SMART composite restorations of carious primary molar teeth after minimal caries removal

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2019 – 2022
Declaration

This report entitled “SMART composite restorations of carious primary molar teeth after minimal caries removal” was composed by me and is based on my own work. Where the work of the others has been used, it is fully acknowledged in the text and in captions to table illustrations. This report has not been submitted for any other qualification.

Saud Hamdan A Almaeen

25/07/2022
Acknowledgments

I would like to thank the following people, without whom I would not have been able to complete this research project:

My supervisors, Prof Anne Young and Prof Paul Ashley, for their enthusiasm, time, insight, knowledge, and consistent guidance and support throughout the whole process of my project.

Also, I would like to say thank you for Dr Nicky Morden, Dr Graham Palmer and Dr George Georgiou and all the laboratory staff at Royal Free Hospital for their advice, help and collaborative effort during my laboratory experiments.

My colleagues at Eastman Dental Institute, especially Lubabah, Maryam and Rawan….Thank you for sharing your experiences, thoughts and feelings and I won’t forget your consistent encouragement

Special thanks to Dr Arwa Almusa for her support, help and sharing her lab materials, as a part of her PhD, which allowed me to complete my lab experiments… apologise for the extra work Arwa!

Thank you to Dr Sana Movahedi (Regional Associate Postgraduate Dental Dean) for her insights and support to complete my retrospective data collection and the focus group… Also, I won’t forget Ms Zoe Buontempo for her enthusiasm, dedication and unconditional support in the data collection and the recruitment process… without you I would not have made it through… sorry for the extra work Zoe and I wish you all the best

Thank you to the foundation dentists who took a part in data collection and participated in the focus group… thank you so much for your time, thoughts and insights… I’m sure your voice will make a change

From the bottom of my heart, I would like to express my biggest thanks to my wife Ohud, thanks for taking care of me….without you in my life, I simply couldn’t have done this…I promise you, I will now take all the papers off the bedroom!

For my children (Joury, Jana and Mohammed)… apologise for being ‘grumpy’ sometimes!... you were my real inspiration… without you, I would have stopped these studies a long time ago

And thanks to my parents (Hamdan and Muznah) and my family for their support and prayers… we will be together soon
Abstract

Background:

Placement of high-quality restorations to restore carious primary molars is possible, though technique sensitive. Consequently, Renewal MI composite, which potentially needs no local anaesthesia or drilling, was developed.

Aims:

First, to assess the ability of the Renewal MI, with and without adhesives, to bond to sound bovine dentine and to inhibit the activity of the matrix metalloproteinase (MMP). Second, to investigate the clinical experience of GDPs to restore carious primary molars and the long-term fate of the used restorative materials. Last, to explore the attitude and willingness of foundation dentists (FDs) to treat child patients and their treatment approaches.

Methods:

To investigate the ability of the Renewal MI to form resin tags into sound bovine dentine; extracted bovine teeth were used. ISO 29022:2013 instructions were followed to test the Macro-Shear Bond Strength (SBS) of the Renewal MI, with and without adhesives. A fluorescent probe (EnzCheck Collagenase Assay Kit) was used to check the activity of MMPs under Confocal Light Scanning Microscopy (CLSM).

To investigate the most common restorations placed and their long-term outcome, a retrospective review of child patients' records, from eight GDP dentists in London, was undertaken.
The willingness of eight dentists to restore carious primary molars and possible barriers in general dental practices was explored through a focus group.

**Results:**

SEM of Renewal MI, without adhesives, showed no resin tags formation and large gaps with sound bovine dentine. Furthermore, Renewal MI, without adhesives, failed to achieve proper adhesion to sound dentine. However, with adhesives, it showed statistically significant SBS (16.8MPa), which was comparable to Z250 (18.4 MPa).

CLSM images suggested Renewal MI was able to inhibit MMPs activities with or without adhesives.

The GDPs’ audit revealed that GIC were most commonly used for carious primary molar teeth (75.8%). On up to three years follow-up, one third of the GIC restorations failed and needed replacement.

The FDs were usually happy to offer PMCs as the first treatment option for multi-surface carious primary molars. GIC restoration was their first alternative option.

**Conclusion:**

Renewal MI, requires an adhesive to gain bonding to sound dentine. GIC restorations were the treatment of choice for carious primary molars among GDPs surveyed, but had high failure rate on long-term follow-up. In contrast most participating FDs claimed that PMCs would be their first treatment option.
Dental caries is one of the most common chronic oral diseases that affect humans. It is a non-communicable disease that is caused by oral microorganisms that are able to ferment sugars in the diet and produce acids that are able to demineralise hard dental tissues (Machiulskiene et al., 2020). For decades, it has been recognised by the World Health Organisation (WHO) as a worldwide problem and it was estimated that more than 500 million children have caries in their primary teeth (Peres et al., 2019). Hallett and O'Rourke (2006) reported that the prevalence of early childhood caries was 60-90% worldwide. According to the last oral health surveys by the Public Health England (PHE), 10.7% and 23.4% of 3-year-old and 5-year-old children, respectively, have dental caries into dentine (PHE, 2019; 2020). What is more, only 10.3% of the carious primary teeth among 5-year-old children in England were restored (PHE, 2019).

Given that dental caries can be prevented and treated using restorations successfully on individual level, it remains a global public health problem that most teeth with dental caries remain untreated. Untreated dental caries has a profound negative impact on children. Pain is one of the main impacts on child quality of life. In the UK, according to the figures reported by the Children’s Dental Health Survey in 2003, about one quarter of 8 and 15-year-old children had reported dental pain (Nuttall et al., 2006). Furthermore, 30% of 12-year-old children had experienced dental pain. Similar figures have been reported by national surveys from different countries such as Thailand and the US (Krisdapong et al., 2009; Lewis and Stout, 2010). Other reported negative impacts of dental caries on children included sleeping and eating.
disturbances, time off school and affected social activities (Krisdapong et al., 2009; Prasertsom et al., 2020; Zaror et al., 2022).

Primary dental care has a responsibility to prevent and manage dental caries among children. However, for many reasons, children are still suffering the negative impacts of untreated dental caries and the numbers of referrals to the secondary and tertiary dental care units are increasing. NHS figures showed that there were more than 44 thousand surgical interventions under general anaesthesia to remove at least one tooth among children and young people in 2018/19 in England, which cost the NHS more than £40 million.

The COVID-19 pandemic has placed the NHS, including dental care, under an unprecedented pressure to already compromised services. Due to the instructions to stop all routine dental services, especially during the first lockdown between March 2020 and June 2020, and the subsequent restrictions and reduction in the care provisions mainly aerosol generating procedures (AGPs), children will now need to wait for longer while suffering pain and infection (Lyons-Coleman et al., 2021). As a result, it has been suggested that Minimal Invasive Dentistry (MID) might play an important role in the mitigation of COVID-19 risks and at the same time help dentists to treat more patients safely (Vivek and Abhishek, 2021).

At EDI, a group of researchers are working on a novel dental restorative material aimed to help dentists, especially GDPs, in treating more children. It is an easy to place material that is less technique sensitive and needs no drilling (non-AGP) or local anaesthesia use. This project is a part of this team’s
efforts to test this novel material, both at laboratory and clinic, regarding its safety and clinical effectiveness.
COVID-19 impact statement

The original plan for my research project was to complete a single arm randomised clinical trial (RCT) to test the safety and clinical effectiveness of a novel restorative composite material developed at EDI. Furthermore, a retrospective data collection of the treatment approaches and used restorative materials and their outcomes on up to three years follow-up of a convenience GDPs sample.

In March 2020 and following the announcement of the UK government regarding the national lockdown, the University College London (UCL) moved to online teaching and all on-site research activities stopped. Furthermore, in order to mitigate COVID-19 risks, UCL encouraged research students to move towards research projects alternatives were are not interventional and need no ethical approval. Doctorate and PhD students were excluded; however, the priority was on COVID-19-related studies. This state of uncertainty, not only at the UCL but worldwide, moved me from the original planned clinical trial to test the novel composite, to an alternative project research which included laboratory studies to test the properties of the novel dental material. However, laboratory studies at the Free Royal Hospital (RFH) were also restricted and there was no expected date for returning. The decision was made, after a discussion with my supervisors, to continue planning the laboratory studies and apply for the ethical approval of my other non-interventional clinical studies, including patients’ data and dentist interviews. The ethical application was a lengthy process as the priority was for COVID-19 related studies as mentioned above and the UCL was very restricted regarding risks assessment.
process. Luckily, in November 2021, I managed to start my laboratory studies as the restrictions were eased at the RFH.

During and after the pandemic, I have learnt that flexibility and resilience are important factors to success, not only as a dentist treating child patients but also in my career as a researcher. Furthermore, the pandemic has changed my plan towards laboratory studies, which might give me more research opportunities at future. Now, I have good experience regarding confocal laser scanning microscopy (CLSM) and scanning electron microscopy (SEM) of dental tissues which were not a part of my original plan.
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<th>Description</th>
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<tr>
<td>°C</td>
<td>Degree Celsius</td>
</tr>
<tr>
<td>2-HEMA</td>
<td>2-hydroxylmethyl methacrylate</td>
</tr>
<tr>
<td>4-META</td>
<td>4-methacryloyloxyethyl trimellitate anhydrous</td>
</tr>
<tr>
<td>AGP</td>
<td>Aerosol Generating Procedure</td>
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<td>ART</td>
<td>Atraumatic restorative treatments</td>
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<tr>
<td>BDA</td>
<td>British Dental Association</td>
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<tr>
<td>Bis-GMA</td>
<td>Bisphenol A-glycidyl methacrylate</td>
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<tr>
<td>BSPD</td>
<td>British Society of Paediatric Dentistry</td>
</tr>
<tr>
<td>Ca</td>
<td>Calcium</td>
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<tr>
<td>CHX</td>
<td>Chlorhexidine</td>
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<tr>
<td>CLSM</td>
<td>Confocal light scanning microscopy</td>
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<tr>
<td>DMP-1</td>
<td>Dentine matrix protein-1</td>
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<tr>
<td>DSPP</td>
<td>Dentine sialophosphoprotein</td>
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<td>EDH</td>
<td>Eastman Dental Hospital</td>
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<tr>
<td>EDI</td>
<td>Eastman Dental Institute</td>
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<tr>
<td>EDX</td>
<td>Energy dispersive X-ray</td>
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<tr>
<td>ES</td>
<td>Educational Supervisor</td>
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<tr>
<td>E&amp;R</td>
<td>Etch and Rinse</td>
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<tr>
<td>FD</td>
<td>Foundation Dentist</td>
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<tr>
<td>FTIR</td>
<td>Fourier-transform infrared spectroscopy</td>
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<tr>
<td>GA</td>
<td>General anaesthesia</td>
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<tr>
<td>GDP</td>
<td>General Dental Practitioner</td>
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<td>GDP</td>
<td>General Dental Practice</td>
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<td>GIC</td>
<td>Glass ionomer cement</td>
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<tr>
<td>Acronym</td>
<td>Definition</td>
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<tr>
<td>HA</td>
<td>Hydroxyapatite</td>
</tr>
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<td>HCL</td>
<td>Hydrochloric acid</td>
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<tr>
<td>ICCC</td>
<td>International Caries Consensus Collaboration</td>
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<tr>
<td>M</td>
<td>Molar</td>
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<tr>
<td>MCPM</td>
<td>Monocalcium phosphate monohydrate</td>
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<tr>
<td>MHRA</td>
<td>Medicine and Healthcare products Regulatory Agency</td>
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<tr>
<td>MID</td>
<td>Minimal invasive dentistry</td>
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<td>Mm</td>
<td>Millimetre</td>
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<tr>
<td>MMP</td>
<td>Matrix metalloproteinases</td>
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<td>NHS</td>
<td>National Health Services</td>
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<td>pH</td>
<td>Potential of hydrogen</td>
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<td>PHE</td>
<td>Public Health Education</td>
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<td>PLS</td>
<td>PolyLysine</td>
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<td>PMC</td>
<td>Preformed Metal Crown</td>
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<td>RCT</td>
<td>Randomised Clinical Trial</td>
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<td>RFH</td>
<td>Royal Free Hospital</td>
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<td>RMGIC</td>
<td>Resin modified glass ionomer cement</td>
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<tr>
<td>SBS</td>
<td>Shear bond strength</td>
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<td>SBU</td>
<td>Scotchbond Universal adhesive</td>
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<tr>
<td>SDCEP</td>
<td>Scottish Dental Clinical Effectiveness Programme</td>
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<td>SDF</td>
<td>Silver diamine fluoride</td>
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<tr>
<td>SE</td>
<td>Self etch</td>
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<td>SEM</td>
<td>Scanning electron microscopy</td>
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<tr>
<td>SOP</td>
<td>Standard Operating procedure</td>
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<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>TEGDMA</td>
<td>Triethylene glycol dimethacrylate</td>
</tr>
<tr>
<td>UCL</td>
<td>University College London</td>
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<tr>
<td>UDMA</td>
<td>Dimethacrylate</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>μm</td>
<td>Micrometre</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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Chapter 1: Introduction and literature review
1.1 **Tooth structures:**

Teeth have three distinct hard tissues: enamel, dentine and cementum. These hard tissues are formed through highly complex mechanisms which consist of cellular and biochemical processes which start at the intra-uterus phase and extend for several years after birth.

1.1.1 **Enamel:**

Dental enamel is produced by highly specialised cells, ameloblasts. It is the hardest tissue in the human body due its minerals content, more than 98%, and the rest is organic matrix and water. Due to its acellular nature when formation is completed, enamel lacks the capacity of regeneration; however, it is in a continuous and dynamic equilibrium of demineralisation and remineralisation processes (Abou Neel et al., 2003). Enamel is transparent in colour but its colour might change when its mineral formation or content is disturbed, e.g. caries. Enamel thickness varies significantly not only between primary and permanent dentitions but also within and between different teeth, genders and populations (Smith et al., 2006). The thickness of enamel among permanent teeth is approximately 1-2 mm compared to only 0.5-1 mm in primary teeth (Ten Cate, 2016).

1.1.2 **Dentine:**

Dentine is the most abundant dental hard tissue, which is covered by either enamel or cementum. With a composition of approximately 70% mineral and 30% organic matrix and water, dentine is less hard than enamel and similar to bone, but without the ability to remodel (Ten Cate, 2016). The organic matrix
of the dentine is formed of type I collagen and non-collagenous proteins, mainly dentine sialophosphoprotein (DSPP) and dentine matrix protein 1 (DMP1) (Goldberg et al., 2011). Similar to enamel, dentine is produced by end-differentiated and highly specialised cells known as odontoblasts. However, in contrast to ameloblasts, odontoblasts remain active throughout the lifespan of a human tooth, provided it remains viable (Ten Cate, 2016). Thus, when noxious stimuli threaten the pulp, it is protected by the production of secondary dentine. Therefore, odontoblasts exist permanently in pulp tissue and have the ability to help repair and regenerate dentine (Huang et al., 2011).

A wide variety of enzymes which are present in human dentine can play an important role, when activated, in the deterioration of proteins such as Type I collagen in the dentine collagen matrix. Such enzymes consist of either cysteine cathepsins or are members of the matrix metalloproteinases group (MMPs) which are calcium/zinc-dependent endopeptidases (Tjäderhane et al., 2013).

1.2 Differences between primary and permanent teeth:

Primary teeth are not merely small permanent teeth. In addition to sizes, primary teeth have unique morphologies, less enamel and dentine thickness, broad and more gingivally located contact areas, and larger pulp chambers. Furthermore, Sumikawa et al. (1999), in their laboratory study, concluded that significant differences in the microstructure of the dentine of primary teeth were detected. These differences included the high occurrence of the dentine micro-canals and their different location when compared to permanent teeth.
which, in turn, might affect caries progression and the quality of bonding into dentine. Even though many of these differences might complicate the restorations of primary teeth, some might be in their favour. For example, larger pulp chambers make it easier to perforate but also at the same time give primary teeth high potential to repair. What is more, the transit nature of primary teeth, and as they eventually will be replaced by their permanent successors, might give the dentist more flexibility regarding selection of restorative materials.

1.3 Dental caries:

In a joint workshop of the European Organisation for Caries Research (ORCA) and the International Association for Dental Research (IADR) Cariology Research Group, 16 experts in cariology agreed to define dental caries as ‘a biofilm-mediated, diet modulated, multifactorial, non-communicable, dynamic disease resulting in net mineral loss of dental hard tissues’ based on the published international scientific literature (Machiulskiene et al., 2020).

1.3.1 Aetiology of dental caries:

Dental caries is a complicated dynamic disease involving continuous interactions between the microbial biofilm (plaque), tooth structures and fermentable carbohydrates in the presence of predisposing and protective factors. Over the years, several hypotheses were proposed to explain the aetiology of the dental caries.

Based on the work of Black (1884) and Miller (1890), Loesche (1976) suggested ‘The non-specific plaque hypothesis’ that concluded dental caries
is caused by microflora present in dental plaque. Then, the ‘Specific Plaque Hypothesis’ has suggested that a small number of species within the biofilm, particularly S. mutans and S. sobrinus, were responsible for carious lesions which could, therefore, be prevented by their eradication.

More recently, an ecological hypothesis became more popular whereby the environmental changes in the oral cavity, which lead to a significant modification and overgrowth of particular, more cariogenic, microflora and subsequent shift in their metabolic activities and disturbances in the stability of the tooth surface, balance towards net mineral lost rather than remineralisation (Marsh, 1994; Takahashi, 2005; Takahashi and Nyvad, 2008; 2011).

1.3.2 Caries into enamel:

The first component of the tooth to be impacted by caries is dental enamel, as this is the external covering. Damage to enamel can be quite fast. It has been suggested that, when dental plaque remains undisturbed for about two weeks, this can lead to the emergence of a non-cavitated “white-spot lesion” on the surface of the enamel. Such lesions are initially non-cavitated but can progress to become cavitated. Furthermore, after a period of three to four weeks, an opaque and dull lesion appears on the surface of the enamel, which can be seen even without air drying (Kidd and Fejerskov, 2004).

The early stages of dental caries in enamel might be successfully managed only with prevention, mainly fluoride, and diet control. However, in cases where irreversible breakdown through enamel happened, restoring the
cavities with fillings might be recommended, especially when the control of the surface plaque is needed.

1.3.3 Caries into dentine:
When dental caries continues undisturbed, further damage to the underlying layers of human teeth is expected. As human dentine contains fewer inorganic components compared to enamel, caries into dentine might be faster. What is more, the sudden collapse of dentine collagen matrix after inorganic part demineralisation might also accelerate cavities formation. Several enzymes in dentine might also have important roles in the destruction of the organic component of dentine. These enzymes involve the collagenolytic enzymes, cysteine cathepsins and, most importantly, matrix metalloproteinases (MMPs). They are usually present as inactive enzymes activated by acids production during caries progress. There is increasing thought that host-derived MMPs play an important role as a mediator in the process of degrading of the extracellular matrix (ECM) components (Tjäderhane et al., 1998; Hannas et al., 2007); however, the pathological roles of the MMPs are not well-understood.

1.3.4 Dentine caries zones:
Carious dentine can be divided into two layers, an infected outer layer and an affected inner layer. Furthermore, both layers also can be divided into different zones (Marshall et al., 1997). Pugach et al. (2009) reported that four zones of carious dentine have been identified when they used Caries Detector staining technique. What is more, they have reported that each layer has its unique
mineral contents, mechanical properties and microstructural characteristics. A significant finding of their study is that the most outer layer of the demineralised dentine has about 25% of the mineral content of sound dentine and they concluded that this might encourage maintaining carious dentine. However, affected mechanical and microstructural characteristics might affect the bonding of restorations into this layer. As a result, management of caries into dentine and how much of carious dentine should be removed before the restoration might present challenges to the treating dentists.

1.3.5 Prevalence:
Even though it is largely a preventable disease, dental caries is still one of the most common chronic diseases among human with worldwide failure to control. According to the estimation of the Global Burden of Disease Study 2017, more than 530 million children have caries of primary teeth. In a recent systematic review, the prevalence of early childhood caries varied globally and ranged from 23% to 90% in children at ≤71 months of age (Chen et al., 2019). In the UK, the latest statistics from PHE revealed that 23.4% of 5-year-old children in England had experience of dental caries with an average of 3.4 primary teeth were affected (PHE, 2019). These findings showed no continuing improvement since the last two surveys by the PHE.

1.3.6 The impact of dental caries:
Pain as a consequence of dental caries is well-documented. In the UK, the Children’s Dental Health Survey, 2013, reported that 18% and 15% of children aged 12 years and 15 years had experienced dental pain, respectively. In a
recent study that investigated the impact of untreated dental caries on children, more than half of the surveyed children, aged 4-9 years, reported dental pain (Banihani et al., 2018).

Other related negative impacts of dental caries on the quality of life of children have also been reported. These include difficulties in eating and brushing, disturbances in sleeping, time off school and negative effects on social interaction, emotions and general health (Banihani et al., 2018; Prasertsom et al., 2020; Zaror et al., 2022).

1.4 Management of carious primary teeth:
Management of dental caries is expensive and represents more than 5% of the total health expenditure in most developed countries (WHO). In the UK, the elective admission to hospital for teeth extraction, due to dental caries, under general anaesthesia, is the most common reason in the 6-10 year old age group. In England, in the Position statement released by the Royal College of Surgeons of England in 2019, nearly 78,000 children aged 5–9 years in 2015–2018 were admitted to hospital for dental treatment under general anaesthesia (Faculty of Dental Surgery, 2019). In England, the estimated cost of dental general anaesthesia for caries-related tooth extraction among children and adolescents was £35 million in the financial year 2014/15 (Local Government Association, 2016). Despite the well-reported positive improvements and outcomes among children and their families following general anaesthesia (Acs et al., 2001; Ridell et al., 2015; Knapp et al., 2017; Park et al., 2018), the increasing use of general anaesthesia in the UK for the treatment of highly preventable disease such as caries is of high concerns due
to its negative impacts. First, several studies reported that morbidity was high and children commonly experienced significant postoperative pain and bleeding after teeth extractions under general anaesthesia (Atan et al., 2004; Hosey et al., 2006a). Second, it is reported that a range of 37-52% of the children who had general anaesthesia for dental treatment showed signs of new carious teeth about six months after (Lawson et al., 2017). As a result, paediatric dentists tend to extract more teeth, even those which could be restorable, to avoid repeating general anaesthesia (Harrison and Nutting, 2000, Hosey et al., 2006b). Third, the high costs and special facilities needed for the general anaesthesia are among the most important burdens of dental caries on the NHS, as discussed above.

1.4.1 Restorative management of carious primary teeth:

When preventive measures of caries alone fails, caries must be controlled and managed to eliminate or at least reduce the risk of pain and sepsis. However, management of dental caries among child patients is largely different to adult patients and has many implications. Several factors should be taken in consideration before planning of caries management. This includes child cooperation and maturity, caries risk, parents’ motivation and access to dental services. As a result, a number of treatment approaches with different restorative materials have been proposed to restore carious primary teeth. The rationale of restoring carious primary teeth is ultimately to maintain primary tooth healthy and painless until it is exfoliated naturally. Furthermore, stopping caries progression, reducing plaque stagnation areas, maintaining tooth structure integrity and pulp health are also benefits of the restorative
management. However, restorative therapy is not without risks, for example, pulp exposure, restoration failure, recurrent lesions and damage to adjacent teeth are the most reported common drawbacks reported in the literature (Downer et al., 1999; Lenters et al., 2006). In addition, Berge et al. (2002) reported a significant correlation between child’s dental restorative experience and development of dental anxiety. The next part will discuss those approaches and different used restorative materials and their clinical performances.

1.4.2 Total caries removal and conventional restorations:
The management of deep carious lesions, which are close to a healthy dental pulp tissue, presents a challenge to dentists and is an area of controversy. The treatment approaches of such lesions range from total caries removal of all infected and affected dentine, through partial caries removal, into non-operative arrest/prevent of cariogenic activities. The old recommendation of the British Society of Paediatric Dentistry (BSPD) was to remove caries lesions and restore them with restorations as the optimal treatment approach to restore primary teeth with caries (Fayle et al., 2001). However, since the evidence showed that dental caries is not an infectious disease (Kidd, 2011), less invasive treatment approaches have evolved (Santamaría et al., 2020). Over the years, several dental materials have been developed and used to restore carious primary teeth. The next section will discuss the most commonly used restorative materials, their properties and clinical performance.
1.4.2.1 Dental amalgam:
Since it was introduced by Bell, an English chemist, in 1819, mercury-based dental amalgam restoration has been the most commonly used restoration in posterior teeth. Dental amalgam contains approximately 50% mercury and a mixture of metals such as silver, copper and tin (Mackey et al., 2014). Over the past decade, the use of dental amalgam has declined and been gradually phased-down globally after the Minamata agreement. The agreed regulation on mercury use by the European Parliament (2017), recommended that no dental amalgam should be used to restore deciduous teeth in children under 15 years, from the 1st of July, 2018 (British Dental Association, BDA).

1.4.2.2 Composites:
Since it was introduced in dentistry more than half century ago, resin-based composites are increasingly used, especially after the restrictions on the use of dental amalgam (Opdam et al., 2010). Chemically, composites consist of organic polymer matrix and inorganic filler particles in addition to Silane coupling agents, initiators and accelerators (Sakaguchi et al., 2019). Resin composites are usually classified according to the particles size due its impact on physical properties, aesthetic and polymerisation shrinkage. The larger particle size provides the higher strength and wear resistance; however, they will result in less aesthetics (Burgess et al., 2002).

Despite the continuous improvement in the resin composite, it remains a highly technique sensitive material when compared to amalgam and other available restorations. The success rate of composite is dependent on several factors, such as isolation, dentist experience and restoration size (Bernardo et al.,
As a result, resin composite might not be the restoration of choice among children where cooperation and proper isolation are challenges (Antony et al., 2008).

In primary molars, a recent systematic review of composite restorations concluded that RCTs showed evidence that occlusal composite restorations are more successful than proximal cavities and showed low annual failure rate (AFR) (Chisini et al., 2018). In a recent RCT and after 36 months follow-up, the survival rates of composite restorations in primary molars were only 57% for selective caries removal which increased to 81% for total caries removal (Liberman et al., 2020). Furthermore, they reported that proximal restorations and gingival bleeding during restoration were the main predictors for failure.

