the individual tooth. Multiple sites per patient were thus included. This reduced the number of subjects recruited for the study (n = 152) facilitating management of recall visits, although the risk of placing more than one restoration per child might be affected by loss of patients to follow up. However, out of the 152 children, 87 (57%) had a single restoration placed [Table 9, page 140].
This is important as one of the main limitations of a clinical trial is the potential of a high dropout rate, particularly in the type of field trial undertaken here.

The number of restorations included in the present study is relatively small, with one operator placing 251 restorations out of the total 288. This operator also carried out the six-monthly follow-up of all 288 restorations over the 24-month period. The results of the present study may not therefore be directly comparable with those of other studies. The majority of the long-termed clinical reports available are retrospective, where the inclusion as well as the baseline criteria are not clearly defined. This gives rise to more subjective results (Braff 1975; Levering & Messer 1988; Holland et al 1986; Roberts & Sherriff 1990; Einwag & Dunninger 1996; Mertz-Fairhurst et al 1998; Medeiros & Seddon 2000; Attin et al 2001). (List of the retrospective studies on primary teeth illustrated in Appendix VIII a).

The use of different materials in the same patient’s mouth might raise the possibility of material interaction, particularly in relation to the release of fluoride. The influence of fluoride release is not necessarily confined to one individual tooth (Hals 1976). The selection criteria used were established primarily in an attempt to reduce dropout numbers. Other factors that influenced selection included the ability to record an impression and the availability of a suitable carious lesion.

The use of two groups of children from two different countries increases the applicability of the findings to the general child population. The UAE group particularly were representative of the ‘every day’ work of dentists providing care to children under general dental conditions. The UK population, whilst similar in most criteria, were less representative, as the clinic at the Eastman Dental Hospital is a referral centre and most of the children were referred by their GDP for more advanced dental treatment. The patients frequently required special care under GA and / or could not cope with restorative treatment under local anaesthesia. It is widely believed that children who
exhibited minimal resistance to even simple conservative treatment require 'excessive' chair-side time and so are referred by the GDP. It is not possible to determine the truth of this statement, all but five of the children in the UK group were able to accept treatment with behaviour management and local anaesthesia in the EDH clinic [Tables 15 and 16 pages 146-147]. Reasons for dropouts in the two groups may vary. In the UAE, change of schools or travel difficulties may often result, whereas in the UK patients may migrate back to their GDP because of the original nature of the referral, or they might not wish to continue due to travel expenses.

In this study the percentage of children for each category on the Frankl behaviour scale were similar for both the UAE and the UK children, and any small differences were non-significant \( P = 0.70 \). However, in the UK children, it was necessary to use Inhalation Sedation (IS) on 14 (9%) of them. This perhaps indicates that a small proportion of the UK group who were referred had genuine difficulty in cooperating with routine dental treatment, which might suggest that this group of children do not represent the treatment need of the whole UK children population. It could also be that the operator, with the availability of such an effective technique as IS, reverted to this rather than continue with vigorous behaviour management. In the UAE inhalation sedation was not available.

Conducting clinical research in the two different countries had the advantage of being trans-cultural, permitting two different populations to be examined with their different dental treatment needs, caries risk, and prevention awareness. This enables comparisons to be made where social and cultural influences determine whether patients continue to attend for review visits. This was clearly illustrated by the dropout rates, which were much greater in the UK (36%), when compared with children in the UAE (25%) [Table 19, page 150].
This difference was attributed to the fact that the UAE Children were recruited from selected primary schools where the dental clinic was situated within the school buildings\(^1\).

Considerations were made to match the children for their caries experience, but to do this would reduce the numbers available to a very low level. Furthermore, changes in caries activity occurring over the trial period may negate the claimed benefits of matching by caries activity at baseline.

Randomly selected UAE children were called from their classrooms, according to their caries records from a previous screening clinic\(^2\). In this respect, the study evaluated materials performance in a community health service This made it relatively easy to contact non-attendees to ensure that a replacement review appointment was kept. This was in distinct contrast to families in the UK, where an appointment-based system was adopted. Despite assurance of willingness to attend for 'at least four review appointments', to help with the research, the initial interest and enthusiasm faded and it was often impossible to persuade some parents to carry on participating in the study. One of the reasons occasionally given was the fact that the teeth were asymptomatic 'giving no problems'. It is tempting to view the restorations placed in the children as 'successful', while this cannot be justified, because the restorations were not clinically

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\(^1\)For schools and locations, see Appendix VI.

\(^2\)The screening clinic is part of a public health preventive programme established in the UAE. (Al-Hosani 1998).
assessed, it nevertheless gives some indirect support for the use of the 'all successful assumption' of the sensitivity analysis [see page 184, Fig 23].

One of the disadvantages of this type of study was inevitably the difficulty of coordinating and balancing treatment facilities and recall systems. This was partly due to the necessity for the primary examiner to travel between the UK and the UAE\(^1\) every 6 months. Some consideration was given to standardising baseline caries level at the planning stage, but it was recognised that this would dramatically reduce the numbers of children available for inclusion in the study. It is possible that in general, children of the Middle East are at higher caries risk than children of the UK, as their dietary constituents and habits are different.

\section*{6.2. Restorative Treatment and Material Selection}

\subsection*{6.2.1. Criteria for Restorative Treatment}

Treatment of caries should meet the needs of each particular patient based on the individual caries risk. All the materials offered fall within this simple but important definition. Restorative decisions for the primary dentition are based on different objectives and expectations than those for the permanent dentition. Since primary teeth have a limited life span of 8-9 years maximum (McLean & Wilson 1977; Welbury et al 1991; Welbury et al 2000), a restoration will be required to function for a limited time in the oral environment. Selecting the 'appropriate' restoration involves understanding

\footnote{Reports of field trips see Appendix Ic.}
Chapter 6
Discussion

the limitations imposed by the primary dentition, especially the relatively rapid advance of caries, which quickly makes the tooth 'unrestorable' with conventional materials such as amalgam.

6.2.2. Reasons for Materials’ Selection

The selection of materials for clinical evaluation is always difficult. The choice of comparator to represent the present 'Gold Standard' is straightforward. The criteria for this were determined by the number and details of previous clinical trials. In this respect, dental amalgam is widely regarded as the most appropriate material to act as a comparator. In many areas, performance is better than other existing restoratives. Further, there is a long and well-published record of its ability to remain as a functioning restoration for many years. For these reasons, it was chosen as the comparator (Fuks 2002). Definitive studies have shown the durability of dental amalgam in the permanent dentition (Hickel & Voss 1990; Welbury et al 1991).

In the primary dentition, the survival rate of amalgam restorations varies from 50% after two years (Qvist et al 1986b), to 38-48% after three years (Holland et al 1986), and up to 67% after five years (Roberts & Sherriff 1990) It is also a material which could be used by a variety of operators with reasonable reliability (Roberts & Sherriff 1990). Composite resin materials, as reported from a substantial number of trials, provide an alternative as comparator for the primary dentition (Nelson et al 1980; Oldenburg et al 1987; Tonn & Ryge 1988; Letzel 1989; Varpio 1993) as well as the permanent dentition (Wilder et al 1991; Mair 1998; Raskin et al 1999).

The consistency of results is not as good as amalgam, with reported failure rates up to 40% and 50% (Raskin et al 1999). Composites are technique sensitive and time consuming (Garcia-Godoy 2000), do not normally release fluoride ion, and should preferably be placed in cavities that do not extend beyond the proximal line angles
(Donly & Garcia-Godoy 2002). Furthermore, the variations both in base resin and type of filler introduces even more variables which will influence the outcome. In this respect, the basic formulation of amalgam is more reliable. This, along with the relatively poor performance of composites, supports amalgam as the primary choice of comparator. It was felt that the only clinical standard acceptable with consistent results was dental amalgam, despite its shortcomings. In this respect composite would provide variable results (Leinfelder & Vann, Jr. 1982; Roulet 1988; Hickel et al 2000; Burgess et al 2002). Glass ionomers have limited application according to previous reports (Hickel & Voss 1988; Kilpatrick 1993b; Andersson-Wenckert et al 1995). Other studies (Knibbs et al 1986; Welbury et al 1991; Roeters et al 1998) have postulated that some adhesive materials are capable of being considered as alternatives to amalgam. In particular, the relation between wear rates and marginal seal were of importance as the prime determinants of restoration durability in the deciduous and mixed dentition. Conventional glass-ionomer materials were excluded from this study, as a number of clinical trials proved to have unsatisfactory long-term results (Kilpatrick 1993b; Andersson-Wenckert et al 1995) and showed that these materials, while having some advantages, do not perform consistently in the primary dentition.

The use of resin hybrid materials demonstrated promising results (Kilpatrick 1993b; McCabe 1998), yet limited information is available concerning the survival of such variable mixtures in 'real time' clinical use. Dyract AP, a polyacid modified composite, has mechanical properties similar to those of composite resins but is considered to be less susceptible to exposure to contaminants than conventional composite resins. In addition, the reported high acceptance by practitioners is attributed to its ease of handling properties. It is reported to have leachable fluoride, which will encourage remineralisation of the surrounding tooth tissue (Eichmiller & Marjenhoff 1998). However, this has been measured as being substantially below that of glass ionomer
cement. Early work on the initial version of the material indicated that it had wear problems (van Dijken 1995) but the current modified material is reported to have overcome this to some extent. However, only limited long-term evaluations have been carried out particularly in the juvenile dentition.

Resin-modified glass-ionomer cements (RMGIC’s) may be regarded as a link between conventional glass-ionomers and composites. They have been available for a number of years but the clinical evaluation of these materials is still in its infancy.

RMGIC’s have proved in certain workers’ hands to be quite successful and there is strong evidence that substantial fluoride release will occur over an extended period of time (Forsten 1995; Musa et al 1996; Rothwell et al 1998). There is also evidence that the materials themselves will take up fluoride and then re-release the ions (Musa et al 1996). The materials contain a water-soluble monomer HEMA and are therefore less susceptible to moisture contamination when compared with conventional composite restorations and glass ionomer cements. Within the generic group of materials, which are known as RMGICs, substantial formulation differences exist (e.g. Fuji II LC and Vitremer). Further, the behaviour of the materials during setting is different. It has been observed that the degree of conversion of the resin phase does vary quite markedly between each manufacturer’s products (Kanchanavasita et al 1998). This will, of course, have considerable bearing on the longer term performance of the materials (Kanchanavasita et al 1998). It is with these considerations in mind that this trial was set up to examine the performance of the three materials under clinical testing.

All of the materials, with the exception of amalgam, have been reported to provide sustained fluoride ion release, which might possibly provide cariostatic properties (Donly et al 1999). With the exception of amalgam, the selected materials were all capable of mechanic-chemical/ chemical bonding to tooth structure. It is very important to take into account advantages associated with the use of adhesive materials in
children. They allow less destructive cavity preparation and a smaller restoration. This in turn reduces treatment time, and local anaesthesia may be unnecessary (Welbury et al 1991). The long-term fluoride release from resin-modified glass-ionomer cements and compomers may have benefits for the child patient. These materials have been shown to be re-charged by exposure to fluoride solutions and gels (Bilgin & Ozalp 1998).

The use of dental restorative materials with additional benefit of a preventive effect has accordingly received increasing emphasis with time. The concept of combining the strength, rigidity, and fluoride-release properties of silicate cements with biocompatibility and adhesive qualities of polyacrylic cements led to the introduction of fluoride-releasing materials. However, there is no conclusive evidence for or against the preventive effect of fluoride containing restorative materials (Randall & Wilson 1999), as the mechanism by which fluoride moves from the material into the enamel as well as exact amount to inhibit caries remains unclear (Van Dijken et al 1997; Eichmiller & Marjenhoff 1998). Despite these perceived advantages and since the use of amalgam has diminished significantly during the past few years (Fuks 2002), more studies with long-term follow-up of resin-modified glass-ionomers, compomers and other aesthetic materials are essential before they can be proposed as alternatives for amalgam in the primary and early mixed dentitions (Fuks 2002), as only limited long-term clinical evaluation is available (Kilpatrick 1993b; Croll & Helpin 1995; Mass et al 1999).
6.3. Subjects Taking Part in the Study

6.3.1. Number

Children that participated in the present study were not chosen randomly, since they all had at least one carious lesion in need of restorative treatment according to inclusion/exclusion criteria [Sec 3.1 and 3.2 materials and methods]. The patients selected represented a group of children and adolescents with active carious lesions at the start of the study. Recruitment of the patients was carried out on a screening visit prior to the actual treatment visit and consent forms were completed by the parents or carers.

6.3.2. Age

It was anticipated that there would be no significant difference in the mean age between the two groups. The age of the patient is one of the important factors in restoration placement and durability. As reported in previous studies, restorations placed in children under three years of age lasted on average less than a year (Holland et al 1986), while when placed in children under four years of age restorations might last up to six years (Levering & Messer 1988). It has also been reported that restorations placed in the first primary molar had a shorter survival time than those placed in the 2nd primary molar (Holland et al 1986). Previous studies suggest the age of the child influences her/his behaviour during dental treatment, which itself changes during the course of restorative treatment. This however, may compromise the long-term outcome of the treatment (Croll & Helpin 1995; Brill 2001; Brill 2002). In this study patient behaviour appeared to be unrelated to the need for replacement of restorations. Of the eight patients who displayed a definitely negative cooperation only one child with a single occluso-mesial restoration required replacement.
There was a much broader age range in the UK patients with the minimum age of four and maximum age of 15 years. The age range of the UAE patients was narrower as these patients were recruited from their primary school (grade 1 and 2). The majority were of a similar age range [97\% of the patients with an age range 7.3 years, with a minimum age of six years and maximum age of 14 years].

6.3.4. Gender

From the UAE group there were 85 boys participating in the study compared with only seven girls. The female School Dental Health Authority Department was unwilling to allow female students to participate in the study. This was in contrast to the male Dental Health Care Authorities, who were very cooperative in providing facilities. This was achieved by the provision of special school buses to take the children to the recall visit, when their school did not have its own dental clinic. This was found to be necessary because during the course of the study, some children moved on to more senior schools, which did not have a dental clinic. For the girls, the schools refused to provide such a facility. Since, there were only seven girls; the impact of four girls failing to complete the study was limited.

It has been noted in the literature that the prevalence of dental caries in girls is higher than in boys (Mansbridge 1959; Jose Leopoldo et al 2003). This is attributed to the early eruption of the first permanent molar in girls. However, several other studies (Clarkson & Worthington 1993; Chen & Andersen 1997; Ostberg et al 1999) have suggested that girls are more proficient in health practices such as flossing and brushing of teeth, diet, and self-esteem.
6.4. Clinical Procedures

In the present study, time and attention were devoted to the placement techniques and to the materials themselves, both of great importance for clinical success. (Rasmusson & Lundin 1995).

6.4.1. Operators

Prospective clinical trials in the literature involve either a larger number of restorations or the collaboration of several operators (Tonn & Ryge 1988; Hickel & Voss 1990; Mjor & Jokstad 1993; Peters et al 1996; Andersson-Wenckert et al 1997; Roeters et al 1998), or well controlled but limited paired studies following a split mouth technique (Welbury et al 1990; Welbury et al 1991; Welbury et al 2000; Hubel & Mejare 2003). Prospective well-controlled clinical trials with a single main operator similar to the present study are those reported by Holst (1996), Cehreli & Altay (2000) and Rutar et al (2000) (Appendix VIII b).

The author, as the main operator, placed 251 restorations while 37 restorations were placed by the dental therapist. Calibration sessions were attended to standardise placement techniques. A restorations placement protocol was carefully followed by both operators, minimizing the risk of variation both in technique and in primary assessment. This was carried out using plastic and extracted primary and first permanent molar teeth. The effect of the operator in this study was considered to be of minimal importance. There were two operators who had above average manual skills and a strong motivation and interest in clinical research, having participated in a number of studies previously. The longevity of restorations is affected by the experience and techniques of the operators (Charbeneau et al 1986; Rupp 1987; Mjor et al 1990; Hse & Wei 1997).
The number of failed restorations originally placed by the therapist were only two (5%) representing a very small proportion of the therapists’ work (n=37). [7% of the overall failed 30 restorations, and 0.7% of the originally placed 288 restorations].

The author had 28 (11%) [10% of the overall 288 restorations] failed restorations out of the 251 placed. The effect of this was found to be non-significant to the overall survival rate of the restorations [P value = 0.073].

A high level of reproducibility of the clinical assessment of the restorations was maintained throughout the whole period of the trial. This is an important factor supporting the value of the work and was achieved by placing all the restorations for the trial within the first eighteen months during which intra and inter examiner reproducibility evaluation was performed three times. At each time the Kappa statistics showed ‘good agreement.’ This again gives strong support to the conclusions drawn from the results of this body of work.

The primary operator reviewed all 288 restorations at each of the review visits, and provided replacements of the failed restorations (n=30). This had the advantage of consistent patient management technique, operative work and reproducible clinical assessment of restorations (Roberts & Sherriff 1990). However, independent assessment of the restorations was carried out indirectly at a later stage. This minimised the potential possibility of single operator bias.
6.4.2. Restorations

6.4.2.1. Cavity Design

A minimal invasive technique was adopted for cavity design for both amalgam (Robinson 1985) and resin-based materials (Garcia-Godoy 1986; Sturdevant et al 1987), the cavity being limited to caries removal with the addition of retention grooves for mechanical retention. This mechanical retention was used for the resin-based materials, which excludes adhesive failure as a cause of restoration failure.

