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An eight year retrospective study investigating tooth survival after primary non-surgical root canal treatment in a United Kingdom military cohort.

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Abstract:	<p>Introduction Root canal treatment plays an important role in preserving the dentition by deferring other invasive treatments. Data on tooth survival and predictive factors for tooth loss after root canal treatment in the military cohort is lacking. This investigation aimed to determine the proportion of teeth surviving in an 8 year period after root canal treatment (RCT) and identify potential predictive factors for tooth loss, in a United Kingdom military cohort.</p> <p>Methodology A retrospective review of an integrated electronic health record (iHR) for military patients who had received RCT was performed in a random sample of 205 patients (n = 219 root-filled teeth) that had received RCT between 01 January 2011 and 01 January 2012. Tooth survival was defined as tooth presence, regardless of signs or symptoms, and measured from the point of root-filling until either the end of the designated study period or time of extraction. Survival was evaluated using Kaplan-Meier estimates and association with tooth loss using the Chi-squared test. Potentially significant predictive factors were investigated using univariate Cox regression.</p> <p>Results Tooth survival following RCT was: 98% after 24 months; 88% after 48 months; 83% after 72 months and 78% after 96 months. Four predictive factors were found to affect tooth loss as follows: pre-operative pain (hazard ratio [HR] = 3.2; P < 0.001), teeth with less than 2 proximal contacts (HR = 3.0; P = 0.01), teeth with cores involving more than two surfaces (HR = 2.0; P = 0.03); and post-operative unscheduled dental attendances (UDA) (HR = 2.7; P = 0.01).</p> <p>Conclusions Within the limitations of this study, the presence of pre-operative pain; teeth with less than two proximal contacts or with cores involving more than two tooth surfaces; and occurrence of post-operative unscheduled dental attendance were found to significantly increase the hazard of tooth loss.</p>

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3 **An eight year retrospective study investigating tooth survival after**
4 **primary non-surgical root canal treatment in a United Kingdom**
5 **military cohort.**
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14 **Key messages**
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19 > Long-term predictive survival of endodontically treated teeth that maintains the
20 dentition should be of mutual importance to both the patient and the military
21 organisation.
22 > Tooth survival data of teeth root canal treated in the military was investigated
23 to provide insight and analysis of factors influencing tooth loss.
24 > The survival rate of teeth after root canal treatment was 98% at 24 months;
25 88% at 48 months but dropped to 78% by 96 months.
26 > Four significant predictive factors for tooth loss were identified.
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ABSTRACT

Introduction Root canal treatment plays an important role in preserving the dentition by deferring other invasive treatments. Data on tooth survival and predictive factors for tooth loss after root canal treatment in the military cohort is lacking. This investigation aimed to determine the proportion of teeth surviving in an 8 year period after root canal treatment (RCT) and identify potential predictive factors for tooth loss, in a United Kingdom military cohort.

Methodology A retrospective review of an integrated electronic health record (iHR) for military patients who had received RCT was performed in a random sample of 205 patients (n = 219 root-filled teeth) that had received RCT between 01 January 2011 and 01 January 2012. Tooth survival was defined as tooth presence, regardless of signs or symptoms, and measured from the point of root-filling until either the end of the designated study period or time of extraction. Survival was evaluated using Kaplan-Meier estimates and association with tooth loss using the Chi-squared test. Potentially significant predictive factors were investigated using univariate Cox regression.

Results Tooth survival following RCT was: 98% after 24 months; 88% after 48 months; 83% after 72 months and 78% after 96 months. Four predictive factors were found to affect tooth loss as follows: pre-operative pain (hazard ratio [HR] = 3.2; $P < 0.001$), teeth with less than 2 proximal contacts (HR = 3.0; $P = 0.01$), teeth with cores involving more than two surfaces (HR = 2.0; $P = 0.03$); and post-operative unscheduled dental attendances (UDA) (HR = 2.7; $P = 0.01$).