### 1.4.2.3 Glass-ionomer cements (GIC):

Since it was developed and launched into the dental market in the 1970s, GIC has gradually become an important alternative as an “easy-to-use” restorative material. Conventional GICs consist of polymeric water-soluble acid (e.g. polyacrylic acid, polymaleic acid and itaconic acid), basic fluoroaluminosilicate glass, and water which set via an acid-base reaction (Tyas, 2003). Apart from its less technique sensitive application process, GIC shows other important features, including reliable chemical bond to enamel and dentine, biocompatibility and fluoride release and uptake (Wiegand et al., 2007; Sidhu and Nicholson, 2016). However, available clinical trials regarding caries prevention effect as a direct effect of fluoride release of GIC restorations in primary teeth showed inconsistent evidence and further well-controlled clinical
trials are necessary to explore this issue in order to have more consistent evidence (Dias et al., 2018). On the other hand, compared to amalgam and composite resin restorations, conventional GICs have several disadvantages including high rate of wear, low fracture toughness and flexural and tensile strengths, which might affect the survival rates of GICs restorations, mainly at stress bearing areas (Almuhaiza, 2016). In an attempt to improve their physical and mechanical properties, high viscosity GICs were developed. With smaller glass particle size and an increase of the powder:liquid ratio, high viscosity GICs show significantly higher compressive strength and surface hardness, which improve wear resistance and solubility when compared to conventional GICs (Frankenberger et al., 1997; Guggenberger et al., 1998).

Clinical longevity of GICs as restorations in primary molars depends on a range of factors, operator skills, patients’ characteristics and cooperation, and the number of tooth surfaces involved (Chisini et al., 2018). Several systematic reviews have evaluated the survival rates of restorations in permanent teeth; however, only limited reviews concerned with primary dentition. A recent systematic review and meta-analysis investigated clinical performance of glass ionomer cement and composite resin in proximal restorations in primary teeth revealed that isolated clinical studies regarding the longevity of direct restorations in primary teeth show conflicting evidence, especially in occluso-proximal cavities, which might complicate the process of best restorative material selection for dentists (Dias et al., 2018). This systematic review concluded that both composite resin and GICs restorations in primary molars showed similar clinical performance, including failure rate, marginal adaptation, anatomical integrity and marginal discolouration. However, GICs
restorations exhibited significantly lower occurrence of secondary carious lesions especially with the resin-modified GIC used with rubber dam isolation.

The main reported reasons for failure of primary teeth restorations were secondary caries (36.5%) followed by restoration loss (19.6%) and marginal adaptation (15.6%) (Chisini et al., 2018). Nevertheless, they reported that the low number of studies included and the high number of subgroups/variations are important limitations of their review, emphasising the need for well-controlled RCTs addressing those relevant variables related to the longevity of restorations in the primary teeth. What is more, the review revealed that 45.2% of the included studies performed in dental school settings and 36% of the restorations were carried out exclusively using rubber dam, which might affect the chance to generalise its findings on primary dental care setting and GDPs. However, even though the effect of moisture control is considered a paramount factor for posterior teeth restorations’ success, especially occluso-proximal cavities, systematic reviews present conflicting evidence regarding the influence of isolation on the longevity of restorations (Cajazeira et al., 2014; Wang et al., 2021). Furthermore, the meta-analysis of different aspects of clinical performance of different restorations for primary teeth done by Dias et al. (2018) reported no significant differences between different types of isolation except for GIC restorations, which showed better results concerning the occurrence of secondary caries lesions.
1.4.2.4 Resin-modified glass-ionomer cements (RMGICs):

Resin-modified glass-ionomer cements (RMGICs) were introduced into dentistry in the late 1980s in an attempt to combine the advantages of both conventional glass ionomer cements and composites. RMGICs consist of fluoroaluminosilicate glass, polycarboxylic acid in addition to hydrophilic methacrylate monomer (HEMA) or Bis-GMA which are needed for the supplemental resin light cure polymerisation. In 2010, the results of the prospective long-term studies on the clinical performance of different restorations in primary teeth among primary care were published by Qvist et al. They reported that the 75% survival times, class II restorations, of compomer was the highest (4 years) followed by RMGIC and Amalgam (3.8 years). GIC restorations showed significantly poor survival time with only 1.4 years. Another published systematic review investigated the clinical performance and reasons for failure of seven different restorative materials used to restore primary teeth and reported success rates as high as 96.1% with Preformed metal crowns (PMCs) followed by RMGIC (93.6%), Compomer (91.2%), Conventional GIC (88.7%), Amalgam (82%), Composite (79.3%), and Metal-reinforced GIC (57.4%) (Chisini et al., 2018).

1.4.2.5 Preformed metal crowns (PMCs):

Since they were first described by Engel, in 1950, PMCs have become an invaluable option to restore primary molars with high success rate. Their clinical performance outperformed all other conventional restorations when PMCs were used to restore carious primary molars with two or more involved dental surfaces. In a Cochrane review (2015), they concluded that PMCs are
less likely to cause post-operative complications, such as abscesses or pain, when compared to other dental restorations (Innes et al., 2015). As a result, they are recommended as the treatment of choice in the UK National Clinical Guidelines in Paediatric Dentistry for extensive carious lesions (Kindelan et al., 2008). However, to be fitted, conventional PMCs will require local anaesthesia and tooth preparation which needs considerable child cooperation.

1.4.3 Minimal invasive restorations and sealing carious tissues:
Despite the highly reported success rates of conventional treatment approaches, including complete removal of carious lesions from the carious primary teeth, those traditional approaches have been challenged and more biological treatments, including partial or no caries removal, have been suggested (Ismail et al., 2013). The main goal for these biological approaches is to maintain dental tissues and pulp health to avoid invasive treatments that might need local anaesthesia and might not be practical among child patients. The suggested biological approaches rely on the principle of cavity tight seal over carious lesions to isolate the biofilm from the oral cavity/nutrients in order to arrest the caries. In the literature, several dental materials have been used successfully, including PMCs, for primary teeth, and composite resin or glass-ionomer mainly for non-cavitated lesions among both primary and permanent teeth.

Banihani et al. (2018), in a recent cohort study, concluded that both biological approaches of caries management at primary dentition, Hall technique PMCs or indirect pulp capping, and conventional approaches, including complete caries removal, with or without pulp therapy, are equally effective.
1.4.3.1 Enhanced prevention, fluoride:

Fluorides have been widely and successfully used for caries prevention for decades. Furthermore, fluorides might be used to manage dental caries by shifting the dental mineralisation balance into remineralisation side. The *Prevention and Management of Dental Caries in Children* guidance (2017), from SDCEP (Scottish Dental Clinical Effectiveness Programme) recommended ‘site specific prevention’ of initial carious lesions by using fluoride in order to arrest or at least slow down the process of dental caries to minimise the need for future restorative treatment of carious teeth. Furthermore, fluorides might also play an important role to arrest/slow down caries process in the symptomless healthy teeth with cavitated lesions among very young or uncooperative children. Gao et al. (2016), in their systematic review, concluded that 5% sodium fluoride varnish and silver diamine fluoride (SDF 38%) were effective in arresting caries into enamel with reported 63.6% and 65.9% of enamel remineralisation, respectively. What is more, a systematic review by Chibiniski et al. (2017) concluded that silver diamine fluoride (SDF 38%) is about 90% more effective in arresting caries among primary teeth, the quality evidence was graded as high quality, when compared to other treatments or placebo.

1.4.3.2 Hall technique:

Innes et al. (2015), in their randomised controlled trial 5-year results, concluded that ‘sealing in caries by the Hall Technique statistically and clinically outperformed General Dental Practitioners’ standard restorations, in the long term’. In a retrospective study investigated patient records to compare
the Hall technique to standard PMC preparation found that a success rate of 97% was observed with Hall technique compared to 94% success rate for conventionally prepared PMCs; however, the difference was statistically insignificant.

Even though the evidence supporting Hall technique has established its effectiveness to restore carious primary molars, several years might be needed for transfer of any novel healthcare approach from research study to daily clinical practice (Innes et al., 2016). Furthermore, limited clinical experience in placing PMCs during undergraduate studies in dentistry might highlight why graduate dentists prefer multi-surface direct restorations over PMCs. O’Donnell et al. (2018), in their survey, reported that only 16% of the participant dentists had placed one Hall crown in the previous 12 months and they concluded that further training, PMC availability and funding (at Band 2 in England and Wales) need to be addressed to encourage its use. What is more, Lakshmi et al. (2018) reported that Hall technique is a procedure that needs more clinical time compared to Atraumatic Restorative Technique ART and, in some cases, might need several visits to place orthodontic separators to facilitate PMC placement without crown preparation.

1.4.3.3 Atraumatic Restorative Technique (ART):
ART approach based on the minimal intervention philosophy includes mainly removal of the carious infected dentine and severely weakened enamel with hand instruments and then by restoration with a chemically cured dental material, usually high-viscosity GIC. A systematic review with meta-analysis
showed that ART presents similar clinical longevity to other treatment options when used for the management of single-surface cavities in both primary and permanent teeth (de Amorim et al., 2012). However, inconsistent evidence supporting the clinical longevity of GIC ART restorations in primary dentition with multi-surfaces cavities is available (Ruengrungsom et al., 2018). A Cochrane review concluded that low quality evidence advises that ART restorations of primary teeth might have higher failure risks compared to conventional restorations (Dorri et al., 2017).

1.5 Unmet dental needs:
The care index (CI) defines the proportions of carious teeth that have been managed by either extraction or restorations and is measured by the formula \[ CI = \frac{\text{filled (F)}}{\text{decayed (D)} + \text{missing (M)} + \text{filled (F)}} \] while the restorative index (RI) is defined as \[ \frac{\text{F}}{\text{D} + \text{F}} \]. The CI and RI reported by the PHE over the last three decades in the UK showed that the majority of primary teeth with caries are unrestored. In 2019, almost 80% of surveyed 5-year-old children in England had untreated caries lesion into dentine and only 10.3% had restored carious teeth and 10.7% had extracted teeth involving those admitted to hospital for treatment under general anaesthesia (PHE, 2019). Furthermore, the number of referred children for dental extraction under general anaesthesia (DGA) from the GDPs has been increased significantly during the last few years. As discussed earlier, unrestored carious teeth might have negative impacts on children and families. Dental pain, difficulties in eating and brushing, disturbances in sleeping, time off school and negative effects on social interaction, emotions and general health were the most commonly
reported negative impacts (Banihani et al., 2018; Prasertsom et al., 2020; Zaror et al., 2022).

1.6 Potential barriers and limitations to oral healthcare for children:

Children are one of the vulnerable groups who often face challenges to have access to the oral healthcare (Guay, 2004). What is more, evidence reported that certain groups among children, such as low socioeconomic status and medically compromised, have higher levels of dental caries but they are also less likely to have routine oral care, which might maximise the burden of dental caries on their oral health. According to the NHS data, the attendance rate to dentists, between Oct 2017-Sept 2018, was less than 50% among children in London. The next part will discuss the most common potential barriers to have dental care at the levels of the child, parents/carer, organisation and dentist.

1.6.1 Child-related barriers:

Dental anxiety among children is considered one of the most common barriers for dental care. It creates challenges not only for the child but also parents and dental team and can result in poor oral health outcomes as a result of dental treatment avoidance and behaviour management difficulties (Merdad and El-Housseiny, 2017). Dental anxiety might be a consequence of the child’s stage of psychological/personality maturity and development, or, in some cases, it might relate to parental dental anxieties. In a recent systematic review, they concluded that dental anxiety is common among children worldwide and the pooled estimate of dental anxiety prevalence among preschool children was
the highest, 36.5% (Grisolia et al., 2021). In the UK, the Children’s Dental Health Survey 2013 reported high prevalence of anxiety among children aged 12 and 15, 14% and 10%, respectively. Furthermore, specific treatment approaches including injections, drilling and extractions are also well-known sources of pain and dental anxiety among children (Humphris and King, 2011). As a result, the management of dental caries with treatment approaches that reduce or eliminate the needs for injections and drilling might play a crucial role in reducing child dental anxiety and the subsequent treatment avoidance.

1.6.2 Family-related barriers:
Children from families with low socioeconomic and educational levels were identified to be not only at higher caries risk but also facing more difficulties with regard to attending regularly their dentists. This could possibly be due to several factors. First, those children tend to have higher dental anxiety (Abanto et al., 2017) and subsequently poorer oral health, as discussed earlier. Second, even though dental treatment for children in the UK is free, those families might perceive dental health as a low priority compared to their daily life difficulties, which might make the indirect financial implications, such as taking time off work and transportation, significant barriers, especially when multiple visits are needed (Baldani et al., 2011; Amin et al., 2017).

1.6.3 Dentists-related barriers:
The GDPs are responsible for the treatment of the majority of children with dental caries. Therefore, they have the greatest impact on children’s oral health as they represent about 90% of the registered dentists in the UK (GDC,
Registration Statistical Report 2021). However, the lack of training and confidence in treating children among GDPs could be a barrier to maintain good oral health (Dao et al., 2005; Thomas et al., 2017). Furthermore, GDPs encounter several challenges when restoring the carious primary molars among child patients. These challenges include the additional difficulties faced when treating children and lack of appropriate remuneration for dentists to treat children in primary care. Tickle et al. (1999) in their study which investigated the fate of the carious primary teeth of children who regularly attend the general dental services found that only 29% of regularly attended 5-year-old children had restored carious teeth compared to worse figures among irregular attenders, with only 3% having restored carious teeth.

1.6.4 Organisational level barriers:

The majority of GDPs are independent contractors who can provide both NHS and private treatment. Up to 2005, GDPs who were working for the NHS were paid a fee-per-item of treatment. Then, they moved to a payment system based on units of dental activity where the GDP needs to complete a target number of dental activities per a year to be paid. Re-introduced financial incentives by the Department of Health have been adopted to encourage GDPs to treat children; however, the available evidence from the PHE surveys showed that no significant improvement has been achieved among the care index of children during the last decades.

Furthermore, the BSPD has raised concerns regarding the decreased numbers of specialists in paediatric dentistry. What is more, Robin Mills, in this report regarding the UK specialist paediatric dentistry workforce analysis,
concluded that children might face inequality of access to specialist paediatric dentistry care as 44% of the UK postal areas have no specialist paediatric dentists (Mills, 2020). In London, which represents only 16% of the population in England, about 45% of all speciality training posts in England are based (Health Education England, 2018).

1.6.5 Dental material limitations:
Regardless of whether teeth have been restored with composite amalgam or glass ionomer materials, they can sometimes fail. There are a number of reasons for this, one of the most common of which is micro-leakage at the edges of the restorations, which can result in recurrence of caries. The level of bacterial activity and growth at the tooth/restoration interface is, however, determined by the material used (Cazzaniga et al., 2015).

Microleakage is a frequent and unwanted phenomenon that might occur at the tooth/restoration interface and can lead to imperceptible movement of fluids, microorganisms, and nutrients between the cavity walls and the filling (Radhika et al., 2010). This can result in discolouration, recurrent (secondary) caries beneath the restoration, and the restored tooth becoming hypersensitive. The primary reason for this phenomenon was found to be differences in the thermal expansion coefficient between the filling and the structure of the tooth (Bullard et al., 1988). Furthermore, despite the huge improvement in resin composite restorations properties, restoration polymerisation shrinkage occurs. A greater incidence of recurrent caries continues to be evident in composite restorations of the posterior teeth, which
do not last as long as the amalgam (Moraschini et al., 2015). Furthermore, polymerisation shrinkage of resin composite restorations might result in either the material or the tooth fracturing, leading to discomfort and post-operative sensitivity (Shah et al., 2014). Consequently, clinicians need to be exceptionally well-trained in placing composite restorations and the control of moisture in the oral cavity needs to be exact. It can be especially difficult, even impossible, to ensure a totally dry cavity, complete removal of caries, and implement the multiple steps involved in placing a restoration in children.

Another well-reported limitation of some currently used dental materials to restore carious primary teeth is poor physical and mechanical properties. GIC showed mechanical properties that are below the standards required and they exhibit low fracture strength and wear resistance (Xie et al., 2000). Consequently, GIC restorations do not last as long as the other materials and might need to be replaced more frequently due to their high failure rates.

1.7 Bonding to tooth structure:

1.7.1 Bonding to enamel:

There are two mechanisms in which bonding to enamel can take place: first, chemical bonding to apatite and second is the micromechanical retention of resin tags on etched enamel surfaces. Currently, regarding the latter, the optimal approach to achieve is through demineralising enamel surface with highly concentrated phosphoric acid of 35% (generally, pH < 1.0). Following that, coating the etched enamel surface with primers and then adding resin
composite overlayers in order to achieve a considerable micromechanical bond to phosphoric-acid etched enamel.

Another used mechanism of bonding is self-etch strategy. In this technique, phosphoric acid etching of enamel is no longer needed and the acidic functional monomers that are incorporated in the self-etch primer are able to decalcify the enamel surface and allow the resin monomers to penetrate enamel surface to enhance the micromechanical bonding of the composite restorations. As a result, composite restorations will be less technique sensitive as it requires shorter clinical application time and fewer steps. When compared to phosphoric acid etching technique, self-etch strategy, in vitro, showed less bond strength to uncut enamel surfaces (Perdigao and Geraldeli, 2003). However, while the bond strength for certain self-etching systems to ground enamel surfaces is better, it still falls short of the reliability and strength of etch-and-rinse systems (Perdigao et al., 2005).

1.7.2 Bonding to dentine:
Due to its different microstructure and high organic and water contents, dentine has more complicated and more sensitive method of composite resin adhesion. The most widely accepted explanation for resin composite adhesion to dentine is the hybridisation theory first proposed by Nakabayashi et al. (1982). In this technique, phosphoric acid is used to demineralise the inorganic components of the dentine allowing the resin to penetrate the dentinal tubules forming resin tags that create the “hybrid layer” which is thought to be the
primary source for the micromechanical retention of the composite restoration (Gwinnett, 1993).

In addition to the previously discussed theory of hybridisation, researchers have described chemical bonding of the resin composite to the mineral and protein components of dentine (Di Renzo et al., 1994; Xu et al., 1997). What is more, reactions with bonding sites within dentine collagen may also occur with compounds containing carboxyl, hydroxyl, amido, and amino groups (Xu et al., 1997).

Similar to enamel, adhesion of resin composite is best achieved by using “etch-and-rinse” adhesive technique (Yoshiyama et al., 1998). However, the use of self-etching, self-priming adhesives and, more recently, self-etching self-priming resin composites to simplify their clinical application has become of great interest. Those adhesives and resin composites contain hydrophilic acidic monomers and acidic molecules with low pH that can etch and infiltrate into the dentine and create micromechanical retention of the resin composites (Spencer et al., 2007). However, studies showed that the resulting bond strength of those self-etching adhesives has lower bond strength when compared to the etch-and-rinse adhesive technique (Spencer et al., 2007).

1.7.3 Bonding to caries-affected dentine:

In recent decades, remarkable developments have taken place in dentine adhesive systems. Fusayama (1979), in their early research regarding diagnosis and management of carious dentine, reported two unique layers within carious dentine: an inner layer of affected dentine, and an outer layer of
bacterially infected dentine. The inner layer ‘caries-affected dentine’ should be preserved during caries management as it is not infected, partially demineralised, and physiologically remineralisable. Conversely, the outer layer “caries-affected dentine” is highly demineralised, physiologically unremineralisable, and contains irrevocably denatured collagen fibrils and an almost complete absence of cross-linkages. In a real clinical scenarios and following the partial caries removal approach, large sections of the cavity floor consist of caries-affected dentine and the bonding substrate is usually caries-affected dentine rather than normal dentine.

As a result, bonding of resin composite to caries-affected dentine is important for the restoration success. However, a small number of studies on bonding to caries-affected dentine is available and they have found that the bond strengths are weaker than those of normal dentine, regardless of whether this is an etch-and-rinse system or self-etch system (Ceballos et al., 2003; Doi et al., 2004; Nakajima et al., 2005). The most reported mode of failure was the cohesive failure at the bonding and dentine interface (Ceballos et al., 2003). The alterations in dentine chemical and morphological features due to caries process, including partial demineralisation, mean that dentine will be more vulnerable to acid etching, resulting in the creation of a deeper demineralised zone and thicker hybrid layers which, in turn, will compromise bonding to dentine (Doi et al., 2004; Nakajima et al., 2005).
1.8 Dental adhesive systems:

1.8.1 Etch and rinse adhesive systems:

The aim of applying phosphoric acid etchants to the surfaces of normal and caries-affected dentine is to entirely remove the smear layer, demineralise dentinal sub-surfaces, and expose the collagen fibrils to allow resin penetration. However, due to dentine unique properties, achieving this aim is a critical and sensitive step even for unaffected dentine. This will be harder to achieve with caries-affected dentine. Several factors have been suggested that might interfere with the formation of proper resin/dentine bonding. First, if the demineralised zone is too deep, it becomes much harder for the resin monomers to reach the bottom of the exposed dentine collagen matrix. Second, also within this demineralised zone, the penetration of adhesive resin monomers would have to compete with a greater quantity of water when compared to normal dentine. Third, higher water content among demineralised dentine might dilute the acid etchants and interfere with their ability to remove the smear layer and precipitated mineral deposits in the dentinal tubules. Furthermore, residual water might interfere with the conversion of the resin adhesive resulting in the adhesive monomers failing to polymerise as effectively as they should (Spencer et al., 2005).

1.8.2 Self-etch adhesive systems:

Similar to etch and rinse technique, lower bond strengths to caries-affected dentine compared to normal dentine are also evident in self-etch systems, while the hybrid layers in caries-affected dentine are thinner than those of etch-and-rinse systems, but thicker than those of normal dentine (Yoshiyama et al.,
Because demineralisation and penetration by resin monomers take place at the same time, there is less of a discrepancy between resin monomer penetration and the depth of the demineralised zone when self-etch adhesives are used. In the caries-affected dentine interface of one-step and two-step self-etch systems, light microscopy evaluation with Masson’s trichrome stain revealed more extensive areas in which the collagen was not encapsulated, suggesting that self-etch adhesives were unable to penetrate adhesive monomers fully into the demineralised zone (Erhardt et al., 2008).

In caries-affected dentine, the smear layer is thick and irregular, and, unlike normal dentine, seems to be augmented with organic components (Kunawarote et al., 2011). Therefore, even when it is etched with phosphoric acid, it is difficult to remove the haphazard collagen and/or the minerals trapped within the gelatinised collagen. Both the gelatinous layer and the haphazard collagen may impede the penetration of resin monomers and create a seal at the interface between resin and dentine that is imperfect (Wang and Spencer, 2002). Thus, the poor adhesion of self-etch adhesives to caries-affected dentine is compounded by the caries-affected dentine smear layer augmented with organic components.

1.9 Bonding durability to caries-affected dentine:
The resin-dentine interface is susceptible to aggressive factors such as thermal, mechanical, and chemical stresses, which might compromise the integrity of the resin composite restorations. As discussed earlier, few studies have been conducted on the durability of bonding to caries-affected dentine.
Among those that have been conducted, Erhardt et al. (2008) revealed that, when the interface was directly exposed to water for six months, bond strengths were reduced by caries-affected dentine irrespective of the adhesive systems used. This suggests that bonded interfaces of caries-affected dentine exhibit greater susceptibility to hydrolytic degradation than the bonded interfaces of normal dentine. What is more, study by Pashley et al. (2004) indicated that exposed and unprotected collagen within acid-etched dentine that is not fully resin-infiltrated is degraded by host-derived matrix metalloproteinases (MMPs) enzymes in the dentine matrix.

The penetration of fluid into the interface between resin and dentine takes place through dentinal tubules under continual hydrostatic pulpal pressure, and also through the dentine margin, may also play an important role in the adhesive durability. Thus, the durability of bonding between normal and caries-affected dentine may change when mineral deposits are present in dentinal tubules. Nakajima et al. (2006) found that the bond strength of a two-step self-etch system to normal dentine decreased significantly under continual hydrostatic pulpal pressure when stored for one month, but there was no comparable effect on caries-affected dentine. It may, therefore, be the case that the penetration of water into the interface is reduced due to the lower permeability of caries-affected dentine, which means that, when direct exposure to water close to the surrounding bonded enamel is absent, the interface will exhibit greater stability in the long term. When water fluxes from caries-affected dentine are absent, a more effective seal along the interface might at first be created by one-step self-etch adhesives (Tay et al., 2005). Over time, however, the water absorbed in the adhesive layer will result in the
resinous materials undergoing hydrolytic degradation, negatively impacting cohesion of the interface between the resin and dentine.

1.9.1 Effect of caries dentine removal on bonding strength:
How much carious dentine should be removed before restoring the tooth is controversial; however, many studies concluded that not all demineralised dentine should be removed. The International Caries Consensus Collaboration (ICCC) recommended that only soft, decomposed dentine should be removed till the firm, demineralised dentine is reached. They have defined soft dentine by ‘tissue that will deform when a hard instrument is pressed onto it and can easily be scooped up (hand excavator) with little force being required’ while firm dentine as ‘tissue that is physically resistant to hand excavation and some pressure needs to be exerted through an instrument to lift it’. In the literature, several methods have been proposed to remove soft dentine ranging from using only hand instruments to rotary burs. However, no method is considered the gold standard and removing of soft dentine is still subjective and relies on the dentist’s tactile sensation.

1.10 Development in dental composites:
Due to the restrictions that have been applied to restore primary teeth with amalgam, many dentists are concerned that current restorative alternatives need extra clinical time, more cooperation and higher costs. Despite its high success rates, PMCs are still not popular, especially among GDPs, and might need additional training, more time and special armamentarium. Resin composites become the dental material of choice; however, placing of
composite is a technique sensitive procedure which might jeopardise its clinical performance. During the last decades, extensive efforts by scientists worldwide have been underway to enhance resin composites’ clinical performance by improving their compositions and microstructure and simplifying clinical procedures to overcome their main drawbacks such as the need for meticulous wet isolation and high recurrent caries risk.

1.10.1 Self-adhesive composites:
In attempts to facilitate composite restoration use and eliminate extra steps that are time-consuming and technique sensitive, self-etching and/or self-adhesive monomers have been added to the resin composites to enable composites to etch, penetrate and potentially chemically bond to hydroxyapatite of the dental tissues (Poitevin et al., 2013). Currently, several companies, such as Vertise flow (Kerr), offer such composites for clinical use; however, limited studies and data on their properties and their bond strengths are available. As discussed before, available data showed that immediate bond strengths of self-adhesive composites into both intact and caries affected dentine were lower.