A narrow contoured matrix band was adapted to the tooth and wedged for every proximo-occlusal restoration as previously described (Welbury et al 1991; Roeters et al 1998).

Reports demonstrate that improper or inappropriate cavity design affects the longevity of amalgam restorations (Charbeneau et al 1986; Mjor et al 1990), and that a typical small amalgam restoration in a child's tooth will usually serve for the expected life of that tooth (Holland et al 1986; Levering & Messer 1988). Large amalgam restorations tend to chip out around the enamel margins in both primary (Christensen 1996; Christensen 1998; Christensen 2001) and permanent teeth (Osborne & Gale 1981; Robinson 1985). For resin-based materials, preservation of tooth structure is one of their main advantages (Mjor & Jokstad 1993; Lutz 1996; Tyas 1996; Gray 1999).

The results of this study, in general terms, were in agreement with previous reports (Welbury et al 1991; Espelid et al 1999; Folkesson et al 1999; Hubel & Mejare 2003) (see Appendix VIII a,b). The reasons for failure of the amalgam restorations were usually bulk fracture, a similar finding from previous studies and assessments (Lavelle 1976; Lemmens et al 1987), while loss of marginal integrity and secondary caries were common causes of failure of resin-based materials (Wilson et al 1997).
Chapter 6
Discussion

It is essential to provide sufficient bulk of material and to avoid shallow keyways and narrow isthmuses when restoring the primary dentition with amalgam (Holland et al 1986). It has also been suggested that the resin-modified glass-ionomer material would be better placed in non-stress bearing areas, surrounded by well-supported cusp and marginal enamel (Croll & Killian 1993a). It is therefore recommended that the prepared cavity has mechanical as well as chemical retention, particularly in larger cavities (Papagiannoulis et al 1999). The influence of the cavity design on the survival rate of compomers has not yet been evaluated (Peters et al 1996).

6.4.2.2. Restorations for the Child Patient and Pain Control

A. PATIENT COOPERATION AND RESTORATIONS’ REPLACEMENT NEED

One of the difficulties in performing this study was the limited cooperation of young patients. Consequently, the handling characteristics of the materials, including following the manufacturers’ instructions, were considered to be very important in reducing the chances of early failure (Peters et al 1996; Roeters et al 1998). One of the factors, which influence the outcome, was the fact that two of the resin-based materials did not require hand mixing (Dyract AP and Fuji II LC). Vitremer, a ‘powder – liquid’ system, requires hand mixing similar to conventional glass-ionomers. Previous studies have showed that conventional GICs are difficult to handle (Smales & Greke 1990; Mjor & Jokstad 1993). This probably explains why some clinicians prefer working with Dyract AP and Fuji II LC rather than Vitremer (Mount 1998; Luo et al 2000; ADA 2003).

It is worth mentioning at this point that both Vitremer and Fuji II LC have a tri-cure setting reaction (Mitra 1992), developed to overcome the problem of depth of cure. A ‘third setting reaction’ is incorporated to allow complete curing in the deeper parts of
the restoration. This process should proceed rapidly enough to allow trimming of the restoration and preparation of a core soon after placement. Once a ‘tri-cure’ material has been mixed, its working time becomes finite, and makes the concept of ‘command set’ and ‘ease of handling’ less valid (Sidhu & Watson 1996).

B. PAIN CONTROL AND RESTORATIONS’ REPLACEMENT NEED

Of the 288 restorations placed, 224 were in primary molars while 61 restorations were placed in first permanent molars. Only three restorations were placed in premolars. There were a total of 156 occlusal restorations and 132 proximal restorations, primarily occluso-mesial. 93% of the restorations (n=267) were placed using local anaesthesia, compared with 7% (n= 21) restorations placed with behaviour management alone.

From the results, there was no significant difference between the replacement need of the restorations and type of pain control used (page 147)

6.4.2.3. Moisture Control

The clinical trial was designed to mimic as far as possible normal day-to-day practice, following the manufacturer’s recommendations for materials’ placement. The reasons for this were to ensure general applicability of the results.

Rubber dam isolation was used whenever possible (Mjor & Jokstad 1993; Croll & Helpin 1995; Marks et al 1999b) as recommended by the manufacturers. Alternatively,

1 Common practice in clinical trials of this nature (Wellbery 1989, Kilpatrick 1993a).
partial isolation methods using cotton rolls, dry guard, and/or high volume suction were used. From the results, there was no significant difference between the survival of the restorations and the method of isolation used. Out of the 30 failed restorations, 17 were performed under rubber dam isolation while 13 had cotton rolls as the method of isolation. This tends not to support the general notion that when placing a resin-based material, the use of rubber dam isolation is essential. This may be attributed to the fact that in those materials (Dyract AP, Fuji II LC and Vitremer), water plays a part either in the initial setting stages of the material, or subsequently to achieve fluoride release. This may not be desirable when using a composite resin material, since polymerisation should take place before water is introduced, and may also to some extent affect comomers.

In general, the routine use of rubber dam isolation in the UK general practice is particularly low (Marshall & Page 1990; Kilpatrick 1993b), since many clinicians would rather reduce the need for local anaesthesia and lessen trauma to the gingiva, while maintaining patient cooperation (Roeters et al 1998; Cehreli & Usmen 1999; Wucher et al 2002; Hubel & Mejare 2003). It is of note that studies comparing restorations placed with or without rubber dam give similar failure rate results (Welbury et al 1991; Roshan et al 2003; Hubel & Mejare 2003) (Appendix VIII b). This does raise questions as to why rubber dam is usually recommended. In this day of evidence based dentistry, the advocates of rubber dam can no longer claim that its use leads to superior restorations, although this may occur in individual patients. The main reason for using rubber dam is to reduce the possibility of dropped objects being swallowed or inhaled (Zitzmann et al 1999; Fishelberg & Hook 2003).
In addition, when old amalgam restorations are being cut from the teeth it is suggested that it is easier to control the dispersion of the debris, thus minimising the hazard of mercury vapour (Berglund & Molin 1997; Kremers et al 1999; Whitworth et al 2000). Some patients as well as dentists feel it is more comfortable whilst operative work is being carried out on isolated teeth (Brackett et al 1989; Stewardson & McHugh 2002).

6.4.2.4. Restorations and Primary Dentition

Longitudinal studies on primary dentition will potentially present problems as the primary teeth exfoliate, and the follow-up times in clinical trials on the survival of restorations in primary molars are often relatively short (Kilpatrick 1993b; Andersson-Wenckert et al 1995; Qvist et al 1997). In this study, a total of 35 teeth exfoliated mostly during the intervals between the 3rd and 4th visit. This clearly has an impact on the interpretation of the results, as it is justifiable to consider exfoliated teeth as non-failures.

In the literature (Braff 1975; Holland et al 1986; Hickel & Voss 1990; Welbury et al 1991; Holst 1996) (Appendix VIII a,b), different methods have been used to assess the proportion of successful restorations in primary teeth. Although there is no reliable way to deal with exfoliated teeth, failure incidence is usually helpful when comparing the durability of different restorative materials. Thus, all the restorations contribute with their individual follow-up time until the tooth exfoliates or is lost to further follow-up. This can be considered a disadvantage as it assumes that the failure rate is constant over time, which was not the case in the present study. The maximum proportion of failures was observed during the period of 18 to 24 months (4th and 5th visits), a time at which some primary teeth were ready to exfoliate [Table 20, page150]. This may appear incorrectly to reflect the durability of the restorative material used, since including or
excluding these teeth will under/over-estimate, respectively, the failure rate in the calculation of the results (Andersson-Wenckert et al 1997).

6.4.2.5. Restorations Follow-Up

Every effort was made to ensure that patients attended the review visit, yet the number of patients who attended all the review appointments was only 25 with 56 restorations present. A total of 66 patients with 177 restorations failed to attend the last review appointment. In a clinical trial of this nature losses occur because people either move away, or ignore the request to attend a review visit. Only 17 patients with 44 restorations withdrew from the trial mostly during the interval between the 3\textsuperscript{rd} and 4\textsuperscript{th} visit (Table 20, page 150), as some patients moved homes and the journey became too long to justify attendance for a review visit. Others could not take time off work to accompany their children to the dental appointment and some were not keen to continue attending review visits. This suggests that patient / parent tolerance of repeated visits to participate in research is limited to periods between 12-18 months. This is important as planning of future studies needs to take account of, or find a way around this difficulty.

In agreement with previous studies (Welbury et al 1991; Peters et al 1996; Roeters et al 1998; Welbury et al 2000), no instances of postoperative sensitivity were reported either immediately after placement or during the 2-year evaluation period. This can be attributed to the sealing ability of the adhesive resin-based materials used (n=218, 76%). None of the amalgam (non-sealing material) restorations (n=70, 24%) demonstrated any symptoms of postoperative sensitivity.
Another explanation is possibly the application of calcium hydroxide and/or glass-ionomer lining over the exposed dentine in deep cavities, which would potentially reduce symptoms (Materials and Methods, page 108).

During the 24-month period of the study, 30 restorations failed primarily due to fracture in proximal restorations. It is clear that the failure rate of occluso-proximal restorations is over three times that of occlusal or single surfaced restorations. This is consistent with the results of other surveys as well as clinical studies (Varpio 1993; Kilpatrick 1993b; Andersson-Wenckert et al 1995; van Dijken et al 1999).

This is an important issue for clinicians aiming to restore primary teeth successfully. It may explain the reasons for the choice of many clinicians to use stainless steel crowns when the anticipated cavity preparation and presumably the extent of the cavity preparation is greater than which is recommended for a ‘classical’ preparation (Messer & Levering 1988; Roberts & Sherriff 1990) (Appendix VIII a,b).

### 6.4.3. Restorative Materials

#### 6.4.3.1. Physical Properties

The physical properties of amalgam, resin composite and glass-ionomer materials vary markedly. If values for compressive strengths are compared for these materials, they may be summarized as follows:

- Amalgam has the highest compressive strength values indicated to provide good longevity (Downer et al 1999)
- Modern resin composites can approach the strength of acceptable amalgam alloy materials.
- The restorative types of glass-ionomer materials, including the reinforced cermet type, exhibit lower strength values than that of amalgam


- It was reported that the physical properties of RMGICs (Fuji II LC & Vitremer) and compomers (Dyract AP) were inferior to those of resin composites (Attin et al 1996). However, they are suitable materials to restore primary molars (Attin et al 1998; Attin et al 2001; Hubel & Mejare 2003)

The incidence of bulk fractures of both amalgam and resin restorations in the present study suggests that the physical properties for use in conventional Class II cavities are inadequate as they behave as a brittle material (Wilson et al 1997).

This finding confirms results for similar studies of glass-ionomer materials used in Class II cavities in deciduous dentition (Ostlund et al 1992; Andersson-Wenckert et al 1995) and permanent teeth (Hickel & Voss 1988). This clearly shows that this reliance on one mechanical property as a predictor of performance is not appropriate. Further, even with a range of parameters the only clear predictor of success or failure is clinical performance.

6.4.3.2. Handling of the Restorative Material

Finishing of amalgam restorations was limited to the elimination of surface roughness around the edges of the restorations when reported by the patient (Hickel & Voss 1990; Welbury et al 1991). No attempts was made to polish any of the restorations to a high shining finish as this would have introduced an element of material loss that would have been difficult to quantify.

It is recommended that all resin-based materials can be contoured and finished with fine polishing diamonds and flexible discs (Mount 1993; Croll & Helpin 1995; Roeters et al 1998; Luo et al 2000; Demirci & Ucok 2002). In this study, the combination of 12-fluted carbide burs and flexible discs of the Sof-lex (3M Dental Pdts, St Paul, MN,
USA) type were used, which provided the most consistent results for modified glass-ionomers. This is in accord with previous reports (Watson 1990).

In all the cases in this study, it was necessary to adjust the set material after placement and setting. One of the greatest advantages of RMGICs (Fuji II LC and Vitremer) over conventional glass-ionomer materials is the ability to finish the restoration as soon as the light-curing process is complete. However, it has been suggested that early finishing of these materials upsets the water balance, which is critical in a glass-ionomer system (Sidhu et al 1995).

6.4.3.3. Protecting the Set Material

After polymerisation, resin composites are said to be resistant to early contamination by water due to the formation of an organic matrix. They do not require any additional protection (Wilson 1990). This is in contrast with conventional glass-ionomer materials as well as RMGIC’s which can be severely stressed by hydration washout or dehydration shrinkage, so it is recommended that they be protected by a suitable agent (Watson 1990; St Germain & Meiers 1991; Watson & Banerjee 1993). However, it is not clear how susceptible GIC’s (Causton 1981; Earl & Ibbeston 1986) and RMGICs are to hydration or dehydration immediately after light-curing (Sidhu et al 1995), although the application of a surface coating is reported to preserve the water balance in the system (Earl et al 1985; Sidhu et al 1995). This is to ensure protection of the more slowly forming glass ionomer cement matrix (Kanchanavasita et al 1995).
This technique was followed in the present study. In the case of Vitremer the manufacturer’s recommendations were followed and a coating varnish was applied then light-cured. For both Fuji II LC and Dyract AP a thin layer of lightly filled low-viscosity single-component light-cured resin was applied. As has been previously shown (Sec 5.7.1.5 page 201), the measurement effect of the protective layer on the wear behaviour of the three resin-based restorative systems was clinically non-significant.

These protective layers ensure improved physical characteristics (Dickenson & Leinfelder 1993) of the surface of the resin based filling materials, rendering the restoration surface more resistant to occlusal forces once the protective layer was lost. This has been confirmed to some extent with in vivo testing where different surface treatments were applied to protect the occlusal surface of resin-modified glass ionomer cement restorations (Wu & Smales 2001). Although the durability as well as the thickness of these protective layers in vivo has not been confirmed. It appears that the protective layer, however thick or thin, is probably worn away quickly over time. For this reason, unlike other studies (Sachdeo et al 2004), marginal integrity of all restorations was recorded at baseline. Thus, the marginal wear recorded at the first six months (first recall visit) would be a combination of both the wear of the protective layer and the restorative material, which was exposed to wear as the protective layer was lost.
The treatment visit to six months recall is therefore not completely comparable with the six months to one-year interval and so on. However, the objective of this study was to assess the restorative system including the coating recommended by the manufacturers. For amalgam restorations, no protection to the restorations was required (Christensen 2001; Fuks 2002). All the restorative techniques used here were similar to those used in previous clinical trials (Welbury et al 1991; Croll & Helpin 1995; Luo et al 2000; Wucher et al 2002; Hubel & Mejare 2003).
6.5. Survival Analysis

6.5.1. Life Table

The life table method has commonly been used in medical research since the 1970s (Davies 1987). This makes it possible to use all the survival information accumulated up to the closing date of the study, providing a snap-shot view of the survival experience. This method of analysis has been used frequently in longitudinal clinical trials in dentistry (Holland et al 1986; Welbury et al 1991; Roeters et al 1998; Welbury et al 2000; Cehreli & Altay 2000) (Appendix VIII a,b)

In the present study, the survival analysis for replacement need (failure rate) of all 288 restorations after two years using the Log Rank test demonstrated a non-significant difference between all four restorative materials used (combining data from UK and UAE). There was however, a statistically significant difference in survival experience of the restorations with the UK children having a better survival rate experience than the UAE children. All four materials were considered together. In the UK, out of the 157 restorations 105 (66%) were unavailable for re-evaluation at the 5th visit or two year post placement review. In contrast, in the UAE there were a total of 131 restorations, of which 72 (54%) were unavailable for review at two years post placement.

Comparing only the results at 2 years, this leads to a statistically significant difference [P value = 0.039, Chi-Square value = 4.28, Fisher’s Exact Probability test P value = 0.040]. Although two operators placed the restorations, the bulk (n= 251) was undertaken by one operator working under similar clinical conditions. Despite the control of these variables a significant difference remained.
It is difficult to be sure of the reasons for this difference. The following explanations may be given:

- The UK children were from scattered population from north London both within and beyond the M25 ring road
- Attendance to the clinic was by an appointment system and any failures needed to be followed up by telephone calls and/or further appointments
- In the UK, parents/carers had to accompany their children to the dental appointment, which meant taking time off work as well as school. This created considerable amount of difficulty for a number of families
- The UAE children were recruited from a closely related community attending the same school
- UAE children who failed to attend could be called immediately from their classroom, as parents attending the dental appointment with their children was optional.

This improved control over the follow up and review system experience in the UAE is a compelling reason for conducting studies in a primary dental health care unit based within the community. This is of importance for planning future studies.

6.5.2. Cox Survival Analysis

The multilevel Cox proportional hazard analysis was used (Kirkwood & Sterne 2003a) to take into account the effect of clustering [i.e. having multiple restorations per child.] From the results of the analysis, it appears that clustering had a minimal effect. When Cox survival analysis was performed ignoring the clustering effect, it produced virtually identical results to those obtained when clustering was taken into account. It is worthy
of note that the Cox regression analysis does not regard review visits as interval data, as they are in this study, this circumspection was also employed.

This raises a further issue related to the design of clinical trials comparing restorative materials. The split mouth technique is often regarded as the most reliable (Ahovuo-saloranta et al 2004), especially when testing two restorative systems/ or techniques (Welbury et al 2000; Duggal et al 2002; Foley et al 2004) (see Appendix VIIIa). This is despite the differences observed in chewing, which like manual dexterity is usually one-sided. A further problem is the considerable difficulty needed to obtain sufficient numbers of matched or paired cavities. The trials using the split mouth design are usually small (Welbury et al 1991; Welbury et al 2000; Gross et al 2001; Duggal et al 2002) (Appendix VIII b) especially when compared with field trials (Arrow 2000; Brunthaler et al 2003). Given that the effect of clustering is of little or no significance, the use of multiple cavities within a single mouth with several restorative materials offers significant benefits. The main ones are rapid recruitment and the opportunity to compare more than two restorative systems. This, has been one of the major advantages of the present study.