Conclusions Within the limitations of this study, the presence of pre-operative pain; teeth with less than two proximal contacts or with cores involving more than two tooth surfaces; and occurrence of post-operative unscheduled dental attendance were found to significantly increase the hazard of tooth loss.

INTRODUCTION

Dentistry in the UKAF is delivered by a tri-Service healthcare organisation (Defence Primary Healthcare [DPHC]) and consists of both military and civilian dental practitioners and dental care professionals. DPHC delivers occupationally focused primary dental care, aiming to force generate personnel in readiness for military operations and ensure operational effectiveness by reducing dental morbidity.[1]

Dental care is consistently rated as a top retention factor in the military. Along still being 'free' for eligible serving personnel, there is also likely to be a desire to maintain a functional dentition into older age, perhaps influenced by population trends and cosmetic awareness in the popular media.[2-6] Tooth loss can result from multiple reasons that include: trauma, periodontal disease, caries, extensive tooth surface loss, cracks/fractures, associated pathosis affecting the crown/root or as a component of multi-disciplinary treatment planning.[7,8] Tooth loss can affect a patients function and quality of life.[9] The replacement of teeth with prostheses or dental implants may not always be indicated or provide adequate restoration of function and can be clinically time consuming and expensive.[10] Provided a tooth is deemed restorable, RCT plays an important role in preserving a natural functional dentition by deferring more invasive treatments to later stages in the restorative cycle, facilitating efficient and cost-effective use of dental resources.[11] The provision of predictable RCT, to ensure that the dentition has longevity, with reduced risk of morbidity, is of mutual importance to both the patient and DPHC. Well-designed studies, evaluating the clinical outcomes of RCT undertaken using gold standard protocols within controlled clinical environments, have identified the following specific broad prognosticators affecting tooth survival: general patient;

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3 pre-operative; intra-operative and post-operative restorative factors.[12,13] The
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5 findings from these studies have influenced the provision of RCT in UKAF,
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7 underpinning the clinical standard operating procedures, guidance and referral
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9 pathways employed by DPHC dental clinicians. Whilst there is benefit to drawing
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11 clinical inferences from these outcome studies, they fail to account for the unique
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13 nature of the military's mobile population, often occupying physical roles in austere
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15 and often stressful environments with limited access to dental care.[14] There is a
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17 need for additional military focused clinical outcome studies to fill gaps in evidence
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19 base. This would enable DPHC clinicians in making predictable clinical decisions
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21 on the survival of teeth requiring RCT. This pilot study aspired to address this
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23 deficiency in evidence with the aim of determining the proportion of teeth surviving
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25 in an 8-year (96 month) period after primary non-surgical root canal treatment and
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27 identify potential predictive factors for tooth loss, in a UKAF cohort.
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34 **METHODS**

35 **Ethical approval and data access**

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37 Approval to conduct this service evaluation was granted by the Royal Centre for
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39 Defence Medicine (Reference: RCDM/Res/Audit/1036.19/0501). A Data Protection
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41 Impact Assessment was completed by the investigator. Ministry of Defence
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43 Research Ethics Committee (MODREC) approval was not required for this study.
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50 **Patient and tooth inclusion criteria**

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52 All serving members of the Tri-Service British Armed Forces: British Army; Royal
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54 Navy or Royal Air Force, 16 years or older and having received RCT, between 01
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56 January 2011 and 01 January 2012, and still in-service on 01 January 2019, were
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3 included. All permanent teeth having undergone RCT in the designated period were
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5 included.
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8 9 **Patient and tooth exclusion criteria**

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12 Patients were excluded from the study if they had received RCT in the designated
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14 period but had subsequently left the British Armed Forces before 01 January 2019.

