The Impact of Preservation of Tooth Structure on the Outcome of Endodontic and Restorative Treatment

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The Impact of Preservation of Tooth Structure on the Outcome of Endodontic and Restorative Treatment

A Thesis submitted for the degree of

Doctor of Philosophy

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Abstract

Aims:

To investigate the effects of preservation of tooth structure on the outcome and clinical performance of CAD-CAM generated onlays and crowns as post endodontic restorations.

Methodology:

A systematic review helped in identifying a gap in literature, namely the evidence for the use of onlays as post endodontic restorations.

A prospective study was conducted a Guy's Hospital, Kings College, London. A cohort of 143 patients participated in the clinical trial. Root canal treatment of teeth was performed followed by provision of a CAD CAM generated onlays or full crowns. 124 patients returned to have their restorations assessed.

An ex- vivo laboratory study was conducted to assess the wear of enamel and polymer infiltrated nano ceramics and compare this to the wear measured in vivo in the clinical trial.

Results:

The pooled relative risk of failure in the root canal treated teeth was 2.27 with 95% confidence interval from 1.77 to 2.91, indicating more frequent failures in root canal treated teeth compared to vital teeth.

The prospective data revealed no statistically significant difference between the clinical performance of onlays and crowns on ETT. The results assessed using FDI and modified USPHS criteria were similar. Statistically significant prognostic factors for endodontic treatment included presence of voids, length of root canal filling,

presence, and size of periapical lesion. The favourable outcome using CBCT was 78.5% while it was 88.8% using PA radiography.

The novel nanohybrid ceramics displayed significantly more wear than enamel ex vivo. However in vivo the wear of enamel was not significantly different from that of Cerasmart, this is a very important property of this nanohybrid ceramic, particularly considering that many of the other commonly used ceramic materials such as zirconia and lithium disilicate display less wear than enamel and are known to cause significant wear of the opposing teeth.

Conclusions:

The meta-analysis was in accordance with similar studies. Within the limitations of this study, the success and survival of CAD-CAM generated onlays in the restoration of endodontically treated teeth was similar to that of full crowns. The wear of nanohybrid ceramic in vivo is not significantly different from that of enamel in vivo.

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Abbreviation	Meaning	First Use (Page no)
CAD CAM	Computer Aided Design Computer Aided Manufacture	2
ETT	Endodontically Treated Tooth	2
FDI	Federation Dentaire Internationale	2
USPHS	United States Public Health Service	2
CBCT	Cone Beam Computed Tomography	3
PA	Peri Apical	3
EDTA	Ethylene diamine tetra acetic acid	27
MOD	Mesio Occluso Distal	29
GIC	Glass Ionomer Cement	40
pdl	Periodontal	52
3D	Three dimensional	52
CDJ	Cemento Dentinal Junction	52
PRI	Probability Index	55
PAI	Periapical Index	56
PESS	Periapical and Endodontic Status Scale	57
COPI	Complex Periapical Index	57
ETTI	Endodontically Treated Tooth Index	57
1° RCT	Primary root canal treatment	67
2° RCT	Secondary root canal treatment (Retreatment)	67
PICOS	Patient, Intervention, Comparison, Outcome measured	78
PROBE	Preferred Reporting of Observational Studies in endodontics	119
T0	Baseline	122
kV	Kilovolt	123
mA	milliAmpere	123
FOV	Field of View	123
IQR	Interquartile range	131
GEE	Generalised Estimation Equations	131
OR	Odds Ratio	131
CI	Confidence Interval	131
ICC	Inter class Correlation	131
WTM	Wall Thickness Mesial (marginal ridge)	149
WTMB	Wall Thickness Mesio Buccal (cusp)	149
WTD	Wall Thickness Distal (marginal ridge)	150
WTDB	Wall Thickness Disto Buccal (cusp)	150

WTDL	Wall Thickness Disto Lingual (cusp)	150
WTML	Wall Thickness Mesio Lingual (cusp)	150
WHMB	Wall Height Mesio Buccal (cusp)	150
WHML	Wall Height Mesio Lingual (cusp)	150
WHDB	Wall Height Disto Buccal (cusp)	150
WHDL	Wall Height Disto Lingual (cusp)	150
AAE	American Association of Endodontists	166
TRI	Tooth Restorability Index	166
DPI	Dental Practicality Index	168
IO Scanner	Intra Oral Scanner	170
CDA	California Dental Association	175
T1	1 year recall	208