The benefits and disadvantages compared with the split mouth technique will undoubtedly be revealed in further studies. The use of advanced statistical techniques of multilevel analysis may offer an effective solution to any concern related to clustering of the data in dental research (Gilthorpe et al 2000; Gilthorpe et al 2002).

6.5.3. Assessment of Missing Data

In the present study, the failure of restorations was defined as the need to replace the restorations due to loss of anatomical form with crevice formation, fracture of the restoration and/or recurrent caries.
Exfoliated teeth however, were censored (Altman 1991b; Andersson-Wenckert et al 1995; Qvist et al 1997). Some or even most of these would have had satisfactory restorations placed. This decision tended to lower the proportion of successful restorations at each follow-up visit (Hubel & Mejare 2003). This also highlights the unreliability of the life table method when comparing data with a high proportion of cases lost to follow-up (Merrell & Shulman 1954; Cutler & Ederer 1958). This is especially the case in the UK group. It is important to have a longer period of follow-up, in order to obtain a clear picture of the pattern of survival when there is a low incidence of early failure (Davies 1987). This was demonstrated in 1999, where a substantial number of failures beyond two years of observation of Ketac-silver and Vitremer restorations occurred (Espelid et al 1999).

Reviewing the results of this study, it is apparent that more than half of the 30 failures (n=23, 77%) occurred during the 18-24 month interval. This suggests that the possibility of failure may be higher with a longer follow-up period. To investigate this, it would be advantageous to have a long study based on a community clinic attached to a school. Ideally, this type of study should run for sufficient time to answer the questions raised above. This could be 2.5 years, 5 years, or even 10 years. There is no objective evidence as to the optimal length of a clinical trial of restoration durability. Assessing all the studies quoted throughout the thesis, it is probably somewhere between 2 and 7 years. This indicates that case selection and venue may be critical. However, extending the study time is self-limiting; these limitations include:

- Ever increasing dropout rates
- Increased losses due to exfoliation of the primary dentition, which are difficult to interpret
• All of these would require a greater number of participants taking part in the trial.

In the present study, the survival rate of the restorations was 88% after two years. This should be viewed cautiously because of the large number of subjects who failed to attend for the reviews. Although it is not possible to ignore the high dropout rate, it is apparent that this particular finding is consistent with the experience of other investigators (Duggal et al 2004; Eden et al 2004). Furthermore the apparent influence of the high dropout rate was investigated using sensitivity analysis. It is important to note that using the extreme assumptions of ‘all successes’ or ‘all failures,’ for the restorations not reviewed, did not alter the findings of the study. However, even with the benefit of this statistical estimate, it is still desirable to plan future studies in a way that would limit the number of dropouts.

The inherent trap in this approach is to use a (near) captive group of subjects such as dental students (Norman et al 1988; Lundin & Koch 1989; Wilson & Norman 1991). The essential requirement is to produce a study, the results from which can be applied to the general population, the so-called principle of ‘universal applicability.’ As is so often with any research, the limitations are not fully apparent until the work is completed (Eames et al 1974; Krejci et al 1994; Hse & Wei 1997; Sachdeo et al 2004).

6.6. Assessment of Dental Restorations

6.6.1. Direct Clinical Assessment of Dental Restorations

The method for direct clinical observation of restorations used in this study was the subjective, descriptive criteria, defined by the U.S. Public Health Service (Cvar & Ryge 1971; Ryge & Snyder 1973). This rating system is based on an operational approach which has been developed for quality assessment of dental restorations. It is clear and easy to use, as well as having the advantage of universal applicability.
6.6.1.1. Limitations of Direct Clinical Assessment

The use of subjective assessment criteria methods for clinical research has many disadvantages, including the need to train and maintain evaluators at the arbitrary but widely recognised 85% level of agreement. Problems such as this make indices such as those used in this study difficult to compare internationally (Cvar & Ryge 1971). The original criteria were designed for use in the evaluation of large numbers of restorations (above a thousand). Over time, this has been used for smaller studies but with the inherent problem of influencing the outlined findings to a greater degree. Further, because of the small number of categories or ratings used with these subjective, descriptive methods, small differences within or between various materials cannot readily be detected (Merrill et al 1975; Osborne et al 1976). This is important if significant differences between new products or examiners are to be found within a relatively short time-span. Attempts to increase the number of descriptive ratings have resulted in poorer inter-evaluator agreement (Mjor & Haugen 1976).

All clinical assessment methods require the clinician to objectively evaluate her/his own work. This is particularly difficult in the application of clinical criteria since evaluators often apply objective criteria in a subjective manner by taking account of the clinical problems, which they have encountered e.g. patient age and level of cooperation. There are many people walking around with asymptomatic failed restorations, and only rarely does objective assessment alone determine the fate of such restorations. It is common to find that the diagnosis of a failed restoration is usually a dental diagnosis and thus the need for replacement of a restoration is usually dentist driven.
6.6.1.2. Assessment Criteria of Direct Clinical Evaluation

A. Marginal Integrity

The changes in the adaptation of the restoration to the tooth periphery are presumed to start immediately, although they are not discernible until the 12 to 18 month periods of follow-up, when 31% of the restorations moved from code 1 to codes 2 or 3 (Table 8, pages 120-121). Loss of marginal integrity with crevice formation was recorded for all of the four materials at the 24-month follow-up visit.

The margins of some amalgam restorations demonstrated slight ledges or ditches at the amalgam / enamel interface, detectable with a probe. This was not the case for the resin restorations (Dyract AP, Fuji II LC and Vitremer); these did not exhibit ‘ditching’ but developed a slight ‘step’ that could be detected with a probe. Many studies reported the poor retention and insufficient adhesion of the material to tooth surface of Dyract AP restorations (van Dijken 1995; Andersson-Wenckert et al 1997; Mass et al 1999). However, the adaptation of Dyract AP material to cavity walls seemed to improve if placed under pressure (el Kalla & Garcia-Godoy 2000). In this study, pressure application was performed during the packing process of the material using hand instruments (ball burnisher, beaver-tail burnisher).

Both Fuji II LC and Vitremer are said to bond chemically to enamel and dentine without the use of bonding agents. The bond strength of the resin-modified cement to dentine is

1 (Kidd & Joyston-Bechal 1997)
significantly higher than that of conventional glass-ionomer cement and the bond is thought to be stable due in part to the chelation reaction (Walls et al 1988a; Hse et al 1999). It may be due to the slowness of the acid-base reaction in the modified cement that the polyacid is available for a longer period, resulting in the formation of a stronger adhesive bond (Nicholson & Anstice 1994). The polymerisation shrinkage on setting may, however, influence bond durability. It is very important to use a thin coat of low-viscosity intermediate resin enamel bond (adhesive system) to ensure sealing, of the interface between the enamel and dentine.

The excess bonding agent is blown off using 3-1 syringe, then light-cured before the resin material is placed (Mount 1993).

**B. Anatomical Form**

The results clearly show that anatomic form demonstrated changes over the 24-month study period. Time had a significant influence on the restoration discontinuity from the cavity wall from the one-year review visit onwards. The total numbers reported with bulk fracture in this study were small and results showed no statistically significant differences between materials. Amalgam, demonstrated a total of five restorations with bulk fractured by the 24-month review visit. Dyract AP demonstrated bulk fracture in three of its restorations while Fuji II LC and Vitremer had one bulk fractured restoration each. It was previously reported that the second main cause of restoration failure after recurrent caries is bulk fracture (Qvist et al 1990b). Therefore, cavity design incorporating a shallow cavity with a narrow isthmus should be avoided (Lemmens et al 1988; Papagiannoulis et al 1999). Bulk fracture can be caused by the physical, mechanical and chemical properties of the alloy material and low fracture toughness of Dyract AP compomer (Kerby et al 1997). It has been suggested that after the second-year period, compomers behave more like
composites than glass-ionomer cements as their friction resistance to opposing teeth decreases (Meyer et al 1998). Occlusal stresses on resin-modified glass-ionomers may explain the presence of occlusal cracks (Smales & Greke 1990).

C. Marginal Discolouration

Marginal discolouration signifies the degree of staining or mismatch by looking to the enamel surrounding the restoration; a white or brown spot around the restoration should be noted as it could indicate recurrent caries (Kidd & Joyston-Bechal 1997).

Marginal discolouration was evaluated by direct visual inspection and ranked according to severity. The results of the ‘marginal discolouration’ ratings showed large differences in the colour matching ability of the resin-based restorations, especially towards the end of the study period. For amalgam restorations, marginal discolouration of the enamel margin was always compared with the adjacent sound dentition.

The change in marginal discolouration was recorded as early as the first six months (visit 2). By the 24 months review visit (visit 5), 89% of the restorations demonstrated discolouration changes from codes 10 and 11 to codes 12 and 13. (Table 8, pages 120-121).

Vitremer demonstrated the maximum discolouration (22%) when compared with Dyract AP (17%) and Fuji II LC (17%), while amalgam demonstrated the least (6%). Discolouration around restorations with intact margins is very difficult to interpret. With amalgam, a grey or blue discolouration was observed. This appearance may represent residual caries left when the cavity was originally prepared. It may also represent active caries due to a micro-leakage and may indicate demineralised dentine, corrosion products from the amalgam, or may simply be caused by light reflecting from
the amalgam itself through the relatively translucent enamel (Kidd & Joyston-Bechal 1997).

Changes in the colour of polyacid-modified composite resin materials (composers) were explained as translucency changes, where the extent of the acid-base reaction, the water sorption and disruptions of both polymerisation reactions and surface characteristics (scattering of light) would explain colour changes of composers (van Dijken 1996; Demirci & Ucok 2002). Another reason was reported to be the disruption in the polymerisation reaction, a possible influence on the clinical long-term colour stability of composers (Marks et al 1999a). It has been reported that Vitremer has a lower level of conversion than Fuji II LC (Kanchanavasita et al 1998), which potentially will affect the change in colour of the restoration (van Dijken 1996). This is supported by the finding here, where greater discolouration was observed with Vitremer than Fuji II LC. This may be the result of residual amine not being completely used up during polymerisation.
D. Contact Point

The longevity and the clinical performance of proximo-occlusal resin restorations has been a topic of numerous clinical trials. The contact point is usually assessed by passing a piece of un-waxed floss in an occluso-cervical direction then out through the embrasure between teeth contacts. There should be resistance to passage of the floss. In this study, chances for disturbing the approximal contact were minimal as this was carried out after the restorative material has set.

Finding cervical gaps indicates the changes that occur in the restorative material-tooth tissue contact area, which can be attributed to erosion or proximal caries. If the floss is cut or shredded, there is the strong possibility of either a roughened enamel surface which may be starting to cavitate, or cervical overhangs of a restoration, with a potential of plaque build-up and food stagnation.

It is been suggested that the maintenance of a tight and smooth approximal contact is important to prevent food impaction [food packing] (Kidd et al 2003a). In the present study, it was clear that the contact point began to be lost with the first six months. This may be associated with physiological tooth movement, and anatomical shape of the proximal surface of deciduous teeth.

The total number of proximal restorations was 132. During the first six months three Dyract AP and one Fuji II LC restorations showed loss of approximal contact. The rate of deterioration appeared to accelerate in the second six month period when a further 11 restorations showed loss of the approximal contact [four amalgams, two Dyract AP, three Fuji II LC, and 2 Vitremer]. By the end of the 2 year trial period a further six restorations showed loss of the contact point [two Dyract AP, three Fuji II LC, and one Vitremer].
It is difficult to explain this finding. The data for ‘poor contact’ at completion of the restorations was limited by the fact that many children refused to allow the contact area to be tested. Their cooperation, such as it was, had run out. It may be that the poor contacts identified at the first six month review appointment were the result of a poor contact at the time of placement.

This however, cannot be the reason for the additional number of poor contacts observed at one year (visit 3) and two years (visit 5) assessment. Although all resin-based materials were placed in increments, possible reasons for poor contact points can be related to:

- The constant problem in contouring the proximal area when using a resin restorative material, especially when cooperation plays an important role with young child. These materials are difficult to condense against adjacent tooth / matrix band

- Unstable placement of the matrix band at time of placement of restorative material

- Crown morphology of primary molars makes the placement of the matrix band difficult, as they are wider in the mesio-distal dimension (bulbous) compared with their crown height than the permanent molars
E. Recurrent Caries

As mentioned before, recurrent caries describes caries underneath and/or around the margin of a restoration, also known as secondary caries (Kidd et al 1992; Kidd 2001). Cross-sectional studies have established that recurrent (secondary) caries is the main reason for failure of amalgam and resin composite restorations in permanent teeth including class II restorations (Qvist et al 1990b). Recurrent (secondary) caries is less likely to be the main reason for failure of glass-ionomer restorations (Wilson & McLean 1988a; Forsten & Karjalainen 1990; Mjor & Jokstad 1993).

In this study, the presence of recurrent caries was recorded primarily by visual examination, combined with probing for roughness and softening of decalcification after cleaning and drying the examined tooth (Jackson 1950; Konig 1966; Hennon et al 1969). An explorer was used to remove any plaque from the fissures to allow meticulous visual examination as well as air-drying and cleaning of the restoration. The examination identified any discolouration, cavitations, and grey appearances of enamel undermined by caries (Downer & O'Mullane 1975). Rigorous probing was avoided to prevent the creation of traumatic defects of the enamel surface (Bergman & Linden 1969, Ekstrand et al 1987).

The diagnosis for the purposes of the study was based solely on visual and tactile criteria. However, in the UK children only, bitewing radiographs were available to help with the initial diagnosis for clinical care. In a review paper, it was reported that bitewing radiographs improve the diagnosis of caries detection by up to 50% of caries lesions (Kidd & Pitts 1990). However, in an earlier study (Sognnaes 1940) when caries examination included cleaning as well as drying of the teeth examined, which was adopted in this study, bitewing radiographs discloses only an additional 5% of lesions.
The data for comparison of the UK and UAE children was based on the visual diagnosis and therefore the results of the two groups were comparable. The possibility of missing recurrent proximal caries and/or new lesions was minimised as the clinical examination included cleaning and drying of the teeth (Boomer 1939; Sognnaes 1940; Kidd et al 1993). It is worth noting that with respect to amalgam restorations over the 2-year trial period, recurrent caries could not be detected.

This is in agreement with previous reports (Letzel et al 1989). Ditching observed around an amalgam restoration usually occurs on the occlusal surface of an amalgam filling and both laboratory and clinical studies have shown that it is not indicative of recurrent caries (Kidd & Pitts 1990; Kidd et al 1995). Discolouration around an amalgam restoration with clinically intact margins is a poor predictor of infected dentine beneath the restoration (Kidd et al 1995). An obvious cavitation or a defect between the filling (for both amalgam and tooth-coloured materials) and the tooth which is wide enough to admit the tip of a periodontal probe have been associated with infected dentine beneath and indicates the need for replacement (Kidd 1984; Kidd 1998).

As previously reported, the progression of residual caries may be delayed by a proper seal of the restorative material (Mertz-Fairhurst et al 1986).

Previous work reported a dmft of 8.4 in the City of Abu Dhabi (Al Hosani & Rugg-Gunn 1998), which is much higher than the 1.8 dmft reported in the UK survey (O'Brien 1994). This raises a potentially serious problem, as children with a higher dmft (UAE) are believed to have a higher rate of recurrent caries than children with a low dmft (UK). This might result in a higher failure rate of restorations in the UAE children. In this study this appeared to be the case with six (4%) of the restorations diagnosed as needing replacement in the UK group, compared with a total of 24 (18%) UAE
restorations needed replacement. It was not possible to identify the exact reason for this
difference, since the inclusion criteria were identical for both groups.

F. Materials Replacement Need Over Time

There was no significant difference between the four restorative materials in survival
rate over the 24 month study period

(1) Amalgam

Amalgam restorations demonstrated a total of 10 (14.2%) failed proximo-occlusal
restorations [all were in primary molars] due to bulk fracture. This is in agreement with
previous studies (Letzel & Vrijhoef 1984; Holland et al 1986; Osborne & Friedman
1986). Failure of amalgam restorations due to bulk fracture is attributed to:

- Faulty cavity preparation (Robinson 1985; Osborne & Gale 1990)
- Insufficient bulk of amalgam (Richardson & Boyd 1973)
- Improper manipulation of the amalgam (Elderton 1976b; Barnes et al 1991)
- Presence of occlusal trauma (Mjor & Haugen 1976; Lavelle 1976)
- Presence of corrosion products (Mjor & Haugen 1976; Lavelle 1976)
- Limitations in amalgam strength (Rupp 1987).

This suggests that amalgam, being brittle, needs to be placed in bulk, as it is prone to
fracture in thin sections (Kilpatrick 1993b). Alternative explanations for poor durability
of dental amalgam in primary teeth include differences in crown morphology, cavities
too small to condense amalgam properly, and poor access to the oral cavity during the
operative procedure (Holland et al 1986; Levering & Messer 1988). Furthermore, dental
amalgam requires mechanical retention features placed in the cavity design (Kilpatrick
1993b). This means that both caries and sound tooth material are removed to
accommodate the restorative materials (Roeters et al 1998).
In a study on high-copper amalgams, it was indicated that the influence of the alloy compositions increases in importance with time, suggesting that the older the restoration, the more important the influence of the alloy on the marginal fracture. (Letzel & Vrijhoef 1984). In this study a high-copper amalgam was used.