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16 Any tooth that did not receive RCT in the designated period was excluded.
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19 20 **Determination of outcome**

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23 Tooth survival was the chosen outcome measure. The root-filled tooth was judged
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25 to have survived if it was still present at the end of the study period (01 January
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27 2019), regardless of signs or symptoms. The tooth was considered to have 'not
28
29 survived' if it had been extracted before the end of the study period. The date of
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31 extraction was determined from the patient iHR. The date of root-filling was taken
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33 as the reference for the time to extraction to be calculated (in months). To enable
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35 censoring for statistical analysis, the date of the last review visit for each service
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37 person was recorded to take account of those teeth surviving past the end of the
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39 study period.
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46 47 **Study cohort allocation**

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49 The department for Defence Statistics identified and collated the service numbers
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51 of patients that had received RCT between 01 January 2011 to 01 January 2012
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53 and were still in-service on 01 January 2019 (n = 2005). The sample size of the
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55 population was calculated using a clinically detectable effect size of tooth loss,
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57 hazard ratio (HR) 2.5, and assuming 80% of root-filled teeth to survive 7 to 8-years.
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3 By applying a two-sided significance of 0.05 and a power of 0.8, a sample of 205
4 patients (n= 219 root-filled teeth) was determined. The sample was subsequently
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6 selected from the study population, using a random number generator.
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10 11 **Data collection and management** 12

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14 A custom-designed data collection form, using Microsoft Excel®, was used to collect
15 patient information. All data collection and analysis were anonymised, to ensure
16 conformity with the Data Protection Act 2018. The data collection form was
17 designed to include variables that were considered to be either prevalent among
18 the military cohort or had previously been reported as significant, within NSRCT
19 survival studies. Specific variables were designated under the umbrella categories
20 of: patient general; pre-operative; intra-operative and post-obturation factors.
21 Patient general factors included: Service; gender; age at time of treatment;
22 decayed, missing and filled teeth (DMFT); medical condition; smoking status and
23 tooth type and location. Pre-operative variables included: pain; presence of sinus
24 tract; pockets greater than 3mm; proximal contacts with adjacent teeth; use of tooth
25 as an abutment; terminal tooth location; presence of cracks and reported
26 parafunction. Intra-operative factors included: all expected canals located; all
27 canals recorded as patent; use of an apex locator; use of sodium hypochlorite; use
28 of Ethylenediaminetetraacetic acid (EDTA); mechanical preparation method;
29 instrument fracture reported; fate of the separated instrument; perforation reported;
30 inter-appointment pain or swelling; obturation method; number of canals obturated;
31 seal of gutta percha and number of treatment visits. Post-obturation variables
32 included: type of core placed; number of surfaces involved; type of indirect
33 restoration placed; extent of indirect restoration and presence of post. Untoward
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3 events were recorded. These were categorised as: unscheduled dental attendance
4 (UDA), defined as any unplanned dental attendance due to restorative failure
5 (restoration fracture, repair or decementation) or pain and/or swelling; antibiotics
6 prescribed; root canal re-treatment; or surgical re-treatment. Reasons for
7 extractions were documented and grouped into either peri-apically related problems
8 or restorative failures.
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18 A single researcher reviewed the iHR within the randomised patient sample,
19 following this standardised data collection protocol. A pilot data collection exercise
20 was undertaken on 10 patients, by the researcher and two experienced DPHC
21 Dentists, with the aims of assessing the sensitivity of the protocol and to ensure
22 calibration of the researcher.
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31 **Statistical analyses**

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34 Statistical analyses were performed with SPSS® statistics version 22.0 (IBM®
35 Corporation, Armonk, NY) software package. Survival was evaluated using Kaplan-
36 Meier estimates and association of factors with tooth loss using the Chi-squared
37 test. Potentially significant predictive factors were investigated using univariate Cox
38 regression. The effect of clustering at patient level was accounted for utilising robust
39 standard error.
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RESULTS

Root-filled teeth (n = 219) in 205 serving patients in the UKAF (male, 83%; female, 17%), with a mean age of 35 years old (M = 35, SD = 9.8) were included for analysis. Thirteen patients (6%) had more than one root-filling carried out between 01 January 2011 and 01 January 2012. The mean DMFT was 14.6 (range = 2 - 26) and tobacco smokers made up 20% of the cohort. The majority of patients were fit and well (n= 200). Four conditions were non-relevant consisting of mild asthma and seasonal allergenic rhinitis. One (n = 1) had type 2 diabetes that was well controlled.