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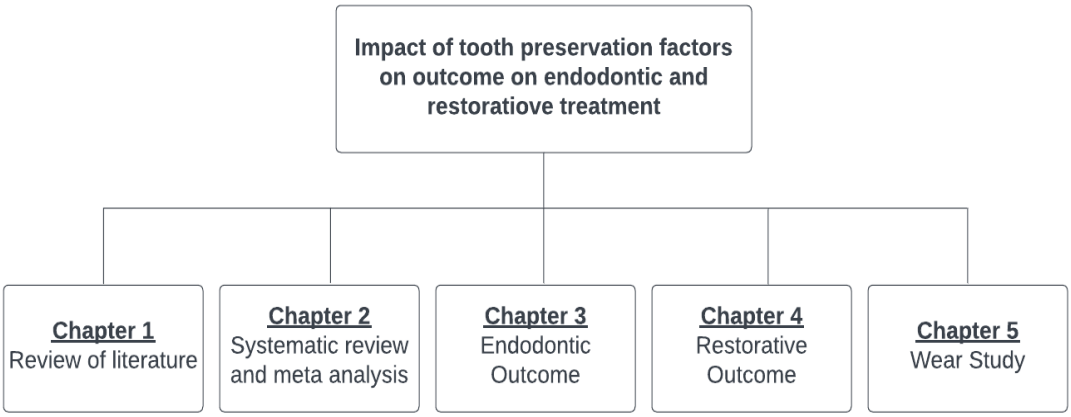
Structure of the thesis



There are not many prospective studies on the outcome of root canal treatment and restorations where conservative tooth restorations such as onlays have been used to restore endodontically treated teeth (ETT). This study aims to assess the impact of the preservation of tooth structure-related factors on the outcome of both endodontic and restorative treatment. This thesis is therefore divided into five main chapters.

Chapter 1. A review of the literature is presented in this chapter. The review describes the evidence base for restorative care for an ETT highlighting the differences between the restoration of a vital tooth and that of an ETT. Different types of restorations and materials used for ETT and their survival studies are explored. Finally, the outcome of root canal treatments assessed using radiograph and CBCT is revisited.

Chapter 2. A systematic review and meta-analysis of survival of tooth-coloured indirect restorations on vital and non-vital teeth is presented in this chapter. The systematic

review examined partial crowns (onlays) on ETT and compared their success and survival with those of partial coverage restorations in vital teeth.

Chapter 3. A prospective CBCT-based endodontic outcome study is presented. A three-dimensional radiographic outcome assessment of variables that affect tooth preservation including variables not routinely seen on a periapical radiograph, such as furcation involvement, fenestrations and dehiscence, and their effect on endodontic outcome, are investigated in this chapter.

Chapter 4. The fourth chapter is a prospective study assessing the clinical performance and survival of nanohybrid CAD-CAM-generated onlays and crowns as a post-endodontic restoration. Digital techniques for assessing tooth preservation factors and their effect on restorability outcomes are tested here.

Chapter 5. An ex-vivo study assessing the simulated one-year wear of nanohybrid ceramics is compared to a clinical, in-vivo assessment of wear of the same duration.

Justification of the Study

The endpoint of non-surgical root canal treatment is to return the tooth to its correct form, function and aesthetics and protect the remaining tooth structure from catastrophic fracture (European Society of Endodontology developed, Mannocci et al. 2021)

The importance of restoring an ETT is also essential for the success of the root canal treatment (Ng, Mann et al. 2011) as well as the survival of the endodontically treated tooth (Aquilino and Caplan 2002, Salehrabi and Rotstein 2004, Nagasiri and Chitmongkolsuk 2005, Stavropoulou and Koidis 2007, Ng, Mann et al. 2011).

Traditionally, the full crown restoration has been regarded as the gold standard restoration for restoring ETT (Aquilino and Caplan 2002). Preparing a tooth for a full crown reduces the remaining tooth structure at the critical peri-cervical area where the root canal orifices are also enlarged, making the tooth restored with a full crown weak in the cervical area and potentially prone to catastrophic fracture (Clark and Khademi 2010). However, this hypothesis still needs to be verified by ex-vivo or in-vivo studies.

Preservation of tooth structure has been reported to significantly increase the survival rate of ETT in prospective and retrospective studies (Nagasiri and Chitmongkolsuk 2005, Al-Nuaimi, Patel et al. 2017).