1.10.2 SMART composite (Renewal MI):
Since the 2000s, Eastman Dental Institute has started the development of novel composite material with enhanced properties. The final product, SMART (Self – etching, Mechanically strong, Adhesive, Remineralising, Tooth mimicking) composite is characterised by less technique sensitive, self-etching and bonding to both intact and carious tooth structures,
The final formulation of SMART composite (Renewal MI) consists of urethane dimethacrylate (UDMA) as the bulk monomers while diluent monomer is triethylene glycol dimethacrylate (TEGDMA) (Alkhouri, 2019). Furthermore, it includes camphorquinone and 4-META as photonitiators and self-adhesive monomers. In addition to different sizes of glass particles, SMART composite also consists of monocalcium phosphate monohydrate (MCPM) and polylysine (PLS) as remineralising agent and antibacterial agent, respectively. Different formulae of SMART composite have different concentration of MCPM and PLS. While F0-0 formula has no MCPM or PLS, F16-8 formula has 8wt% PLS and 16wt% of MCPM. The optimal formulation of SMART composite (Renewal MI) has 4wt% PLS and 8wt% of MCPM.

The enhanced Renewal MI composite has been effectively packaged in the form of compules where it exhibits strong stability and a shelf life similar to commercial composites. In vitro investigations at the EDI also demonstrated that, compared to commercial composites, Renewal MI exhibited better adaptation to the cavity wall, the formation of resin tags, and microleakage at the surface interface between the restoration and the structure of the tooth. Moreover, its rate of monomer conversion was greater than 75%, and the
modulus strength of 3.5GPa and biaxial flexural strength 120MPa were deemed sufficient. In addition, laboratory investigations revealed that, within just three days of placement, the Renewal MI composite inhibited MMP activity, stabilised caries activity and improved the process of remineralisation. Such properties could be the result of adding MCPM and PLS to the composite.

Notable laboratory improvements in bonding capacity, potential reinforcement of the interface between resin and dentine, and prevention against secondary caries could transform the way in which primary teeth with caries are restored.

In response to the positive results obtained from experiments regarding efficacy and safety, the first-in-human safety study of the Renewal MI composite was approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) in 2018. The sample comprised seven paediatric patients who were planning to have their carious primary molars extracted. The preliminary unpublished results indicated that all restorations remained intact until they were extracted, and no unpleasant reactions were reported, such as pain. Once extracted, the teeth were subjected to additional laboratory investigations. Radiographs of the teeth revealed strong adaptation of the restorations to the cavity walls. However, light microscopy images revealed gaps in the gingival floors of the proximal cavities. The authors recommended that, to ensure effective adaptation, future clinical trials should include the use of sectional matrices or celluloid strips.
1.10.2.1 Antibacterial & remineralising properties of Renewal MI composite:

Two novel agents, Poly-Lysine (PLS) and Monocalcium phosphate monohydrate (MCPM), were added to a standard composite filler of the new composite. PLS functions as an antibacterial molecule; therefore, it was added to the lattice to destroy residual bacteria at the interface between the substrate and restoration. This effect has been demonstrated previously in our laboratory tests (Lygidakis et al., 2020; Yaghmoor et al., 2020). The MCPM ability to remineralise the demineralised dental surface was also demonstrated previously (Panpisut et al., 2016). Together, both processes serve to minimise the risks related to the formation of micro-gap at the restoration/tooth interface and help to reduce the gap by minerals precipitation which will be enhanced by MCPM, thereby enhancing surface adhesion.

1.11 COVID-19 impacts:

Not only paediatric dentistry has been affected by the COVID-19 pandemic and its imposed challenges, almost all our life aspects have been affected, including health, education, social and finance. In England, according to the advice of the Chief Dental Officer (CDO), on the 25 March, 2020, all non-urgent dental care was postponed (NHS England). What is more, even when the dental services were resumed in June, the number of patients to be seen was restricted due to social distancing requirement and the need for additional personal protective equipment and procedures, especially with aerosol-generating procedures (AGPs). Furthermore, some families are still concerned
to seek dental treatment for their children, particularly when non urgent treatment is needed.

The interruption of routine oral care also involves reduced access, cancellation in some periods, to the elective dental care under general anaesthesia (GA), which was already struggling to cope with the increased number of referred children before the pandemic. As a result, more waiting lists and waiting times for GA are expected. The challenge post-pandemic is that not only paediatric patients are the ones who are desperately waiting for GA to be fully resumed, all other health surgical modalities will compete to catch up. The medical directors and clinical leads will decide upon the prioritised categories of GA; however, the concern is that paediatric dentistry might not be at the top of the list and a tough few months are expected ahead. As a result, paediatric dentistry might need more time for recovery compared to others specialties.

The COVID-19 pandemic and its negative sequences, without doubt, will have a significant impact on paediatric dentistry. Claire Stevens, BSPD spokesperson, reported that ‘Truth be told, we don't fully understand the full impact of 2020 yet’. Several innovative practices of Minimal Intervention Dentistry (MID) which usually need no AGP, are highly acceptable by parents and children, involve less clinical time and visits, and show promising clinical performance might play a crucial roles in the management of children with caries post-pandemic.

The interruption of routine dental care among both general dental practices and dental hospitals, including the cancellation and rescheduling of elective extraction of carious teeth among children under general anaestheti, will have
a significant impact on children’s oral health and place the dental care under huge pressure for the full resumption of routine dental care as before the pandemic. Adjustment to the dental care under the new norm might be recommended to compensate and alleviate the negative impact of COVID-19 on children’s oral health. This might include the use of novel treatment approaches and dental materials. Lyons-Coleman et al. (2021) recommended that general dental practitioners should be involved more in the management of the children with dental/oral diseases in order to minimise the strain on the paediatric specialist services and reduce the impact of oral diseases on children while they are waiting for specialised dental services. They have suggested several tips regarding diagnosis, management and referral criteria.

1.12 Statement of the problem:
Dental composite is the suggested ideal dental material for direct restoration, especially after the restrictions on using dental amalgam in children. However, placement of commercially available composite restoration is a technique-sensitive procedure that needs local anaesthesia and proper isolation, which could be tricky among children, especially at primary dental care settings. Furthermore, GIC restorations, which are the most used dental materials to restore carious primary teeth, show high failure rates. The novel composite Renewal MI (under development) has been suggested as a feasible alternative that could overcome these drawbacks of currently used restorative materials among GDPs, but it needs to meet specific laboratory properties and clinical safety/efficacy features before it can be approved for clinical use.
Following laboratory studies that showed promising results and the successful completion of phase I clinical trial of Renewal MI with no reported side effects, it is now the time for phase II clinical trials to test this novel composite efficacy in a randomly selected sample of child patients with dental caries. The planned trial was a single arm RCT and, as there were no available recent data from GDPs regarding the long-term clinical outcomes of dental restorations of carious primary molars (as a comparative), a retrospective data collection from GDPs practices was planned. Furthermore, as Renewal MI has no CE mark, ethical approval application was submitted to the Medicines and Healthcare products Regulatory Agency (MHRA). However, due to COVID-19’s impact on the ethical approval process and as the MHRA subsequently asked for further information regarding the ability of PLS in Renewal MI to penetrate the dentine, phase II clinical trial was postponed. As an alternative, laboratory studies that investigate Renewal MI properties were suggested and completed.

Renewal MI’s ability to bond, seal and form resin tags to carious dentine has been investigated widely in the department. On the other hand, its ability to bond to sound dentine was found limited. As a result, in this thesis, laboratory studies that investigate the ability of Renewal MI to bond to sound dentine were planned. These studies were intended to demonstrate the ability of Renewal MI to bond and establish resin tags formation to sound dentine with acid etching and use of commercially available adhesives (SBU and G-Bond).

Renewal MI showed high capacity to inhibit MMPs activity. However, no data are available on the effect of using adhesives prior to the application of
Renewal MI on its ability to inhibit MMPs activity. In order to test that, a laboratory study was planned and completed.

The available data regarding GDPs willingness to treat child patients with dental caries and the possible barriers are sparse. So, a focus group study was planned to investigate and find out the most common treatment approaches and used materials. These findings will help in the understanding of the GDPs’ behaviours and beliefs regarding dental restorative materials and give an insight as to whether the developed novel composite would be an attractive alternative and help GDPs treating more child patients or not.

1.13 Aim:

The general aim of the in vitro studies was to investigate the effect using commercially available adhesives (SBU and G-Bond) on the ability of Renewal MI to bond to sound dentine, compared to a group of commercially available dental restorative materials, and their effect on its ability to inhibit MMPs activity. The specific aims of each chapter were:

1) To evaluate the ability of the Renewal MI to seal dentine structures through resin tags, limit microgap formation and form a bond to sound bovine dentine (Chapter 2).

2) To evaluate the ability of the Renewal MI to inhibit the activities with and without adhesives, immediate and after 6 months (Chapter 3).

3) To explore GDPs’ willingness and views regarding current restorative practices to restore carious primary molar teeth and possible barriers (Chapter 4).
4) To explore the treatment approaches followed by a convenience sample of GDPs early in their training in London to restore carious primary molar teeth (Chapter 5).
Chapter 2: Adhesion to sound bovine dentine
2.1 Abstract:

Aim:

To evaluate the ability of the Renewal MI to seal dentine structures through resin tags, limit microgap formation and form a bond to sound bovine dentine.

Materials and methods:

Labial dentine surfaces of bovine dentine incisors were exposed using water-irrigated #220 grit SiC paper under water-cooling, then polished using a series of silicon carbide papers to form a smear layer. This layer was restored with Renewal MI (with and without adhesives) and commercial restorations (3M Z250 and ACTIVA with etch and SBU, Fuji II LC following 10% polyacrylic acid application and Vertise Flow applied following manufacturer instructions). Samples were sectioned, treated with acid and hypochlorite to expose the restoration-dentine interface and resin tags then dehydrated and sputter coated with gold/palladium before examination by SEM.

ISO 29022:2013 instructions were followed to test the Macro-Shear Bond Strength (SBS) of the Renewal MI, with and without adhesives, comparing to commercially available restorative materials, as mentioned above (n=10 for each test group). Samples were stored in deionised water once restored then incubated at 37°C for 1 day before testing shear bond strength.

Results:

Renewal MI showed no resin tags formation within sound bovine dentine. Treatment of Renewal MI / dentine interfaces when no adhesive was applied
resulted in microgaps of 6-50 µm. This was irrespective of light cure time (immediate or 60s after application to allow self-etch) or following 35% phosphoric acid etch use. When adhesives were used with Renewal MI or Z250 resin tags formed and no microgap.

Renewal MI, without adhesives, failed to bond to sound dentine. Conversely, with SBU and G-Bond adhesives bond strengths were 16.8 and 8.9 MPa respectively for Renewal MI and comparable with those with Z250, 18.4 MPa.

Conclusion:

Renewal MI exhibited limited capacity to bond to sound bovine dentine with no resin tags formation and large microgap at the restoration-dentine interface. However, when adhesives are used Renewal MI could show bonding capacity and resin tags formation comparable to Z250 (etch and bond).
2.2 Introduction:

Effective bonding of dental restorations with dentine is key for their retention and sealing of the restoration/dentine interface. With the increasing shift towards minimally invasive dentistry strategies, durable adhesion to dentine, without the need for macro-mechanical retentive features, might be the key factor in the longevity of these new strategies (Green & Banerjee, 2011). However, the achievement of effective adhesion is a critical and clinically sensitive step that can be easily compromised by dentine microstructure, organic components and moisture which lead to less durable resin-dentine adhesion (Breschi et al., 2008, Pashley et al., 2011). It has been suggested that ideal dentine adhesives should have the following characteristics; grant immediate and strong bonding to dentine, proper cavity seal to minimise the risk of recurrent caries and eliminate sensitivity, hinder bacterial and possible enzymatic degradation, and easy to use (Burke, 2004).

Adhesion depends on the infiltration of the resin into the dentine and the formation of a so-called ‘hybrid layer’ which represents the fundamental of the micromechanical retention of the resin restoration (Nakabayashi et al., 1991). Several factors might affect the resin infiltration into the dentine such as etching agent, caries depth and type of the resin monomers. Although there are some promising results regarding bonding capacity with simplified self-etching resin into dentine, ‘etch-and-rinse’ adhesive systems remain the gold standards due to their high and more reliable bonding into dentine (Spencer et al., 2007). De Munck et al. in their systematic review and meta-analysis reported bond strengths of self-etching resins with dentine between 9 and 45.3 MPa (De Munck et al., 2012). Despite reasonable reported bond
strengths of self-etching resins, they have shown higher permeability when they compared to etch-and-rinse adhesive systems which might raise concerns regarding their long term adhesion capacity (Spencer et al., 2007).

Microgaps formation at the restoration-dentine interface might be the most important variable that enhances the microleakage at the interface and ultimately leads to secondary caries formation (Nedeljkovic et al., 2015). It has been suggested that this gap should not be big enough to encourage cariogenic biofilm formation which has been reported to be more than 225 μm (Thomas et al., 2007) to only about 15 μm (Khvostenko et al., 2015). In a recent study by Maske et al., 2019, they concluded that 30 μm gaps at the restoration-dentine interfaces were enough to develop secondary caries irrespective the caries activities of the participants (Maske et al., 2019). However, to determine a gap threshold for secondary caries at the restoration-tooth interface might be too simplistic an assumption. It ignores other important variables related to the oral cavity and also to the restorative materials used. On the other hand, suggesting minimum gap width at the restoration-tooth interface that can harbour a biofilm and might lead to secondary caries might help in the prediction of a restorations clinical success.

Previous laboratory studies at UCL regarding Renewal MI penetration and sealing of demineralised dentine revealed promising results. However, limited data are available regarding its adhesive capabilities to sound dentine compared to commercially available restorations. Several tests are usually used to test adhesion to tooth structures but this chapter will focus on marginal
gap formation, resin tags formation, and Macro-Shear Bond Strength (SBS) Tests.

2.3 **Hypothesis:**

The null hypothesis is:

There are no differences in the ability of Renewal MI to form resin tags within dentine, marginal gap formation, and bond to sound dentine when compared to commercially available restorations.

2.4 **Aims and objectives:**

The aim of this study is to evaluate the ability of Renewal MI to adhere to sound dentine structures

Objectives:

1) Develop a bovine dentine model to test adhesive restorations as an alternative to human primary teeth

2) Compare Renewal MI, with and without adhesives, versus common commercially available restorations (3M Z250, ACTIVA, Vertise Flow and GIC Fuji II LC) regarding:

- Dentine/restoration interface microgap formation upon acid and hypochlorite application followed by vacuum drying and coating for SEM

- Resin tags formation

- Bond strength to sound bovine dentine
2.5 Materials:

2.5.1 Used teeth and storage:
Bovine incisors (Rocholl GmbH, Germany) were used to perform tests in this research instead of human teeth to reduce variability in results since many factors affect human teeth and render them not an ideal substrate. Furthermore, bovine teeth were used to avoid possible ethical complications related to human teeth collection and use.

Bovine teeth were stored in deionised water in the fridge and used within 6 months of extraction. All samples were stored in deionised water (dH$_2$O) before they are tested except when the teeth were mounted in epoxy resin where they have been left dry at room temperature for 24 hours to allow resin to be polymerised.

2.5.2 Chemicals used:
1) Formic acid (4M):
31.8mL of acid was added to 50mL of deionised water carefully and then topped with water to a final volume of 200mL.

2) Sodium hypochlorite (6%):
50 ml of the stock solution (12% sodium hypochlorite) was diluted to 100ml with deionized water.

3) Hydrochloric acid (HCL), 6 M.

4) Commercial restorative materials are detailed in table 2.1.
2.5.3 Armamentarium:
- Light-cure (Demiplus, Kerr, \(\sim 1500\text{mW/cm}^2\) light intensity).
- Metal flat plastic instrument by DentsplyTM to place and shape restorative materials.
- Automatic microtome Struers Accutom 50 was used to cut each tooth. The cut was performed at 2000 rpm, 0.350 mm/s speed and irrigation (Accutom-50; Struers Gmbll, Copenhagen, Denmark).
- Amalgamator
- Grinding machine (Struers Ltd., Denmark)
- Ultrasonic bath
- Balance

2.5.4 The imaging and equipment used for visualizing the samples:
- Scanning electron microscope (Zeiss EVO MA 10).
- Used with their designated software (ZEISS SmartSEM).

2.5.5 Training and intra-examiner calibration:
The student researcher had a formal training and professional/technical support regarding bovine teeth preparation, using cutting and grinding machines, and also software operation and calibration for SEM, CLSM and Image J. However, there was no intra-examiner reproducibility test was commenced.
2.6 Methods:

2.6.1 Dentine tubules observation:

2.6.1.1 Effects of phosphoric acid application time on bovine dentine microstructure:

In order to test the ability of 35% phosphoric acid gel to remove the smear layer and open the dentinal tubules, it was applied to exposed labial dentine surface of two extracted bovine mandibular incisors for different time, 15s and 40s.

Two extracted bovine mandibular incisors were selected. The labial dentine surfaces were exposed using water-irrigated #220 grit SiC paper (Stuers A/S, Ballerup, Denmark). Then, dentine surface was polished using series of silicon carbide papers #500, 1000, and finished with #1200 grit (figure 2.1). They were then rinsed thoroughly and placed in water in an ultrasonic bath for 3 minutes. They were etched with 35% phosphoric acid, one for 15 and the second for 40 seconds. Finally, both samples were dehydrated according to the UCL SOP (see below) and prepared for SEM.
2.6.1.2 The effect of phosphoric versus hydrochloric acid (HCL) on ability to expose resin tags and assess dentinal tubules orientation:

To assess dentinal tubules orientation and compare the effects of hydrochloric versus phosphoric acid application on the ability to expose resin tags, one bovine tooth was used. The labial surface dentine was exposed and polished in the same way as previous two samples. Then, dentine was restored with a composite restoration 3M Z250 (with etch and SBU) of 1 mm depth. This was placed over the exposed labial dentine surface following manufacturer instructions. The sample was then mounted in epoxy resin in an upright position with the incisal edge immersed in the epoxy resin. This was left for 24 hours in room temperature to allow the resin to set before removing samples from the mould (Figure 2.2). A cutting machine (Accutom-50; Struers GmbH, Copenhagen, Denmark) was used to cut the tooth into two identical samples with the restoration-dentine interface exposed. After cutting, one half
of the sample was etched with 6 mol/L of HCL for 25 seconds. The other half of the sample was etched using 37% phosphoric acid at the dentine/restoration interface for 15 seconds. Both were washed thoroughly with distilled water. Washing was also repeated after immersion in 6 % sodium hypochlorite for 3 minutes for deproteinization of the demineralised dentine-restoration interface. Resultant samples were dehydrated for Scanning Electron Microscopy (SEM) as detailed below.

Figure 2.2 A. Shows a sample with composite restoration covering the labial dentine and mounted in epoxy resin in an upright position with the incisal edge immersed in the epoxy resin. B. Red line shows the place where the samples were sectioned.
2.6.1.3 SEM imaging of restoration-dentine interface:

For SEM imaging, samples were dehydrated at room temperature in a series of graded ethyl alcohols, started with 70% for 15 minutes, then 90% for 15 minutes and ended with 100% for 10 minutes. For critical point dry, the samples were immersed in Hexamethyldisilazane (HMDS) in a foil cup for 5 minutes. Dried samples were mounted onto aluminium pin stubs, using blue tack. Finally, samples were sputter coated with gold/palladium before they were examined via SEM (Zeiss EVO MA 10) operating at 10kV.

2.6.2 Marginal microgap and resin tags formation:

2.6.2.1 Tooth surface preparation and the placement of restorations:

14 extracted bovine mandibular incisors were used. Samples were ground using P220 grit paper to expose an adequate flat surface of labial dentine then polished using series of silicon carbide papers #500, 1000, and finished with #1200 grit. Exposed dentine was restored with experimental and commercial restorations, of 1mm depth, according to the protocols and manufacturer instructions. Table 2.1 summarises the restorative materials used and the followed protocols and manufacturers' instructions for commercial dental materials. Restored teeth were mounted in epoxy resin in an upright position with the incisal edge immersed in the epoxy resin. These were left for 24 hours in room temperature to allow the resin to set before removing samples from the mould. Samples were then placed in a cutting machine (Accutom-50; Struers GmbH, Copenhagen, Denmark) and had the tooth cut into two identical samples to expose the restoration-dentine interface (figure 2.3).
Figure 2.3 A. Shows the exposed dentine-restoration interface (red line) after the sample was sectioned. B. Shows the three labial thirds of sectioned bovine tooth examined.
<table>
<thead>
<tr>
<th>Group</th>
<th>Dental material</th>
<th>Application procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Renewal MI only</td>
<td>The composite resin was placed on the prepared dentine surface and then immediately light-cured for 20s (Demiplus, Kerr, ~1500mW/cm² light intensity).</td>
</tr>
<tr>
<td>2</td>
<td>Renewal MI wait for 60 sec</td>
<td>The composite resin was placed on the prepared dentine surface, following 60s delay to allow self-etch it and then light-cured for 20s (Demiplus, Kerr, ~1500mW/cm² light intensity).</td>
</tr>
<tr>
<td>3</td>
<td>Renewal MI and acid etch for 15 sec</td>
<td>Dentine was acid etched for 15 sec with phosphoric acid 35% gel (Universal etchant, 3M ESPE) thoroughly washed and dried, Renewal MI was placed and then light cured for 20s (Demiplus, Kerr, ~1500mW/cm² light intensity).</td>
</tr>
<tr>
<td>4</td>
<td>Renewal MI and SBU</td>
<td>Dentine was acid etched for 15 sec with phosphoric acid 35% gel (Universal etchant, 3M ESPE) thoroughly washed and dried. Then bonding agent (Universal Scotchbond adhesive, 3M ESPE) was applied on etched surface and rubbed for 20s, air-spread for 5s then light-cured for 10s (Demiplus, Kerr, ~1500mW/cm² light intensity). Finally, Renewal MI placed and light cured for 20s.</td>
</tr>
<tr>
<td>5</td>
<td>Renewal MI and G-Bond etch and rinse</td>
<td>Dentine was acid etched for 15 sec with phosphoric acid 35% gel (Universal etchant, 3M ESPE) thoroughly washed and dried. Then bonding agent G-Bond (GC Corp, Tokyo, Japan) was applied on the dentinal surface, left undisturbed for 10 seconds and dried with a strong blast of air for 5 seconds then light-cured for 10s. Finally, Renewal MI was placed on the dentine light cured for 20s (Demiplus, Kerr, ~1500mW/cm² light intensity).</td>
</tr>
<tr>
<td>Step</td>
<td>Procedure</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>6</td>
<td>Renewal MI and G-Bond self-etch (SE)</td>
<td>G-Bond SE (GC Corp, Tokyo, Japan) was applied on the dentinal surface, left undisturbed for 10 seconds and dried with a strong blast of air for 5 seconds then light-cured for 10s. Finally, Renewal MI was placed on the dentine light cured for 20s (Demiplus, Kerr, ~1500mW/cm² light intensity).</td>
</tr>
<tr>
<td>7</td>
<td>F16-8 immediate</td>
<td>F16-8 SMART composite formula was directly placed on the dentine without acid etching or bonding then was light cured for 20s (Demiplus, Kerr, ~1500mW/cm² light intensity).</td>
</tr>
<tr>
<td>8</td>
<td>F16-8, wait 60s</td>
<td>F16-8 SMART composite formula was directly placed on the dentine without acid etching or bonding then waited for 60s before it was light cured for 20s.</td>
</tr>
<tr>
<td>9</td>
<td>F0-0 immediate</td>
<td>F0-0 SMART composite formula was directly placed on the dentine without acid etching or bonding then was light cured for 20s.</td>
</tr>
<tr>
<td>10</td>
<td>F0-0, wait 60s</td>
<td>F0-0 SMART composite formula was directly placed on the dentine without acid etching or bonding then waited for 60s before it was light cured for 20s.</td>
</tr>
<tr>
<td>11</td>
<td>Activa and SBU</td>
<td>Dentine was acid etched for 15 sec with phosphoric acid 35% gel (Universal etchant, 3M ESPE) thoroughly washed and dried. Then bonding agent (Universal Scotchbond adhesive, 3M ESPE) was applied on etched surface and rubbed for 20s, air-spread for 5s then light-cured for 10s (Demiplus, Kerr, ~1500mW/cm² light intensity). Finally, Activa was placed on the dentine and light cured for 20s.</td>
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<tr>
<td>12</td>
<td>GIC LC II</td>
<td>Applied GC Cavity Conditioner (10% polyacrylic acid) for 10 seconds and rinse. GIC restoration was applied and then 20 second light-cured (Demiplus, Kerr, ~1500mW/cm2 light intensity)</td>
</tr>
<tr>
<td>13</td>
<td>Z250 and SBU</td>
<td>Acid etching (15s dentine) with phosphoric acid 35% gel (Universal etchant, 3M ESPE) then thoroughly washing and drying. Then bonding agent (Universal Scotchbond adhesive, 3M ESPE) was applied on etched surface and rubbed for 20s, air-spread for 5s then light-cured for 10s (Demiplus, Kerr, ~1500mW/cm2 light intensity). Composite restoration was placed and light cured for 20s.</td>
</tr>
<tr>
<td>14</td>
<td>Vertise flow</td>
<td>Vertise Flow dispensed to the prepared dentine with a dispensing tip. Light cured for 20 seconds (Demiplus, Kerr, ~1500mW/cm2 light intensity).</td>
</tr>
</tbody>
</table>

Table 2.1 The restorative materials used for bonding tests, including resin tags formation and SBS test, and the details of the followed placement protocols.
2.6.2.2 SEM imaging of marginal microgap and resin tags:
After cutting, the samples were etched with 6M of HCL for 25 seconds and washed thoroughly and then immersed in 6 % sodium hypochlorite for 3 minutes for deproteinization of the dentine-restoration interface to expose resin tags. The samples were then thoroughly washed and ultrasonic clean for 3 minutes to remove any remnants. One half of each sample was then dehydrated and examined by SEM (Zeiss EVO MA 10) operating at 10kV as discussed above.