Tooth survival

The tooth survival rate after primary non-surgical root canal treatment (figure 1) was: 98% (95%CI 97%, 99%) after 24 months; 88% (95%CI 86%, 90%) after 48 months; 83% (95%CI 80%, 85%) after 72 months and 78% (95%CI 76%, 80%) after 96 months.

A total of 49 root-filled teeth were lost by the end of the 8-year (96 month) period from the date of obturation until 01 January 2019. Table 1 presents the reasons for tooth loss, which could be categorised broadly into two groups.

Table 1 Reasons for tooth loss after primary non-surgical root canal therapy	
Periapically related problems	9
Acute pain	
Chronic pain	7
Swelling	4
Sinus/Suppuration	6
Subtotal	26(53%)
Restorative failures	
Fractured tooth (unrestorable)	16
Trauma	1
Tooth surface loss/caries	6
Subtotal	23 (47%)
Total	49 (100%)

Extraction occurred between 11 and 93 months after treatment (Table 2). Most teeth were extracted between 24 – 48 months (43%).

24 months	24-28 months	48-72 months	72-93 months
4 (8%)	21 (43%)	13 (27%)	11 (22%)

Survival by tooth type, in descending order was: maxillary incisors and canines (89%); mandibular incisors and canines (79%); mandibular premolars (78%) and molars (79%); maxillary pre-molars (72%) and molars (71%).

Predictive factors

Univariate Cox regression, using robust standard error, identified four predictive factors for tooth loss (Table 3). Pre-operative factors were: pain (hazard ratio [HR] = 3.2; $P < 0.001$) and teeth with less than 2 proximal contacts (HR = 3.0; $P = 0.01$). Post-operative factors were: teeth with cores involving more than two surfaces (HR = 2.0; $P = 0.03$); and unscheduled dental attendance after completion of root canal treatment (HR = 2.7; $P = 0.01$).

	Predictive factor	HR	95% CI	P -value
Pre-operative factors	Pain	3.2	1.8, 5.7	<0.001
	Less than two proximal contacts	3.0	1.6, 5.5	0.01
Post-operative factors	Cores involving more than two surfaces	2.0	1.1, 3.7	0.03
	Unscheduled dental attendance	2.7	1.5, 4.8	0.01

DISCUSSION

Study design and methodology

The primary aims of this pilot study, to determine the proportion of teeth surviving in the 8-year period after RCT in a UKAF cohort and to identify predictive factors for tooth loss, were achieved. The sample of extracted teeth following RCT (n=49) was small. As a result, the subsequent analysis was only possible in a homogenous non-partitioned cohort. Low event rates for certain tooth level variables led to a requirement for grouping of data to improve statistical power, whilst other variables could not be analysed at all due to insufficient available data. The retrospective approach (as opposed to a prospective design) to data collection was too imprecise to capture the complex interactions inherent in RCT, conducted in multiple stages and taking into consideration the inter-individual variations and potential confounding factors that ultimately cannot be controlled or accounted for. Whilst prospective clinical studies can be rigidly designed to overcome such data collection problems, they are time-consuming to implement and generally lie outside the scope of primary care delivery organisations. An increased sample group would have facilitated analysis in partitioned cohorts and offering scope for subgroup survival analysis at a single-service, patient or tooth restorative outcome level.