The concept of minimally invasive dentistry is recognised and accepted in caries management (Banerjee, Frencken et al. 2017, Bjorndal, Simon et al. 2019) and

adhesive dentistry. However, this is less widely applied in endodontic-restorative treatment, despite emerging evidence in this area (Clark and Khademi 2010, Plotino, Grande et al. 2017).

A partial coverage crown, such as an onlay, is more conservative than a full crown and would also provide the cuspal coverage needed for protecting the ETT. With advances in adhesion, more conservative tooth preparations can effectively allow the bond of the restoration to the preserved tooth structure.

Well-designed clinical trials are scarce on the restoration of endodontically treated teeth, including clinical trials that investigate the survival of both teeth and restorations. A systematic review comparing tooth-coloured onlays on vital and ETT revealed only nine clinical trials over the past two decades (Chapter 2). This systematic review on the restorations of endodontically treated teeth using tooth-coloured onlays and comparing their survival on vital and non-vital teeth formed the basis for the prospective longitudinal study. Therefore, the important unanswered question remains: would a more conservative cuspal coverage restoration like an onlay be as successful as a full crown for ETT while preserving tooth structure?

A comprehensive review of the literature of studies on post-endodontic restorations and root canal treatment outcomes is presented next.

Chapter 1 : Review of Literature- Post Endodontic Restorations

1.1 Introduction

Endodontic treatment is performed on teeth to eliminate pulpal and periapical inflammation (European Society of 2006). The success of endodontic treatment relies on following proper aseptic techniques, cleaning and shaping of the root canal to eliminate or minimise the pathogens, as well as adequate obturation and finally restoring these teeth to prevent reinfection by microbial ingress into the root canal system (Saunders and Saunders 1994, Gillen, Looney et al. 2011).

Long-term survival of the treated tooth depends, among other factors, on providing a cast restoration (Ng, Mann et al. 2011). The restorations also protect the tooth from catastrophic fractures. It has been reported that restorative complications are one of the most common reasons for extracting the ETT (Vire 1991, Fuss, Lustig et al. 1999).

Persistent and chronic apical periodontitis has been associated in cross-sectional studies with poor-quality root canal treatment (Kirkevang, Orstavik et al. 2000, Boucher, Matossian et al. 2002) and with poor-quality coronal restorations (Ray and Trope 1995, Kirkevang, Orstavik et al. 2000).

The evidence for placing full crowns on endodontically treated teeth is provided by retrospective studies which showed more survival of teeth that had full crowns compared to direct restorations (Sorensen and Martinoff 1984, Aquilino and Caplan

2002, Salehrabi and Rotstein 2004, Ng, Mann et al. 2011, Pratt, Aminoshariae et al. 2016).

A variety of materials have been used to restore ETT, including amalgam (Nayyar, Walton et al. 1980, McCabe 1995), composite resin (Lynch, Burke et al. 2004, Mannocci, Bertelli et al. 2009), glass ionomer cement (GIC), gold restoration (Studer, Wettstein et al. 2000, Dammaschke, Nykiel et al. 2013), metal ceramics and all-ceramic restorations (Leempoel, Eschen et al. 1985, Pjetursson, Sailer et al. 2007, Walton 2013). It is widely accepted that the survival of restorations on vital teeth is higher than those on ETT.

1.2 Why should vital and ETT be treated differently?

Several studies have shown that the risk of fracture of ETT is higher than that of vital teeth (Loewenstein and Rathkamp 1955, Chan, Lin et al. 1999, Fuss, Lustig et al. 2001).

The removal of the pulp in endodontic treatment and the insult of sodium hypochlorite, ethylene diamine tetra acetic acid (EDTA) and calcium hydroxide on dentine may affect its biomechanical properties (Grigoratos, Knowles et al. 2001).

The changes in biomechanical properties following root canal treatment have been attributed to differences in tissue composition, dentine micro and macrostructure, and tooth structure (Helfer, Melnick et al. 1972, Randow and Glantz 1986, Reeh, Messer et al. 1989, Panitvisai and Messer 1995).

1.2.1 Altered physical properties of endodontically treated teeth.

Non-vital teeth have dehydrated dentine and are hence more brittle than vital teeth with hydrated dentine, which is more viscoelastic.

This hypothesis was first proposed by GV Black and given credibility by Helfer et al., who determined that pulpless teeth had 9% less moisture than vital teeth (Helfer, Melnick et al. 1972).