The two-year clinical performance of amalgam resulted in a survival rate of 69% for primary molars [both occlusal and approximal restorations], and 93% for permanent first molar [occlusal] restorations. This is in agreement with previous studies (Walls et al 1985; Roberts & Sherriff 1990; Bjertness & Sonju 1990; Welbury et al 1991). None of the first permanent molars restored required replacement over the two-year trial period. This is in accord with previous studies (Lavelle 1976; Walls et al 1985; Qvist et al 1986a).

(ii) **Dyract AP**

Dyract AP restorations demonstrated failure in a total of nine (12%) restorations of which seven were placed in primary molars while the remaining two were placed in the first permanent molar. Three restorations failed primarily due to bulk fracture at the isthmus. It has been shown that it is desirable to avoid narrow isthmuses when restoring primary molars (Hse & Wei 1997).

The remaining six restorations failed due to recurrent caries. This is in contrast to a study carried out in the North of England where there was very little recurrent caries when Dyract AP was used (Welbury et al 2000).

A possible reason may relate to the fluoride leaching effect of Dyract AP, thought to be useful in preventing secondary caries (Marks et al 1999b). It has been reported previously that the cumulative amount of fluoride released from compomer materials is low when compared with conventional glass-ionomers (Wilson & McLean 1988a;
Forsten & Karjalainen 1990; Forsten 1991) and resin-modified glass-ionomers (RMGICs) (Marks et al 1999a). This may be attributed to the fact that an initial high fluoride release is not present in the compomer (Friedl et al 1997; Bala et al 1997; Forsten 1998; Shaw et al 1998; Verbeeck et al 1998), although contradictory results were reported by de Araujo (de Araujo et al 1996), where the amount of fluoride release at days one and two by Dyract AP was high and similar to that of Fuji II LC. However, they were alone in reporting this effect. It was reported that long-term release of fluoride by compomers and resin-modified glass-ionomers is sustained (Forsten 1998; Verbeeck et al 1998). Although, the exact amount of fluoride necessary to prevent recurrent caries is still unknown (Forsten 1990; van Dijken et al 1997; Forsten 1998; Shaw et al 1998; Marks et al 1999b).

Other explanations for the detection of recurrent caries in Dyract AP can be attributed to faulty placement (Luo et al 2002) and marginal seal breakdown of the restoration-tooth interface caused by polymerisation shrinkage during the setting process (Toledano et al 1999; Mjor & Toffenetti 2000) leading to gap formation and microleakage (Forsten et al 1982; Peters et al 1996; Demirci & Ucok 2002; Chen et al 2003). Chemical and physical properties of Dyract AP have been reported similar to those of resin composites (Meyer et al 1998). The shrinkage of the compomer material occurs mostly during and shortly after light polymerisation and before water ingress (el Kalla & Garcia-Godoy 1999), leading to initial gap formation and possibly recurrent caries (Dauvillier et al 2000).

The two-year clinical performance of Dyract AP in both primary and first permanent molars resulted in a survival rates of 69% and 93% respectively, which is in agreement with previous studies (Peters et al 1996; Roeters et al 1998; Luo et al 2002).
(III) FUJI II LC

A total of seven (10%) Fuji II LC restorations failed during this study, of which six were due to recurrent caries. Although resin-modified glass-ionomers leach fluoride, whether sufficient fluoride is released to prevent recurrent caries is still unknown (Mjor 1996; Wilson et al 1997; van Dijken et al 1997). The remaining Fuji II LC restorations failed due to fracture and loss of marginal integrity.

According to previous reports, it is essential to provide bulk of material and avoid shallow keyways and narrow isthmuses when restoring primary molars (McLean & Wilson 1977). The two-year clinical performance of Fuji II LC in both primary and first permanent molars resulted in a survival rates of 75% and 96% respectively.

(iv) VITREMER

In agreement with previous studies (Croll 1992; Croll & Killian 1993a; Croll & Killian 1993b; Croll & Helpin 1995; Donly et al 1999) Vitremer appeared to be an effective restorative material in the primary dentition over the two year period of the study.

However, the failure rate was not statistically significantly different from that of Fuji II LC, Dyract AP and amalgam. A total of four Vitremer (5%) restorations failed. Three failed due to recurrent caries and one due to loss of contact point and loss of marginal integrity. The nature of the failure due to material loss may be related to the chemical composition of Vitremer, where lower conversion on setting has been observed (Kanchanavasita et al 1998). This leads to higher water uptake and loss of residual monomer. These in time will lead to degradation of the material rather than fracture. The two-year clinical performance of Vitremer (in both primary and first permanent molars) resulted in an 85.2% and 99.5% survival rates respectively.
6.6.2.2. Indirect Assessment of Dental Restorations

6.6.2.1. Rank Ordering System

The evaluation of wear was improved by the use of pre-calibrated standard casts as an aid to generating semi-quantitative estimates from an ordinal scale for marginal wear. It makes it then possible to project the long-term performance of posterior restorations at an earlier date than can be achieved by other methods (Leinfelder et al 1986b).

The rank ordering method of evaluation of clinical restorations was by direct comparison of the cast replicas of the clinical restorations with the standard casts of the Vivadent model. The casts (Sec.4.8.3.1 and Figs 3 & 4) resemble the entire occlusal surface exhibiting differing and known levels of material loss at the cavo-surface margin (Leinfelder et al 1986b). The casts represent marginal wear or material loss in increments of 25μm up to 200μm then increases by 50μm up to 400, and every 100μm thereafter until 1000μm. Since the increments between the replicas are not always equal, the scale is a relative measure rather than one that provides real numerical measurements. This causes confusion when attempting to quantify and/or measure the amount of substance loss using an ordinal scale in a nominal manner. In the present work it has been made clear that the data is not truly quantitative by using the Friedman test, Wilcoxon Sign Rank test and the Kruskal-Wallis one-way analysis of variance for statistical analyses. All assessments were by ranks (categorical), rather than absolute (ordinal) values.
A. Reproducibility of Rank Ordering System

It was important to ensure that individual evaluators obtained similar results on repeated evaluations of the same casts; consequently the degree of agreement attainable between separate evaluators was measured. Three evaluators rank ordered a series of models independently; two evaluators ranked double blind whilst the third evaluator (the primary operator) was aware of the materials used. It appeared that two of the evaluators had better intra-evaluator agreement (Kappa values) than the third evaluator. Both evaluators ‘2 and 3’ had Kappa values ≤ 0.8 suggesting very good agreement, while evaluator ‘1’ (Kappa value ≤ 0.6) demonstrated only moderate agreement.

The inter-evaluator agreement was fair among all three evaluators according to Landis and Koch (Landis & Koch 1977). With time the evaluators became more familiar with the rank ordering method used in the evaluation and this improved their inter-evaluator agreement from their initial Kappa values (Sec.5.7.1.1 and Fig 24). To overcome the inter-evaluator variations, it would have been desirable to have a longer training (calibration) period. The evaluators thus needed to rank order more cast replicas over a longer period of time. Since this option was not available due to time constraints the evaluators were asked to rank order replicas previously ranked. This was carried out without their knowledge of earlier assessment. The ranks on repeated occasions were compared and demonstrated very good repeatability (Table 28, Page 189). This gave considerable robustness to the data derived using this method.

Each cast was evaluated separately three times by each of the three evaluators, and then the final agreed score was used. As in previous studies (Peters et al 1996; Peters et al 1999), when the evaluators’ ranks did not agree, this was discussed by all three evaluators until consensus among the three was achieved. A potential problem
encountered during rank ordering of the cast replicas was defining the area to be examined. The primary operator used a periodontal probe to outline the margins of the original cavity on the cast replica, identifying any defects and/or air bubbles that were possibly incorporated during impression taking. The area of interest was then closely scrutinised by all three evaluators. Again, this gives considerable robustness to the findings.

It is important while using the indirect method to identify the *marginal* wear rather than the *bulk* wear of the material. Failure to do this resulted in some variations in the ranks, as one of the evaluators occasionally gave higher ranks by looking at the site where he consider maximum wear occurred over the whole occlusal surface, ignoring the restoration-tooth margin that was evaluated using this method.

It is worth indicating that the relatively thin enamel of deciduous teeth tends to wear over time, prior to their natural exfoliation (McDonald & Avery 1983). This may explain the decrease in the total amount of occlusal-marginal wear after 18 months by 25μm to 50μm in some cases (Tables 31, 32, pages 198, 199), as the occlusal surface tended to be flatter and smoother. This highlights the importance of identifying the true restoration margin on the cast replica.

It is notable that having two different populations participating in the trial could result in different wear patterns, since the level of occlusal wear can be affected by the abrasive nature of diet and food shedding pathways (Mair 1995). Although this was a potential problem, from the results obtained, this effect could not be detected.
B. Wear Intervals and Replacement Need of Restorations

Sixteen staff members of the Department of Paediatric Dentistry at the Eastman Dental Institute, were asked for their judgment, as to what level of occlusal wear is indicative for replacement of a restoration, by answering a short questionnaire. This helped in the development of codes and wear criteria (Table 17, page 148). However, most of the participants highlighted the problem that important characteristics of dental restorations such as colour matching, secondary caries, and post-operative sensitivity cannot be measured effectively unless direct clinical evaluation is available. Other characteristics such as levels of occlusal wear, anatomical form, and marginal integrity in particular, would benefit more from the use of indirect techniques.

It is worth mentioning that the direct clinical evaluations based upon the USPHS method uses standard criteria for the classification of the degree of wear, but they are conceptual rather than physical and are designed more for the determination of appropriate clinical action than for the measurement of quantitative changes. The indirect method is capable of determining the rate of change from one category to another. However, it cannot quantify actual loss of material from the occlusal surface.
C. Materials’ Marginal Wear Behaviour Over Time

It was reported that the rank ordering methods for indirect evaluation can demonstrate greater sensitivity than direct clinical evaluation (Leinfelder et al 1986a; Leinfelder et al 1986b) and may be capable of making consistent discrimination within groups, which would receive ranks using the USPHS methods. The rank ordering method offers relative wear measures, rather than quantitative results on a linear scale. For this reason the median value was used to represent the relative amount of wear in this study.

From the results, the median loss of the four restorative materials at six months was 125μm - 150μm. By 12 months, 70% of the restorations demonstrated a median wear of 175. At the end of 24 months, the amount of wear increased by a further 100μm. The maximum median wear was primarily identified during the interval between the 4th and 5th visits (18 - 23.9 months) for all four restorative materials. There was a significant difference between amounts of wear for each of the restorative materials at each of the five visits (Tables 32, page 19).

There were occasions where total loss of the material was identified, in both amalgam and Dyract AP materials. These occasions indicated bulk fracture identified clinically, and were not considered as material wear.

The maximum material loss for amalgam was between 600μm to 700μm, Dyract AP was between 700μm and 800μm, Fuji II LC was about 350μm, and for Vitremer the maximum loss of material was 500μm. Whether the wear rate will continue to decrease cannot be predicted and should be subjected to further investigation as suggested by Peters et al in 1996.
When evaluating each material for marginal wear behaviour over time, in this section amalgam is looked at separately to the resin-based materials:

(i) **Amalgam**

Clinically an amalgam restoration had to be carved to match the opposing occlusal surfaces, as primary molars usually possess well-defined and relatively sharp cusp anatomy (McDonald & Avery 1983).

This sometimes appeared to resemble a degree of wear leading to potential high rank order initially [for the ‘blind’ evaluators] yielding a base line median wear values of 100µm. By six months, an increase of 50µm was noted. During the period between 12 and 18 months, the median wear demonstrated a further increase of 25µm, and by 24 months, the median wear of amalgam restorations reached 200µm. In two cases, a total loss of the material was noted, and were excluded from the wear study.

(ii) **Resin-Based Restorative Materials**

It was reported that protecting the occlusal surfaces of resin based restorative material using lightly filled or unfilled resin-based materials, may help reduce the amount of material wear (Croll 1992; Dickenson & Leinfelder 1993; Croll & Cavanaugh 1997). This method was adopted in the present study.

**Dyract AP**

The wear behaviour of Dyract AP using the cast replicas for evaluation revealed a median loss of material of about 125µm at the first six-month follow-up, and by the end of the first 12 months it was 175µm.
This appears to be in agreement with previous work (Peters et al 1996; Hse & Wei 1997) that interpreted the ADA specifications, and supported the suggestion that Dyract AP 'new generation compomer material' (Luo et al 2000) can be an adequate restorative material for primary teeth (Croll & Helpin 1995; Peters et al 1996; Roeters et al 1998; Marks et al 1999b; Luo et al 2000). From the results, Dyract AP (a compomer material), demonstrates a different wear behaviour than composites, as composite resin wear rates are higher during the first six months but decrease over time (Sturdevant et al 1988; Barnes et al 1991). During the first 12 months, the amount of occlusal wear of Dyract AP could not be detected clinically, which is in agreement with previous results (Hse & Wei 1997; Roeters et al 1998; Mass et al 1999). However, it has been reported that Dyract AP exhibits a total marginal wear rate about three times that of a resin composite over one year (Hse & Wei 1997; Luo et al 2002). It is important to remember that marginal gaps were consistently reported (Roeters et al 1998; Papagiannoulis et al 1999), thus, keeping marginal integrity at the cervical margin is a challenging issue when placing Dyract AP (compomer) restorations.

Wear levels during the period of 18 - 24 months demonstrated two cases of complete loss of the restoration and was a clear clinical indication for replacement. This indicates the need for more extensive follow-ups to assess long-term performance (Mass et al 1999; Papagiannoulis et al 1999).

(III) RESIN-MODIFIED GLASS-IONOMER(S) (RMGICS)

In the literature (Smales & Koutsikas 1995; Koutsikas et al 1996), resin-modified glass-ionomer materials were shown to exhibit unacceptably high wear rates when used as occlusal restorations in permanent teeth. However, the use of a thin, low viscosity unfilled resin coating may exhibit some protection to the occlusal surface of the
restoration (Dickenson & Leinfelder 1993; Croll & Cavanaugh 1997) and help extend its range of clinical application.

**FUJI II LC**

The median baseline ‘marginal wear’ values were 75µm, and an additional 75µm marginal wear was noted after the first six months. With Fuji II LC, an additional 75µm was noted at each review visit, reaching a maximum of 350µm by the end of 24 months (noted in eight cases n = 18 at visit 5).

**VITREMER**

Initially Vitremer demonstrated lower wear median values than those of Fuji II LC. It then demonstrated greater median wear at 24 months, the maximum wear values reaching up to 500µm (150µm more than Fuji II LC). Although both materials were protected by the use of a thin coating layer of lightly filled resin, the effect appeared to be minimal (Kilpatrick 1996; Gray 1999). It would be appropriate to consider co-curing of the RMGIC and resin composite (Knight 1994), as it has been reported in previous studies that this markedly reduces the occlusal wear of the RMGICs (Wu & Smales 2001). The differences in wear values between Fuji II LC and Vitremer can be attributed to the unconverted monomer within Vitremer after polymerisation, which may lead to greater substance loss when compared with Fuji II LC.

The indirect rank ordering method of cast replicas for material assessment offers relative measures only, and does not lead to quantitative results as suggested by Leinfelder in 1986. However, in spite of these limitations, these ranking procedures will often lead to earlier discrimination between the wear of restorative materials than the USPHS method (Leinfelder et al 1986a; Leinfelder et al 1986b).
6.6.2.2. Quantitative Measure of Wear

One of the main shortcomings of any dental restoration especially in the posterior region, is substance loss. This is the total loss of material due to both marginal and occlusal surface (bulk) wear over the main body of the restoration, leading to an unfavourable influence on the durability of the restoration. Bulk loss of dental restorations has been investigated extensively under laboratory conditions. However, *in vitro* wear resistance does not correlate, or correlates only weakly, with the wear resistance *in vivo*. In order to try and calculate volumetric loss and measure depth of wear, a pilot study was conducted to evaluate some of the methods reported in the literature (Vrijhoef et al 1985a), where the thickness of the impression material corresponds to material wear (Vrijhoef et al 1985b). Results of the data analysis (Tables 21, 22 and 23, Pages 153, 162, 166) demonstrated that it was not possible to obtain a single reproducible measure corresponding to material loss, and this method proved to be unsatisfactory, in contrast to the results reported from the Netherlands (Vrijhoef et al 1985a; Vrijhoef et al 1985b).
Chapter Seven.

Summary and Conclusions
7.1. Summary and Conclusions

The following are the main conclusions of the clinical investigation into the survival of resin-based restorative materials compared with the universal standard of a high-copper, silver mercury alloy 'Dispersalloy', in the teeth of young children and adolescents.

7.2 Assessment of Restorations

The reliable assessment of 'marginal wear' of the material is important as in all clinical studies of this nature; wear is closely related to the perceived need for restoration replacement. In practical terms, it was necessary to carry out such assessment using Direct Clinical Assessment (in vivo) and Indirect Assessment (in vitro).

7.2.1. Direct Clinical Assessment of the Restorations (in vivo)

The method used was the USPHS methodology which uses descriptive clinical criteria that have output in the form of a rank ordering system. In the present study, this was found to be highly reproducible (Fig 24, page 190). This is important for such studies and hence the reproducibility was assessed at regular intervals before, during, and after the study. This clearly demonstrated that clinical acuity of the assessors was consistent. The next feature of the Direct Clinical Assessment was its ability to discriminate sufficiently between different levels of clinical wear over the time period of the study. This discriminatory ability was clearly apparent for all the different aspects of clinical wear studies, viz. Marginal Integrity, Anatomical Form, Contact Point, and Need for Replacement. Each of the elements of wear are as important as one another, alone or in combination and may lead to restoration failure. It was clear from the results of this study that the Direct Clinical Assessment is an effective way of assessing restorations as
they deteriorate. In addition, the statistically and clinically significant differences at each review visit interval of the materials were time related.