2.6.3 Macro-Shear Bond Strength (SBS) Tests:
ISO 29022:2013 instructions were followed. Details of tooth preparation, exposing bonding surface and testing procedure are detailed in the next section. Bovine mandibular incisors were used for this study. Teeth were divided into 13 groups (n=10) and restoration buttons placed to the exposed labial dentine as summarise in table 2.1. On average, the placement of each restoration took about one minute before they had been light cured except when different time was suggested as detailed in table 2.1. A plastic ring of approximately 3.7mm diameter and 2mm height was used to place the restorations before they light cured. Samples were then stored in deionised water once restored then incubated at 37°C for 24 hours before testing shear bond strength.
2.6.3.1 Tooth surface preparation and the placement of restorations for Macro-Shear Bond Strength (SBS) Test:

1) Teeth were mounted in self-cure epoxy resin horizontally with the labial surface facing upwards. Mounted teeth were ground using P220 grit paper then polished using P500 grit paper to expose a sufficient flat surface of labial dentine for the placement of restoration button as in Figure 2.4.

2) Then, samples (with exposed labial dentine) were kept in water at room temperature for 24h at least before applying restorations button. Bonding surface (labial dentine) was blot dried using filter paper. Plastic rings, about 3.7 mm in diameter and 2 mm height, were used to apply the restorative materials buttons to the exposed dentine surfaces (Figure 2.4). All restorations were applied according to the manufacturer instructions.

Figure 2.4 Mounted bovine tooth with exposed labial dentine before and after the application of the restorative material using plastic ring for Macro-Shear Bond Strength (SBS) Test.
3) Samples (with restorations buttons) were stored in water and incubated at 37°C for 1 day before testing shear bond strength.

4) Plastic rings were removed immediately before SBS test, sharp blade used.

2.6.3.2 Testing Macro-Shear bond strengths:
A Shimadzu Autograph testing machine (AGS-X, Kyoto, Japan) was used with crosshead speed 1mm/min. The adhesion surface was loaded with a parallel force using a sharp blade in contact with that surface until failure.

One-Way ANOVA and Tukey’s Post-hoc test was used in this study to compare the shear bond strength means of different restorative materials. The significance level was considered 0.05.
2.7 Results:

2.7.1 Dentine tubules observation:

2.7.1.1 Effects of phosphoric acid application time on bovine dentine microstructure:

SEM images of bovine dentine etched for 15s, with phosphoric acid 35% gel (Universal etchant, 3M ESPE) showed that the smear layer was removed leaving opened dentinal tubules with a well-defined circumference and uniform appearance (Figure 2.5). Image J software (calibrated) used to count the number of dentinal tubules (tubules/mm\(^2\)), measure the tubules diameter of 5 randomly selected tubules and the intertubular dentine width from the SEM images. The number of tubules was 7315 tubules/mm\(^2\) while the tubule diameter mean was 4.8 \(\mu\)m. The average intertubular width was 3.7 \(\mu\)m.

![SEM image of bovine dentine](image-url)

Figure 2.5 Representative SEM image of the mid-labial surface of lower incisor bovine dentine following etch for 15s with phosphoric acid 35% gel (Universal etchant, 3M ESPE) then rinsing with water. Smear layer is removed and tubules are uniform and open with a regular arrangement.
Conversely, bovine dentine etched for 40s showed rough and scaly surfaces. There were still opened tubules but in addition there were precipitated particles and some possible collapse of the tubules (Figure 2.6). However, there were no obvious differences in the number or the size of the dentinal tubules.

2.7.1.2 The effect of phosphoric versus hydrochloric acid on ability to expose resin tags:

Figure 2.7 and 2.8 SEM images show the interface of Z250 (with etch and SBU)/ bovine dentine exposed through 15s of 35% phosphoric acid versus 25s of 6M hydrochloric acid. In both cases hypochlorite was subsequently used to remove demineralised dentine. The specimen treated by HCL gave a
clearer restoration-dentine interface with greater depth of dentine removal. HCl was therefore used in the following.

Figure 2.7 Representative SEM image of the Z250 (with etch and SBU) / bovine dentine interface following 15s exposure to phosphoric acid 35% gel (Universal etchant, 3M ESPE) then 6% sodium hypochlorite: the resin tags can be observed.
Figure 2.8 Representative SEM image of the Z250 (with etch and SBU) / bovine dentine interface following 25s exposure to 6 M HCL then 6% sodium hypochlorite: Greater depth of dentine removal allows easier observation of the resin tags.
2.7.1.3 The effect of dentine location on the tubule orientation:

Figures 2.9-2.11 provide representative SEM images of restored (Z250 with etch and SBU) bovine dentine at incisal, mid and cervical regions. The images indicate no significant difference in penetration of SBU or the angles of the tubules at the interface. The formed angles between the resin tags and the dentine surface were ranging from about 33-45 degree. There was no area where the resin tags were at right angle to dentine, irrespective the dentine location.

Figure 2.9 Representative SEM image of the Z250 (with etch and SBU) / bovine dentine interface (incisal labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: Resin tags at about 33 degree to the dentine surface.
Figure 2.10 Representative SEM image of the Z250 (with etch and SBU) / bovine dentine interface (middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: Resin tags at about 45 degree to the dentine surface.

Figure 2.11 Representative SEM image of the Z250 (with etch and SBU) / bovine dentine interface (gingival labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: Resin tags at about 45 degree to the dentine surface.
2.7.2 Microgap and resin tags formation with intact bovine dentine:

SEM was used to evaluate the ability of several commercially available restorations and different formulae of SMART composites, including Renewal MI, to infiltrate dentinal tubules and form resin-tags into sound dentine surfaces of bovine teeth.

Representative SEM images showed that all restorations, when adhesives were used, demonstrated resin-tags into sound bovine dentine, more than 20 μm long, except with G-Bond adhesive where no obvious tags were observed. All other materials with no adhesives, including all different formulae of SMART composite, showed no resin tags at the dentine-restoration interfaces (Figures 2.12-2.25).

All formulae of SMART composites, including Renewal MI, and Vertise flow showed gaps formation at the restorations-dentine interfaces. However, all restorations, including SMART composite, Activa and Z250 with adhesives applied prior to restorations placement showed no gaps formation and clear resin tags. SMART composite showed clearly detectable gaps in 100% of the interfaces. The RMGIC, Fuji II LC (with Conditioner), showed small gap formation in a limited area along the restoration-dentine interface. Table 2.3 shows the results of gap formation measurements of the different used restorative materials. Representative SEM images of the restoration-dentine interfaces of the different restorative used materials are presented in Figures 2.12-2.25.
<table>
<thead>
<tr>
<th>Restorative material</th>
<th>Application protocol</th>
<th>Gap (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Renewal MI</td>
<td>Immediate light cured</td>
<td>6-8</td>
</tr>
<tr>
<td>2 Renewal MI</td>
<td>60 seconds wait before light cured</td>
<td>24-34</td>
</tr>
<tr>
<td>3 Renewal MI</td>
<td>15 second etch, rinse</td>
<td>40-50</td>
</tr>
<tr>
<td>4 Renewal MI and SBU</td>
<td>Etch, rinse and SBU</td>
<td>0</td>
</tr>
<tr>
<td>5 Renewal MI and G-Bond</td>
<td>Etch, rinse and B-Bond</td>
<td>Minimal*</td>
</tr>
<tr>
<td>6 Renewal MI and G-Bond SE</td>
<td>Self-etch G-Bond</td>
<td>Minimal*</td>
</tr>
<tr>
<td>7 F16-8</td>
<td>Immediate light cured</td>
<td>22-24</td>
</tr>
<tr>
<td>8 F16-8</td>
<td>60 seconds wait before light cured</td>
<td>30-36</td>
</tr>
<tr>
<td>9 F0-0</td>
<td>Immediate light cured</td>
<td>78-82</td>
</tr>
<tr>
<td>10 F0-0</td>
<td>60 seconds wait before light cured</td>
<td>22-28</td>
</tr>
<tr>
<td>11 Activa and SBU</td>
<td>Etch, rinse and SBU</td>
<td>0</td>
</tr>
<tr>
<td>12 GIC LC II</td>
<td>Apply GC Cavity Conditioner for 10 seconds and rinse</td>
<td>Minimal</td>
</tr>
<tr>
<td>13 Z250 and SBU</td>
<td>Etch, rinse and SBU</td>
<td>0</td>
</tr>
<tr>
<td>14 Vertise flow</td>
<td>Immediate light cured</td>
<td>30-34</td>
</tr>
</tbody>
</table>

*Limited separated areas with small gaps, < 2 micrometre, detected.
Figure 2.12 Representative SEM image of the Renewal MI (without etch or bond and immediate light curing) / bovine dentine interface (Middle labial third). The dentine surface was exposed to 25s of 6 M HCL then 6% sodium hypochlorite after restoration to remove its surface layer: No resin tags formation and about 6-8 µm microgap are observed.
Figure 2.13 Representative SEM image of the Renewal MI (without etch or bond but waited 60s before light cured) / bovine dentine interface (Middle labial third). 25s exposure to 6 M HCL then 6% sodium hypochlorite was used to dissolve the tooth surface: No acid or hypochlorite stable resin tags were observed but instead a 24-34 μm microgap containing a polymer-like layer (Red arrow).
Figure 2.14 Representative SEM image of the Renewal MI (with 15s etch, phosphoric acid 35% gel, and no bond) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: No resin tags formation, 40-50 µm microgap and thick resin phase separation (Red arrow).
Figure 2.15 Representative SEM image of the Renewal MI (with etch and SBU) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: The resin tags can be observed with no microgap.

Figure 2.16 Representative SEM image of the Renewal MI (with etch and G-Bond) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: no resin tags can be observed and limited minimal microgap (Red arrow).
Figure 2.17 Representative SEM image of the Renewal MI (with G-Bond SE) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: no resin tags can be observed and limited minimal microgap (Red arrow).

Figure 2.18 Representative SEM image of the F16-8 formula (without etch or bond and immediate light curing) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: No resin tags formation and about 22-24 \( \mu m \) microgap.
Figure 2.19 Representative SEM image of the F16-8 formula (without etch or bond but waited 60s before light cured) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: No resin tags formation, about 30-36 µm microgap and thick resin phase separation (Red arrow).
Figure 2.20 Representative SEM image of the F0-0 formula (without etch or bond and immediate light curing) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: no resin tags formation, 78-82 μm microgap and thin layer of resin phase separation (Red arrow).

Figure 2.21 Representative SEM image of the F0-0 formula (without etch or bond but waited 60s before light cured) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: no resin tags formation, 22-28 μm microgap and resin phase separation (Red arrow).
Figure 2.22 Representative SEM image of the ACTIVA (with etch and SBU) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: The resin tags can be observed with no microgap.

Figure 2.23 Representative SEM image of the Fuji II LC (with 10% polyacrylic acid Conditioner) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: no tags can be observed and minimal microgap (Red arrow).
Figure 2.24 Representative SEM image of the Z250 (with etch and SBU) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: The resin tags can be observed with no microgap.

Figure 2.25 Representative SEM image of the Vertise Flow (without etch or bond and immediate light curing) / bovine dentine interface (Middle labial third) following 25s exposure to 6 M HCL then 6% sodium hypochlorite: No resin tags formation and about 30-34 µm microgap.
2.7.3 Shear bond strength:

Table 2.4 shows the average bond strengths and standard deviations of several dental materials to sound bovine dentine, following immersing of the samples in deionised water at 37°C for at least 24 hours, including different formulae of SMART composite.

All formulae of SMART composites, without adhesives, failed to achieve proper adhesion and the composite button debonded, either before or during plastic ring removal, before shear bond strength test. Q-Q Plots assumed normal distribution of the data. One-way ANOVA revealed significant differences between tested groups (p ≤ 0.05). Tukey’s test showed that all used restorative materials that involved acid etching and SBU, including Z250, RMI and ACTIVA, demonstrated significant higher bond strength comparing to all other restorative groups (p ≤ 0.05). Renewal MI (G-Bond SE), Renewal MI (etch and rinse, GB), and RMGIC (Fuji II LC with conditioner) showed comparable values of shear bond strength to bovine dentine, 8.91, 7.86 and 7.73MPa, respectively which were statistically insignificant (p > 0.05). Vertise flow showed low shear bond strength, 3.79MPa, which was significantly lower than all other used restorative materials except SMART composites without bonding (p ≤ 0.05). Figure 2.26 compares the shear bond strength of the different used restorative materials to sound bovine dentine.
<table>
<thead>
<tr>
<th>Restorative material</th>
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<th>Gap (µm)</th>
</tr>
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<td>1 Renewal MI</td>
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</tr>
<tr>
<td>3 Renewal MI</td>
<td>15 second etch, rinse</td>
<td>40-50</td>
</tr>
<tr>
<td>4 Renewal MI and SBU</td>
<td>Etch, rinse and SBU</td>
<td>0</td>
</tr>
<tr>
<td>5 Renewal MI and G-Bond</td>
<td>Etch, rinse and B-Bond</td>
<td>Minimal*</td>
</tr>
<tr>
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<td>14 Vertise flow</td>
<td>Immediate light cured</td>
<td>30-34</td>
</tr>
</tbody>
</table>

Table 2.3 Shows the results of microgap formation measures of the different used restorative materials. * Limited separated areas with small gaps, < 2 micrometre, detected.
Figure 2.26 Shear bond strength test results of Renewal MI (with adhesives), Z250, ACTIVA, Vertise flow and RMGIC (Fuji II LC and Conditioner), n= 10 samples for each tested group.
2.8 Discussion:

Reliable bonding of composite resin to dentine is of profound importance in restorative dentistry. What is more, in primary teeth, this might be of an extra importance as primary teeth enamel is thin and bonding to dentine might be key for success. The ability of resin to form an acid resistant hybrid layer seems to be dependent on the ability of the resin to penetrate the dentinal surface (Cassandra and McCourt 1993; Sundfeld et al., 2005). Since they have been introduced in restorative dentistry, self-etching adhesives and restorations, their ability to etch, penetrate and effectively bond into dentine has been questioned. However, due to their advantages, such as single step application, less technique sensitive and shorter clinical time, they are of a great interest, especially in paediatric dentistry.

In this study, lower incisors bovine teeth were used to standardise the samples and minimise the risk of variation of the structural, chemical and mechanical properties of each tooth. Few studies have presented information on the use of bovine teeth as an alternative to human primary teeth in bonding studies. Bovine teeth are suggested as a reliable alternative to human teeth in dental bonding studies as the results of this experimental study revealed comparable results to previously performed similar studies on extracted human teeth. Bovine teeth are easy to obtain and collect as they need less ethical consideration and also possibly show less variability and are less affected by genetic influences, when compared to extracted human teeth as it is possible to standardise the age, diet and environment (Soares et al., 2016). Schilke et al. (2000) concluded that there were no statistically significant differences in the number and diameter between bovine coronal dentinal tubules and human
primary and permanent third molar teeth. Fröhlich et al. (2021) reported that bovine dentine show some differences in the chemical composition and structure when compared to human primary teeth dentine, but these differences do not affect the bonding strength of adhesives and they concluded that bovine teeth can be used as reliable alternative of human teeth.

The preliminary findings of this study confirmed that the acid etching of bovine dentine for 15s or 40s were able to remove smear layer and open dentinal tubules. However, different etching times with the phosphoric acid, at the same concentration, would result in different dentine surface micro-morphology. This observation is consistent with the results reported from studies on human dentine (Brajdić et al., 2008; Gateva et al., 2016). Prolonged acid etching created less clean dentinal surface with obvious precipitants. These residues would be parts of the dissolved smear layer and inorganic precipitates. On the other hand, the residue might be silica particles that are usually added to the etching gels, to make it thicker, which is not entirely removed with rinsing (Perdigão et al., 1994).

In this study, when the number of bovine dentinal tubules, per square millimetre, was compared to the reported previous studies (bovine and human primary teeth), using Image J, the number was considerably smaller. The reported numbers of dentinal tubules per square mm² for both bovine and human primary teeth varied significantly between studies. Lopes et al. (2009) reported that bovine dentine had significantly fewer number of tubules (15,964) than in human dentine (22,329) irrespective of the location. Conversely, Sumikawa et al. (1999) reported smaller number of dentinal
tubules in human primary teeth, which ranged from 4,400 tubules/mm² to 11,800 tubules/mm² depending on the dentine location. On the other hand, considerably higher average number of dentinal tubules in primary teeth was reported, 124,329 per mm² (Lenzi et al., 2013). However, due to the sample size, lack of standardisation of the dentine location and lack of intra-examiner calibration, it was impossible to draw a conclusion and further studies with larger size, standardisation and intra-examiner calibration are needed.

Results for dentinal tubule diameters and intertubular dentine width were comparable to the means described in the literature. Lopes et al. (2009) found that the dentine tubules diameter in bovine teeth range from 4.21 μm (superficial dentine) to 3.14 μm (deep dentine) which were significantly larger than dentine tubules diameters in human primary teeth However, different studies have different etching protocol which might have a significant impact on the diameters of the tubules and subsequently the intertubular dentine width. As a result, larger sample size and more standardised studies are needed.

Several studies have revealed that the orientation of the dentinal tubules at the dentine-restoration interface plays an important role in the formation of the resin tags and the hybrid layer formation (Banomyong et al., 2007; Pongprueksa et al., 2014). When the bonding interface is perpendicular to the dentinal tubules, the resin will flow more inside the dentinal tubules and the resin tags will be easier to be observed (Phrukkanon et al., 1999). However, when the bonding interface is parallel to the orientation of dentinal tubules, the hybrid layer will be thinner and hard to be observed under SEM. It has been
found that microscopic resin tags observation of self-etch adhesive is quite
dependent on the direction of the dentinal tubules (Schupbach et al., 1997;
Phrukkanon et al., 1999). As a result, the observed resin tags were long and
clear when the dentinal tubules orientation were favourable, up to 100 μm in
length.

On the other hand, the bonding strength values of adhesives when the bonding
surface was parallel to the dentinal tubules were significantly higher than when
the bonding surface was perpendicular to the dentinal tubules (Cehrel and
Akca, 2003; Eliguzeloglu and Omurlu, 2012; Guo et al., 2018). It has been
suggested that the migration of water in the dentinal tubules and the higher
mineral content of the peritubular dentine than the inter-tubular dentine at the
perpendicular orientation might compromise the bond strength (Oilo, 1993;
Eliguzeloglu et al., 2012).

In view of the results obtained with 6M HCl, which gave a clearer restoration-
dentine interface with greater depth of dentine removal, it seems that this effect
was due its low pH and pKₐ. HCL acid has a pKₐ of -7.0 while phosphoric acid
has pKₐ of only 2.16. As a result, HCL acid has more free proton (H⁺)
compared to 35% phosphoric acid (about 6M). Furthermore, it has been
reported that 0.39M HCL has similar pH to 7M phosphoric acid (Okamoto et
al., 1991), which indicates that 6M HCL has much lower pH.

The null hypotheses were rejected as Renewal MI showed significant
differences in the formation of microgap, resin tags and bond strength to sound
dentine when compared to the conventional restorative materials except when
adhesives were used. These findings are in accordance with results of
previous reports, which concluded that self-etch adhesive systems showed questionable adhesive capability into sound dentine (Poitevin et al., 2013). The etch-and-rinse adhesives systems remain without doubt the gold standard for composite resin bonding into sound dentine (Spencer et al., 2007). In order to allow the penetration of adhesive monomers into dentinal tubules, the permeability of dentine should be increased first through acid etching process (Nakabayashi et al., 1982). Pashley et al. (2011) reported that the separate step of dentine etching is needed to remove the surface smear layer in addition to about 5–8 μm of the mineral contents of the dentine surface, which, in turn, might result in the formation of the optimised hybrid layer at the restoration-dentine interface. On the other hand, self-etching adhesive resin systems contain weak acids, which might be not be strong enough to remove the smear layer, affecting the permeability of the dentine.

It should be highlighted that the formation of the resin tags as well as formation of the hybrid layer and its thickness were not influenced by the increasing time of SMART composites applications. In agreement with these findings, Sundfeld et al. (2004) stated that prolonged application of self-etching adhesive, Adper Prompt L-Pop, had no significant effect on the hybrid layer or resin tags formation. Furthermore, in agreement with the aforementioned study, SEM showed that acid etching prior to the application self-etching SMART composite might result in thicker hybrid layer. SEM also showed that this formed thicker hybrid layer is separated from the dentine by a visible large microgap in the absence of any resin tags.
Regarding the gaps formed at the restoration-dentine interface, despite the fact that Renewal MI showed gap formation, 6–8 μm, this is still significantly smaller than the suggested thresholds for the secondary caries formation, which range from 15 μm to more than 225 μm (Thomas et al., 2007; Khvostenko et al., 2015). What is more, previous study showed that Renewal MI showed smaller gaps at the restoration-dentine interface with restoration ageing, which suggested that MCP added to it encourages minerals precipitation (Sawat et al., 2020). As a result, this reduction in the gaps at the interface might add an extra protection to the secondary caries formation in the long-term prospective. What is more, the formed microgap might be only at the superficial surface of the interface as all restorations were not debonded.

When the different SMART composite formulae were placed and waited for 60 seconds prior to being light cured, SEM images showed a phenomenon known as resin phase separation at the dentine-restoration interface. It could be due to the evaporation of the solvents which might lead to the separation of the water from the wet dentine (Monticelli et al., 2007). Further studies that include surface chemistry (Raman and Fourier transform (FTIR) spectra) are needed to investigate this formed layer.

The different tested adhesive systems in this study showed different performance in their bonding strengths to bovine dentine. All formulae of SMART composite that involved single-step application procedure failed to bond to sound bovine teeth. However, the use of acid etching and adhesion prior to the placement of the restoration increased the bond strengths of RMI to dentine significantly and the bond strengths were comparable to Z250 and
ACTIVA (both etch and bond) especially when SBU adhesive was used. Furthermore, the use of self-etching adhesive, G-Bond, prior to the placement of RMI resulted in significant improvement in its potential to bond to sound bovine dentine, which is comparable to the bonding strength of RMGIC or after acid etching and bonding using G-Bond. However, the bonding strength values were significantly lower than those with etch-and-rinse mode and SBU adhesive; a similar result was observed in another study (Leite et al., 2018). SBU adhesives showed higher bonding strength when compared to G-Bond adhesive which is comparable to previous studies (Hegde et al., 2008). It has been suggested that uncured HEMA, with low molecular weight and hydrophilic, which presents in SBU and some other adhesives, plays a key role in the water attraction due to increasing the osmotic pressure, which will lead to droplet formation and ultimately thicker adhesive layer with lower water permeability (Landuyt et al., 2008). Furthermore, the limited capacity of different SMART composite formulae to bond to sound dentine might be due to their weak ability to remove the smear layer and open the dentinal tubules.

2.9 Conclusion:
Renewal MI showed limited capacity to form resin tags and bond to sound bovine dentine. Furthermore, it showed a wider gap formation at the restoration-dentine interface when compared to Z250, Activa with adhesive and Fuji II LC. On the other hand, Renewal MI showed smaller gap formation when compared to Vertise Flow and other formulae of SMART composite. Both acid etching and 60 seconds waiting before the placement of Renewal MI to the prepared dentine surface showed wider gap formation at the
interface. Using of etch and bond adhesive or self-etch adhesive showed significant improvement in the bonding capacity of the Renewal MI which was comparable to the bonding strength of Z250 when SBU adhesive was used.
Chapter 3: Renewal MI capacity to inhibit MMPs activities of demineralised dentine with and without the use of adhesives
3.1 Abstract

Aim:

To evaluate the ability of the Renewal MI to inhibit the activities of the Matrix metalloproteinases (MMPs) at the restoration-demineralised dentine interface, with and without adhesives, immediate and after 6 months. The objectives of this study are to develop demineralised, caries like dentine, model of bovine teeth using formic acid 4M and to test the depth of the MMPs activity.

Methods:

2 bovine dentine discs (1mm and 2mm thick) were used to test the ability of the 4M formic acid to demineralised different thickness bovine dentine to produce caries like models. Dentine discs were placed in 15 ml of formic acid (4M) for 48 hours where the mass changes of the dentine discs were recorded over 48 hours. 6 bovine dentine discs with about 1-2.5 mm thickness were used to test the MMPs activity. First, discs were fully demineralised by immersion in (4M) formic acid for 48 hours. Then, a green fluorescent probe (EnzCheck Collagenase Assay Kit) was applied on the surface of the demineralised dentine discs for 5 minutes. Finally, Renewal MI (with and without adhesives), F0-0 and F16-8 formulae were placed over the applied probe and light cured for 20s. Dentine discs then stored in humidified containers and incubated at 37°C. After 24 hours, samples were sectioned, to expose the demineralised dentine-restoration interface area, and imaged using Confocal Light Scanning Microscopy (CLSM). It was impossible to check the MMPs activity after 6 months as the placed restorations were separated from the dentine discs.
Results:

Qualitative evaluation of the CLSM revealed that Renewal MI, with or without adhesives (SBU or G-Bond), and F16-8 showed no obvious MMPs activities at the restorations-demineralised dentine interface at 24 hours.

Conclusion:

Preliminary results suggested that Renewal MI has the capacity to inhibit the MMPs activities with or without adhesives.
3.2 Introduction:

Despite the great advances in resin bonding to dentine, it is still by far a less durable and more sensitive procedure than bonding to enamel. In addition to the well-reported challenges that might complicate the bonding to dentine, increasing emphasis has been placed recently on addressing the effect of the endogenous Matrix metalloproteinases (MMPs) and cysteine cathepsins enzymes on the durability of resin bonding to dentine over time.

In 1980s, Dayan et al. reported the collagenolytic activity in dentine (Dayan et al. 1983). Then after, Tjäderhane et al. in 1998 has identified MMPs as the responsible component for the collagenolytic activity in dentine (Tjäderhane et al. 1998). More recently, in human dentine, MMPs have been classified mainly into six groups which include 23 members (Visse and Nagase 2003). They are usually present as inactive enzymes (Hannas et al. 2007), that can be activated during caries progression by acids produced by bacteria which can mediate the process of organic matrix degeneration (Tjäderhane et al. 1998; Hannas et al. 2007). Activated MMPs are able to break down almost all of the extracellular matrix of the dentine.