Kishen et al. (Kishen and Asundi 2005, Kishen and Vedantam 2007) described free and bound water in dentine and reported that the loss of free water from porosities in dentine was the reason for reduced viscoelastic properties and increased brittleness (Kishen 2015).

However, no significant difference was noted in the moisture content between endodontically treated teeth and vital teeth (Papa, Cain et al. 1994), nor was there a significant difference in the modulus of elasticity of vital and non-vital teeth (Stanford, Weigel et al. 1960). Furthermore, it was reported that there was no significant difference between vital and non-vital teeth in compressive or tensile strength due to moisture loss (Huang, Schilder et al. 1992). Finally, Sedgley and Messer (Sedgley and Messer 1992) did not find non-vital teeth to be more brittle than vital teeth after studying their biomechanical properties.

These conflicting findings could be due to the different methodologies employed (Sedgley and Messer 1992, Papa, Cain et al. 1994) in these ex-vivo studies (Panitvisai and Messer 1995). The storage media for extracted teeth in the study by Sedgley and

Messer (Sedgley and Messer 1992) was saline, which could have potentially rehydrated the tooth and re-established its viscoelastic properties. Likewise, Papa et al. (Papa, Cain et al. 1994) stored their teeth in aluminium foil till the experiments were carried out. It has been reported that under normal conditions, 80-85% of the free water in dentine is lost within the first two hours (Jameson, Hood et al. 1993). Thus, the hydration status of the samples could have been different, leading to different biomechanical properties.

Another insult to dentine that comes during the root canal treatment is the use of irrigating solutions such as sodium hypochlorite and EDTA, and intracanal medications such as calcium hydroxide which can affect the biomechanical properties of dentine (Grigoratos, Knowles et al. 2001).

1.2.2 Loss of proprioception & occlusal forces

Loewenstein and Rathkamp (Loewenstein and Rathkamp 1955) reported that teeth have a protective feedback mechanism that is lost when the pulp is removed. They reported that non-vital teeth lose the protective proprioceptive features and thus lose the perception of increased chewing load, leading to an increased risk of fracture. Non-vital teeth reportedly had an elevated pain threshold which was more than twice that of vital teeth (Randow and Glantz 1986).

The relevance of occlusion and chewing forces, especially in patients with parafunctional habits, cannot be excluded from fracture analysis. There are hardly any studies researching parafunction and fracture of ETT (Mannocci, Bitter et al. 2022). It

has been estimated that the parafunctional chewing load can be about six times the normal chewing force for an extended period of 35 minutes a day (De Boever, McCall et al. 1978, Cosme, Baldisserotto et al. 2005).

Aquilino and Caplan (Aquilino and Caplan 2002) reported that the failure of the second molar was higher than any other tooth, suggesting occlusal forces to be a factor in this prognosis.

Ng et al. reported a poorer survival rate on the most terminal tooth by almost 96% compared to teeth that were not the distal-most in the arch (Ng, Mann et al. 2011). They also noted that among the extracted terminal teeth, 68% were fractured teeth, while only 38% were fractured from the extracted teeth with two proximal contacts. This would seem to suggest a key role for occlusal forces in the most terminal tooth about its survival.

However, it must be noted that lower survival rates for second molar may also be associated with the lower aesthetic value of the last tooth in the arch and with the increased complexity in performing orthograde and retrograde endodontic treatment on these teeth.

1.2.3 Loss of tooth structure

The major changes in biomechanical properties of a pulpless tooth have been attributed to loss of tooth structure due to caries, access cavity preparation, and tooth

preparation for post-endodontic restoration (Mondelli, Steagall et al. 1980, Larson, Douglas et al. 1981, Dietschi, Duc et al. 2007).

The largest reduction in tooth stiffness has been reported to be associated with the loss of the marginal ridges as shown in ex-vivo investigations (Reeh, Messer et al. 1989). For a MOD cavity with endodontic access, there can be up to 63% reduction in stiffness. Furthermore, it was shown that cuspal deflections increased following an increase in access cavity size and depth (Panitvisai and Messer 1995). These studies reinforce the importance of cuspal coverage following endodontic procedures to minimise the risk of fracture or marginal leakage.

According to Nagasiri and Chitmongkolsuk's study (Nagasiri and Chitmongkolsuk 2005), greater remaining tooth structure after endodontic therapy equates to greater longevity. Al-Nuaimi et al. (Al-Nuaimi, Patel et al. 2017) concluded that the loss of tooth structure is an objective parameter that can be used to predict the outcome of root canal retreatments. When less than 30% of the original tooth structure was remaining, there was a significantly higher failure rate of root canal retreatments.