Tooth survival

The survival rate of teeth having RCT completed between 01 Jan 2011 and 01 Jan 2012 was 98% at 24 months, 88% at 48 months but dropped to 78% by 96 months in the military cohort. For comparison, well-designed studies have reported survival rates of 95% over a 48-month prospective study period, in cases completed in a postgraduate hospital setting and comprehensive systematic review up to 2007,

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3 has reported that the pooled probabilities of tooth survival 2-10 years after RCT
4 ranged from 86% to 93%.[12,13] In this pilot study, survival rates over 2 and 4 years
5 (98% and 88% respectively) were therefore generally comparable to those reported
6 in the wider literature but were lower than expected by 8 years (78%). Why the 8
7 year survival is lower in the military population should take into consideration the
8 unique elements of the military. The requirement to be mobile and regularly occupy
9 stressful physical roles in austere environments may impact an individuals dental
10 health. Despite the potential for differences in delivery of RCT in the general
11 population, access to clinical guidance, available materials and clinical time in the
12 military should not be limiting factors to the ability to deliver RCT to gold standards
13 in DPHC when following extant standard operating procedures. Despite this,
14 differences in the nature of the study cohorts, study designs, the quality of data and
15 statistical analyses used, all impact on the ability to draw direct comparisons
16 between the results in this pilot study and the existing available evidence. [12.13]
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18 Additional military research analysing a larger sample size, over the medium to long
19 term, is therefore recommended to establish whether the emerging trends in this
20 pilot study are supported. If so, identifying the specific barriers to achieving higher
21 survival rates in the unique military cohort will be important to improve clinical
22 outcomes.

47 **Predictive factors**

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51 The investigation to determine predictive factors for tooth loss was limited by the
52 low number of teeth extracted, although potential factors of significance were
53 identified at the 5% level. Accounting for correlations between variables and
54 clustering between patients, enabled univariate Cox regression using robust
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3 standard error. Subsequently, 4 significant factors were identified to increase the
4 hazard of tooth loss in the military cohort as follows: (1) pre-operative pain, (2) less
5 than 2 proximal contacts, (3) restorative cores involving more than 2 tooth surfaces
6 and (4) unscheduled dental attendance (UDA) after RCT. Teeth with pre-operative
7 pain had an increased likelihood of extraction than those without pain (HR = 3.2; P
8 = < 0.001; 95%CI 1.8, 5.7), a finding in keeping with other well-designed studies. In
9 the military cohort, teeth with less than two proximal contacts were more likely to be
10 extracted (HR = 3.0; P = 0.01; 95%CI 1.6, 5.5), as were teeth with restorative cores
11 placed that involved more than two tooth surfaces (HR = 2.0; P = 0.03; 95%CI 1.1,
12 3.7). The number of proximal contacts and the extent of the core placed are both
13 important considerations for fracture susceptibility and tooth survival and relates to
14 occlusal loading patterns and force distribution.[15-21]. Military personnel are
15 frequently tasked in high stress roles and perhaps as a cohort are more susceptible
16 to sustained episodes of parafunctional activity. It makes intuitive sense that a root-
17 filled tooth lacking adjacent contacts, with a multi-surface restorative core that is
18 subject to sustained occlusal overloading, could be at an increased risk of
19 catastrophic fracture by mechanical failure. There is the ample evidence that
20 supports the utility of timely provision of indirect restorations on root-filled teeth, to
21 prevent tooth fracture. [22-24] Unfortunately, data for placement of indirect
22 restorations in the military cohort was limited and no association with tooth loss was
23 identified. Based on this pilot study findings, consideration should be given to further
24 military research that explores more closely the restorative outcomes of root-filled
25 teeth. This will be useful to understand the extent to which the recommended
26 provision of cuspal coverage restorations following RCT is provided in the military
27 cohort. This would offer insight to whether root-filled teeth are being provided