Not only acids produced by bacteria, but also that present in saliva or those are present in the acid etchants might have a role in the activation of these enzymes. During restorative procedures of resin composite, acid etching or acidic monomers incorporated into resin adhesives or restorations potentially activate the MMPs, mainly MMP-2 and MMP-9, in demineralised dentine. Subsequently, this might lead to the breakdown of the collagen fibrils within the hybrid layer (Mazzoni et al. 2013). As a result, it has been claimed that MMPs are directly involved in the degeneration of the collagen fibrils in the
hybrid layer of resin restorations (Mazzoni et al. 2013; Tjäderhane et al. 2013) so affect the stability of the restoration-dentine interface which might lead to gap formation, reduction of bonding strength and subsequently restoration failure over time (Breschi et al. 2008).

In order to minimise the effect of those enzymes on the hybrid layer integrity, several inhibitors, for example chlorhexidine, benzalkonium chloride and galardin, were suggested (Carrilho et al., 2007). In a recent systematic review and meta-analysis by Kiuru et al., more than 21 different enzyme inhibitors were tested. It concluded that MMP inhibitors help preserve the resin-dentine bonds over time and they strongly recommended the clinical use of chlorhexidine, to maintain the long-term integrity of the resin restoration-dentine interface. They have reported that after restoration aging up to 24 months, 35 out of the included 43 studies demonstrated at least 50% lower loss in bonding strengths after using enzyme inhibitors and meta-analysis revealed that chlorhexidine showed significantly lowest loss in the bond strength when compared to the control groups.

The use of enzyme inhibitors, such as chlorhexidine, to inhibit the activities of MMPs in demineralised dentine could improve the stability of resin restorations over time. The studies showed that the efficacy of the incorporated inhibitors are highly dependent on the type of the adhesive system used. Unfortunately, it has been reported that enzymes inhibitors might showed better efficacy with etch-and-rinse rather than self-etch systems. This might make the use of inhibitors an impractical process as the use of etch-and-rinse systems themselves are clinically sensitive process especially with uncooperative paediatrics patients. Furthermore, the loss of inhibition capacity of some of the
common used inhibitors over time might be also another important limitation. As a result, Mazzoni et al. in their review recommended the development of new MMPs inhibitors that overcome the current chemicals limitations (Mazzoni et al., 2015).

At EDI, two chemicals were added to the novel composite material; Monocalcium phosphate monohydrate (MCPM) and Poly-Lysine (PLS) which are patent protected (WO2015015212A1). The aim of MCPM addition was to enhance the remineralisation of demineralised, carious, dentine and for self-repair capacity of the novel composite while the PLS was added as an antibacterial and to enable affected dentine sealing. Previous studies at the department showed that Renewal MI was significantly more effective than other commercially available materials in the inhibition of both immediate and after two weeks MMPs activities at the restoration-demineralised dentine interface. However, there is no data regarding the effect of Renewal MI on the MMPs activity when adhesives are used before the restoration.

### 3.3 Hypothesis:

The null hypothesis is:

There is no difference in the ability of the Renewal MI to inhibit Matrix Metalloproteinase functions after adhesives application when compared to only Renewal MI restoration in addition to different SMART composite formulae with different PLS and MCPM concentrations.
3.4 **Aims and objectives:**
The aim of this study is to evaluate the ability of the Renewal MI to inhibit the immediate and 6 months activities of MMPs at the restoration-demineralised dentine interface with and without adhesives.

**Objectives:**
- Develop demineralised, caries like dentine, model of bovine teeth using formic acid 4M.
- Test the depth of the MMPs activities.

3.5 **Materials and methods:**

3.5.1 **Matrix Metalloproteinase (MMP) activity at the restoration-dentine interface of the demineralised bovine dentine:**
The ability of Renewal MI and other two formulae of SMART composite and different commercially available restorative materials to inhibit the MMP activity were tested by evaluation of the demineralised dentine-restorations interfaces using CLSM. The surface of the demineralised discs was treated by a green fluorescent probe, EnzChek® collagenase/gelatinase kits.

3.5.2 **Dentine discs preparation:**
Dentine discs were prepared using extracted bovine teeth, lower incisors. P220 grit paper was used to create rectangular dentine discs from the mid-labial surfaces of the exposed labial dentine of about 1-2.5 mm thickness and
about 10-12 mm in diameter (figure 3.1). Discs were stored in deionised water when they were not in use.

![Figure 3.1 Diameter and thickness of the bovine dentine discs.](image)

### 3.5.3 Demineralising protocol:

As no available data regarding creating totally demineralised dentine from bovine teeth to mimic carious dentine, and as previously available laboratory studies from EDI used extracted human teeth, 1 and 2 mm thick dentine discs were used to test the ability of the 4M formic acid to demineralised bovine dentine as detailed below.

- Preparing demineralising solution: Formic acid (4M): 31.8mL of acid was added to 50mL of deionised water carefully and then topped up with water to a final volume of 200mL.
- Dentine discs (n=2) were placed in 15 ml of formic acid (4M) for 48 hours. The mass changes of the dentine discs immersed in formic acid over 48 hours were recorded. Acid was changed after 24 hours.

### 3.5.4 Preparation of green fluorescence probe solutions:

The probe was prepared following the suggested protocol which was used in several previous laboratory studies regarding MMP activities in demineralised dentine. First, prepared 1X reaction buffer by diluting 2 mL of the provided 10X Reaction Buffer in 18 mL of deionised H2O. Second, the collagen substrate (type I collagen) was prepared by dissolving the vial contents (1mg) in 1mL of deionised water, in order to have a concentration of 1mg/mL, and then agitated in an ultrasonic water bath for 5 minutes to facilitate mixing. Then, 20μL of the prepared collagen substrate mixed with 80μL of 1X reaction buffer to bring down the concentration to 200μg/mL.

### 3.5.5 Applying of the probe into the demineralised dentine:

One demineralised dentine disc was used to test each different restoration. 20μL of the previously prepared green fluorescence probe solution was applied on the surfaces of the demineralised dentine and allowed to soak in for about 5 minutes before 1 mm thick restorative materials were applied to the treated dentine surfaces. The used restorative materials involved three different formulae of SMART composites with different PLS and MCPM concentrations. The tested groups including only Renewal MI (SchottlanderTM), Renewal MI where SBU or G-Bond adhesives were applied
and light-cured for 10s before, and 0-0 and 16-8 formulae of SMART composite. A control sample without any restorative material was applied after the application of the green fluorescence probe solution was prepared. Then, samples were stored in containers which humidified with deionised water by socked paper tissue at the bottom of the containers and then incubated at 37°C.

3.5.6 MMPs activity testing:
The samples were sectioned, to expose the demineralised dentine-restoration interface area, ground using P200 grit paper. Then the samples were imaged using Confocal Light Scanning Microscopy (CLSM), (BioRad Radiance2100, ZeissTM, Welwyn Garden City, Herts, UK) using a water objective lens (X40).
3.6 Results:

3.6.1 Demineralising bovine dentine to create caries-like standardised model:

The average mass change percentages over time of both 1mm and 2mm thick dentine discs were similar. Table 3.1 shows the samples’ mass changes and loss percentages over time upon immersion in formic acid. The mass changes were proportional to the time with linear decrease until 24 hours when the mass change was levelled. Neither of the two samples showed substantial further mass changes between 24 and 48 hours of immersion in the formic acid (Figure 3.2). The mass loss percentages recorded for 1mm thick sample were -46.4% and -47.3% after 24 and 48 hours respectively of immersion in the formic acid. 2 mm thick sample showed similar mass loss percentages of -45.1% and -46.3% after 24 and 48 hours respectively. The formic acid had been changed after 24 hours with fresh acid to avoid saturation with dissolved inorganic components of the dentine discs.
<table>
<thead>
<tr>
<th>Time in hours</th>
<th>Sample 1 mass in grams</th>
<th>Sample 1 mass change percentage %</th>
<th>Sample 2 mass in grams</th>
<th>Sample 2 mass change percentage %</th>
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</thead>
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<td></td>
<td>0.2061</td>
<td></td>
</tr>
<tr>
<td>0.5</td>
<td>0.1107</td>
<td>-7.75</td>
<td></td>
<td></td>
</tr>
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<td>0.1801</td>
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<td>0.1670</td>
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<td>0.1107</td>
<td>-46.29</td>
</tr>
</tbody>
</table>

Table 3.1 Shows the samples’ mass changes and loss percentages over time upon immersion in formic acid.

Figure 3.2 Shows dentine discs (1 & 2mm thick) mass change percentage versus SQRT of time upon immersion in formic acid. Mass change is proportional to SQRT of time until 24 hours then levels off.
3.6.2 Immediate Matrix Metalloproteinase (MMP) activity at the restoration-dentine interface of the demineralised bovine dentine:

At day one, qualitative observation of the restoration-demineralised dentine interfaces after probe application showed different levels of MMPs activities among tested dental materials. Figure 3.3 is representative CLSM images of the MMPs activities. The control sample (without restoration or adhesives) showed obvious MMPs activities at the restoration-dentine interfaces. F16-8 formula (without adhesives) and Renewal MI (with and without previous application of adhesives) showed obvious inhibition of the MMPs activities at the day one. On the other hand, F0-0 SMART composite formula (without adhesives) showed MMPs activities at the interface.

At six months, almost all samples showed that restorations were detached from the dentine and there was a rotten smell. As a result, the test of late capacity of the restorations to inhibit MMPs activities was impossible.
Figure 3.3 Confocal Light Scanning Microscopy (CLSM) images of the immediate matrix metalloproteinase enzyme (MMP) activity. The green fluorescence represents the MMPs activities with black colour at the top are the restorations while the black colour at the bottom of the images are the demineralised dentine discs. The green fluorescence in the CLSM image of Renewal MI (without adhesives) is due changing of image contrast to show dentinal tubules and does not represent MMPs activity.
3.7 Discussions:

In real life, progressive demineralisation of dentine and subsequent loss of tooth structures can happen because of dental caries or erosion (Herschfeld and Miller, 1978; Nunn et al., 2003). It is well known that acids produced by cariogenic bacteria through metabolising of the fermentable carbohydrates are responsible for dentine demineralisation and damage.

In attempts to create standardised caries like dentine models of both human and bovine teeth in laboratory studies that mimic clinical situations, several strategies have been suggested in the literature. These strategies include use of microbiological (bacteria), chemical (acids) and buffer solutions. Buffer solutions strategy involves multiple pH cycling in order to mimic natural caries process which includes repeated alternative cycles of demineralisation and remineralisation of the dental tissues. All proposed methods are not without limitation. Use of chemicals might only demineralise superficial dentine surface when weak acids are used while chemical changes and collagen collapse might be encountered when very strong acids are used. On the other hand, microbiological and buffer solutions methods might result in very soft dentine compared to natural caries (Marquezan et al., 2009) or highly variable results depending on the used protocol (Besinis et al., 2014; Abou Neel et al., 2016).

It has been suggested that using acids such as formic acid might be the standard for preparing dentine models (Eggert and Germain, 1979; Besinis et al., 2014). However, Deery et al. in their recent review concluded that there is no standard method for demineralisation of dentine as current literature showed huge variation in the followed protocols, including concentrations and...
time, and that the selected demineralisation strategy should fit the purpose of the laboratory study (Deery et al., 2021). Formic acid showed promising results as a rapid and reliable demineralising agent. It has been reported that formic acid was the only used method that successfully managed to dissolve more than 500µm deep of the dentine surface without causing significant structural changes of the dentinal collagen (Pacheco et al., 2013).

In this chapter, both 1mm and 2mm thick dentine discs showed similar behaviours regarding mass changes over time. 70% mass loss, however, which is equal to the inorganic content (minerals) in dentine, was never achieved: only about 45% maximum. Previous studies in the department have managed to reach 70% loss of mass after 48 hours of immersion in formic acid however, human dentine discs were used. Further studies, including Raman spectrum and EDX, are needed to determine the loss of hydroxyapatite (HA) and tracing calcium (Ca) and phosphate (P) atoms. CLSM showed opened dentinal tubules, both 1mm and 2mm thick bovine dentine discs, which suggested sufficient dentine demineralisation and no collapse of the dentine collagen fibres.

MMPs can be activated either by endogenous acids by cariogenic bacteria or acids used for the placement of the restorations. Furthermore, microgaps at the restoration-dentine interface might expose the dentine to oral acids that might activate the MMPs at the later stages. Several strategies have been suggested to improve the stability of the restoration-dentine bonding. These include adding of natural bioactive or synthetic agents that aim to inhibit the destructive activities of the endogenous enzymes of the organic matrix of dentine. These substances can be added in different ways; to the acid
etchant, incorporated into the adhesive systems or apply separately to the
dentine after acid etching step (Huang et al., 2018, Siqueira et al., 2019,
Simmer et al., 2019). What is more, it has been suggested that MMPs activities
could be inhibited by achieving a hermetic seal at the restoration-dentine
interface (Kuhn et al., 2016, Jun et al., 2018). In this pilot study, Renewal MI
(with or without adhesives) and F16-8 formula showed no obvious MMPs
activities which might be due to proper sealing at the resin-dentine interfaces.
Furthermore, in addition to the possible effect of hermetic seal of Renewal MI
and F16-8 to demineralised dentine, adding of the PLS to the novel composite
might play an important role in the inhibition of the MMPs activities as this has
been tested and proved previously at the department. One of the suggested
theories is that the hydrophilicity of added PLS and MCPM to Renewal MI, and
other SMART composite formulae, might cause water sorption into the novel
composite away from dentine. As a result, in the absence of water in dentine,
MMPs will be inhibited. The theory that PLS is able to inhibit the MMPs
activities might be supported in this study, by the fact that F0-0 formula
(without PLS and MCPM) showed MMPs activities compared to other SMART
composite formulae with different concentrations of PLS and MCPM.
It has been suggested that self-etching resins might show significant inferior
capacity of MMPs activity inhibition when compared to etch and rinse systems
(Mazzoni et al., 2006; Nishitani et al., 2006). However, more recent study by
Mazzoni et al., 2013, showed an increase in the MMPs activities regardless of
the used adhesive system (Mazzoni et al., 2013).
Results from this study are in conflict with the results reported in previous
studies. In this study, adhesives using (SBU or G-Bond) showed no obvious
immediate MMPs activities. This might be due to hermetic seal as a consequence of the use of restorations (Renewal MI) after adhesives application and light curing. What is more, it is well known that MMPs are inactive in the absence of water and as adhesives have organic solvents, such as ethanol, this might replace the water with resins in the demineralised dentine and show a short term inhibition of the MMPs at the adhesive-dentine interface. Furthermore, the used methodology is also an extremely sensitive technique and the results might be merely an error as only one tooth sample was used for each sample group as a part of this pilot study.

CLSM showed only signs of active MMPs at the restoration-dentine interface but not deeper. This might be explained by that MMPs are only active at the superficial surface of the demineralised dentine or because the acid concentration is higher superficially and diluted by the dissolved HA when you go deeper. However, it might be just due to the possible limited ability of the assay molecules to penetrate deeper so, as a result the MMPs activities cannot be detected. Further studies are needed to investigate this phenomenon.

These findings require accepting of the null hypothesis that the immediate MMPs activities are not different regardless the use or not use of adhesives prior to Renewal MI restoration.

3.8 Limitations:
The limitation of this study is that it is only a pilot study with only one sample for each tested group which make it impossible to draw conclusion based on
a statistical analysis and rely mainly on subjective qualitative observation. Furthermore, the used methodology is difficult (multiple sensitive steps) which might increase the chance of errors. Also, the used methodology is not suitable to test the late activities of the MMPs of the demineralised dentine as the chance of restorations debonding is high. The rotten smell might indicate that dentine collagens might be collapsed and might suggested some micro-organism activities. We suggest further investigation with larger sample groups.

3.9 Conclusion:
All formulae of SMART composites with PLS showed capacity to inhibit the immediate activity of the MMPs at the restoration-demineralised dentine interface. Furthermore, use of adhesives prior to Renewal MI showed no effect on the capacity of the novel composite to inhibit the immediate MMPs activities.
Chapter 4: An audit of dental materials used to restore carious primary molars and their outcomes among a convenient sample of general dental practitioners in London
4.1 Abstract:

Aim and objectives:

The aim of this study was to explore the treatment approaches followed by a convenience sample of GDPs early in their training in London to restore carious primary molar teeth. Furthermore, to identify the most used dental restorative materials among children and their fate up to three years later.

Materials and methods:

The data presented were a result of secondary processing of a retrospective collected data from dental records of paediatric patients of a convenience sample of general dental practitioners (GDPs). All restorations completed during a pre-determined four-month period (September 2018 to December 2018) were included.

Results:

A total of 81 primary molar teeth from 44 child patients had restorations. GIC restorations were the most used restorative materials (75.8%) among GDPs who were working in general dental practice settings. What is more, it showed a high failure rate (35.6%) on up to three years follow-up. Only six PMCs were used with only one needing replacement due to the parent’s aesthetic concerns. PMCs were the most commonly used restorative materials among the GDPs working in the CDS setting (85.7%) with a 100% reported success rate.

Conclusion:
Despite its high failure rates, GIC is still the restorative material of choice among this selected group of GDPs. GDPs working at a CDS setting used considerably more PMCs to restore carious primary molars than those who were working at GDP settings. Composite restorations were rarely used, with high reported failure rate.
4.2 Introduction:

GDPs are trained to provide primary dental care, including caries prevention and management, for children. In the UK, the commissioning standard for paediatric dentistry states that dentists, level 1, should be competent in assessing children's oral health needs, perform both urgent and routine oral treatments and refer for specialist assessment when appropriately needed (Commissioning Standard for Dental Specialties – Paediatric Dentistry, 2018).

Placement of high-quality restorations in children with good long-term clinical outcome is possible, though technically demanding. However, despite the available evidence supporting management of dental caries in primary molars, a degree of uncertainty regarding what is the most effective and efficient treatment approach among GDPs is faced. As discussed before, a recent national multicentre RCT, FiCTION trial concluded that there was no evidence supporting the clinical superiority of any of the three different treatment strategies regarding the incidence/episodes of both dental pain or infection, which ranged from 40% with biological/prevention approach up to 45% with prevention strategy only.

Among a group of GDPs in the North West of England, Milsom et al. (2002) concluded that GIC restorations were the material of choice with 61% of first primary molars and 55% of second primary molars restored with GIC restorations. However, GIC restorations were significantly more likely to be replaced with 42.5% compared with only 27.4% of teeth restored with amalgam restorations. A recent retrospective review of children’s dental records (661) which investigated whether a group of FDs and GDPs, at South West of England, were following the paediatric dentistry guidelines, regarding
treatment and recall, concluded that the guidelines were not always followed (Harford et al., 2018). Furthermore, they found that GIC was the most frequently used restoration and only twelve PMCs were placed. Unfortunately, there is no up to date data from the UK which has investigated the clinical long-term outcomes of restorations placed by GDPs in general dental practices.

Due to the restrictions on amalgam use in the treatment of primary teeth in the UK from July 2018, limited acceptance of PMCs and high reported failure rates of direct restorations among GDPs especially GIC, they might face a challenging situation in the selection of the proper restorative materials for carious primary teeth which fit their busy daily clinics, facilities, level of training, views and children’s cooperation level.

4.3 Research rationale:
Currently, UCL Eastman Dental Institute is working on a project of developing a self-bonding, easy to place dental material, Renewal MI composite, which might overcome the drawbacks of currently used dental materials, especially at dental primary care level where technique sensitivity and high patient cooperation might be barriers to restore carious teeth in children effectively and efficiently. Furthermore, similarity to GIC restoration in their clinical steps, as the most popular restorative material among GDPs, might give the Renewal MI composite higher acceptance over other restorative alternatives. Laboratory studies showed promising physical and mechanical properties of Renewal MI composite. Furthermore, the first clinical trial at EDH regarding the possible adverse events of using Renewal MI to restore carious primary
teeth reported no adverse events, and that it could be used safely to restore primary teeth with minimal restorative technique. However, lack of recent and reliable reports from the UK regarding the most popular dental materials used to restore primary teeth and their clinical performance among GDPs, might be a barrier to develop an RCT to test Renewal MI composite as a minimal invasive alternative treatment approach. As a result, cross-sectional studies investigate the most used dental materials among GDPs and their clinical performance in Public Dental Health practices which reflect the “real-life dentistry” needed.

4.4 Aim and objectives:

Aim:

To identify the treatment approaches and the restorative dental materials most used to restore carious primary molars among a selected group of GDPs in London.

Objectives:

1. To compare the survival rates of different used dental materials.

2. To identify the most common causes of failure/replacement and their relationship to the selected restorative material.

3. To investigate the influence of the patient age/tooth on the selection/longevity of different restorative material.
4.5 Materials and methods:

Ethical approval:

Ethical approval was obtained from the UCL Research Ethics Committee, Project ID: 21963/002

Study design:

This study was a secondary data processing of retrospective collected data from dental records of paediatric patients of a convenient sample of General Dental Practitioners (GDPs) who are providing NHS dental care for children in London. Originally, clinical data were collected from the dental records by Foundation Dentists (FDs) and were submitted to Health Education England Kent, Surrey and Sussex (HEE KSS) Deanery as a part of a held learning agreement and regular quality monitoring audit of the placed dental restorations. The participated FDs in this HEE KSS audit were from the same practices who were also participated in the focus group interview, chapter 5. However, the included restorations in this study were completed by different practitioners. All extracted data were fully anonymised.

Then, this database was shared with the researcher student on June 2022. All restorations completed during a pre-determined four-month period (September 2018 to December 2018), that fulfilled the inclusion criteria with up to three years follow up and clinical outcome data, were involved in the analysis.

Baseline data evaluated included both patient and tooth-related variables which involved:
• Age
• Reason for restoration
• Radiographs taken
• Type of restoration
• Dental material
• Patient cooperation
• Oral hygiene

**Follow up data:**

The outcome of the posterior teeth restorations at the end points were:

• Retained tooth
• Replacement of restoration
• Tooth exfoliated
• Tooth extracted

**Inclusion criteria:**

- The initial placement reason must be caries.

- Older than three years and less than 12 years old at the day of restoration.

- Patient at named sites who have at least one filling of a carious primary molar which was placed between September 2018 and December 2018.

- Complete history including diagnosis and provided dental treatment.
Exclusion criteria:

- Dental restorations due to dental anomalies but not caries.

- Significant medical condition that could potentially influence restorative material placement, e.g. Special Needs, bleeding disorder, etc.

Recruitment

Data were collected from centrally held records held by the Regional Associate Postgraduate Dental Dean (Workforce & Dental Foundation)-Dental Department – London & KSS Health Education England. As part of the learning agreement that Foundation Dentists hold with KSS, they are obliged to provide details of treatment provided. Data selected were from all foundation dentists currently registered with KSS.

Patient and public involvement (PPI)

We have involved service users (GDPs) in the design and intend to involve them in undertaking research and dissemination. We have not involved patients in this research process.

Peer and regulatory review:

The study has been peer reviewed in accordance with the requirements outlined by UCL/UCLH

- This study has been peer reviewed within UCL by an independent and relevant peer reviewer on 20/11/2020. The Sponsor has accepted these reviews as adequate evidence of peer review.

Statistical analysis:
The original plan was to analyse collected data using Stata 11.0 for the failure analysis and the factors associated with failure using multivariate analysis utilising Cox regression models. However, a significance level of 5% was proposed, as the collected data were not enough to run inferential statistics, so only descriptive statistical analysis was completed.

4.6 Results:

The number of participating GDPs was eight dentists from eight different practices, all of whom were working in primary care units except one who was working in a CDS unit. A total of 81 restorations, from 44 paediatric patients’ records, met the inclusion criteria and their details were collected. Sixty restorations were completed by GDPs in primary dental care units while 21 by a GDP in a CDS unit. As a result, data will be treated separately for each different setting. The mean ages of children in GDP and CDS settings were 8.2 and 5.9 years, respectively. Only about 28% of the evaluated records reported that radiographs had been done before restorations. Regarding teeth, second primary molars were the most restored teeth in both GDP and CDS settings, 58.3 and 61.9%, respectively, with 45% and 38.1% classified as single surface and 55% and 61.9% as multiple surfaces restorations, respectively. Table 4.1 presents the number and percentage of teeth that had restorations while Table 4.2 shows the details of caries site and extent of restored teeth.
<table>
<thead>
<tr>
<th>Tooth</th>
<th>GDP N(percent)</th>
<th>CDS N(percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First primary molar</td>
<td>25 (41.7)</td>
<td>8 (38.1)</td>
</tr>
<tr>
<td>Second primary molar</td>
<td>35 (58.3)</td>
<td>13 (61.9)</td>
</tr>
<tr>
<td>Total</td>
<td>60 (100)</td>
<td>21 (100)</td>
</tr>
</tbody>
</table>

Table 4.1 Summary of the number and percentage of teeth with restorations in both general dental practice (GDP) and community dental service (CDS) settings.

<table>
<thead>
<tr>
<th>Caries site and extent</th>
<th>GDP N(percent)</th>
<th>CDS N(percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occlusal caries into enamel</td>
<td>8 (13.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Occlusal caries into dentine</td>
<td>18 (30)</td>
<td>8 (38.1)</td>
</tr>
<tr>
<td>Proximal caries into enamel</td>
<td>2 (3.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Proximal caries into dentine</td>
<td>31 (51.7)</td>
<td>13 (61.9)</td>
</tr>
<tr>
<td>Smooth surface caries</td>
<td>1 (1.7)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Table 4.2 Number and percentage of restored primary teeth categorised according to the site and extent of caries.

The most commonly followed treatment approach among the GDP settings was the conventional approach, drill and fill, 61.7%. In contrast, biological approach of caries management involving minimal caries removal or sealing over caries was followed in the CDS setting at 95.2%.

Among the GDPs who were working in GDP settings, GIC was the most commonly used restorative materials (75.8%, n=45) whereas RMGIC and PMCs represented only 20% of the used restorative materials, (n= 6 each).
Only one composite restoration was used. On the other hand, in the CDS setting, PMCs were the dominant used restorative material, at 85.7% (n= 18). The majority of included children showed either fair or poor oral hygiene, 42.4 and 21.2%, respectively.