Dietschi (Dietschi, Duc et al. 2007) reported the cavity depth, isthmus width and cavity configurations as critical factors in determining the reduction of stiffness and risk of fracture.

These studies indicate the need to preserve teeth to minimise the risk of fracture and improve the outcome of root canal treatment.

1.2.4 Other causes

Other causes for increased susceptibility to fracture could be poor gutta percha condensation procedures, and placement of pins and posts. Dismantling the coronal restorations for teeth requiring retreatment can significantly affect the remaining tooth structure. Shaping the root canal using rotary instruments and Gates Glidden drills can weaken the residual tooth structure, including the critical cervical area of the tooth and the furcal zone of the root. Ikram et al. (Ikram, Patel et al. 2009) reported a significant removal of tooth structure is associated with access cavity preparations and cast-metal post-space preparations. A table showing the summary of changes in ETT and its effect is shown below (**Table 1.1**).

Table 1.1 Summary of changes in ETT and its effect on ETT

Structural integrity	Changes	Studies	Effect on ETT
1.	Loss of tooth structure	Ikram et al. 2009	-Increased risk of fracture -Reduced retention and stability for restoration
2.	Access cavity preparation	Reeh 1989 Pantivisai and Messer 1995	Increased risk of fracture
3.	Root canal preparation	Hansen and Assmussen 1993	Increased risk of fracture
4.	Tooth preparation for definitive restoration	Reeh et al. 1989	-Increased risk of fracture -Reduced retention and stability for restoration
Biomechanical effects			
1.	Changes in free water content	Helfer et al. 1972 Sedgley and Messer 1972	Increased risk of fracture
2.	Collagen Alteration	Driscoll et al. 2002 Reddington et al. 2003	Increased risk of fracture
3.	Mineral composition and content		Reduced adhesion
4.	Effect of irrigants and medicaments	Grigoratos et al. 2001 Marending et al. 2007	-Increased risk of fracture -Reduced adhesion
5.	Effect of root canal filling materials and techniques	Fuss et al. 2001	Increased risk of fracture
Loss of Proprioception		Loewenstein & Rathkamp 1955 Randow & Glantz 1986	Increased risk of fracture

1.3 How to protect ETT from fracture

Factors that may impact the survival of an ETT include:

- Provision of cuspal coverage restoration.
- Preservation of tooth structure.
- Timing of restoration following root canal treatment
- Direct or indirect restoration
- Choice of restorative material
- Adhesion vs cementation

1.3.1 Provision of cuspal coverage restoration (direct vs indirect restorations)

There is consensus (Sorensen and Martinoff 1984, Vire 1991, Aquilino and Caplan 2002, Salehrabi and Rotstein 2004, Stavropoulou and Koidis 2007, Ng, Mann et al. 2011, Toure, Faye et al. 2011, Fransson, Dawson et al. 2016) that cuspal coverage should be provided to increase the survival of endodontically treated teeth, especially for posterior teeth.

Sorensen and Martinoff's retrospective study on 1273 teeth having endodontic treatment for up to 25 years showed a significant increase in survival of endodontically treated teeth when cuspal coverage restorations were placed on posterior teeth. Anterior teeth, however, did not have any benefit (Sorensen and Martinoff 1984).

Vire analysed 116 ETT that were extracted over one year and reported that teeth that were crowned had higher survival than teeth that were not crowned. They noted that if a crown was placed, the average time to extraction was 87 months, while it was 50 months if no crown was present. They were also classed into prosthetic

failures (59%), periodontal failures (32%) and endodontic failures (8.6%). Among the prosthetic failures, most were catastrophic fractures of the tooth or crown (Vire 1991).

An epidemiological study (Salehrabi and Rotstein 2004) found a 97% survival of endodontically treated teeth after eight years with a sample size of nearly 1.5 million teeth. The analysis of the extracted teeth revealed that 85% of them had no full coronal coverage.

A review (Stavropoulou and Koidis 2007) showed that posterior teeth restored using full crowns survived longer after 10 years (81% +/- 12%) than teeth restored using direct restorations (63% +/-15%).

Ng et al. reported a four-year survival rate of 95%, and the presence of a cast restoration compared to a temporary restoration was identified as a positive prognostic factor (Ng, Mann et al. 2011).