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3 adequate protection in this potentially high risk cohort. Future research should also
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5 consider analysing the restorative complexity of treatments undertaken in DPHC
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7 against the skills and experience of the operator. Of relevance to DPHC, is the
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9 recent implementation, in 2019, of Falcon's model for assessing treatment
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11 complexity, for use in a newly established restorative Managed Clinical Network
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13 (MCN).[25] This tooth survival study was conducted prior to the inception of the
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15 MCN and endodontic complexity was not analysed. The proportion of case difficulty
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17 was therefore unknown. The interface between operator skill and the restorative
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19 complexity is likely to be a factor that influences overall tooth survival rates in the
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21 military and warrants further investigation. A useful extrapolation of this pilot study
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23 would also explore restorative outcomes of endodontically treated teeth completed
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25 by general practitioners (defined as Tier 1 providers) and Tier 2 practitioners that
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27 hold additional post-graduate restorative training. Findings would inform future
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29 decision making and treatment protocols in DPHC. This would provide a useful
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31 insight in support of any recommendations for prospective change aimed at
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33 improving tooth survival in medium to long-term.
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41 **CONCLUSIONS**

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43 Within the limitations of this pilot study, retrospective data found the tooth survival
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45 rate after RCT to be: 98% after 24 months; 88% after 48 months; 83% after 72
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47 months but dropped to 78% after 96 months. Four significant predictive factors for
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49 tooth loss in the military cohort were identified: Pre-operative pain; teeth with less
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51 than 2 proximal contacts; teeth with restorative cores involving more than 2
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53 surfaces; teeth with a history of UDA (unscheduled dental attendance [due to
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55 fracture, repair, pain and/or swelling]) after RCT. Further research exploring
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restorative complexity and is required to inform clinical recommendations that aims to improve restorative outcomes over the medium and long-term.

For peer review only

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3 **Figure 1** Kaplan-Meier survival curve as a function of tooth loss for teeth having undergone primary
4 non-surgical root canal treatment in the military cohort between 01 January 2011 and 01 January
5 2012. Cum = Cumulative.
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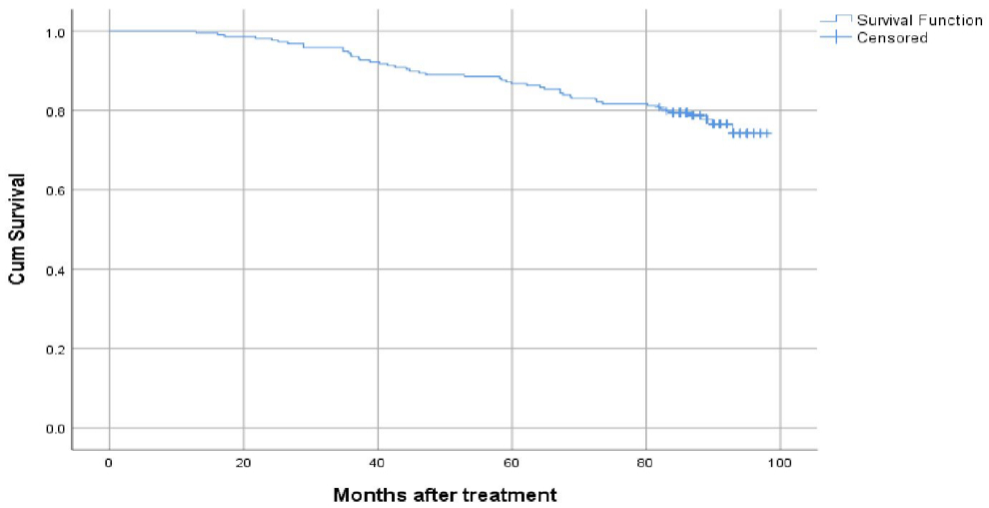


Figure 1 Kaplan-Meier survival curve as a function of tooth loss for teeth having undergone primary non-surgical root canal treatment in the military cohort between 01 January 2011 and 01 January 2012. Cum = Cumulative.

668x344mm (38 x 38 DPI)

Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cohort reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

			Page
		Reporting Item	Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary	3

of what was done and what was found

Introduction

Background / [#2](#) Explain the scientific background and rationale for the 4
 rationale investigation being reported

Objectives [#3](#) State specific objectives, including any prespecified 5
 hypotheses

Methods

Study design [#4](#) Present key elements of study design early in the paper 5-9

Setting [#5](#) Describe the setting, locations, and relevant dates, including 5-9
 periods of recruitment, exposure, follow-up, and data collection

Eligibility criteria [#6a](#) Give the eligibility criteria, and the sources and methods of 5-9
 selection of participants. Describe methods of follow-up.