In this study, failure of the restoration was defined as the need for the replacement, correction, pulp therapy or extraction due to pain or sepsis. The overall failure rate of all restorations among GDP settings after up to three years of follow-up was 30% compared to only 9.5% among CDS setting. The failure rates of each different restorative materials among GDP settings were 33.3% (n= 15) for GIC and 100% (n= 1) for composite restoration. Only one placed PMC needed replacement due to aesthetic concerns with no other clinical indications whereas no RMGIC restorations needed replacement. Seven GIC restorations showed signs of marginal discolouration; however, the clinical decision was made to replace only one restoration within the period of the follow-up. On the other hand, the two placed RMGIC restorations among CDS setting needed replacement due to wear, whereas all placed PMCs showed no failure up to three years of follow-up. Only one composite restoration placed in the CDS setting reported recurrent caries but no further action needed. Figure 4.1 summarises the percentages of reasons for failure by each restorative material that needed replacement among GDPs.
Figure 4.1 Shows the reasons of failure of restorations needed replacement
4.7 Discussion:

This retrospective study provides information regarding GDPs clinical approaches to treat carious primary teeth among potentially cooperative and healthy children and their outcomes up to three years follow-up. Even though the sample size was small and not randomised, our study gave an insight into the practices of the GDPs to restore carious primary molar teeth. As a result, we hope the findings of our study will truly reflect the everyday dental clinical practice of the GDPs and help us in the design of the future RCT to test SMART composite.

In our retrospective longitudinal study, GIC restorations were the most frequently used restorative material among a convenience sample of the GDPs in London. This is in contrast to the self-reported data by the participant FDs, in the focus group study (Chapter 5), who claimed that PMCs would be their first treatment option. This finding might highlight the limitations of self-reported data and the high risk of bias.

The survival rates of the restorations performed by the GDPs were evaluated for a period of up to three years after placement, where the used restorations exhibited variable survival rates and clinical outcomes. GIC restorations exhibited the highest failure rate among used restorative materials despite the used treatment approaches, drill and fill or biological/minimal caries removal. Fifteen out the 45 placed GIC restorations by the GDPs in the primary care settings needed to be replaced, corrected, pulp treated or extracted within three years of their placement. Only one composite restoration was placed, which was replaced later due to poor anatomic form (wear). Recurrent caries and bulk fracture of the restorations were the most commonly reported
reasons for the replacement of the restorations, which is similar to the reasons reported by a recent systematic review (Chisini et al., 2018). On the other hand, all PMCs placed by GDPs, in both primary care and CDS settings, showed no complications and needed no further treatment over the three years of follow-up. Only one PMC restoration needed to be replaced due to parent’s concern regarding the colour of the crown, which highlights the importance of communication and management of parents’ expectations before the placement of restorations.

RMGIC exhibited better clinical outcomes when compared to GIC, only two out of the used eight RMGIC has been replaced, due to wear, over the three-year follow-up period. What is more, these two restorations were in the same patient, a poorly cooperative four-year-old child. In a recent review, when high-viscosity glass ionomer cement was used to restore carious primary molars, it showed the highest failure rate at 36 months (Amend et al., 2022). Hübel and Mejäre (2003) reported that GIC (Fuji II, GC) showed more than five times higher failure risk when compared to RMGIC (Vitremer, 3M ESPE) at three years follow-up. Our study findings regarding high failure rates of GIC are similar to that reported by other studies.

The results of this study indicate that, regardless of the reported high failure rates of the GIC restorations and also as GIC is not a recommended treatment for carious primary molars, especially multi-surfaces cavities, among the UK guidelines, GDPs still prefer it over others restorative materials. Seventy-five per cent of the placed restorations among carious primary molars by the GDPs, in primary care settings, were GIC restorations while only 10% were PMCs. These findings are similar to the results reported by Harford et al.
(2018), where 661 dental records of paediatric patients in general dental practices based in the South West of England were reviewed retrospectively, and showed that 74% of the placed restorations by dentists were GICs. Furthermore, only about 10% and 8% of placed multiple-surface restorations were PMCs and composite restorations, respectively. The rest of the carious primary teeth were managed by either no restorative treatment or extraction, about 30% and 18%, respectively; however, regarding this point, it is impossible to compare to our study as we focused on the restorations rather than the treatment approaches. They concluded that, in general dental practice, neither treatment nor recall guidelines were followed.

Selection of the restorative approach is a complicated process that is affected by several factors related to the patient, dentist and also the dental care system (Kay and Locker, 1996). Amalgam has been used successfully to restore carious primary teeth for decades. However, following the global effort to implement the Minamata Convention on Mercury (2013), which attempts to phase down the use of mercury, including amalgam, and following the change in EU regulations (European Union Regulations 2017/852) that placed restrictions on the use of dental amalgam to restore primary teeth starting from the 1st of July, 2018, these changes might enforce and place further pressure on the dentists to use alternative restorative materials with higher clinical failure rates, such as GIC, as the available alternative which are more time-consuming, need high cooperation and more technique-sensitive, such as resin composite.

GDPs may take different approaches to manage and restore carious primary molars compared to paediatric dentists. In a national cross-sectional survey
by Tickle et al. (2007) 322 GDPs and 115 paediatric dentist in England participated and four hypothetical clinical case scenarios among a 6-year-old cooperative boy child were used to test their treatment approaches, and concluded that a wide variation between the two groups regarding their clinical choices had been detected and GDPs usually tend to follow less comprehensive restorative treatment, including no restorative treatment, ART or extraction. Similar results has been demonstrated in another study in Hong Kong (Lee et al., 2013). In a questionnaire series regarding the dental practices among GDPs in the UK, 87% of participated GDPs indicated the use of GIC and RMGIC, 55% and 32%, respectively, to restore primary molar teeth with occluso-proximal caries (Wilson et al., 2019). On the other hand, only 6% of the participants reported that they are using preformed metal crown (PMC) routinely to restore such lesions.

According to literature and guidelines in paediatric dentistry, such as SDCEP, preformed metal crowns are the first choice to restore primary molars affected by multiple-surface caries; however, they are seldom used in general dental practice. In our study, only five PMCs (Hall) crowns were used, among two child patients, which showed no complications up to three years of follow-up, which is in line with reported high success rates of the Hall technique crowns (Innes et al., 2015). It has been suggested that undergraduate training might play a role in that; however, despite having the knowledge and the positive experience regarding PMCs (Hall technique), recent graduates still might be reluctant to use them in general dental practice (Gilchrist et al., 2013). Other suggested barriers might include the cost, lack of equipment and busy practices. Interestingly, in our study PMCs (Hall technique) were the first
choice of one of the participant GDPs working in community dental setting (CDS), 18 out of the 21 used restorations were PMCs, and GIC was not used to restore carious primary molar teeth. This finding might reflect the importance of the armamentarium availability and the possible specialist input and support at the CDS settings.

4.8 Limitations:
This study is a retrospective data collection from patients’ records. In addition to the inheritance limitations of the retrospective studies, there was an increased risk of selection bias of the included cases as the data were collected by one of the direct care team. Furthermore, due to the small number of the restorations in this study, only descriptive statistical analysis was made whereas inferential statistics to test hypothesis were impossible. However, the findings of this study give an insight into the daily practices, “real life”, and the long-term clinical outcomes of dental restorations completed by the GDPs who work for the NHS.

4.9 Conclusion:
GIC is still the material of choice to restore carious primary teeth in the primary dental care units. It showed high failure rate on review up to 36 months. Recurrent caries, lost restoration and fracture are the most common reasons to replace. Conventional treatment approaches including “drill and fill”, were the treatment of choice among GDPs who were working in primary dental care. PMCs showed high success rate at the hands of the GDPs despite the clinical
settings, but it seems that they are more popular in the CDS than GDP settings. The availability of PMCs kit and possible specialist support and help at CDS might play an important role in the GDPs’ attitude towards PMCs rather than direct restorations.
Chapter 5: A focus group on dental caries management among potentially cooperative children with foundation dentists (FDs): their attitude, potential barriers and opinions.
5.1 Abstract:

Aim:

To explore general dental practitioners’ willingness and views regarding current restorative practices to restore carious primary molar teeth and possible barriers.

Method:

A pilot exploratory qualitative study, using a convenience sampling technique with a focus group discussion through a secure virtual call (Microsoft Teams). The participants were recruited through the Health Education England London & Kent, Surrey and Sussex, Regional Associate Postgraduate Dental Dean. Eight foundation dentists from several general dental practices in London participated in this study.

Results:

Five topic themes were obtained during the analysis process. All participating FDs reported desire and willingness to treat carious primary molars. The majority of participants claimed that PMCs would be their first treatment option as they feel confident to place PMC using Hall technique. GIC restoration would be their alternative option. It has been suggested that barriers to use PMCs would include time, cooperation, aesthetic concerns and armamentarium shortage. UDAs and financial aspects of running dental practice might be higher priority for ESs and associates so they more lean towards GIC restorations.

Conclusion:
Participant FDs showed evidence-based and resilience in their clinical decision-making process. However, the findings of this focus group discussion were in contrast to our findings regarding GDPs’ experience in the previous chapter, which might highlight the limitation of self-reported studies.
5.2 Introduction:

Despite the advancement in the treatment approaches and the dental restorative materials, dental caries is still one of the most common chronic diseases among human with worldwide failure to control. In the UK, the latest statistics from Public Health England (PHE) revealed that 23.4% of 5-year-old children in England had experience of dental caries with an average of 3.4 primary teeth affected (PHE, 2019).

As discussed earlier, the care index reported by the PHE over the last three decades in the UK showed that the majority of primary teeth with caries are unrestored. Furthermore, significant inequalities in the oral health of children continue to exist and the number of referred children for dental extraction under DGA from the GDPs has increased significantly during the last few years. Tickle et al. (1999) found that only 29% of regularly attended 5-year-old children had restored carious teeth compared to worse figures among irregular attendees with only 3% having restored carious teeth.

Children with carious teeth are suffering from pain, infection, time off school, poor diet and subsequently possible impaired growth. The waiting lists for treatment of carious teeth under DGA at secondary and tertiary dental care units are expanding. At Eastman Dental Hospital, the number of referred children during the last decade has increased significantly, from about two thousand referrals per year to more than 5000 thousand referrals. What is more, the COVID-19 pandemic has had a significant impact on the numbers, of referrals and waiting, which has made the situation even worse.
GDPs are the first line of the dental care and they are responsible for the treatment of the majority of children with dental caries. Unfortunately, the available studies, especially from the UK, regarding GDPs’ willingness, treatment approaches and barriers to treat children patients with dental caries are sparse. It has been suggested that undergraduate education and the lack of training and confidence in treating children among GDPs could be a barrier to maintaining good oral health (Dao et al., 2005; Simons et al., 2013). Furthermore, GDPs also might encounter several challenges when restoring the carious primary molars among child patients. These challenges include limited cooperation of some child patients and lack of appropriate remuneration for dentists to treat children in primary care. What is more, financial incentives and payment bands among GDPs who are working for the NHS have been reported as possible barriers for some sort of dental treatment, such as PMCs (O’Donnell et al., 2018).

Currently, a group of researchers at EDI are developing a novel dental restorative material that needs no local anaesthesia or drilling to restore primary teeth with decay among children. The development of this novel material aims to help GDPs to treat more children with decay and reduce the number of children who are referred to hospitals for treatment. However, there is no recent data regarding willingness of the GDPs who are working for the NHS to treat children with carious teeth and the most common barriers to treat children at primary dental care settings. Furthermore, identification of their opinions to improve current practice will be of great importance. Without a doubt, identifying GDPs’ attitude, barriers to treat children and their opinions
and views are important in the process of developing any treatment approach or new dental materials.

5.3 **Aim:**

To evaluate the attitude and clinical decision-making to select the dental restorative material and identify the challenges faced by a general dentist in treating potentially cooperative child patients.

5.4 **Subjects and methods:**

**Ethical approval:**

Ethical approval was obtained from the UCL Research Ethics Committee, Project ID: 21963/001

**Design:**

This study was a pilot exploratory qualitative study, using a convenience sampling technique with a focus group discussion through a secure virtual call.

**Participants:**

The original plan was to recruit GDPs from different representative groups. However, due to the impact of COVID-19 on the ethical approval process and time limitation, a convenient sample of eight foundation dentists (FDs), newly graduated, from several general dental practices in London, who were working...
for the NHS, were recruited through the Health Education England London & Kent, Surrey and Sussex, Regional Associate Postgraduate Dental Dean. All participated FDs were provided with a participation information sheet first and written consents were obtained and signed before starting the study.

**Inclusion criteria:**

- Foundation dentist
- Working for the NHS in a general dental practice

**Exclusion criteria:**

- Specialist, paediatric dentist and private dentist

**Focus group session:**

The facilitators (the principal investigator and the student researcher) conducted and recorded the discussions. A secure Microsoft Teams virtual call, using UCL and NHS emails were used to conduct and record the focus group discussions. The discussion recording involved audio, video and screen sharing activities. The focus group discussions took place on June 2022 and the session lasted for about an hour.

The meeting was stored on Microsoft Stream which is part of UCL Office 365 and then downloaded according to permissions enabled by account administrators, principal investigator and student researcher. Recording was only for note taking purposes and was deleted immediately after the data had
been transcribed by the student researcher and reviewed by the principal investigator. All identifiable personal data are pseudonymised.

Data were stored and managed in a password protected UCL university computer systems, using UCL Data Safe Haven. Data were stored securely in accordance with UCL University’s data protection policies for data handling as a part of the research record.

Questions and data collected:

- Demographic data: gender, undergraduate dental school, area of practice.
- An open ended interview with participants leading the discussion. Three open-ended questions:
  - First, the introductory question: What do you think of the restorative/preventive care of children with carious primary molars in your practice?
  - Then, the main question: What is your treatment approach and used materials to manage carious primary molar?
  - Finally, the closing question: Do you want to add anything more?
- Following the participants answers to the open-ended questions, there were some auxiliary questions regarding their clinical decision-making and encountered barriers to restore carious primary teeth.
At the end of the focus group, the facilitators reviewed the main obtained information by debriefing and the participants were thanked for their time.

**Data analysis:**

First, the focus group video recording was transcribed by the student researcher verbatim, to avoid bias in transcription, and reviewed by the principal investigator, then it was analysed inductively with a content-based thematic analysis. More specifically, a six-step process approach which was developed by Braun and Clarke (2006) was followed. The suggested process involves familiarisation with the collected and transcribed data, coding, creating and reviewing themes, defining themes and finally write up the analysis. Microsoft Excel was used initially to help in the organisation of the focus group text prior to coding stage. The thematic analysis was carried out by the student researcher in collaboration with the principal investigator. Then, sub-themes were developed, agreed and discussed. Data saturation was concluded when there were no additional themes or sub-themes generated with further discussions.
5.5 Results:

The study included eight foundation dentists, of whom six were female while two were male. All the participants were newly graduated from dental schools in the UK except one who was graduated from a dental school in Spain. The focus group discussions lasted for about an hour. Five topic themes were obtained during the analysis process. Table 1 summarises the five themes and their emerged sub-themes.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-themes</th>
</tr>
</thead>
</table>
| Dentist related factors | - Willingness, passion and dedication  
                          | - Education, knowledge and training                                          |
| Clinical factors     | - Time  
                          | - Units of Dental Activity (UDAs)  
                          | - Practice type and armamentarium  
                          | - Educational supervisor (ES) and clinical supervisor.                      |
| Dental materials factors | - Easiness, time  
                          | - Technique sensitivity, need for caries removal, LA and rubber dam isolation  
                          | - Evidence-based performance                                                  |
| Patient related factors | - Cooperation and compliance  
                          | - Age  
                          | - Mouth size  
                          | - Aesthetics  
                          | - Restorative burden  
                          | - Symptoms                                                             |
| Parents related factors | - Motivation and time  
                          | - Aesthetics and refusal  
                          | - Restoration longevity                                                      |

Table 5.1 Shows the obtained five themes and emerged sub-themes.
5.5.1 Theme 1: Dentist-related factors

In this theme, all participant dentists showed the desire and willingness to treat carious primary teeth. However, the final decision to treat and the selection of the restorative material is based on multiple factors. Interestingly, undergraduate education and training might play an important role in the dentist decisions and practices. One of the participants found Hall crown might be technically difficult and she preferred GIC as her first clinical choice to treat carious primary teeth.

*Obviously, as an undergrad, we got to do a Hall crown technique and we did it on phantom heads and I'm quite comfortable doing them.*

...*recently they brought in our undergrad curriculum trying to drill in the Hall crown technique more. Was it like other units? I don't know. I feel like I would continue doing it. I feel like it takes really the same amount of time as it does to give LA and do the fillings and things.*

...*I think my experience was very different to university in contrast to being an FD. I went to university in Spain and we were restoring teeth. We would rarely, rarely do extractions on children unless it was an absolute necessity, to the point where I've done pulpotomies and pulpectomies and we always used to put crowns on top... I was used to treating the paediatric patient as if it was like I would do a normal crown prep that I would do in Spain... We never really worked with GIC. We would do permanent composite fillings on these cases and whatever adult dentistry there was.*
I have done a few Hall crowns, but the problem I get with Hall crowns is like the separators, sometimes they don't seat fully and then you have to do interproximal slicing anyway.

5.5.2 Theme 2: Clinical factors

The key findings regarding clinical factors were time, practice type and educational supervisor/clinical supervisor experience and preference. There were comments that due to busy clinic and the difficulty to offer multiple visits, sometimes they tend to use GIC rather than Hall crowns even if the child is cooperative and PMCs are clinically indicated.

It's just such a busy practice that if I say to the parents, I don't have appointments until this date, they'll say, we'll just do the fillings...

You don't have time for rubber dam, so don't do a composite, just do GIC...then I look at the diary now and I'm seeing that they're booking in check-ups for five minutes... you can't do an exam, bite-wings on a child...

The participants expressed that ES might have different approach to treat carious primary teeth and they usually lean towards GIC restorations following minimal caries removal. The suggested reasons, which have been mentioned by many participants, were limited clinical experience of the ES regarding Hall
crowns and also that the use of GIC might be a faster way to meet UDA
targets. Furthermore, one of the participants suggested that the lack of proper
understanding behind Hall technique by some of the ES might play a crucial
role in their clinical decision and the preference of GIC restorations.

My ES they've attempted them, but they don't find it something they can
easily do.

I think in my practice, a lot of the other associates will just use GIC and
minimal caries removal of that normally won't even use LA.

...they've not said yes or no to anything, but I think they lean towards GIC.

I think they feel more comfortable just doing GIC...15-20 years of
experience, they find it so much more straightforward to just put some
GIC in.

I think it's just one of those things that they haven't been trained in doing
as well as we have and so they just do what they used to.

I think it's basically just a lack of understanding of the technique more
than anything else.
When you're thinking about potentially, like, UDA accounts, slapping some GIC in as a much faster way to get your UDAs than bringing them back for Hall crowns.

It's a quick one UDA...

One of the participants directed attention to the effect of the type of the practice and the availability of the armamentarium on the decision-making process. The participant is working in a dental primary care practice as well as a community dental unit. She highlighted the huge effect of the availability of the PMC armamentarium on her decision. As a result, she might avoid PMCs in the general dental practice due to the shortage in the PMCs sizes.

I work across two different places and, in one of my jobs, Hall crowns are like bread and butter. We do it all the time. Everything there is really good.... In my other job, I'm not going to lie to you, the practice, I don't feel as comfortable putting them in because I know that we don't have all the sizes available and I know that we don't have time.

5.5.3 Theme 3: Dental materials factors
While clinical and dentist factors played roles in the dentists’ decision-making process, dental materials factors have also been reported as an important determinant. The impression gained from the discussions was that evidence-based selection of the restorative dental material might not be the key factor in the process, while the ease of placement and the time needed to place
restorations are the major factors. The majority of the participants reported that Hall technique might be easier than direct restorations, especially when there is need for LA, caries removal or rubber dam isolation. What is more, some participants showed some concerns regarding the clinical failure of GIC restorations. However, due to its easiness of clinical application, GIC might still have a place in the general dentist daily activities to manage carious primary teeth.

Overall, I prefer that compared to sticking a GIC into a child if I'm completely honest, because I feel like you don't have to worry about LA, you don't have to worry about whether or not you've got the caries out, you don't have to worry about whether the child can tolerate you drilling and filling for ages and ultimately you've managed the problem somewhat.

... I would definitely say that it's easier than trying to pick up a drill. It's less sensations and it's quicker.

I feel like it (Hall crown) takes really the same amount of time as it does to give LA and do the fillings and things.

But I think using LA and that sort of thing, if you're doing it properly, then Hall crown usually I find is faster.
I always give the option of Hall crowns along with restoring with normally GIC in the practice

...I can't say I've worked in the UK long enough to know how I feel about GIC yet just because I've had a lot of patients come back with those things coming out. I'd say that's like the major problem with GIC

5.5.4 Theme 4: Patient-related factors
In this theme, the participants expressed how important is the case selection on the clinical decision-making regarding selected restorative dental materials. They highlighted the profound effects of factors such as child cooperation, age, mouth size, and restorative burden. Aesthetic of the restorative material is generally not an issue for the children but it might be for some parents, which will be discussed later.

...I've done a number of them this year and I found that I have to be quite selective of the patients...

Just case selection, really. You got to find a tooth that's asymptomatic but it's not enamel caries, because then you can just use fluoride. Trying to find the case for (PMCs) it is quite difficult.

I think the child is usually happy to sit and do whatever is needed, as long as you're able to communicate that with them properly.
Overall, I prefer that (PMCs) compared to sticking a GIC into a child if I'm completely honest... you don't have to worry about LA... you don't have to worry about whether the child can tolerate you drilling and filling for ages...

...but I would say generally because it's a community based job and it's children with autism or severe anxiety, I would definitely say that it's easier (PMCs) than trying to pick up a drill. It's less sensations and it's quicker...

I've not really done that many (PMCs). Had a problem with basically if there's either gingival growth into the cavity, things like that or when you just got a child with multiple carious lesions, then you just think, if I'm going to give an ID block, I might as well just do composites in the whole quadrant kind of thing.

I think it also depends as well if they're getting symptoms from it or if the tooth previously has had symptoms and then no longer does, because that means the pulp probably dead on there, in which case it might just be worth just putting a GIC in and leaving it, basically.

I don't really think that GIC is any easier. I think it will depend on the patient. But I think if you can put separators in the Hall crown, you'd be able to do either or, in my opinion
We have a lot of anxious patients, so I guess in that respect it's (GIC) quite useful.

I tend to find if I fail in my composite or my GI because of LA or compliance or whatever

...I'm not sure really but I feel like it's always been children, they need to be out the chair as soon as possible so you don't lose compliance. You don't have time for rubber dam, so don't do a composite, just do GIC.

...it can be a bit challenging to put the rubber dam on depending on the patient and obviously making sure that they're fully numb before putting the clamp on and things. It does mean that I spend more time in my diary for composites.

Then I think the size of the child also matters for me as well. If you get a really little six year old or younger, it's actually quite difficult to put those all the separators on, because you have to put so much pressure onto the tooth and the gum. They find it quite difficult to tolerate.

I think sometimes my patients or my parents will say, yes, we want a white filling, we don't want a cap for various reasons. Like they know it's going to change the bite or aesthetics or whatever.
By giving the participants a clinical case scenario of a four or five-year-old who needs a filling, the majority of the participants would offer Hall crowns as the first option but two of the participants reported GIC preference as they thought children at this age will not be able to tolerate PMCs and GIC would cause fewer issues.

*I'd be doing a Hall crown if I could and depending on compliance. If I couldn't do a composite with the rubber dam, then I wouldn't do a rubber dam. I would just probably put a GI in and then keep assessing it...*

*I would always try a Hall crown. Obviously, if they wouldn't let me, then I would think of other options but I'm always quite happy to try first of all and then see.*

*I offer both crowns and fillings but I usually do fillings.*

*I would most likely put GIC in someone that young because I don't think they'd be able to tolerate anaesthetic very easily...*

*Probably I'll just do a GIC, to be honest. Just seems to have fewer issues when I do them.*
5.5.5 Theme 5: Parents-related factors

As discussed in the previous themes, almost all participants would offer Hall crowns, as the gold standard, to restore primary molars with multiple surfaces caries. However, they reported that parents’ attitude, beliefs and motivations might have an impact on their clinical decision-making. It has been reported that some parents rejected PMCs for several reasons, such as aesthetic concerns, bite alteration, and one participant reported that the parent was concerned regarding the risk of choking if the PMC debonded. Furthermore, the need for multiple visits to restore carious primary teeth using PMCs might be a barrier that makes some parents lean towards direct restorations such as GIC, especially when they have many children who need multiple restorations.

...not just the children that I'm treating, but the parents as well. It's like, can I bring them on board? I'll tell them that this is the best evidence base. Some of them will understand, some of them will be happy, they'll be like, you're providing the best care for my child.

Some people are just really not happy with the fact that it's silver, even though it's temporary, even though it's at the back of the mouth, it's just not aesthetically pleasing.

Now I've got a lot of parents who prefer the white fillings that look like the tooth. Even in kids’ teeth, even though there is very little time before that tooth is going to be exfoliated they would prefer a white filling and they're quite adamant.
I've only had a few times where the patient, their parents have been concerned with having metal in the mouth and didn't want to go down that route.

I think. I've had a lot of problems with patients bite and the mum not wanting the stainless steel crown.

...it's the parents that really don't like the idea. What if it (PMC) falls off and it comes out and they choke on it, like the choking hazard?

Two of the participants highlighted the importance of the communication, especially regarding PMCs, with the parents during treatment planning as this might have a huge impact on parents’ expectation and their acceptance of some treatments such as PMCs. One of the participants suggested that leaflets about PMCs that are available at the community dental unit where she does work might explain why more PMCs are placed at community dental units than general dental practices.

Although one thing I have definitely learned from this year is making sure I've explained everything. The look of the Hall crown is an interesting one, like the aesthetics of it because I've had a patient with a mother who was all for it and I showed her it. That was all fine, cemented it. Her words were literally I didn't realise it would be that visible... It ends up coming off again.
That's another thing that I think really influences how good your information sheet is. My practice doesn't have one. My community has one, which is probably why the uptaking community is so much higher.

5.6 Discussion:
The present focus group study provided a preliminary insight into the willingness, attitude, clinical decision-making and barriers of a convenience cohort of GDPs who are treating child patients and working for the NHS in London. On order to overcome the restrictions placed on the face-to-face meetings, due to COVID-19, and to facilitate the participation, an online virtual meeting was agreed and arranged. Several studies concluded that online focus group discussions collect similar amount of data which are comparable in their quality to that produced by face-to-face focus groups (Woodyatt et al., 2016; Kite and Phongsavan, 2017). Online focus groups also help mitigate possible COVID-19-related risks that might be encountered with face-to-face meetings.