7.2.2. Indirect Assessment of the Restorations (in vitro)

This was used to overcome the logistic difficulties of semi-quantitative assessment made in vivo including: poor cooperation, limited angle of viewing, and the inability to involve further evaluators for more than a very small number of cases. A further major advantage of the indirect method is the fact that accurate casts are made of the individual restoration at each review visit. This provided the opportunity for evaluators to re-examine the casts during the study with the accessibility to ‘look again’ when deemed appropriate. Further, the indirect method has enabled evaluators to discriminate between levels of marginal wear as little as 25μm (Leinfelder & Vann, Jr. 1982). This was also found in this study, the levels of wear over each six month period were as little as 25μm ranging up to 800μm. Only by Indirect Assessment was it possible to rank order marginal wear of the material. This has a direct correlation to the clinical performance of the material and, most importantly, the need for replacement of the restoration.

7.2.3. Quantitative Measure of Wear

Despite the encouraging results of the indirect method of assessing marginal wear, there remains the need to develop an accurate technique to measure the depth of wear both at the margins of the restorations and over the remainder of the occlusal surface. This was attempted using polyvinyl stents. The results were disappointing and cannot be recommended. Some thought was given to the principles of this technique which are, in essence, sound. The technique could be developed using cast metal stents. However, the enormous technical work load necessary to use this technique in more than a limited
number of teeth is its major limitation (Vrijhoef et al 1985a). Possibly, the most accurate (and expensive) way forward would be the use of a high technology three dimensional laser scanner coupled to appropriate computer software, which will calculate the amount of wear highly accurately. Even this methodology has its limitations in that it is difficult to identify and superimpose sequential images accurately. At present this method is too expensive, time consuming, and unwieldy for use in field trials such as that described in this thesis.

7.3. Assessment of Missing Data

All clinical studies result in varying numbers or proportions of missing subjects. This has varied from the almost unbelievable ‘no subjects missing’ 0% (Lumley & Fisher 1994), to 85% subjects missing (Wood et al 1993). These enormous variations occur in the area of clinical research such as prosthetic hip and knee replacements (Bhatia & Obadare 2003), and prospective dietary habits and dental health for early childhood caries (Habibian et al 2001). Studies carried out on appropriately representative members of the population at large are particularly prone to high losses. However, the general applicability of such studies, compared with ‘captive’ groups such as dental students shows that the limitations of subject loss have to be accepted. The problems created by this uncontrolled loss are mitigated by statistical techniques, particularly sensitivity analysis. In the present study, the sensitivity analysis gave very similar results for ‘all missing data as success’ where restorations did not need replacement, and ‘all missing data as failures’ where restorations had to be replaced. The unambiguous outcome was that the results presented on the teeth followed for two years indicates the reliability of the findings presented here.
7.3. Overall Conclusion

The results of this extensive study for amalgam are in agreement with similar clinical studies on the longevity of dental restorations placed in children. It is reasonable to assume that the assessment criteria used are robust enough to provide reliable data on the three resin-based materials evaluated. However, with the limitation of a 2 year trial period, this was not long enough to clearly demonstrate any differences in material performance. This raises the question of what is the ideal length of such studies.

7.3. Future Research

As with many clinical research projects, on completion of this study one is left with the feeling of being in a strong position to design the ideal study, bearing in mind the difficulties encountered.

WHERE

Probably the most important consideration is the location where the study is conducted. Coupled with this would be stability of the population and stability of the operators placing and assessing the restorations. Appropriate sites would be in a group of schools within the community dental service where the dental facilities are close to the schools. This makes it easier for the children to participate and attend follow-up visits. These two considerations will minimise the loss of subjects to follow-up and provide a suitably large sample size for rigorous testing of several restorative systems simultaneously.
HOW

Statistical considerations as with all studies are important in order to avoid bias by selecting the material for use in each subject randomly. However, this may lead to imbalance in the numbers of subjects with for example RMGIC’s and amalgam. To overcome this, the method of restricted randomisation should be used.

A single restoration per child if used, would make the assessment of restorations both clinically and statistically easy, as well as limiting the problem of losses to follow-up. However, the problem of recruiting the desired sample size would require a longer study period and comparative studies would not be possible.

The technique of the ‘split mouth design’ whilst subscribing to rigorous statistical techniques, limits each subject to only two materials. This results in a high number of subjects to be screened at the recruitment stage, and a less rigorous recruitment is likely to provide the sufficient numbers for study in a shorter time. It is clear that considerably more information is available when two methods are combined [Direct and Indirect Assessments]. The simplicity of the methods described in this thesis are of particular relevance as a cost-effective method for overall assessment of restorations in teeth with a lifespan of up to eight years. For the permanent teeth, it would be appropriate to consider a more sophisticated methods such as three dimensional laser scanners.

WHO

To ensure long term consistency and overall direction of the research, it would be important to have one highly trained lead clinician supported by two or three dental surgeons or dental therapists, trained in assessment methods.
WHAT

The methodology used in this study could be applied to test other restorative systems. These could be developments of existing or completely new restorative materials.

FUNDING

Independence from vested interests is crucial to the academic acceptability of clinical research. It is necessary for the funding body to be unrelated in any way to the products retailers of the restorative systems. The most appropriate body for this is a suitably constituted government supported research body; for example the Medical Research Council in the UK or the Ministry of Higher Education in the UAE. Only in this way can the dental profession provide patients with the best possible preventive dental care. Educating patients in the correct methods of home care and regular dental visits will optimise the restorative care provided. Dental practitioners look forward to the day of the single ‘for life’ restoration.
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References


300


Appendices
Appendix I a

ETHICAL APPROVAL FROM THE EASTMAN DENTAL INSTITUTE IN THE UK
28th March 1998

Professor G Roberts
Department of Paediatric Dentistry

Dear Professor Roberts

RE: JREC APPLICATION
DURABILITY OF DENTAL RESTORATIONS IN CHILDREN

Your above referenced application has been considered by members of the Eastman's Joint Research and Ethics Committee and senior staff of UCLH Trust and it was discussed at the Committee's meeting on 24th March 1998, which you attended. As a result of those discussions the Committee were satisfied and agreed that approval should be given for the project to go ahead.

May I take this opportunity of wishing you every success with your project and I look forward to receiving a progress report from you in due course.

Yours sincerely

PROFESSOR CRISPIAN SCULLY
Chairman, Eastman JREC
Appendix I a

RESEARCH PROTOCOL OF THE EASTMAN DENTAL INSTITUTE IN THE UK
RESEARCH PROTOCOL

RANDOMISED CLINICAL TRIAL OF FOUR DENTAL RESTORATIVE MATERIALS (Silver Amalgam [Dispersalloy], Compomer [Dyract AP], Glass Ionomer [Fuji II LC], Resin Modified Glass Ionomer [Vitremer]) A STUDY OF TOOTH-COLOURED RESTORATIVE MATERIALS PLACED IN CHILDREN

Graham J Roberts  Professor of Paediatric Dentistry
Jonathan Knowles  Doctor of Dental Materials Science
Gavin Pearson  Professor of Dental Materials Science
Duaa E Mustafa  PhD student
Doreen Mathews  Dental Therapist

Summary
Even in the best hands the failure rate of dental restorations in children is between 5 and 20% at 1 year and between 10 and 50% at 2 years. Although silver mercury amalgam outlasts other restorative materials it is unsatisfactory cosmetically and there is increasing concern about the mercury content, especially when used in children. A number of new, tooth-coloured, restorative materials have become available in recent years but limited information is available concerning the survival of such restorations in clinical use. Three materials, a compomer ‘Dyract AP’ a glass ionomer cement ‘Fuji II LC’, and a resin bonded Glass Ionomer Cement ‘Vitremer’ appear to be suitable alternatives to amalgam. All leach fluoride into the enamel wall of a restored cavity and the saliva bathing the tooth surfaces although to varying degrees. The durability of these new materials for children’s dentistry needs to be examined following placement under standard operating conditions (placement under local anaesthesia). It is proposed to conduct a randomised trial of these materials using the two year survival of the restorations as the main outcome measure.

Purpose of the Project
The aim is to:
1. Compare the survival of restorations placed under ‘ideal’ operating conditions in Class I and Class II cavities in primary teeth and Class I cavities in permanent teeth using modern restorative materials and using silver amalgam as the standard for comparison.

Background
The treatment approach to caries has changed in the last decade. Preventive measures have gained a more pronounced place since they are expected to slow down or even arrest the progress of carious lesions, thus avoiding the invasive replacement of carious tissue (Mount 1991). If prevention fails, however, restorative treatment may be necessary to eliminate the caries process. Historically, the use of amalgam was the standard filling material in primary molars, of which satisfactory long-term evaluation results were reported (Welbury et al. 1991, Kilpatrick et al. 1993). Amalgam is still regarded as the common restorative material for posterior teeth. No other restorative material gained such an established position, based on laboratory studies and long-term clinical observation (Mass et al 1999). Poor aesthetic appearance and the rising awareness of the public to possible health hazards encouraged
health authorities and professionals to look for ‘clinically appropriate alternative materials’ to amalgam. The most important examples of those materials are the adhesive materials (Marks et al. 1999).

The advantage of using adhesive materials compared with amalgam are preservation of sound tooth tissue and avoidance of the isthmus, the well known Achilles heel (Forsten and Karjalainen 1990, Mount, 1998). The main reasons of restoration failure in the primary dentition are isthmus fractures, marginal failure and occurrence of recurrent caries (Welbury et al 1991, Ostlund et al 1992, Arends and Dijckman 1995, van Dijken 1996, Mjor 1997, Marks et al. 1999). The advantage of a tooth-coloured material can be seen as an advantage benefit for the patient’s motivation compared with amalgam (Marks et al. 1999).

Composites have proved strong but have the disadvantage of shrinkage from the cavity wall during polymerisation and the lack of fluoride leach. Glass ionomer cements such as ‘Fuji II LC’ adhere to mineralised tissue and release fluoride into the enamel and saliva surrounding the cavity with the potential for profound cariostasis. However, compared with amalgam this material is brittle, causing relatively early marginal breakdown, poor resistance to abrasion and discernible wear in a relatively short period of time. Attempts to overcome the shortcomings of these two materials has led to the development of a restorative material which combines the physical properties of composite with the fluoride leaching properties of glass ionomer cements. This is the so called ‘resin modified glass ionomer’ marketed as ‘Dyract AP’. Clinical experience with “Fuji II LC,” “Dyract AP” , and “Vitremer” suggest that these are generally suitable for restoration of Class I, Class II, Class III and V cavities in deciduous teeth and Class I, III, and V cavities in permanent teeth. However, there is little factual information on the comparative survival of restorations using these materials in either adults or children.

A large part of the work of our specialist department of Paediatric Dentistry is restoration of carious cavities in children who have serious medical problems (for example, patients with congenital heart disease). The health of the teeth and mouth play an important part in sustaining their well-being. Restorations should ideally last for the life of deciduous teeth and for at least ten years in permanent teeth but even in the best hands, the failure rate of dental restorations in children is between 5 and 20% at one year and between 10 and 50% at two years.

As dental surgeons working with children are well aware, the survival of restorations is substantially influenced by the operating conditions. Restorative treatment is difficult to execute in anxious and uncooperative children because of their unpredictable movements. A large proportion of the restorative work is carried out by a Dental Therapist who works under the clinical supervision of a registered dental practitioner. The advantage of this is that a therapist is working on a discrete group of children who benefit enormously from the behaviour management strategies of the therapist who has acquired considerable skill in delivering high quality dental care to young children.
Appendix I a (Cont)

Plan of Investigation:

Specific Objectives

The aim of the study is to measure the one and two year survival of restorations placed using local anaesthesia in Class I and Class II cavities in primary and Class I cavities in permanent teeth in children using either 'Dyract AP', ‘Fuji II LC', 'Vitremer' with Dispersalloy as the standard for comparison.

Hypotheses and Sample Size

The study will test several separate hypotheses. There is no significant difference between ‘Dyract AP' and 'Fuji II LC', 'Vitremer' and 'Dispersalloy' when used to restore:

1) Class I cavities in deciduous molars
2) Class II cavities in deciduous molars
3) Class I cavities in first permanent molars and premolars

Sample Size: The central question is the difference in the survival of restorations using the different materials. It is estimated that the proportion of filling materials surviving two years in each group will be the order of 90% 'Dispersalloy and 70% 'Dyract AP' (similarly for Fuji II LC and Virtomer) (El-Mowafy et al. 1994, Fuks et al. 1984) A difference between groups of more than 20% would be of sufficient clinical importance to substantially influence the choice of material.

[Statistical advice by Dr Aviva Petrie, Department of Trancultural Oral Health, Eastman Dental Institute]

Methods

Patients: Children and adolescents attending the Department Paediatric Dentistry at the Eastman Dental Hospital (Caries Clinic, Referred patients) and judged to require restorations under local anaesthesia for Class I and Class II cavities will form the population from which trial subjects will be drawn. A written explanation will be given to the parents and children. Informed consent will be obtained from parents (and child where appropriate) for entry into the trial. Criteria for inclusion in the study will be the ability to co-operate for treatment under local anaesthesia and their willingness to attend for review at six monthly intervals. The principle outcome measure will be failure of the restoration/restorative material indicated by codes 3, 4, 7, 8, and 15, or 19.

Restorative Procedures: These will be standard procedures and will follow the manufacturer's instructions. The tooth-coloured materials (Dyract AP, Fuji II LC & Vitremer) will be used with minimal destruction techniques (Garcia-Godoy 1988). To take full advantage of the adhesive qualities of the material which enables the cavity size to be kept as small as possible, conventional mechanical retention will be incorporated into the cavity design of both materials to eliminate the risk of loss of restoration from adhesion failure.

Once the cavity preparation is done an intra-oral photograph will be taken with a standard magnification as a base line record of cavity design. The cavity design will depend on the extent of caries and the type of filling material that is going to be used. Rubber dam isolation will used whenever possible.
Appendices

Appendix I a (Cont)

When the restoration has been placed, a replica of it will be made using rubber base impression material to enable a baseline for marginal wear and to aid in the indirect clinical examination criteria. An assessment of the overall status of the teeth and mouth will be scored using standard indices of dental health viz. dmfs, dmft, pi, gi, bi, DMFS, DMFT, PI, GI, BI (Franco et al. 1996).

Assessment criteria of the dental restoration: clinical assessment of the “quality” of an amalgam or resin restoration shortly after being placed means checking the degree of excellence or degree of confidence to the standard.

1. Direct clinical observation:

Using a subjective, descriptive criteria (Ryge et al. 1973, Ryge 1980) must have 85% agreement between examiners The Ryge clinical criteria (Ryge 1980) will be followed to check: surface contour and colour of the restoration, anatomic form, and marginal integrity. This will be carried out using visual examination by the dentist, using a mouth mirror, and an explorer, and supplementary lighting as needed.

2. Indirect clinical observation:

Replicas will be made using a rubber base impression material. These replicas are then observed (Santucci et al. 1979), photographed (Mitchem 1972, Richter et al. 1973), and assessed with a profile recorder or a scanning electron microscope (Pellet 1979, Lutz et al. 1979, Flynn 1978).[need to check with Biomaterials]. General assessment for tooth and restoration wear can be made with such casts, but sub-gingival and proximal carious lesions cannot be detected.

Randomisation of Restorative Material: Children entering the trial will be randomly allocated (using the StatMate software) to one of the four restorative materials. The unit of study will be the individual tooth with the constraint that the same restorative material is used in each mouth to avoid the risk of obtaining very uneven numbers of teeth in the randomisation. The technique of minimisation based on age and tooth type will be added to the randomisation process according to age and tooth-type (Altman 1991). This is a statistical technique that ensures that the number of subjects in experimental groups is very close. In a few instances teeth and/or patients deemed suitable for the trial may need to be allocated to other treatments. If the extent of the carious lesion requires a different approach to the chosen restorative technique then the patient(s) will be withdrawn from the trial. Only one therapist and one dental surgeon will be used to place restorations both of whom have considerable experience in restorative treatment in children.

Data Collection and Follow-up Procedures: Baseline data will be collected at the time of randomisation, at completion of the restoration and at six-monthly intervals for two years. The data items will be collected in standard format. Every effort will be made to ensure that follow-up occurs at six-monthly intervals, but provided that the time of review is within one month of the chosen interval, the review will be categorised to the nearest six-monthly period. The analyses will be presented using life-table survival curves for ‘Replacement of restoration needed’. The rubber base impressions will be used to assess wear over the period of the study.
Appendices

Appendix I a (Cont)

Justification

An important part of children’s dentistry is the placement of restorations in deciduous and permanent teeth. The present rate of replacement is unacceptably high. This is especially so for deciduous teeth where a restoration should last until the tooth is exfoliated. For permanent teeth the life of a restoration should be at least 10 years. The assessment of restorations is not yet subject to regular audit.