Eligibility criteria [#6b](#) For matched studies, give matching criteria and number of 5-9
 exposed and unexposed

Variables [#7](#) Clearly define all outcomes, exposures, predictors, potential 5-9
 confounders, and effect modifiers. Give diagnostic criteria, if
 applicable

Data sources / [#8](#) For each variable of interest give sources of data and details of 5-9
 measurement methods of assessment (measurement). Describe
 comparability of assessment methods if there is more than one
 group. Give information separately for for exposed and
 unexposed groups if applicable.

1	Bias	#9	Describe any efforts to address potential sources of bias	5-9
2				
3				
4	Study size	#10	Explain how the study size was arrived at	5
5				
6				
7	Quantitative	#11	Explain how quantitative variables were handled in the	6
8	variables		analyses. If applicable, describe which groupings were chosen,	
9			and why	
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15	Statistical	#12a	Describe all statistical methods, including those used to control	
16	methods		for confounding	
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23	Statistical	#12b	Describe any methods used to examine subgroups and	7
24	methods		interactions	
25				
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27				
28				
29	Statistical	#12c	Explain how missing data were addressed	7
30	methods			
31				
32				
33				
34	Statistical	#12d	If applicable, explain how loss to follow-up was addressed	7
35	methods			
36				
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39	Statistical	#12e	Describe any sensitivity analyses	
40	methods			
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45	7			
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48	Results			
49				
50				
51	Participants	#13a	Report numbers of individuals at each stage of study—eg	9-15
52			numbers potentially eligible, examined for eligibility, confirmed	
53			eligible, included in the study, completing follow-up, and	
54			analysed. Give information separately for for exposed and	
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unexposed groups if applicable.

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4	Participants	#13b	Give reasons for non-participation at each stage 9-15
5			
6	Participants	#13c	Consider use of a flow diagram
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13	Descriptive data	#14a	Give characteristics of study participants (eg demographic, 9-15
14			
15			clinical, social) and information on exposures and potential
16			confounders. Give information separately for exposed and
17			unexposed groups if applicable.
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22	Descriptive data	#14b	Indicate number of participants with missing data for each
23			variable of interest
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31	Descriptive data	#14c	Summarise follow-up time (eg, average and total amount)
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37	Outcome data	#15	Report numbers of outcome events or summary measures
38			over time. Give information separately for exposed and
39			unexposed groups if applicable.
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45	9-15		
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48	Main results	#16a	Give unadjusted estimates and, if applicable, confounder- 9-15
49			
50			adjusted estimates and their precision (eg, 95% confidence
51			interval). Make clear which confounders were adjusted for and
52			why they were included
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58	Main results	#16b	Report category boundaries when continuous variables were 9-15
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1		categorized	
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4	Main results	#16c If relevant, consider translating estimates of relative risk into	
5		absolute risk for a meaningful time period	
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12	Other analyses	#17 Report other analyses done—eg analyses of subgroups and	9-15
13		interactions, and sensitivity analyses	
14			
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17	Discussion		
18			
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20	Key results	#18 Summarise key results with reference to study objectives	9-15
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22			
23	Limitations	#19 Discuss limitations of the study, taking into account sources of	9-15
24		potential bias or imprecision. Discuss both direction and	
25		magnitude of any potential bias.	
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31	Interpretation	#20 Give a cautious overall interpretation considering objectives,	9-15
32		limitations, multiplicity of analyses, results from similar studies,	
33		and other relevant evidence.	
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39	Generalisability	#21 Discuss the generalisability (external validity) of the study	9-15
40		results	
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44	Other Information		
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47	Funding	#22 Give the source of funding and the role of the funders for the	n/a
48		present study and, if applicable, for the original study on which	
49		the present article is based	
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4
5 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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