The involvement of GDPs in dental clinical research is currently limited. Randall and Wilson (1999) concluded that the participation of the GDPs in clinical research testing restorative materials is of a great value. Currently, there is no up to date studies that have explored GDPs' attitude and barriers faced in treating child patients with the NHS in the UK.

Analysis of the five themes revealed that FDs were dedicated and showed willingness to treat children with carious primary molars and they were aware
of their role in the children’s oral health. All participant dentists in this study agreed that carious primary molars should be restored. Different opinions on the suggested restoration were observed. The majority claimed that, ideally, PMCs would be their first choice when multiple caries surfaces are involved. GIC restorations were the alternative only when the PMCs are not indicated. However, for a limited number of the participants, GIC restorations would be their first option as they were not confident doing PMCs in general dental practices. This finding is not in line with the previously reported data among GDPs where atraumatic restorative technique (ART) or less interventional techniques were the most preferred restorative approaches (Milsom et al., 2002; Tickle et al., 2007). Threlfall et al. (2005) reported that only 7% of the participant GDPs in their interview would offer PMCs to restore extensive carious primary molars. One reason for this change in the attitude towards PMCs is due to the introduction of the Hall technique into the undergraduate syllabus of the UK dental schools. Gilchrist et al.(2013) reported that there was a dramatic increase in the number of the dental school students who placed PMCs from less than 2% in 2005 up to 75% in 2010 and the participated students in their focus groups reported positive attitude towards Hall technique. Regarding GIC restorations, our study findings highlighted the fact that GIC is a popular restorative material choice in the hands of the GDPs which might fit their busy clinics. These findings are in line with reported studies that investigated used restorative materials among GDPs (Tickle et al., 2007; Lee et al., 2013; Wilson et al., 2019). Composite restorations were the least popular used restorative material due to its technical sensitive procedure that needs high patient cooperation for LA, complete caries removal and
rubber dam isolation. These findings are suggesting that this sample of GDPs is more leaning towards the least interventional techniques to manage carious primary molars.

In this study, all participant FDs reported that they are confident and have positive experience regarding the use of Hall technique crowns to restore asymptomatic extensive carious primary teeth. In contrast, participants claimed that almost all ESs and associates avoid using PMCs or have negative attitude and limited clinical experience. These findings agree with the results reported by the retrospective study by Harford et al. (2018), where the FDs were the only dentists who placed PMCs in the general dental practices. This might be due to positive experience of the newly graduated FDs regarding Hall technique after the introduction of this technique into the dental schools syllabus in the UK. What is more, FDs might be less stressed regarding UDAs and financial aspects of running a dental practice than ESs and associates.

It has been shown that FDs are aware of the multifactorial process of the decision-making regarding the selection of the most appropriate, ideal, restorative materials and the possible barriers in the primary dental care settings. The most common reported barriers were child cooperation, compliance, expectations and resistance from parents, which are similar to the reported barriers in other published studies (Kay and Locker, 1996; Harford et al., 2018). Other barriers include busy clinics and shortage of the equipment in general dental practices. This situation might place further pressure on the general dental practices in order to resolve the backlog of patient care following the COVID-19 pandemic (Witton et al., 2021).
5.7 Limitations:
The participant dentists in our study were FDs and they were not randomly selected. Consequently, the results of this study cannot be generalised. Furthermore, only one focus group session was completed, which might affect the level of saturation as the discussion was based on the researcher's subjective decision of data saturation. What is more, reported opinions regarding hypothetical clinical situations might not reflect the actual clinical attitude and practices of participating practitioners as they might claim doing things that are different to what they actually do (Helminen et al., 2002).

5.8 Conclusion:
Identified themes provided an insight into GDPs’ practices to restore carious primary teeth. Participant FDs showed willingness to treat child patients and expressed knowledge and flexibility in their clinical decision-making process. In contrast to previous studies, PMCs (Hall technique) was the first treatment option to manage carious primary teeth followed by GIC as an alternative. It has been claimed that ESs and associates more lean towards GIC restorations and PMCs are rarely an option. This might reflect the impact of undergraduate teaching on the newly graduated dentists’ practices. Furthermore, UDAs and financial aspects of running a dental practice might be higher priority for ESs and associates than for FDs. The most commonly reported barriers to restore carious primary teeth were child cooperation, age, busy clinics and parents' expectations.
Chapter 6: Conclusion, study limitations and suggested future work
6.1 Conclusion:
The vitro studies showed that Renewal MI alone has limited ability to bond to sound dentine and microgap formation at the interface. What is more, waiting for 60s prior to the light cure of Renewal MI or acid etching with 35% phosphoric acid without adhesives showed no improvement in its capacity to bond to sound bovine dentine. However, when sound bovine dentine was etched with (35% phosphoric acid) and adhesives were used (SBU or G-Bond) prior to Renewal MI, it showed bonding ability and resin tags formation comparable to Z250 (etch and bond) with no microgap formation. What is more, the use of adhesives (SBU or G-bond) prior to Renewal MI restoration showed no obvious effect on its ability to inhibit the MMPs activity at the interface. These findings suggested that commercial adhesives, such as SBU or G-Bond, could be considered to improve the ability of renewal MI to bond to sound dentine without affecting its capacity to inhibit the MMPs activity. However, this might interfere with the goal of the Renewal MI composite that is aimed to provide the GDPs a simple restoration that needs single step application, minimum child cooperation and tooth isolation.

The audit of the GDPs experience showed that GIC restorations were the most used materials to restore primary molars with multiple carious surfaces. Furthermore, GIC showed high failure rates on follow-up, about one third of the placed GIC restoration needed to be replaced within three years of placement. The most common reasons for GIC restoration failure were bulk fracture of the restorations followed by recurrent caries and infection/sepsis. The number of placed PMCs was limited; however, only one PMC needed to be replaced as parents showed aesthetic concerns. Composite restorations
were the least used restorative materials, only one restoration needed replacement within a three-year follow-up period.

The focus group has provided an insight into GDPs’ practices to restore carious primary teeth. The participant FDs expressed knowledge and willingness to treat carious primary teeth. They claimed that PMCs (Hall technique) would be their treatment option for primary teeth with multiple carious surfaces. The majority of the participants showed confidence in the placement of PMCs. GIC would be their first alternative option to PMCs. FDs claimed that ESs and associates lean more towards GIC restorations and PMCs are rarely an option. Time, shortage of the armamentarium in the primary care units and UDAs were the most reported barriers to use PMCs and, as a result, GIC is the best alternative. Composite restoration was not a popular option to treat primary molars among the majority of the participants. This was due to time, the need for local anaesthesia and isolation.

6.2 Limitations:
The major limitation in the laboratory studies was the size of the samples, one tooth sample for each tested group, except for the SBS where ISO recommendations were followed. Furthermore, only qualitative evaluation and analysis of the formed resin tags and the ability of the Renewal MI to inhibit the MMPs activity were commenced. Another limitation is that only SEM imaging was used to check the microstructure of exposed dentine surface after acid etching and the layer that formed at the restoration-dentine interface. Also, when the Image J software used to measure the diameter of the dentinal
tubules and the micro-gaps at the interface, the software was calibrated but the intra-examiner repeatability was not tested. Furthermore, during the process of dentine disc demineralisation to test MMPs activity, bovine dentine discs showed different behaviour to human dentine, only about 45% of mass loss after 48h of immersion in 4 M formic acid compared to more than 75% with human dentine; it was assumed that no collagen collapsed without further investigation.

Regarding the audit of the GDPs’ clinical experience and the focus group, sample size and the randomisation were also the main limitations. Due to the number of teeth in the audit, only descriptive analysis was performed. What is more, the GDPs represented a convenient sample, which would effect on the ability to generalise the findings. On the other hand, the participants in the focus group represented a convenient sample and saturation based on subjective decision-making with only one session was completed.

### 6.3 Suggested future work:

Based on the work done in this thesis and its limitations, the following further investigations and studies are recommended:

1) Clinical trials:

   Short-term clinical trial to check the efficacy of Renewal MI under real-life situations with small sample size is needed. If Renewal MI shows lower failure rate than GIC after a six-month period, further longer RCTs should be followed.

2) Laboratory studies and investigations:
- Larger sample size with more qualitative analysis, especially regarding resin tags formation and MMPs activity test.

- CLSM of the bovine dentine samples with Rhodamine B dye (0.2%) could be used to check the resin tags formation and ensure no collagen collapse after total demineralisation of dentine discs.

- Further studies that include surface chemistry (Raman and Fourier transform (FTIR) spectra) are needed to investigate bovine dentine tubules and dentine surface after acid etching and to investigate the formed layer (separate resin) in the gap at the SMART composite-dentine interface, especially after 60s waiting before light curing.

- Further investigation with surface chemistry studies regarding the process of creating caries-like dentine discs as, in this study, bovine dentine showed considerably less mass change when compared to human dentine in previous studies at the department.

- As renewal MI showed improved bond strength to sound bovine dentine with commercial adhesives, more work might be needed to develop its own adhesive which is less technique sensitive possibly self-etch bonding.

3) Regarding GDPs’ experience, used materials and their long-term clinical outcomes, a larger randomised sample size of the recruited participants that includes different GDPs groups is needed in order to commence statistical analysis and generalise the results.

4) Similarly, regarding the focus group, a larger randomised sample size of the recruited participants that include different representative GDPs groups and several sessions to ensure saturation is needed.
Appendices

Appendix A: Notification of Ethics Approval of the GDPs’ audit

12/04/2022

Prof Paul Ashley
Eastman Dental Institute
Faculty of Medical Sciences
UCL

Cc: Saud Almaeen

Dear Prof Ashley,

Notification of Ethics Approval
Project ID/Title: 21963/002: An audit of dental materials used to restore carious primary molars and their outcomes among a convenient sample of General Dental Practitioners in London

Further to your satisfactory responses to the reviewer’s comments, I am pleased to confirm in my capacity as Chair of the UCL Research Ethics Committee (REC) that your study has been ethically approved by the UCL REC until 12/04/2023.

Ethical approval is subject to the following conditions:

Notification of Amendments to the Research
You must seek Chair’s approval for proposed amendments (to include extensions to the duration of the project) to the research for which this approval has been given. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing an ‘Amendment Approval Request Form’
http://ethics.grad.ucl.ac.uk/responsibilities.php

Adverse Event Reporting – Serious and Non-Serious
It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator (ethics@ucl.ac.uk) immediately the incident occurs. Where the adverse incident is unexpected and serious, the Joint Chairs will decide whether the study should be terminated pending the opinion of an independent expert. For non-serious adverse events the Joint Chairs of the Ethics Committee should again be notified via the Ethics Committee Administrator within ten days of the incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Joint Chairs will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Office of the Vice-Provost Research, 2 Taviton Street
University College London
Tel: +44 (0)20 7679 817
Email: ethics@ucl.ac.uk
http://ethics.grad.ucl.ac.uk
Final Report
At the end of the data collection element of your research we ask that you submit a very brief report (1-2 paragraphs will suffice) which includes in particular issues relating to the ethical implications of the research i.e. issues obtaining consent, participants withdrawing from the research, confidentiality, protection of participants from physical and mental harm etc.

In addition, please:

• ensure that you follow all relevant guidance as laid out in UCL’s Code of Conduct for Research: www.ucl.ac.uk/srs/governance-and-committees/research-governance
• note that you are required to adhere to all research data/records management and storage procedures agreed as part of your application. This will be expected even after completion of the study.

With best wishes for the research.

Yours sincerely

Professor Michael Heinrich
Joint Chair, UCL Research Ethics Committee
Appendix B: GDPs' audit case report form

## Appendix D: Case report form CRF

<table>
<thead>
<tr>
<th>Case serial</th>
<th>Gender</th>
<th>Age (b/y)</th>
<th>Oral hygiene</th>
<th>Cooperation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caries site</td>
<td>Extent</td>
<td>Radiographs</td>
<td>Treatment visit</td>
<td>Follow up outcome</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Any preventive measures have been involved:

- Yes / No

<table>
<thead>
<tr>
<th>Unit investigation, analysis and instructions to reduce sugar intake</th>
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</thead>
<tbody>
<tr>
<td>Oral hygiene instructions</td>
</tr>
<tr>
<td>Topical fluoride varnish</td>
</tr>
<tr>
<td>Tissue analysis</td>
</tr>
</tbody>
</table>

Data collector initials and signature: Date: Investigator initials and signature: Date:

Management of carious primary molars among GDPs version 1 September 17th 2020

Case report form CRF guidelines:

- All data required should be provided, please follow the attached coding system.
- Regarding comments; if no comments please leave the field blank.
- For mistakes correction; single strike through the original text entered and write the updated text next to the change. Please state when the change has been made and by whom, use your initials and the reason for change.
- Fields should not be left blank; any missing data should be entered NK (not known) or NO (not done).
- Consistent completion of dates and numbers; date should follow dd/mm/yyyy format.
- If more than 4 teeth have been restored, 4 restored teeth will be selected randomly.

Management of carious primary molars among GDPs version 1 September 17th 2020

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## Appendix C: GDPs’ audit clinical outcomes codes

Codes for data collection in the case report form CRF

<table>
<thead>
<tr>
<th>Codes for caries site and extent:</th>
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<tbody>
<tr>
<td>1. Occlusal caries into enamel</td>
</tr>
<tr>
<td>2. Occlusal caries into dentin</td>
</tr>
<tr>
<td>3. Proximal caries into enamel</td>
</tr>
<tr>
<td>4. Proximal caries into dentin</td>
</tr>
<tr>
<td>5. Smooth surface caries</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Codes for treatment approaches:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. No treatment</td>
</tr>
<tr>
<td>7. Prevention only</td>
</tr>
<tr>
<td>8. Conventional approach, drill and fill</td>
</tr>
<tr>
<td>9. Biological approach, seal caries or minimal caries removal</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Codes for restorative dental materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Amalgam</td>
</tr>
<tr>
<td>11. Glass ionomer cement GIC</td>
</tr>
<tr>
<td>12. Resin modified Glass ionomer cement RMGIC</td>
</tr>
<tr>
<td>13. Composite</td>
</tr>
<tr>
<td>14. Compomer</td>
</tr>
<tr>
<td>15. Prefabricated metal crown PMC</td>
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<tr>
<td>16. Others</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Codes for clinical outcomes:</th>
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<tbody>
<tr>
<td>17. Intact restoration or stable condition</td>
</tr>
<tr>
<td>18. Recurrent caries</td>
</tr>
<tr>
<td>19. Marginal discolouration</td>
</tr>
<tr>
<td>20. Bulk discoloration</td>
</tr>
<tr>
<td>21. Marginal fracture / degradation without recurrent caries involvement</td>
</tr>
<tr>
<td>22. Bulk fracture of the restoration</td>
</tr>
<tr>
<td>23. Fracture of tooth</td>
</tr>
<tr>
<td>24. Poor anatomic form (wear)</td>
</tr>
<tr>
<td>25. Pain/sensitivity requiring replacement of restoration</td>
</tr>
<tr>
<td>26. Infection/sepsis</td>
</tr>
<tr>
<td>27. Others e.g. patient concern regarding aesthetic or material</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Codes for actions:</th>
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</thead>
<tbody>
<tr>
<td>28. No further treatment needed</td>
</tr>
<tr>
<td>29. Add / correct restoration</td>
</tr>
<tr>
<td>30. Replacement of restoration</td>
</tr>
<tr>
<td>31. Pulp therapy</td>
</tr>
<tr>
<td>32. Extraction</td>
</tr>
<tr>
<td>33. Refer to specialist</td>
</tr>
</tbody>
</table>

**Record the most dominant reason for the clinical outcome if more than one is applicable.**
Appendix D: Notification of Ethics Approval of the Focus Group

14/01/2022

Prof Paul Ashley
Eastman Dental Institute
Faculty of Medical Sciences
UCL

Cc: Saud Almaeen

Dear Prof Ashley,

Notification of Ethics Approval
Project ID/Title: 21963/001: A Focus Group on Dental caries management among potentially cooperative children with General Dental Practitioners (GDPs): their attitude, potential barriers and opinions

Further to your satisfactory responses to the reviewer’s comments, I am pleased to confirm that your study has been ethically approved until 14/01/2023.

Ethical approval is subject to the following conditions:

Notification of Amendments to the Research
You must seek Chair’s approval for proposed amendments (to include extensions to the duration of the project) to the research for which this approval has been given. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing an ‘Amendment Approval Request Form’
http://ethics.grad.ucl.ac.uk/responsibilities.php

Adverse Event Reporting – Serious and Non-Serious
It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator (ethics@ucl.ac.uk) immediately the incident occurs. Where the adverse incident is unexpected and serious, the Joint Chairs will decide whether the study should be terminated pending the opinion of an independent expert. For non-serious adverse events the Joint Chairs of the Ethics Committee should again be notified via the Ethics Committee Administrator within ten days of the incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Joint Chairs will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.
Final Report
At the end of the data collection element of your research we ask that you submit a very brief report (1-2 paragraphs will suffice) which includes in particular issues relating to the ethical implications of the research i.e. issues obtaining consent, participants withdrawing from the research, confidentiality, protection of participants from physical and mental harm etc.

In addition, please:

- ensure that you follow all relevant guidance as laid out in UCL’s Code of Conduct for Research: www.ucl.ac.uk/srs/governance-and-committees/research-governance
- note that you are required to adhere to all research data/records management and storage procedures agreed as part of your application. This will be expected even after completion of the study.

With best wishes for the research.

Yours sincerely

[Signature]

Professor Michael Heinrich
Joint Chair, UCL Research Ethics Committee
Appendix E: Focus group’s Participants Information Sheet (PIS)

Participant Information Sheet For [General Dental Practitioners]
UCL Research Ethics Committee Approval ID Number: 

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study:
A Focus Group on Dental caries management among potentially cooperative children with General Dental Practitioners (GDPs): their attitude, potential barriers and opinions.

Department:
Eastman Dental Institute Craniofacial & Development Science

Name and Contact Details of the Researcher(s):
Saud Almaeen/ sau.d.almaeen.19@ucl.ac.uk/ [Redacted]
Name and Contact Details of the Principal Researcher:
Paul Ashley/ p.ashley@ucl.ac.uk/ 02034561022

1. Invitation:
As a general dental practitioner who providing NHS dental care in London, we’d like to invite you to take part in our research study. Your participation in this research will be valued and help us to achieve the proposed aim and objectives of this study. Please take time to read this information sheet before you decide to participate. If you have any questions, concerns or you would like further information regarding this study, please don’t hesitate to ask us or discuss it with others if you wish.

2. What is the purpose of the study?
We are at UCL Eastman Dental Institute working on a novel self-etching, easy to place composite restoration, SMART composite, which could be used to restore carious primary teeth with minimal invasive and less technique sensitive approach especially at primary care environment. However, due to limited information available regarding willingness of the GDPs who are working for the NHS to treat children with carious teeth and what are the most common barriers to treat children at primary dental care settings, this study aim to identify those barriers, GDPs’ willingness to treat children, and also their opinions regarding our new dental material, SMART composite, among a selected group of GDPs in London.

A Focus Group on Dental caries management among children with GDPs version 1.0 02/01/2022
3. **Why have I been invited?**

You are invited to participate in this study because you are a general dental practitioner who is working in London and providing NHS dental care for child patients. We are recruiting a convenient sample of GDPs.

4. **Do I have to take part?**

Your participation in this study is entirely voluntary. If you decide to withdraw you can withdraw at any point up to 4 weeks after the group discussion, without the need to give a reason, when withdraw option might be restricted. If you don’t wish to participate or decide to withdraw from the study will not affect you at all.

5. **What will happen to me if I decide to take part?**

If you decide to participate in this study, you will be sent a consent form to your NHS email address and asked to sign and return it to the provided researchers’ emails. Then you will receive an invitation to take part in a virtual focus group session through Microsoft Teams virtual call. The focus group will last between 45 – 90 minutes. The facilitators (the principle investigator and the student researcher) will conduct and record the discussions.

6. **Will I be recorded and how will the recorded media be used?**

The focus group recordings of your activities made during this research (including audio, video and screen sharing activities of Microsoft Team) will be used only for analysis to achieve the aim of this study. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings. All Microsoft Team recordings will be deleted immediately after the data has been transcribed by the student researcher.

7. **Will my taking part in the study be kept confidential?**

All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any ensuing reports or publications. All personal data will be pseudonymised. All data including focus group transcripts will be stored and managed in a password-protected on UCL university computer system. Collected data will be accessible and processed only by the researcher student and the principle investigator/supervisor at UCL university. Data will be stored securely in accordance with UCL university’s Data Protection policies for data handling as a part of the research record.

A Focus Group on Dental caries management among children with GDPs version 1.0 02/01/2022
8. **What will happen to my data?**

Collecting and manipulation of data will follow the principles of the General Data Protection Regulation (GDPR). We will use collected information to achieve this study aim and objectives. UCL Eastman Dental Institute as a data controller will ensure that using of your collected data properly. In order to ensure accurate and reliable research process, up to 4 weeks after the group discussion, your rights to access or change data might be limited.

9. **Are there any risks?**

There are no obvious risks of participation in this study. We will use pseudonymous data and we will follow GDPR and UCL university’s Data Protection policies for collection, manipulation and storage of data.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at (Alex Potts data-protection@ucl.ac.uk).

10. **What will happen to the results of this study?**

As a part of the postgraduate study of the student researcher, the results of this research will be used to evaluate the attitude and identify the challenges faced by general dentists in treating potentially cooperative child patients and their opinion regarding our novel filling material. The results may also be published in a scientific journal and presented at national or international conferences. If you are interested, you might request a copy of the results by contacting the research student. We will send you a copy of the results once the research has completed.

11. **Who is organising and funding the study?**

This study will be organised and funded by UCL Eastman Dental Institute as a part of postgraduate student project.

12. **Who has reviewed the study?**

This study has been reviewed for ethical approval, participants’ protection and given favourable opinion by UCL Research Ethics Committee.

A Focus Group on Dental caries management among children with GDPs version 1.0 02/01/2022
13. What if there is a problem?

If you have any concerns, confusion or complaints regarding any aspect of the study at any time, you should contact: Saud Almaeen, contact details [redacted], email saud.almaeen.19@ucl.ac.uk or principle investigator/ supervisor Prof Paul Ashley (02034561022, email p.ashley@ucl.ac.uk). However, if you feel that your complaint has not been handled to your satisfaction by the student researcher or the supervisor, you can contact the Chair of the UCL Research Ethics Committee – ethics@ucl.ac.uk.

Further information and contact details:

Student: Saud Almaeen – saud.almaeen.19@ucl.ac.uk

Principle Investigator/ Supervisor: Professor Paul Ashley – p.ashley@ucl.ac.uk
Appendix F: Focus group’s participants consent form

CONSENT FORM FOR GENERAL DENTAL PRACTITIONERS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: A Focus Group on Dental caries management among potentially cooperative children with General Dental Practitioners (GDPs): their attitude, potential barriers and opinions.

Department: Eastman Dental Institute, Craniofacial & Development Sci

Name and Contact Details of the Researcher(s): SAUD ALMAEEN, saud.almaeen.19@ucl.ac.uk

Name and Contact Details of the Principal Researcher: Prof Paul Ashley, p.ashley@ucl.ac.uk

Name and Contact Details of the UCL Data Protection Officer:

This study has been approved by the UCL Research Ethics Committee: Project ID number:

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

I confirm that I understand that by ticking/initalling each box below I am consenting to this element of the study. I understand that it will be assumed that unticked/initalled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element that I may be deemed ineligible for the study.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>I confirm that I have read and understood the Information Sheet for the above study. I have had an opportunity to consider the information and what will be expected of me. I have also had the opportunity to ask questions which have been answered to my satisfaction and would like to take part in a group discussion</td>
</tr>
<tr>
<td>2.</td>
<td>I understand that I will be able to withdraw my data up to 4 weeks after group discussion</td>
</tr>
</tbody>
</table>

A Focus Group on Dental caries management among children with GDPs version 1.0 02/01/2022
Table 1: Consent Form

3. I consent to participate in the study. I understand that any personal information (names, gender) will be used for the purposes explained to me. I understand that according to data protection legislation, “public task” will be the lawful basis for processing.

4. Use of the Information for this project only
   I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified.
   I understand that my data gathered in this study will be stored pseudonymised and securely. It will not be possible to identify me in any publications.

5. I understand that my information may be subject to review by responsible individuals from the University for monitoring and audit purposes.

6. I understand that my participation is voluntary and that I am free to withdraw at any point up to 4 weeks after the group discussion without the need to give a reason.
   I understand that if I decide to withdraw, any personal data I have provided up to that point will be deleted unless I agree otherwise.

7. I understand the direct/indirect benefits of participating.

8. I understand that the data will not be made available to any commercial organisations but is solely the responsibility of the researcher(s) undertaking this study.

9. I understand that I will not benefit financially from this study or from any possible outcome it may result in in the future.

10. I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. Yes/No.

11. I consent to Microsoft Teams meetings being recorded (including audio, video and screen sharing activities), and understand that the recordings will be deleted immediately after they have been transcribed. Transcribed personal data will be pseudonymised. Personal data will be encrypted and protected by password. Only student researcher and principle researcher will have access to these data.

12. I hereby confirm that I understand the inclusion criteria as detailed in the Information Sheet and explained to me by the researcher.

13. I am aware of who I should contact if I wish to lodge a complaint.

14. I voluntarily agree to take part in this study.

15. Use of information for this project and beyond
   I would be happy for the data I provide to be archived securely in accordance with UCL university’s Data Protection policies for data handling as a part of the research record.
   I understand that other authenticated researchers will have access to my pseudonymous data.

If you would like your contact details to be retained so that you can be contacted in the future by UCL researchers who would like to invite you to participate in follow up studies to this project, or in future studies of a similar nature, please tick the appropriate box below.

| Yes, I would be happy to be contacted in this way |
| No, I would not like to be contacted |

Name of participant ___________________________ Date ___________________________ Signature ___________________________

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A Focus Group on Dental caries management among children with GDPs version 1.0 02/01/2022
Appendix G: Focus group’s Meeting Recording transcript

Paul Ashley (00:02)
That’s enough. I’m going to start transcription as well, which means I don’t need to see what I’m saying. That’s fine.

Almaeen Saud (00:29)
Should we start?