The information gained from this study will, in the first instance, have application only to children receiving conservative dental treatment under local anaesthesia. However, depending on the outcome, the findings may be applicable to children treated under general anaesthesia. In a more general sense the information gained from this study will be widely applicable. It will indicate whether or not individual restorative materials are of sufficient durability to be used in both children and young adults in the general population. If, as is suspected, the materials demonstrate substantial durability when placed under local anaesthesia this will be a strong indication of a need to modify the clinical techniques of cavity design to overcome the faults identified by this study.
Appendices

Appendix Ia (Cont)

References


Appendix I a (Cont)


Appendix I b

Ethical Approval from the 'Ministry of Higher Education' and the 'Ministry of Health',

UAE

[In Arabic]
RESEARCH PROTOCOL PRESENTED TO THE MINISTRY OF HIGHER EDUCATION OF THE UNITED ARAB EMIRATES.
Appendices

Appendix I b

RANDOMISED CLINICAL TRIAL OF FOUR DENTAL RESTORATIVE MATERIALS
(Silver Amalgam [Dispersalloy], Compomer [Dyract AP], Glass Ionomer [Fuji II LC], Resin Modified Glass Ionomer [Vitremer]) A STUDY OF TOOTH-COLOURED RESTORATIVE MATERIALS PLACED IN CHILDREN

Summary
Even in the best hands the failure rate of dental restorations in children is between 5% and 20% at 1 year and between 10% and 50% at 2 years. Although silver mercury amalgam outlasts other restorative materials it is unsatisfactory cosmetically and there is increasing concern about the mercury content, especially when used in children. A number of new, tooth coloured, restorative materials have become available in recent years. Three materials, ‘Dyract AP’ a compomer, ‘Fuji II LC’ a glass ionomer system, and ‘Vitremer’ a resin bonded glass ionomer system appear to be suitable alternatives to amalgam. All leach fluoride into the enamel wall of a restored cavity and the saliva bathing the tooth surfaces although to varying degrees.

These new permanent filling materials are already been used with a great deal of success in the UK and across Europe. It would be advantageous to use them in the United Arab Emirates, since the use of adhesive techniques will reduce the need for extensive preparation, which makes treatment for the children less traumatic. This will be of great benefit to the children of UAE.

Purpose of the Research
The aim is to:

- Compare the survival of restorations placed under ‘ideal’ operating conditions in Class I and Class II cavities in primary teeth and Class I cavities in permanent teeth using modern restorative materials and using silver amalgam as the standard for comparison.

Materials Used
Three tooth coloured permanent Dental Materials which are: Compomer (Dyract AP), Glass Ionomer (Fuji II LC), Resin modified glass-ionomer (Vitremer) Compared against Amalgam.

Materials will be supplied by the investigator Dr. Duaa Ezzeddin Mustafa.

Number of UAE patients needed
As many as possible but not less than 100 cases, to allow scientific and academic value.

Children taking part in the research not only will receive these new materials but will be closely monitored (six month intervals for 18 months) to ensure that the fillings are maintained to a high standard.

Background
The treatment approach of caries has changed in the last decade. Preventive measures have gained a more pronounced place since they are expected to slow down or even arrest the progress of carious lesions, thus avoiding the invasive replacement of carious tissue (Mount 1991). If prevention fails, however, restorative treatment may be necessary to eliminate the caries process. Historically the use of amalgam was the standard filling material in primary molars, of which satisfactory long-term evaluation results were reported (Welbury et al. 1991,
Appendix I b

Kilpatrick et al. 1993). Amalgam is still regarded as the common restorative material for posterior teeth. No other restorative material gained such an established position, based on laboratory studies and long-term clinical observation (Mass et al. 1999). Poor aesthetic appearance and the rising awareness of the public to possible health hazards encouraged health authorities and professionals to look for “clinically appropriate alternative materials” to amalgam. The most important examples of those materials are the adhesive materials (Marks et al. 1999). The advantage of using adhesive materials compared to amalgam are preservation of sound tooth tissue and avoidance of the isthmus, the well known Achilles heel (Forsten and Karjalainen 1990, Mount, 1998). The main reasons of restoration failure in the primary dentition are isthmus fractures, marginal failure and occurrence of recurrent caries (Welbury et al 1991, Ostlund et al 1992, Arends and Dijckman 1995, van Dijken 1996, Mjor 1997, Marks et al. 1999). The advantage of a tooth-coloured material can be seen as an advantage benefit for the patient’s motivation compared to amalgam (Marks et al. 1999).

Methods

Patients: Children and adolescents attending the Paediatric Dentistry Clinic and judged to require restorations under local anaesthesia for Class I and Class II cavities will form the population. Children will be assessed for their ability to cooperate for treatment under local anaesthesia and their willingness to attend for review at 6 monthly intervals.

Restorative Procedures: These will be standard procedures and will follow the manufacturer’s instructions. The tooth-coloured materials (Dyract AP, Fuji II LC & Vitremer) will be used with minimal destruction techniques (Garcia-Godoy 1988). To take full advantage of the adhesive qualities of the material which enables the cavity size to be kept as small as possible, conventional mechanical retention will be incorporated into the cavity design of both materials to eliminate the risk of loss of restoration from adhesion failure. The cavity design will depend on the extent of caries and the type of filling material that is going to be used. Rubber dam isolation will used when ever possible. When the restoration has been placed, a replica of it will be made using rubber base impression material to enable a baseline for occlusal wear and to aid in the indirect clinical examination criteria.

Justification

An important part of children’s dentistry is the placement of restorations in deciduous and permanent teeth. The present rate of replacement is unacceptably high. This is especially so for deciduous teeth where a restoration should last until the tooth is exfoliated. For permanent teeth the life of a restoration should be at least 10 years. The information gained from this study will have application not only to children receiving conservative dental treatment under local anaesthesia, but may be applicable to children treated under general anaesthesia. In a more general sense the information gained from this study will be widely applicable. It will indicate that these individual restorative materials are of sufficient durability to be used in both children and young adults in the general population.
Appendix I c

Report From Field Trips
Appendices

Appendix I c

Report on Field trips to the United Arab Emirates

Re: UAE children taking part in the Randomised clinical trial of four dental restorative materials

Approval for the study was sought from the 'Ministry of Higher Education' and through the 'Ministry of Health' (Appendix I b). After permission was obtained from these authorities, schools were then approached individually through an arrangement with the school dental health department.

Sample selection
Sampling was carried out to provide a sample of 131 teeth. UAE children [age 5 to 13] (visit 1 sample was 39 subjects visit 3 sample was 92 subjects) attending primary schools, City of Abu Dhabi the Capital of United Arab Emirates.

The UAE population is a mixture of Emirati, Indian and Yemeni as well as Egyptian, Lebanese, Syrian, Palestinian and other origins. There is a high incidence of mixed marriages in the region, with many children being of mixed origin. Non-Emirati children were all Arabic speaking and had lived in the UAE throughout their lives.

To select the sample, a list of all the primary schools in the city that had the facility of a dental clinic was obtained from the dental school health department. The schools were then divided into groups according to gender and grade levels (Lower-primary [grades 1-3], higher-primary [grades 4-6]).

Visit I: (Dec.00-Jan.01) included two primary schools for boys (Al Bateen school for Lower-primary and Al Ahnaff school for higher-primary), sample obtained was 39 subjects ‘fillings / teeth’.

Visit II: (April-May.01) included two primary schools this time one for boys (Al Bateen model school) and the other one for girls (Al Affak model school), sample obtained was 92 restorations 75 restorations placed on boys, 17 restorations on girls.

Visit III: (Dec.01) this visit was mainly to follow-up and locate all the children seen in Jan and May, since it’s the beginning of a new educational year, some of the Children might have moved schools. So to make sure that we keep trace of all the Children in the trial a short visit was made to the schools. Boys who were at (Al Bateen boys school) were divided to two groups, the first group stayed in the same school (n=23 boys) the other group moved to (Al-Mostakbal school, n= 20 boys), 3 more boys had changed schools, and were traced, so special arrangements had to be made to see them through contacting their parents. Boys who were seen in (Al-Ahnaff school) were all traced and found to be still in the same school (n=7) Girls had been all moved to a new girls school in a different location (n=7), but all girls were kept in the same school. Clinical review was done as before at the school dental clinic using a dental mirror and a blunt probe, and another rubber base impression was taken.

Visit IV: (June. 02) as a review visit (n=33 boys, n=7 girls).

Visit V: (Dec.02-Jan.03) final review visit, where all patients were contacted and restorations were reviewed clinically, and final impression were collected, a lot of the primary teeth had already exfoliated, other restorations failed due to bulk fracture as well as recurrent caries.
Appendices

Appendix I c (Cont.)

Clinical examination and caries diagnosis
All children were screened before taking part in the study (part of school dental health regulations in the UAE), so all children who were to be seen were known to have dental caries, but another clinical examination was done under standardised clinical set-up to evaluate the extent of caries and co-operation level. Teeth and surfaces were examined in a standard order and status recorded. Diagnosis was done visually with a plane mouth mirror and an explorer (following the study protocol).

Methods of collecting data
Findings at examination and details of dental treatment were all recorded using Database collecting sheets for UAE children (Appendix III b).

- All children attending the schools selected had already been screened and signed consent was obtained from parents, all children were eligible to take part in the study.
- Children were called alphabetically from their class rooms and treatment took place at the dental clinic of the school. This will help in recalling the children for their follow up in six months time.
- The clinical part of the study included a clinical examination, restorative dental treatment (class I and II for primary first and second molars and class I for first permanent molars and premolars).
- Rubber base impression were made of the restored teeth and will be used for the Indirect assessment of restorations.
- Restorations placed in Dec. and Jan. were all reviewed at the end of visit II, where direct clinical examination, as well as a 2nd impression was taken and photographs (whenever possible) in addition to the

Restorative dental treatment and material selection
- Standard procedures of restorations placed under 'ideal' operating conditions in class I and class II cavities in primary molars and class I cavities in first permanent molars and premolars using modern restorative materials silver amalgam was used as the standard comparison.
- Cavity design depends on the extent of caries and the type of filling material that is going to be used. Rubber dam isolation was used when ever possible.
- A rubber base impression was taken after placement of the restorative material to enable a baseline assessment for occlusal-marginal wear as part of the indirect clinical examination.
- Restorative material selection was randomly allocated according to the StatMate software that was previously used with the UK children at the Paediatric Department Eastman Dental Institute.

Problems faced
- There was always the problem of travelling and taking restorative materials needed abroad.
- When in the UAE there was the problem of locating the schools, and seeking ethical approval from both the school and the parents, which took a while during the 1st visit.
- Having to make sure to work with the same dental nurse whenever possible (mixing tech.) and dealing with only one technician for model pouring (using the same stone material each time).
- Faced a problem with the administration of the females' school (not very cooperative nor keen to take part in the study) so ended up having more boys than girls as candidates for the clinical trial.
- Children moving from one primary school to another, and keeping track of all of them was sometimes time consuming and difficult.
- Faced problems contacting the patients families to arrange for a review visit to the school dental clinic as most of them not interested in the follow up appointment.
Appendix II

EASTMAN DENTAL INSTITUTE AND HOSPITAL
Department of Paediatric Dentistry
Information Sheet and Consent Form on Dental Fillings Study

Dear Parent,

We wish to study different restorations (fillings) in children's teeth to see which last the longest.

We need to study these new filling materials because of the widespread concern over the use of Silver-Amalgam. The study is designed to see if the newer fillings are strong enough to justify their widespread use in children's teeth. We have new tooth-coloured materials called 'Dyract AP' 'Fuji II LC' and 'Vitremer', which have had successful results. They have the advantage that they are tooth-coloured. Also, minute amounts of fluoride are released into the enamel around the cavity, thus helping prevent new decay around the filling.

To evaluate these fillings we need to compare these fillings in a scientific way to see which will last the longest and which provides the greatest benefit to children.

To achieve this we would like to use one of these filling materials or Silver-Amalgam to repair the cavities in your child's teeth. To do this in a scientific way the choice of the material is to be made by using a random allocation. Once this choice has been made there will be no difference to the treatment that your child will receive. On the contrary your child will be closely monitored to ensure that the restoration is always kept in an optimal condition. Please understand that these are materials are already being used in the department. Our reason for asking your permission to use them 'randomly' is so that we can draw firm conclusions about the best treatment for children's teeth.

You are not under any obligation to take part in the study and your child's treatment will not be affected in any way if you do not wish to take part.

I __________________________________, the parent of _____________________________ agree to my child taking part in the 'Dental Fillings' study. I understand that I may withdraw my child from the study at any time without any detriment to his/her care.

Signed ___________________________ Date ____________

IF THERE ARE ANY QUERIES ABOUT THIS STUDY PLEASE CONTACT
MISS D. MUSTAFA/ PROF. G. ROBERTS TEL. 0207 915 1108/ CHILDREN'S DEPARTMENT,
EASTMAN DENTAL INSTITUTE
### Database for Study on Longevity of Restorations

**Department of Paediatric Dentistry: Eastman Dental Institute and Hospital**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Number:</td>
<td></td>
</tr>
<tr>
<td>Restoration Number:</td>
<td></td>
</tr>
<tr>
<td>Surname:</td>
<td></td>
</tr>
<tr>
<td>Forename:</td>
<td></td>
</tr>
<tr>
<td>Date of Birth:</td>
<td></td>
</tr>
<tr>
<td>Gender (1=m, 2=f):</td>
<td></td>
</tr>
<tr>
<td>Today's Date:</td>
<td></td>
</tr>
<tr>
<td>Study No.:</td>
<td></td>
</tr>
<tr>
<td>Visit Number:</td>
<td></td>
</tr>
</tbody>
</table>

**Tooth restored (FDI):**

- [ ]

**Anatomical Configuration:**

- O = 1, M = 2, D = 3, MD = 4, MOD = 5, L = 6, B = 7, OL = 8, OB = 9, IE = 10

**Anaesthetic:**

- 1 = LA infiltration, 2 = LA id block, 3 = none, 4 = RA plus LA infiltration, 5 = RA plus LA id block, 6 = RA alone

**Isolation:**

- 1 = rubber dam, 2 = cotton roll, 3 = dryguard, 4 = drytip

**Lining:**

- 0 = Nil, 1 = dycal, 2 = kalzinol, 3 = GIC, 4 = more than one

**Material used:**

- Dispersalloy = 1, Dyract AP = 2, Fuji II LC = 3, Vitremer = 4

**Varnish over Restoration:**

- 1 = nil, 2 = vaseline, 3 = proprietary varnish, 4 = copal ether, 5 = fissure sealant

**Varnish on Cavity Walls:**

- 1 = nil, 2 = fissure sealant, 3 = copal ether

**Finish:**

- [ ]

**Patient's Co-operation (Frankl Scale):**

- 1 = definitely negative, 2 = negative, 3 = positive, 4 = definitely positive

**Length of appointment (minutes):**

- [ ]

**Estimated operative time (minutes):**

- [ ]

**Marginal integrity (1, 2, 3, or 4):**

- [ ]

**Marginal Discolouration (10, 11, 12, or 13):**

- [ ]

**Anatomical Form (5, 6, 7, 8, or 9):**

- [ ]

**Contact Point (16 or 17):**

- [ ]

**Recurrent Caries (14 or 15):**

- [ ]

**Replacement Needed (18 or 19):**

- [ ]

---

321
Appendices

Appendix III b

Consent Form and Data Collection Sheet (UAE children)

I ................................................................................. The Parent
of .................................................................................. Agree to my child
to participate in the 'Dental Fillings Study'
Signed........................................................................... Date.................................................

Today's date
Study No.
Surname
Forename
Date of birth
Gender 1=m, 2=f
Name of School
Address
Tel.
Fathers Occupation

Restoration No.
Original date of placement
Date of review

Tooth restored (FDI)

Anatomical configuration: O, M, D, MO, DO, MOD

Anesthesia: Infiltration, ID block, none

Isolation: RD, Cotton rolls, Suction

Lining: Dycal, GIC, None

Patient's cooperation:

Length of appointment:

322
Appendix IV

Cast Rank Order Database (UK and UAE Restorations)
Indirect cast evaluation data collation sheet

First evaluator

FDI code for Tooth: ________ Study Number: ________

EV. 1

Occluso-Buccal: ________

Occluso-lingual: ________
Appendix IV (Cont.)

Second Evaluator

FDI code for Tooth

Study Number

EV. 2

Occluso-Buccal:

Occluso-lingual:
Appendix IV (Cont.)

Third Evaluator

<table>
<thead>
<tr>
<th>FDI code for Tooth</th>
<th>Study Number</th>
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</thead>
<tbody>
<tr>
<td>Restoration Number</td>
<td>Date of Restoration</td>
</tr>
</tbody>
</table>

EV. 3

Occluso-Buccal:  
Occluso-lingual:  

Final Score
Appendix V.

Primary Schools Dental Clinic, City of Abu Dhabi, UAE

Al-Bateen Primary school / UAE
Appendix VI.

Primary Schools Visited for Data Collection, city of Abu Dhabi, UAE

1. Al-Bateen School
2. Al-Ghazaly School
3. Al -Affaq 1 *
4. Al-Affaq 2 *
5. Al-Ameen
6. Al-Ahnaf School
7. Al-Rasheed
8. Al-Sae'edyat School *
9. Al-Mostaqbal School
10. Abul-Allah Bin Otaybah School

* Female schools
Appendix VII.

Clinical Pictures of Restorations (before and after Treatment)

65/64 caries and lost restoration (before)

65/64 Amalgam (after)

75/74 caries around old composite

75/74 Dyract AP (after)
75 OB/ 74 M caries (before)

75/74 Fuji II LC + FS (after)

75 Occ/ 74OD caries (before)

75 / 74 Vitremer (after)
### Appendix VIII a: Retrospective / Survey Studies on Durability of Restorations in Primary Molars

<table>
<thead>
<tr>
<th>Study</th>
<th>Numbers in the Study</th>
<th>Number of Operators</th>
<th>Controls / Groups</th>
<th>Duration of data collection</th>
<th>Missing data</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Braff (1975)</td>
<td>76 teeth, SSCs 150 teeth, amalgams</td>
<td>1</td>
<td>2 groups</td>
<td>2 yrs</td>
<td>52% (loss to follow up)</td>
<td>2 yrs SSCs had sig. higher success rate 70% compared to 11% of amalgams (p &lt; 0.001)</td>
<td>Dates of the treatments were censored, No radiographs were used to estimate date of exfoliation, Reasons for loss to follow up not clear</td>
</tr>
<tr>
<td>Holland et al (1986)</td>
<td>1139 teeth 317 subjects</td>
<td>/ 1</td>
<td>/</td>
<td>7 yrs</td>
<td>Total dropout over the study period was 53% recorded as withdrawn</td>
<td>3 years survival rates 46 %, higher among older patients ages 9-10 yrs giving 68% success, Class I showed higher survival rates compared to Class II restorations, 2nd primary molars showed higher survival rates compared to 1st primary molars 48% to 38%</td>
<td>Age of the patient at time of restoration placement is very important, Restorations placed in children &lt; 3yrs of age last on average less than one year, Restorations placed in 1st primary molar had a shorter life span compared to 2nd primary molar</td>
</tr>
</tbody>
</table>

1/ = Not clear/ not stated
<table>
<thead>
<tr>
<th>Study (1986a)</th>
<th>Teeth</th>
<th>Subjects</th>
<th>Groups</th>
<th>Duration</th>
<th>Questionnaire</th>
<th>Reason for Replacement</th>
<th>Other Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qvist et al</td>
<td>6052</td>
<td>/</td>
<td>4</td>
<td>2 yrs</td>
<td>Questionnaire given to 338 dentists</td>
<td>Secondary caries was main reason for replacement of restorations</td>
<td>Other reasons for failures were bulk fracture, as well as marginal discrepancy</td>
</tr>
<tr>
<td>Restorative treatment pattern and longevity of amalgam restorations in Denmark</td>
<td>Subjects / not specified</td>
<td>4 groups (reporting only on amalgam restorations)</td>
<td></td>
<td></td>
<td></td>
<td>Drop out rate not clear</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1772 primary teeth</td>
<td>/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5227 permanent teeth</td>
<td>/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>897 teeth</td>
<td>/</td>
<td>4</td>
<td>2 yrs</td>
<td>Questionnaire to 338 dentists</td>
<td>Main reasons for failures were: secondary caries, loss of the filling and marginal discrepancy</td>
<td>Drop out rate not clear</td>
</tr>
<tr>
<td>Qvist et al (1986b)</td>
<td>Subjects / not specified</td>
<td>4 groups (reporting only on resin restorations)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Restorative treatment pattern and longevity of resin restorations in Denmark</td>
<td>833 Resin restorations</td>
<td>/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>13 Silicate restorations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>51 Cast restorations</td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>Study</td>
<td>Total Teeth</td>
<td>Subjects</td>
<td>Mean Age</td>
<td>Duration</td>
<td>Success Rate</td>
<td>Failure Rate</td>
<td>Other Notes</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>--------------</td>
<td>--------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Levering &amp; Messer (1988)</td>
<td>1898</td>
<td>226</td>
<td>2-9 yrs</td>
<td>2-9 yrs</td>
<td>68%</td>
<td>27%</td>
<td>6 yrs survival of Class I amalgam placed in children &lt; 4 yrs was 75%</td>
</tr>
<tr>
<td>Messer &amp; Levering (1988)</td>
<td>331</td>
<td>226</td>
<td>2-9 yrs</td>
<td>2-9 yrs</td>
<td>88%</td>
<td>12%</td>
<td>Reasons for loss to follow up not clear</td>
</tr>
<tr>
<td>Qvist et al (1990a)</td>
<td>4932</td>
<td>Not Specified</td>
<td>2 yrs</td>
<td>2 yrs</td>
<td>88%</td>
<td>12%</td>
<td>Secondary caries was the main reason for replacement of restorations</td>
</tr>
</tbody>
</table>

Qvist et al (1990a) Placement and longevity of amalgam restorations in Denmark:

- 4932 teeth
- Subjects not specified
- 1519 primary teeth
- 1664 permanent teeth
- 4 groups (reporting only amalgam restorations)
- 2 yrs
- Questionnaire to 341 dentists
- Patients > 16 yrs restorations were placed in 39% due to primary caries, and in 61% as replacement restorations
- Restorations placed in 74% of primary teeth, and 84% of permanent teeth were due to primary caries. Secondary caries recorded in 38% of the restorations
- Drop out rate not clear
<table>
<thead>
<tr>
<th>Study Reference</th>
<th>Number of Teeth</th>
<th>Material Type</th>
<th>Study Design</th>
<th>Follow-up</th>
<th>Follow-up Type</th>
<th>Primary Cause of Failure</th>
<th>Type of Failure</th>
<th>Drop-out Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qvist et al (1990b)</td>
<td>2542 teeth</td>
<td>2353 Composite, 146 GIC, 43 Silicate restorations</td>
<td>4 groups (reporting only resin restorations)</td>
<td>2 yrs</td>
<td>Questionnaire to 265 dentists</td>
<td>Placement and longevity of tooth-coloured restorations in Denmark</td>
<td>Secondary caries, fracture of restorations and loss of filling were main reasons for replacement</td>
<td>Drop-out rate not clear</td>
</tr>
<tr>
<td>Roberts &amp; Sherrif (1990)</td>
<td>2404 teeth</td>
<td>1688 Amalgams, 716 SSCs</td>
<td>1</td>
<td>2 groups</td>
<td>10 yrs</td>
<td>Reported 5 yrs survival rates were: Primary Class I amalgam 73.3%, and Class II amalgam 66.6% Permanent Class I amalgam 76.8%, and Class II amalgam 82.2% SSCs 92%</td>
<td>No relationship between the age of the patient and the age of replaced restorations although in primary teeth Class I and II amalgams placed in 5-6 yrs old children were replaced sig. earlier than other age groups</td>
<td>Drop-out rate not clear</td>
</tr>
<tr>
<td>Study</td>
<td>Teeth / not specified</td>
<td>Groups</td>
<td>Follow up</td>
<td>Composite resin in modified Class II cavities showed a cumulative success rate of 86% at 1 yr and 38% at 6 yrs</td>
<td>Number of teeth / restorations in the study not clear</td>
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</tr>
<tr>
<td>Varpio (1993)</td>
<td>Group 1 194 subjects</td>
<td>2</td>
<td>6 yrs</td>
<td>Bulk fractures were recorded early while recurrent caries were recorded from 2yrs</td>
<td>Interpretation of the over all data not clear</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Group 2 199 subjects</td>
<td>2</td>
<td></td>
<td>Histological investigation of exfoliated / and or extracted teeth disclosed bacteria subjacent to both filling materials in 75% and recurrent caries in 58%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Primary teeth showed no lesions close to the glass polyalkeoate fillings</td>
<td>Reasons for loss to follow up not clear</td>
<td></td>
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<tr>
<td></td>
<td>Teeth / not specified</td>
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<tr>
<td></td>
<td>Group 1 194 subjects</td>
<td>2</td>
<td>6 yrs</td>
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<tr>
<td></td>
<td>Group 2 199 subjects</td>
<td>2</td>
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</tr>
<tr>
<td>Papathanasiou et al (1994)</td>
<td>604 teeth</td>
<td>4 groups</td>
<td>5 yrs</td>
<td>Sig. difference between the four types of treatments with higher survival recorded by SSCs (p &lt; 0.0001)</td>
<td>Data was censored for 18% of restorations</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>128 subjects</td>
<td></td>
<td>46% (loss to follow up)</td>
<td>Reasons for loss to follow up not clear</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>183 SSCs</td>
<td></td>
<td></td>
<td>4yrs survival rate of composite 40%</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>198 Amalgam</td>
<td></td>
<td></td>
<td>5yrs survival rates of SSCs 68%, amalgams 60%. Failures recoded in 34% of the restorations</td>
<td></td>
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<tr>
<td></td>
<td>173 Composite</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>50 GIC</td>
<td></td>
<td></td>
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<tr>
<td><strong>Wendt et al (1998)</strong></td>
<td>Total 6012 teeth (primary &amp; permanent)</td>
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<tr>
<td></td>
<td>3200 primary teeth</td>
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<td></td>
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<td></td>
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<tr>
<td></td>
<td>546 subjects</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>1040 Compomer</td>
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<td></td>
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<tr>
<td></td>
<td>827 GIC</td>
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<tr>
<td></td>
<td>748 ZnO-eugenol</td>
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<td></td>
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<tr>
<td></td>
<td>119 Amalgam</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>87 Composite</td>
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<tr>
<td></td>
<td>11 dentists</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>5 groups</td>
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<td></td>
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<tr>
<td></td>
<td>5 yrs</td>
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<tr>
<td></td>
<td>11% (loss to follow up for known reasons)</td>
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<tr>
<td></td>
<td>Main reasons for failures were recurrent caries, bulk fracture.</td>
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<tr>
<td></td>
<td>36% of the failures recoded in children &lt; 8 yr old</td>
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</tr>
<tr>
<td></td>
<td>Data mixed between primary and permanent teeth</td>
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</tr>
<tr>
<td></td>
<td>Numbers of restorations placed been mixed with number of replaced restorations</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Mass et al (1999)</strong></th>
<th>107 teeth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>42 subjects</td>
</tr>
<tr>
<td></td>
<td>63 Dyract</td>
</tr>
<tr>
<td></td>
<td>44 Amalgam</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Amalgam restorations</td>
</tr>
<tr>
<td></td>
<td>4 yrs</td>
</tr>
<tr>
<td></td>
<td>/</td>
</tr>
<tr>
<td></td>
<td>4 yrs all restorations were recorded acceptable</td>
</tr>
</tbody>
</table>

<p>|                       | Teeth were radiographically examined every 6 months as part of the study |
|                       | Drop out rate not clear |
|                       | Follow up data were provided only for the Dyract restorations |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Teeth/Subjects</th>
<th>Year</th>
<th>Duration</th>
<th>Success Rate</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croll et al (2001)</td>
<td>864 teeth/393 Class I, 406 Class II, 15 Class III, 50 Class V</td>
<td>3 yrs</td>
<td>/</td>
<td>Success rate for Class I was 93%, Class II 93%</td>
<td>In Class II restorations a radiograph was taken 3 yrs post placement, Drop out rate not clear</td>
</tr>
<tr>
<td>Fross &amp; Widstrom (2003)</td>
<td>2186 teeth/1797 subjects (All &lt; 17 yrs)</td>
<td>/</td>
<td>Restorations during a 3 days period</td>
<td>/</td>
<td>Questionnaire sent to 579 dentists, In primary teeth RMGIC was used in 58%, GIC in 39%, and composite was used in 4% of the restorations, In permanent teeth composite was used for 59.1%, RMGIC 20.1%, GIC 20.1%, and amalgam was used for only 6.0%, Failures was recorded in 265 teeth (148 primary, 117 permanent)</td>
</tr>
<tr>
<td>Study Reference</td>
<td>Number of Subjects</td>
<td>Materials</td>
<td>Groups</td>
<td>Follow-up</td>
<td>Survival Estimates</td>
</tr>
<tr>
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</tr>
<tr>
<td>Duggal &amp; Curry (2004)</td>
<td>194 teeth</td>
<td>81 SSCs, 36 Amalgams, 61 Composites, 16 GICs &amp; Compomers</td>
<td>5</td>
<td>5 yrs, 10 yrs</td>
<td>SSCs 89%, Amalgam 61%, Composite 58%</td>
</tr>
<tr>
<td></td>
<td>Subjects not specified</td>
<td></td>
<td></td>
<td>/</td>
<td>Data was censored was for 67%</td>
</tr>
</tbody>
</table>
## Appendix VIII b: Prospective Studies on Durability of Restorations in Primary Molars

<table>
<thead>
<tr>
<th>Study</th>
<th>Numbers in the Study at baseline</th>
<th>Number of Operators</th>
<th>Controls / Groups</th>
<th>Duration of Study</th>
<th>Missing data</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| **Tonn & Ryge (1988)**       | 96 teeth 44 subjects            | 2                   | Amalgam restorations from a previous study | 4 yrs             | 21% after 2 yrs (loss to follow up) 54% after 4 yrs (lost due to exfoliation) | In 2 yrs:
99% had α¹ rating for colour matching
86% had α rating for anatomical form
75% had α rating for marginal adaptation
In 4 yrs:
79% had α rating for marginal adaptation
Restorations showed 124μm (mean wear value) using Indirect Leinfelder Standard Method | Treatment distribution type not clear Comparing results with a previous study on a similar population (Tonn et al 1980) Radiographs were taken annually for proximal caries detection |
| Clinical evaluation of light-cured composite resin restorations in primary molars | 22 Class I 74 Class II |                     |                   |                   |              |                                                                        |                                                                          |
| Parallel design              |                                  |                     |                   |                   |              |                                                                        |                                                                          |
| Randomised                   |                                  |                     |                   |                   |              |                                                                        |                                                                          |
| **Walls et al (1988)**       | 116 teeth 43 subjects           | /²                  | Amalgam restorations | 2 yrs             | 14 teeth (lost due to exfoliation) | Sig. diff. in loss of anatomical form (p < 0.05) after 1 yr
No sig. diff. in loss of anatomical form (p > 0.05) after 2 yrs | Statistical analysis for the one year and two year survival were not clear
Drop out rate not clear |
| Use of glass polyknoate (ionomers) cements (Ketac - Fil) in deciduous dentition | 14 Class I 102 Class II |                     |                   |                   |              |                                                                        |                                                                          |
| Comparative study            |                                  |                     |                   |                   |              |                                                                        |                                                                          |
| Randomisation not stated     |                                  |                     |                   |                   |              |                                                                        |                                                                          |

¹ α = Alfa rating (USPHS)
² / = Not clear / not stated
<table>
<thead>
<tr>
<th>Study Authors (Year)</th>
<th>Details</th>
<th>Sample Size</th>
<th>Design</th>
<th>Randomisation</th>
<th>Duration</th>
<th>Loss %</th>
<th>Success Rate</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forsten &amp; Karjalainen (1990)</td>
<td>Glass ionomers in proximal cavities of primary molars</td>
<td>207 teeth</td>
<td>Parallel design</td>
<td>Randomisation not stated</td>
<td>1,2 yr</td>
<td>4% lost between 5-14 months</td>
<td>Ketac - Silver easier to manipulate than Ketac - Fill</td>
<td>Failures recorded in 20% due to bulk fracture and loss of retention</td>
</tr>
<tr>
<td>Hickel &amp; Voss (1990)</td>
<td>Comparison of glass cermet cement (Ketac - Silver) and amalgam restorations in primary molars</td>
<td>215 teeth</td>
<td>Comparative study</td>
<td>Randomisation not stated</td>
<td>4 yrs</td>
<td>/</td>
<td>Amalgam reported better survival rates over 4 years but no statistical difference between the two materials</td>
<td>Higher survival rates for both amalgam and Ketac - Silver 96.6%-90.5 % among patients ages 8-10 years</td>
</tr>
</tbody>
</table>

*Subjects not specified*
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Randomisation</th>
<th>Design</th>
<th>Follow-up Period</th>
<th>Survival Rate</th>
<th>Findings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barr-Agholme et al (1991)</td>
<td>119 teeth, Class II, 43 subjects</td>
<td>Randomisation not stated</td>
<td>Clinical study</td>
<td>2yrs</td>
<td>28% after 2 yrs (loss to follow up)</td>
<td>In 2 yrs sig. diff. between the two materials was found as 88% of the P30 were classified as α and or Bravo, compared to 68% of amalgam (p &lt; 0.05)</td>
<td>Patients age had not affected the success the rate of the restorations</td>
</tr>
<tr>
<td>Welbury et al (1991)</td>
<td>238 teeth, 76 subjects</td>
<td>Randomisation not stated</td>
<td>Clinical trial comparing a glass polyalkenoate (ionomer) cement (Ketac - Fil) restoration with an amalgam</td>
<td>5yrs</td>
<td>17% after 2yrs (loss to follow up)</td>
<td>Survival rate of amalgam restorations were sig. higher when compared to Ketac - Fil (p &lt; 0.01)</td>
<td>No details on missing data as 40 restorations were not reviewed</td>
</tr>
<tr>
<td>Attwood et al (1994)</td>
<td>635 teeth, Subjects not specified</td>
<td>Randomisation not stated</td>
<td>Assessment of glass polyalkenoate restorations in primary molar teeth</td>
<td>3yrs</td>
<td>43% after 3 yrs (loss to follow up)</td>
<td>At 1 yr 149 (23.4%) restorations failed mostly were in Class II cavities</td>
<td>Cumulative survival analysis of restorations not clear</td>
</tr>
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<td>At 3 yrs a further 142 (22.4%) failed Glass polyalkenoate cements provide a satisfactory restorative material in Class I cavities</td>
<td>Reasons for loss to follow up not clear</td>
</tr>
<tr>
<td>Study</td>
<td>Sample Size</td>
<td>Groups</td>
<td>Follow-up</td>
<td>Notes</td>
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</tr>
<tr>
<td>Kilpatrick et al (1995)</td>
<td>92 teeth 37 subjects</td>
<td>1</td>
<td>2.5 yrs</td>
<td>The use of a reinforced glass-ionomer (Ketac - Silver) cement for Class II restoration of primary molars. 2 yrs sig. lower failure rates 23% of Ketac - Fil compared to 41% of Ketac - Silver (p &lt; 0.05). Ketac - Silver cannot be recommended for the restoration of carious primary molars.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Teeth/Subjects</td>
<td>Follow-up</td>
<td>Failure Rate</td>
<td>Notes</td>
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<tr>
<td><strong>Holst (1996)</strong></td>
<td>172/48</td>
<td>3 yrs</td>
<td>31% after 3 yrs (loss to follow up for known reasons)</td>
<td>Ketac - Silver is not useful for restorations in primary molars especially for large cavities. All restorations were placed under local anaesthesia and inhalation sedation. Assesment of the restorations was carried out by 36 dentists.</td>
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<tr>
<td>Clinical evaluation of Ketac - Silver restorations in primary molars</td>
<td></td>
<td></td>
<td>1 yr 66% successful, 2 yrs 56% successful, 3 yrs 46% successful</td>
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<tr>
<td>Randomised</td>
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</tr>
<tr>
<td>Peters et al (1996)</td>
<td>91/55</td>
<td>1 yr</td>
<td>5% after 1 yr (loss to follow up)</td>
<td>Reasons for loss to follow up not clear</td>
<td></td>
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</tr>
<tr>
<td>Clinical evaluation of Dyract in primary molars</td>
<td></td>
<td></td>
<td>1 yr survival rate of Dyract 97%</td>
<td>Length of the study is short, results are difficult to interpret</td>
<td></td>
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<tr>
<td>Randomisation not stated</td>
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</tr>
<tr>
<td>Andersson-Wenkert et al (1997).</td>
<td>159/79</td>
<td>2 yrs</td>
<td>35% after 2 yrs (loss to follow up)</td>
<td>Large operator variations in failure rates due to technique sensitivity</td>
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<tr>
<td>Polyacid-modified composite resin (compomer / Dyract)</td>
<td></td>
<td></td>
<td>1 yr failure rate 8%</td>
<td>Reasons for loss to follow up not clear</td>
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<tr>
<td>Randomised</td>
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</tbody>
</table>
### Attin et al (1998)

Clinical evaluation of a hybrid composite (TPH-Spectrum) and polyacid-modified composite resin (Compoglass) in Class II restorations in deciduous molars

**Comparative study**

**Randomised**

<table>
<thead>
<tr>
<th>190 teeth, Class II</th>
<th>3</th>
<th>2 groups</th>
<th>1yr</th>
<th>/</th>
</tr>
</thead>
<tbody>
<tr>
<td>52 subjects</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>96 TPH-Spectrum</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>94 Compoglass</td>
<td></td>
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</tbody>
</table>

No sig. diff. between the two materials after 1 yr. Compoglass had scored the lower scores.