Paul Ashley (00:31)
Yeah, we’ll make a slow start. If anyone comes, they can catch up. Thank you everyone who’s logged on. This is a project that… Well, I said my name is Paul Ashley, one of the paediatric dentists of the Eastman. I’m an academic lead there and this is a project that one of our postgraduates, is doing. Z has very kindly helped us as well and has either gelled you or asking you nicely to come this evening.

Paul Ashley (01:00)
Really, this project is related to a different project, so we’re trying to get a new dental material, CMA and it’s USP is that it’s very easy to place. I’ve done service groups of dentists before a few years ago and when you look at the literature, there’s not really anything to explain or understand why dentists make the choices they make when it comes to filling teeth.

Paul Ashley (01:29)
I’m involved with parallel initiatives which are trying to get people to do more Hall crowns, etc. But Hall crown uptake outside of Scotland is really low and I think the view I’m taking is that sometimes in academia and other parts of dentistry, it feels a little bit like it’s very much, well, why aren’t you doing proper fillings? Why aren’t you doing Hall crowns? Why are children not perhaps getting the restorations we think they need?

Paul Ashley (02:02)
We’re not spending enough time asking dentists what are their issues, barriers, difficulties with regards to providing fillings in children. That’s the aim of today, this evening. It’s not about what’s right or what’s wrong, it’s not about looking disapprovingly if you say something that doesn’t fit, what guidance is.

Paul Ashley (02:31)
It’s about really trying to honestly understand why you guys are making the choices you’re making and what you think about that, whether you think what you’re doing is right or wrong or good or bad.

Paul Ashley (02:45)
All of this is anonymous, so please be as open and as honest as you can. There is literally no judgement. Hopefully we’ll get to the point of putting some of this into a publication that will be written in a way that it’s not clear who said what. I don’t want to hold back. I want you to say what you think, because certainly when I’ve done focus groups before, I found it really interesting.

Paul Ashley (03:18)
I mean, I always remember one that I did and the dentists were just like, we can’t do all crowns because either we don’t have a kit, it takes too long and we don’t understand or whatever. That’s the point of this evening. Is that okay? Everyone happy with that? Okay. We really want you to tell us what you think because otherwise this is pointless. I’m going to start off with Saud to get the ball rolling.

Almaeen Saud (03:49)
Thank you, Prof. Thank you all for coming today. As Prof said, it will be like an open discussion. There is no correct or wrong answers. We need your opinions rather than what is in books or in guidelines or others opinions. I’ll start with a general question rather than be specific. We will go down there to be more and more specific.

Almaeen Saud (04:23)
The first, like a question, what do you think of the restorative preventive care of children with Caries primary molars in your practise? Are you happy? Do you think, well, not that much? I’m here to hear from you.

Paul Ashley (04:44)
I’m going to pick on someone and unfortunately for N and E, they foolishly turned their cameras on. N you’re on my left side, so just tell me what you think. Happy? Not happy? What you expected? Not what you expected.

N (04:59)
Obviously, as an undergrad, we got to a Half Crown technique and we did it on phantom heads and I’m quite comfortable doing them. My ES they’ve attempted them, but they don’t find it something they can easily do. Then in practice, I’ve done a number of them this year and I found that I have to be quite selective of the patients.

N (05:22)
Not just the children that I’m treating, but the parents as well. It’s like, can I bring them on board? I’ll tell them that this is the best evidence base. Some of them will understand, some of them will be happy, they’ll be like, you’re providing the best care for my child.
N (06:37)
Then the child will also be, because the parent seems happy with the idea, the child will also be a bit more cooperative. Then I think the size of the child also matters for me as well. If you get a really little six year old or younger, it's actually quite difficult to put those all the separators on, because you have to put so much pressure onto the tooth and the gum. They find it quite difficult to tolerate.

N (06:03)
Some do exception, but I find boys tolerated better than girls. But that's just obviously my small little sample. I think I did 10 this year. Other dentists in my practice, because they know I'm comfortable doing it, they will refer their NHS patients to me. I've seen some from the other associates.

N (06:21)
There's one other associate who qualified just a few years before I have, and so she's happy putting the crowns on as well. Overall, I prefer that compared to sticking a GIC into a child if I'm completely honest, because I feel like you don't have to worry about LA, you don't have to worry about whether or not you've got the caries out, you don't have to worry about whether the child can tolerate you drilling and filling for ages and ultimately you've managed the problem somewhat.

N (06:53)
I hope that I can continue doing it. It depends on which practice I end up in and what demographic I have. Some people are just really not happy with the fact that it's silver, even though it's temporary, even though it's at the back of the mouth, it's just not aesthetically pleasing.

Paul Ashley (07:12)
Let's move along to E. Is your experience the same or different?

E (07:17)
I'd say slightly different. I work across two different places and in one of my jobs, half crowns are like bread and butter. We do it all the time. Everything there is really good.

E (07:36)
Like N says, you do have to be selective about the cases, but I would say generally because it's a community based job and it's children with autism or severe anxiety, I would definitely say that it's easier than trying to pick up a drill. It's less sensations and it's quicker. In my other job, this is going to sound terrible.
Paul Ashley (07:59)
This is the whole point anyway. There's nothing's terrible. I honestly believe nobody's really bothered to our dentists what they do and why. We spend a lot of time, I've spent a lot of time trying to find published work. It doesn't exist. It's like nobody's interested. I really want to know what's going on.

E (08:17)
That's my oven timer. In my other job, I'm not going to lie to you, the practice, I don't feel as comfortable putting them in because I know that we don't have all the sizes available and I know that we don't have time. The last thing I want to do is put seps in and then take them out, put the child through that, because sometimes the children get upset with even that.

E (08:46)
Then find, actually, I don't have all the sizes and then I'm going to look really stupid. The child's gone through something. I think I just feel less confident there because I genuinely don't think they've got the right equipment.

Paul Ashley (09:00)
What would you do instead?

E (09:03)
Obviously if I need to nothing out of the account, but generally I would do restorations there more I tend to. It's not an absolute set rule but I've done a couple of composites, more composites than GI.

Paul Ashley (09:20)
Okay. When you say you don't have the time, what do you mean by that?

E (09:25)
Again, where I'm there only not all the time it's difficult to get the seps in and then get the Caps in the correct amount of time later. It's just such a busy practice that if I say to the parents, I don't have appointments until this date, they'll say, well just do the fillings because it's quicker and we have to come back less. I think that's a factor, is that they don't have to come back.

Paul Ashley (09:52)
No. That's very interesting. We move along now. Sorry. T, how do your experiences compare?
T M (10:03)
I've basically put about three in all year. I've not really done that many. Had a problem with basically if there's either gingival growth into the cavity, things like that or when you just got a child with multiple caries lesions, then you just think, if I'm going to give an ID block, I might as well just do composites in the whole quadrant kind of thing.

T M (10:29)
Just case selection, really. You got to find a tooth that's asymptomatic but it's not enamel carries, because then you can just use fluoride. Trying to find the case for it is quite difficult.

Paul Ashley (10:44)
Yeah, that's perfect. Unfortunately, it's not showing me your first name. O T. How do your experiences correlate with everyone else?

O T (10:58)
Yeah, quite similar actually. I think in my practice, a lot of the other associates will just use GIC and minimal carries removal of that normally won't even use LA. It would just be like a spoon excavator, have a little go and then just pop some GIC.

O T (11:14)
I have seen quite a few of them as emergencies, which have obviously come back having them been painful and then basically saying or trying to deal with that, which should either be numbing them up and then removing that GIC and as much as possible, or just basically taking the teeth out, really.

O T (11:37)
A lot of the time, depending on the kid, that will either be Hall crowns or it would just be for me, it would be numbing up and then removing all the caries and then GIC. I think it also depends as well if they're getting symptoms from it or if the tooth previously has had symptoms and then no longer does, because that means the pulp probably dead on there, in which case it might just be worth just putting a GIC in and leaving it, basically.

Paul Ashley (12:03)
Okay, Z.

Z J (12:07)
Hello. Yes, I think my experience was very different to university in contrast to being a FD. I went to university in Spain and we were restoring teeth. We would rarely, rarely do extractions on children unless it was an absolute necessity, to the point where I've done pulpotomies and pulpectomies and we always used to put crowns on top. That was the go to and we'd even prep the tooth.

**Z J (12:44)**

We do like mini crown preps and put crowns on top. I had not really done the full crown technique before, I was used to treating the paediatric patient as if it was like I would do a normal crown prep that I would do in Spain. She was of shock. We never really worked with GIC. We would do permanent composite fillings on these cases and whatever adult dentistry there was.

**Z J (13:13)**

I think I had a very different way of looking at it. It's quite interesting, actually, seeing GIC in contrast to the techniques I was taught. We do rubber dam every single time and the crowns would always be prep. It's been very different. I can't say I've worked in the UK long enough to know how I feel about GIC yet just because I've had a lot of patients come back with those things coming out. I'd say that's like the major problem with GIC -

**Paul Ashley (13:55)**

Is that what you're expected to do now? Are you expected to put GIC in or are they giving you the opportunity to do rather than composite?

**Z J (14:04)**

I think from seeing my associates work because they've not said yes or no to anything, but I think they lean towards GIC because the patients that we have in our area are quite hard to... Well, I'd say we have quite a few patient management issues, so it's seen as like a fast, very minimal approach and it doesn't give any of the child...

**Z J (14:36)**

We have a lot of anxious patients, so I guess in that respect it's quite useful. If I could get rubber dam on a child and some of the child, they have limited mouth opening and a lot of the time it's the parents in the room. There's a lot of reasons why GIC does work because on the end of the day, on children, they do require different management.

**Z J (15:02)**

But I think I would definitely now, after this year, consider doing composite on D's and E's because that's how I was educated and I've not really seen any downfalls to that. The only one I would say is obviously
there's no fluoride release, which is a major advantage of GIC. But now it's been really interesting and it's been fun to work with GIC more. I think so far there's been no problems, but I would like to explore more into concept for D's and E's.

Paul Ashley (15:36)

S?

S S (15:42)

Yeah, I mostly do GICs for kids. I have done a few Hall crowns, but the problem I get with Hall crowns is like the separators, sometimes they don't seat fully and then you have to do interproximal slicing anyway. I'm thinking if you're going to do interproximal slicing, then patience [problem with the sound] anyway.

Paul Ashley (16:14)

L, L, did you come in, I'm not going to say late, did you come in after I give my little intro?

L (16:23)

Yeah, sorry. I think I came in like halfwayish.

Paul Ashley (16:29)

It's no problem. I think just to reemphasize, we're just really curious why people are doing what they're doing. What they're doing. There's no right or wrong answer here. I don't want people to be thinking, oh, I can't say that. I don't look bad. Honestly, we just want to know because I don't think anyone's ever bothered to really ask before. L, tell me your story.

L (16:51)

I always give the option of Hall crowns along with restoring with normally GIC in the practice. I try to convince, not convince, but tell the parents like it is a really good gold standard option. I've only had a few times where the patient, their parents have been concerned with having metal in the mouth and didn't want to go down that route.

L (17:16)

I'm pretty sure in my practice I'm really the only dentist that does Hall crowns. I don't think anyone else has Hall crown access in their practice, so I feel like it's deemed a foundation dentist thing and then no one else does it. I think most of the associates as well, if they have children with caries they give it to me and refer to me.
They don't want to do it, even though I'm sure they're more than capable of putting some separators in and Hall crowning. It probably wouldn't take them very long either. But I've seen quite a lot of high caries needs in kids. I like the Hall crown technique. It was interesting hearing what Zoha was saying about the composite experience.

I don't know if it was at uni, I'm not sure really but I feel like it's always been children, they need to be cut the chair as soon as possible so you don't lose compliance. You don't have time for rubber dam, so don't do a composite, just do GIC. I'm not sure if I've picked that up wrong or not but I've definitely been doing more GIC than composites on kids.

As you say you think it's an FT thing. Do you think all FT staffs are doing Hall crowns and then something happens?

I know, I don't know.

Over the time, they stopped doing it, or do you see your difference because you've been taught to more undergrad? What does everyone think?

Yeah, I'm not sure. I don't know how recently, but I don't know how recently they brought in our undergrad curriculum trying to drill in the Hall crown technique more. Was it like other units? I don't know. I feel like I would continue doing it. I feel like it takes really the same amount of time as it does to give LA and do the fillings and things.

I don't really see the benefit unless you're, in my opinion, being a bit naughty and not giving LA and not actually getting rid of the decay and you're just slapping on some GIC over the top of it. That's not really good practice.

Almaeen Saud (19:48)
I have just like... For curiosity, I have a question there because I’m working in the hospital, so we have a different approach. How much time usually you give for a child patient?

E (20:07)
For like a check-up?

Almaeen Saud (20:09)
I mean, for restoration, for fillings, or for fill crown?

E (20:15)
I do 30 minutes personally

Paul Ashley (20:22)
Is everyone 30? Anyone less than 30?

L (20:25)
Yeah, similar to me.

N (20:27)
Yeah, I normally do, if it’s for separators 20 minutes and another 20 minutes, but usually finish faster if it’s just a single crown.

Paul Ashley (20:39)
Anyone more than 30? It’s unlikely, but you never know. Okay, I want to go back to using composite. I think you made a good point, L, about composite rubber dam. I’m curious, people placing composite, do you use rubber dam? I expect the answer to be no, but you never know.

N (21:05)
I usually increase the time that I’ve worked out for the patient because sometimes it can be a bit challenging to put the rubber dam on depending on the patient and obviously making sure that they’re
fully numb before putting the clamp on and things. It does mean that I spend more time in my diary for composites.

**Paul Ashley (21:24)**
Okay. Anyone got any other thoughts on that?

**T M (21:27)**
Yeah, I would do a dam if I was doing a full lower quadrant, especially if there was a six or something like that.

**Paul Ashley (21:34)**
What's the age of patient with that be T?

**T M (21:37)**
Maybe eight or nine year old. Just after their sixes have come out and I've got caries sixes.

**Paul Ashley (21:47)**
What about let's say you've got like, a four or five year old who needs a filling? What do you think you guys would be doing in that situation?

**E (21:56)**
I'd be doing a Hall crown if I could and depending on compliance. If I couldn't do a composite with the rubber dam, then I wouldn't do a rubber dam. I would just probably put a GI in and then keep assessing it or I'd...No, I'd probably do that.

**Paul Ashley (22:19)**
That's perfectly fine. N, what about you?

**N (22:22)**
Yeah, I'd say similar to E that if I can then Hall crown. I think the youngest person I've done is a four year old, but he was really compliant and had a really good attitude, and we formed a really good relationship as well. It was easier. I wouldn't necessarily try that with all four year olds.

**N (22:41)**
But like I said that I would most likely put GIC in someone that young because I don’t think they’d be able to tolerate anaesthetic very easily. It would be mostly just hand excavating any soft caries and then make sure the EDJ was clear as I can. But it’s tricky.

Paul Ashley (23:02)
L?

L (23:06)
Yeah, quite similar. I’ve had patients that have been four or five, I would think. I would always try a Hall crown. Obviously, if they wouldn’t let me, then I would think of other options but I’m always quite happy to try first of all and then see.

Paul Ashley (23:23)
O.

O T (23:28)
Same thing, really. I mean, I find a hook and usually sometimes will take less time than a filling anyway, because obviously you don’t have to worry about getting them ready for the needle and all of the LA and everything. Usually it would be Hall crown as first thing.

Paul Ashley (23:45)
Z?

Z J (23:48)
Pretty much the same. Although one thing I have definitely learned from this year is making sure I’ve explained everything. The look of the Hall crown is an interesting one, like the aesthetics of it because I’ve had a patient with a mother who was all for it and I showed her it. That was all fine, cemented it. Her words were literally I didn’t realise it would be that visible.

Z J (24:18)
It ends up coming off again. The aesthetic side to it, I always reiterate it’s going to come off when the tooth exfoliates. The best with an ideal treatment, I think not just patient management with Hall crowns, but the parents sometimes have a lot to say about it. But apart from that, all the others have been fine.

Paul Ashley (24:45)
S?

S S (24:50)
Yeah, I'm the same. I offer both crowns and fillings but I usually do fillings.

Paul Ashley (25:01)
I think T, I don't know if we started with you but I'll ask you again. T?

T M (25:05)
Probably I'll just do a GIC, to be honest. Just seems to have less issues when I do them.

Paul Ashley (25:16)
You've all hinted at or suggested that you're the kind of the DFT and it feels a little bit like you're getting the kids passed on to you. What is your perception or what do you think without telling tales with anyone, what do you think your associates or ES are doing?

Paul Ashley (25:39)
Is the rest of the practise of mix or do you think it's just one kind of treatment? What's your fillings? whatever you want. I'm going to start with N.

N (25:51)
I think they feel more comfortable just doing GIC. For them obviously, they've had many years of experience. I'm borrowing the one associate who's a few years or more qualified than I am, she does walk around. But the identity and the practice, who have, say, 15-20 years of experience, they find it so much more straightforward to just put some GIC in.

N (26:12)
Then they'll see the patient every six months and as long as they are stabilised, then we have to necessarily worry about caries and they focus more all hygiene and things like that. They find the half crowns challenging to place and to then bring the patient back every three to five days later. It just doesn't quite work. I think it's just one of those things that they haven't been trained in doing as well as we have and so they just do what they used to.

Paul Ashley (26:49)
Does anyone agree with what N said? Does anyone have any different perspectives?
T M (26:56)
I agree with N. Yeah.

E (26:59)
To be honest, I think I've only got one associate who is also my ES and I think he's either GIC or refer to somebody else.

Paul Ashley (27:14)
Z, based on some of the data you've got from looking at what's being placed, do you have any different perspectives or any observations on what your colleagues have said so far?

Z (27:25)
From the data collection, it has pretty much been GIC all the way with the occasional half crowns thrown in. Obviously, this was retrospective data but I don't think much has changed, particularly for example, my practise the same dentist they're the same setup with one SD.

Z (27:44)
I think it depends on the family that comes in. I know one of my associates will have family, parents, like five in a row. When you're thinking about potentially, like, UDA accounts, slapping some GIC in as a much faster way to get your UDAs than bringing them back for half crowns.

Z (28:03)
If you're looking at a high caries risk family and you've got three children, always caries that's quite quick. If he sees them in 30, 40 minutes, the whole family, I mean, he can ask other questions about that. But that's the source there. The Hall crowns are very much exclusively reserved for SDs.

Z (28:22)
I think for my ES in particular, who also is the principal dentist, the Hall crown placement was very much to do with, we had to place half crowns as part of our quota this year.

Z (28:37)
It depends, I think on the culture of the practice. It's not something that is practised routinely, from what I've gathered anywhere other than maybe like, community or some of these guys who are exclusively seeing the paed patients. I don't get all the paed patients, so it just depends I think on the cohort.
Paul Ashley (28:54)
No, it's really helpful insight Z. Does anybody fundamentally disagree with Z or do you all think she's got a point? What's everyone else's take on that?

L (29:06)
I was going to say when Z was talking about the UDA thing, I was going to say it was ringing like similarities in my practice, because I see patients, they've come to me and I have a look back and they're 10, older, 15 and there's no bite-wings.

L (29:28)
Then I look at the diary now and I'm seeing that they're booking in check-ups for five minutes. I'm like, well, you can't do an exam, bite-wings on a child, so they just don't. It's a quick one UDA and then they're at the chair, like I just don't think they're very interested, which is bad.

Paul Ashley (29:46)
I think the trouble is there are so many difficulties around working practice, aren't there? Around UDA's in the contract? Obviously, that's bigger than news at the moment.

Paul Ashley (29:56)
I think this gets, L, to the point that I think I'm interested in, which is rather than trying to push techniques like the half crown that maybe some people struggle with to try and make it much easier to do fillings, which is what our separate project is about.

Paul Ashley (30:13)
I think that's why we need to understand what's going on in practice a little bit more. That's been really helpful. I think we won't keep you for too much longer, but let's decide. Should we keep going through the questions?

Almaeen Saud (30:23)
I have another question and then we'll go there. It's just a fast one. Do you suggest that GiC is much, much easier than Hall crown for young children?

Paul Ashley (30:41)
Looks like we've got two head shakers. N and E, you can go first and everyone else can dive in.
Sorry, I don't think it's necessary easier for the child, but it does mean that you can get the treatment done. Now I've got a lot of patients who prefer the white fillings that look like the tooth. Even in kids teeth, even though there is very little time before that tooth is going to be exfoliated they would prefer a white filling and they're quite adamant.

I have similar conversations with all of my parents and kids and stuff, and everyone has a different take on it. If they can come back for one visit, quick half an hour, 20 minutes, whatever it takes and then not see me for another six months, they'd prefer that than having to bring them before school, after school, and managing everything else.

It's more for the parents convenience, I think, than the child. I think the child is usually happy to sit and do whatever is needed, as long as you're able to communicate that with them properly.

E: Your thoughts?

I think I'm almost in part the opposite. I think sometimes my patients or my parents will say, yes, we want a white filling, we don't want a cap for various reasons. Like they know it's going to change the bite or aesthetics or whatever.

Particularly, like I said, I see a lot of patients with sensory problems and they're worried about having a cap on and changing the bite and stuff. I tend to find if I fail in my composite or my GI because of LA or compliance or whatever, that's when I say it's got to be a crown because it's easier.

I definitely find that a crown would be my personal first choice. I would always try and be really proud and I've got my little sheet. That's another thing that I think really influences how good your information sheet is. My practice doesn't have one. My community has one, which is probably why the uptaking community is so much higher.
E (32:41)
But I personally find I always try and go for that. If they're adamant, they want fillings, more often than not, I'll try the fillings, LA will fail and I'll go right to cap, nice and easy. Personally, that's me.

Paul Ashley (32:54)
Thank you. I'm going to go down the list. L, you're next to my screen.

L (32:59)
I don't really think that GIC is any easier. I think it will depend on the patient. But I think if you can put separators in the hall crown, you'd be able to do either or, in my opinion. I think that the hall crown is always best to try first. That's what I do anyway.

Paul Ashley (33:20)
O.

O T (33:24)
It depends what the technique is used for GIC placement. I think, as I say, like a lot of associates, my practice would literally just bring it in and then that would be it done basically. They'd be like goodbye if it falls out and then you get pain, come back and I might put another one in. But I think using LA and that sort of thing, if you're doing it properly, then hall crown usually I find is faster than having to get them desensitised.

Paul Ashley (33:53)
Honestly O, what happens then? What happens between you and the associates? What's the change?

O T (34:01)
I think it's training a lot of those agents. My practice don't know how to use hall crowns. They haven't really used hall crowns at all. I think realistically, it's not a difficult technique once you know how to do it, but I think the idea of it is more than what they used to, just putting it filling in and being done.

O T (34:24)
Whereas, like, you need to put seps in and then you need to figure out what size hall crowns you need to put the hall crown on. I think it's basically just a lack of understanding of the technique more than anything else.
Paul Ashley (34:37)
I'm just going to stay at that point for a second. I will get to the rest of you in a minute. But would it be fair to say, this is a slightly leading question. Would it be fair to say that if you wanted to try and improve outcomes for children having fillings, you're better off making a filling material better that looks like something people understand, rather than trying to teach a new technique like the half crown? Is that fair?

O T (35:03)
Yeah, I think a lot of dentists in themselves are quite stuck in their ways and I'm not saying I'm any different. But I think a lot of the time it's rather than go off from what someone knows, I think you'd rather just stick with something that seems quite familiar and has worked in the past and works.

Paul Ashley (35:25)
Thank you, Z. What do you think, GIC versus crown, particularly with your different experience?

Z J (35:34)
I would actually lean more towards GIC, just because I think this is more patient specific just because a lot of the times I have offered crowns, it's the parents that really don't like the idea. What if it falls off and it comes out and they choke on it like the choking hazard?

Z J (35:59)
Just a couple of patients, parents that would be more inclined to go with GIC, particularly if they had previous settings before. The patient, I think that would come into it as well, like what they have experienced already, what they're familiar with not just what the dentists and other associates are familiar with.

Z J (36:22)
But I would go more GIC first and then explain Half's crown to the parents if there was something that if the fitting debonded or anything like that, or it just didn't work out. Like the other guys have said that we couldn't desensitise them before administering LA but that's my opinion.

Paul Ashley (36:48)
Yeah. Last but not least, T.

T M (36:53)
I would probably still go with the GIC. I think. I've had a lot of problems with patients bite and the mum not wanting the stainless steel crown. GIC just seems to be easier for me.
Z J (37:07)
It's worth mentioning Tom and I are in the same practise, so we've had really similar experiences with parents.

Paul Ashley (37:18)
Okay, good. Saud is there anything else you want to pick up on?

Almaeen Saud (37:23)
Just to clarify that, because I clarify your opinion. Would you change your career management practise in children with caries? I mean, if the new material has developed in Eastman, which is like a composite, which it's self itching, self bonding -

Paul Ashley (37:54)
I don't want to turn it into too much of an effort. I've been thinking about that question, actually. I think I'm really more interested today and just what everyone is doing right now, so I don't think we need to worry too much about that. O has already given us some insights. I think we're okay with that.

Paul Ashley (38:11)
I think we'll let you all go now and I'm really grateful. It's be really useful. Has anyone got any other comments they want to make or anything you think we've missed or any other insights that perhaps will be relevant around how we're filing teeth in children and in general practise particularly?

Paul Ashley (38:30)
No? Okay. I mean, you will be super helpful. I can't really offer you much, but at the very least, if any of you have any burning questions or want any queer advice or whatever, feel free to email me. I'm at the Eastern. I'm very easy to find on Google, etc. I think we'll write this up and then Z will share with you where you're at. Z, do you have any comments you want to make?

Z (38:55)
Thank you so much for coming, guys. I know I've everyone so much, so I really appreciate you coming and contributing. I found it really interesting, actually, so thank you.

Paul Ashley (39:06)
Z feels like everyone loves it now because she won't have it.
Z (39:09)
I have it with some friends.

Paul Ashley (39:12)
Good. Okay. But, yes, you’ve been really helpful. Like I said, if you’ve got any follow up questions you want to ask me or anything clinical related or career related, feel free to drop me a line. I’m very happy to help. Good. We can do a wash up tomorrow. Maybe Z will get together at some point as well, just to think about all that. But it’s really brilliant.

Almaeen Saud (39:30)
Thank you all for -

T M (39:33)
Thank you. [crosstalk 00:39:34]
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