1 yr failure rate 6.4% Compoglass, and 3.1% TPH-Spectrum

Of the total, (n= 29) teeth had pulpal treatment, and were still included in the study.

Drop out rate not clear

### Roeters et al (1998)

Clinical evaluation of Dyract in primary

Randomisation not stated

<table>
<thead>
<tr>
<th>91 teeth</th>
<th>2</th>
<th>/</th>
<th>3 yrs</th>
<th>44% after 3 yrs (lost due to exfoliation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 subjects</td>
<td></td>
<td></td>
<td></td>
<td>Direct assessment after 3 yrs showed: Four restorations failed due to bulk fracture / and or total loss of the restorations</td>
</tr>
<tr>
<td>11 Class I</td>
<td></td>
<td></td>
<td></td>
<td>Crevice formation was recorded in 20% of the restorations</td>
</tr>
<tr>
<td>80 Class II</td>
<td></td>
<td></td>
<td></td>
<td>Marginal discolouration in 14% of the restorations</td>
</tr>
</tbody>
</table>

Dyract showed excellent handling properties and low failure rates over 3 yrs period

This study recommends Dyract as a reliable restorative material in primary molars

Indirect wear was assessed using (Moffa-Lugassy) scale showing 153μm at 2yrs
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Details</th>
<th>Sample Size</th>
<th>Duration</th>
<th>Failure Rate</th>
<th>Study Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Espelid et al (1999)</td>
<td>Clinical behaviour of glass ionomer restorations (Vitremer and Ketac-Silver)</td>
<td>98 teeth</td>
<td>3 yrs</td>
<td>18% after 3 yrs (loss to follow up)</td>
<td>Results after 3 yrs showed: Failures recorded in one Vitremer compared to 13 Ketac-Silver restorations due to recurrent caries and marginal defects Cumulative survival of Vitremer was better than Ketac-Silver Six children received 2-6 pairs of restorations Reasons for loss to follow up not clear</td>
</tr>
<tr>
<td></td>
<td>Comparative Study Randomised</td>
<td>49 subjects</td>
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<tr>
<td></td>
<td>28 D's 21 E's</td>
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<tr>
<td></td>
<td>2 groups</td>
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<tr>
<td></td>
<td>2 yrs</td>
<td></td>
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<tr>
<td>Folkesson et al (1999)</td>
<td>Resin-modified glass ionomer cement restorations in primary molars a multi-centre study</td>
<td>175 teeth</td>
<td>3 yrs</td>
<td>46.5% after 3 yrs (lost due to exfoliation / or extraction), and 14.3% (loss to follow up for unknown reason)</td>
<td>Failures recorded in 8.1% after 1 yr, 11.7% after 2 yrs, 19.8% after 3 yrs Main reasons for failure were recurrent caries and loss of retention Direct assessment of restorations was recorded using a modified USPHS criteria</td>
</tr>
<tr>
<td></td>
<td>Parallel design Randomisation not stated</td>
<td>85 subjects</td>
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</tr>
<tr>
<td></td>
<td>60 teeth, Class II 65 subjects</td>
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<tr>
<td>Papagiannoulis et al (1999)</td>
<td>Clinical evaluation of a polyacid-modified resin composite (compomer / Dyract) in Class II restorations of primary teeth</td>
<td>68 teeth</td>
<td>2 yrs</td>
<td>19% after 2 yrs (loss to follow up)</td>
<td>55 restorations were reviewed in 2 years: 3% showed bulk fracture 38% showed loss of anatomical form 44% showed loss of marginal integrity, and 8% showed marginal discolouration Distribution of treatment type not specified Comparing results between the two materials was not clear Reasons for loss to follow up not clear</td>
</tr>
<tr>
<td></td>
<td>Comparative study Randomisation not stated</td>
<td>25 subjects</td>
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<tr>
<td></td>
<td>20 teeth, Class II 18 subjects</td>
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<tr>
<td></td>
<td>2 Amalgam restorations</td>
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<td></td>
</tr>
<tr>
<td>Study</td>
<td>Description</td>
<td>Sample Size</td>
<td>Randomisation</td>
<td>Follow-Up</td>
<td>Results</td>
</tr>
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</tr>
<tr>
<td>Marks et al (1999a)</td>
<td>Conservative interproximal box-only polyacid modified composite (Dyract) restorations in primary molars</td>
<td>114 teeth 52 subjects</td>
<td>Randomised</td>
<td>Amalgam restorations 1 yr</td>
<td>24% after 1 yr (loss to follow up)</td>
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<tr>
<td>Marks et al (1999b)</td>
<td>Dyract versus Tytin Class II restorations in primary molars</td>
<td>60 teeth 30 subjects</td>
<td>Randomisation not stated</td>
<td>Split-mouth 3 yrs</td>
<td>20% after 2 yrs (loss to follow up) 43% after 3 yrs (loss to follow up)</td>
</tr>
<tr>
<td>Rutar et al (2000)</td>
<td>Clinical evaluation of a glass ionomer (Fuji IX GP) in primary molars</td>
<td>129 teeth 69 subjects</td>
<td>Randomisation not stated</td>
<td>/ 2 yrs</td>
<td>12.4% after 2 yrs (loss to follow up)</td>
</tr>
</tbody>
</table>
### Welbury et al (2000)

Clinical evaluation of paired compomer (Dyract) and glass ionomer (Chemfil) restorations in primary molars

- **Comparative study**
- **Randomisation not stated**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Teeth</th>
<th>Subjects</th>
<th>Design</th>
<th>Follow-up</th>
<th>Survival Rate</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyract</td>
<td>112</td>
<td>29</td>
<td>Split-mouth</td>
<td>42 months</td>
<td>30% after 2 yrs (loss to follow up)</td>
<td>Higher survival rates of Dyract compared to Chemfil (p &lt; 0.001)</td>
</tr>
<tr>
<td>Chemfil</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Distribution of treatment type not specified</td>
</tr>
</tbody>
</table>

- Some restorations placed under GA
- Data was censored for 20 pairs
- Reasons for loss to follow up not clear

### Gross et al (2001)

Compomers (Hytac and Dyract) as Class II restorations in primary molars

- **Comparative study**
- **Randomised**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Teeth</th>
<th>Subjects</th>
<th>Design</th>
<th>Follow-up</th>
<th>Survival Rate</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hytac and Dyract</td>
<td>98</td>
<td>49</td>
<td>2 groups</td>
<td>2 yrs</td>
<td>41% after 2 yrs (loss to follow up)</td>
<td>Over all failure rate recorded in 10.3% of restorations with no sig. diff. between the two materials (p = 0.43). Failure was due to bulk fracture and recurrent caries</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Radiographs were used for caries diagnosis</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td>Reasons for loss to follow up not clear</td>
</tr>
</tbody>
</table>

### Attin et al (2001)

Three-year follow up of Class II restorations in primary molars with polyacid modified composite and hybrid composite

- **Comparative study**
- **Randomised**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Teeth</th>
<th>Subjects</th>
<th>Design</th>
<th>Follow-up</th>
<th>Survival Rate</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPH-Spectrum</td>
<td>190</td>
<td>52</td>
<td>2 groups</td>
<td>3 yrs</td>
<td>50% after 3 yrs (loss to follow up for both materials)</td>
<td>At 3 yrs: TPH composite showed 85.8% success rate compared to 79.5% success of Compoglass</td>
</tr>
<tr>
<td>Compoglass</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No sig. diff. between the two materials with respect to colour matching, cavosurface margin, and anatomic form</td>
</tr>
</tbody>
</table>

- Both materials are suitable as restorative materials for primary molars
- Reasons for loss to follow up not clear
<table>
<thead>
<tr>
<th><strong>Kramer &amp; Frankenberger (2001)</strong></th>
<th>54 teeth</th>
<th>1</th>
<th>/</th>
<th>2yrs</th>
<th>22% after 2 yrs (loss to follow up for known reasons)</th>
<th>2 yrs survival rates 92% for Class I and 66% for Class II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical performance of a condensable metal-reinforced glass ionomer cement (Hi-Dense) in primary molars</td>
<td>17 subjects</td>
<td>/</td>
<td>2yrs</td>
<td>Failures recoded in 15% of the restorations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomisation not stated</td>
<td>19 Class I</td>
<td></td>
<td></td>
<td>SEM showed inferior adhesive performance marginally specially near proximal areas, and occlusal step formation occlusally</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>35 Class II</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>All restorations were assessed clinically and replica's assessed under SEM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Duggal et al (2002)</strong></th>
<th>156 teeth</th>
<th>/</th>
<th>Split-mouth</th>
<th>2yrs</th>
<th>23% after 2yrs (loss to follow up for known reasons)</th>
<th>2 yrs 71% of Dyract restorations were retained with no signs of surface wear compared to 66.6% amalgam restorations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical performance of a compomer(Dyract) and amalgam for the interproximal restoration of primary molars (General Dental practice and dental hospital paediatric clinic)</td>
<td>Subjects / not specified</td>
<td>/</td>
<td>Split-mouth</td>
<td>2yrs</td>
<td>Marginal adaptation for Dyract was sig. better than a amalgam (p &lt; 0.05)</td>
<td></td>
</tr>
<tr>
<td>Comparative study</td>
<td>Number of children in the study not specified</td>
<td></td>
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<tr>
<td>Randomisation not stated</td>
<td>Number of investigators/clinicians in study was not specified</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Assessment of surface wear was not clear</td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Subjects</td>
<td>Groups</td>
<td>Follow-up</td>
<td>Success rates</td>
<td>Reasons for loss to follow up</td>
</tr>
<tr>
<td>------------------------------</td>
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</tr>
<tr>
<td>Hubei &amp; Mejare (2003)</td>
<td>Split-mouth</td>
<td>1</td>
<td>3 yrs</td>
<td></td>
<td>43% after 3 yrs (loss to follow up)</td>
<td>Number of assessors involved in this study was not specified</td>
</tr>
<tr>
<td>Conventional (Fuji II) versus resin-modified (Vitremer) glass-ionomer cement for Class II restorations in primary molars</td>
<td></td>
<td>115 teeth</td>
<td>43% after 3 yrs (loss to follow up)</td>
<td>Sig. diff. in Vitremer success rates 94% compared to 81% of Fuji II (p &lt; 0.05)</td>
<td>Reasons for loss to follow up not clear</td>
<td></td>
</tr>
<tr>
<td>comparative study</td>
<td></td>
<td>40 subjects</td>
<td></td>
<td></td>
<td>62 Fuji II 53 Vitremer</td>
<td>Failures recorded in 11% of the total</td>
</tr>
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<td></td>
<td></td>
<td>3</td>
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<tr>
<td>Eden et al (2004)</td>
<td>Parallel</td>
<td>3</td>
<td>2 yrs</td>
<td></td>
<td>67% after 2 yrs (loss to follow up)</td>
<td>Reason for losses to follow up not clear</td>
</tr>
<tr>
<td>(Conference proceedings,</td>
<td>design</td>
<td>358 teeth</td>
<td>67% after 2 yrs (loss to follow up)</td>
<td>6 months survival rate for ART 81.5%, and 74% for conventional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EAPD 2004)</td>
<td></td>
<td>157 subjects</td>
<td></td>
<td></td>
<td>1 yr survival rate for ART 57%, and 55% for conventional</td>
<td></td>
</tr>
<tr>
<td>Survival rates of composite</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 years survival rate for ART 35%, and 35.1% for conventional</td>
<td></td>
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<tr>
<td>(Pertac II) restorations in</td>
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<tr>
<td>Class II cavities of primary</td>
<td></td>
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<tr>
<td>molars prepared by drill and</td>
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</tr>
<tr>
<td>ART</td>
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</tr>
</tbody>
</table>

**Partial caries removal and cariostatic materials in carious primary molar teeth.**

<table>
<thead>
<tr>
<th>Number</th>
<th>Treatment</th>
<th>Study Duration</th>
<th>Follow-Up Loss</th>
<th>Failure Rate</th>
<th>Additional Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 teeth&lt;br&gt;44 subjects</td>
<td>Split-mouth</td>
<td>2 yrs</td>
<td>30% after 2 yrs were lost to follow up, (of these 17% were lost for known reasons)</td>
<td>In 2 yrs failures were recorded in 26% of 31 restorations&lt;br&gt;More restorations were lost from 1st primary molars 35.3% compared to 2nd primary molars&lt;br&gt;Partial caries removal group showed sig. more abscess/ sinus formation compared to the other treatments</td>
<td>Allocation of the three different treatment type was randomised (partial removal vs. conventional)</td>
</tr>
</tbody>
</table>

**Allocation of restorative material type was according to the operator’s choice**

**Radiographs were taken for assessment every 6 months for 24 months**

### Qvist et al (2004a)

**Study on Conventional glass ionomer (Ketac - Fil) and amalgam restorations in primary teeth.**

<table>
<thead>
<tr>
<th>Number</th>
<th>Treatment</th>
<th>Study Duration</th>
<th>Follow-Up Loss</th>
<th>Failure Rate</th>
<th>Additional Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1058 teeth&lt;br&gt;666 subjects&lt;br&gt;515 Ketac - Fil&lt;br&gt;543 Dispersalloy</td>
<td>Parallel design</td>
<td>8 yrs</td>
<td>50% after 2 yrs&lt;br&gt;90% lost after 5 yrs</td>
<td>69% of the data was censored due to exfoliation&lt;br&gt;Failures recoded in 31%, mainly due to bulk fracture in GIC fillings (p &lt; 0.001)</td>
<td>11% of teeth included were endodontically treated&lt;br&gt;High frequency of failures of GIC material made it recommended as an alternative to amalgam&lt;br&gt;Reasons for loss to follow up not clear</td>
</tr>
</tbody>
</table>
Qvist et al (2004b)

Resin-modified (Photac-fil) and conventional glass ionomer (Ketac - Fil) restorations in primary teeth. (Danish Public Dental Health Service)

<table>
<thead>
<tr>
<th>Parallel design</th>
<th>Randomised</th>
<th>994 teeth</th>
<th>640 subjects</th>
<th>16</th>
<th>2</th>
<th>8 yrs</th>
<th>50% after 2 yrs</th>
<th>90 % lost after 5 yrs</th>
<th>64% censored data due to exfoliation</th>
<th>Failures recorded in 36% of the restorations</th>
<th>Recurrent caries recorded in 20% of the restorations</th>
<th>8 yrs survival was 75%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>853 Primary</td>
<td>170 Permanent</td>
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<tr>
<td></td>
<td></td>
<td>543 Photac-Fil</td>
<td>451 Ketac - Fil</td>
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<tr>
<td></td>
<td></td>
<td>8 yrs</td>
<td>50% after 2 yrs</td>
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<td>90 % lost after 5 yrs</td>
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<td></td>
<td>64% censored data due to exfoliation</td>
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<td></td>
<td>8 yrs survival was 75%</td>
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</tbody>
</table>

Reasons for loss to follow up not clear

RMGICs recommended for Class II restorations while GIC materials would perform better in Class I restorations.