A study by Toure et al. analysed 119 extracted endodontically treated teeth and reported that mandibular first molars without crowns were the most frequently extracted teeth. However, the main reason for extraction was periodontal disease (40.3%), while fractures were only 15.1% of the proposed causative factors, even below endodontic failures (19.3%) (Toure, Faye et al. 2011).

Boren et al. assessed the long-term survival of endodontically treated teeth, performed in a specialist clinic, and noted that teeth with crowns survived significantly better (Landys Boren, Jonasson et al. 2015).

Fransson et al. assessed the survival of root-filled teeth restored by general dental practitioners in the Swedish adult population, and reported that the teeth restored with indirect restorations within six months of the root filling had a higher survival rate than those with direct fillings (Fransson, Dawson et al. 2016).

Pratt et al. reported that teeth that received direct restorations only (amalgam and composite) were 2.29 times more likely to be extracted than teeth that received a crown (Pratt, Aminoshariae et al. 2016).

A systematic review by Shu et al. compared treatment outcomes of direct and indirect restorations on endodontically treated teeth and suggested a weak recommendation for indirect restoration. Indirect restorations, especially full crowns, were reported to have higher five- and 10-year survival rates but no difference in the short term (<5 years), when compared to direct composite or amalgam restorations on both endodontic and restorative outcomes (Shu, Mai et al. 2018).

While most studies have been retrospective and hence offer a lower level of evidence, Mannocci et al. showed in a prospective study that the failure rate of endodontically treated premolars with limited loss of tooth structures restored with fibre post and composite resin was similar to that of teeth restored with full coverage metal ceramic crowns at three years (Mannocci, Bertelli et al. 2002). This opens up the research question of whether a cuspal coverage restoration is needed after all, particularly if we consider that recently, contracted access cavities have been proposed, where cuspal coverage may not be necessary (Plotino, Grande et al. 2017). Also, the three-year period may not be sufficient to assess long-term survival.

Another study with a follow-up of five years (Mannocci, Qualtrough et al. 2005) showed that root-filled premolars that were restored with fibre post and composite fractured less than those restored with amalgam. Composite restorations, on the other hand, showed a higher rate of secondary caries. It is interesting to note that in this study, one-year and three-year recalls showed no significant difference between the two materials. This highlights that for meaningful clinical research into restorative material, follow-up of at least five years is recommended.

A study by Guldener et al. evaluated the survival of single-rooted and multirooted endodontically treated teeth, with or without fibre post and direct composite restoration or single crown over a period of at least five years. The results show better survival for teeth restored with fibre post and direct filling or single crown over teeth restored using the direct composite filling (Guldener, Lanzrein et al. 2017).

A Cochrane review (Sequeira-Byron, Fedorowicz et al. 2015) comparing single crowns versus direct fillings for the restoration of root-filled teeth, concluded that there was insufficient literature evidence to support the placement of the crown over direct restoration for broken down ETT. Only one study (Mannocci, Bertelli et al. 2002) was included in this review which was able to fulfil the strict selection criteria, hence a lack of sufficient evidence.

1.3.2 Preservation of tooth structure

Endodontically treated teeth generally have a good survival rate, even though they are weakened from the removal of tooth due to caries and/or existing filling and from access cavity preparation.

The studies reported in Section 1.2.3 indicate the need to preserve tooth structure to minimise the risk of fracture and improve the outcome of root canal treatment; however, further prospective research is needed to understand the key parameters of tooth structure which influence the outcome.

1.3.3 Time interval between endodontic treatment and cuspal coverage restoration

Based on the best available evidence, it appears that for the long-term survival of ETT, cuspal coverage should be provided as soon as possible (Pratt, Aminoshariae et al. 2016) (Fransson, Dawson et al. 2016, Shu, Mai et al. 2018).

A study by Pratt et al. has shown that teeth with crowns placed four months after root canal treatment were almost three times more likely to be extracted than teeth that had a crown placed within four months of non-surgical root canal treatment (Pratt, Aminoshariae et al. 2016).

1.3.4 Ferrule effect

The “ferrule effect” is referred to as the protective effect of resisting fracture for a restored tooth by the band of cast metal (or porcelain) around the coronal surface of

the tooth (Sorensen and Engelman 1990). Numerous papers and position statements have highlighted the importance of the ferrule effect and the volume of the remaining tooth in the survival of tooth and restorations (Bhuva, Giovarruscio et al. 2021, European Society of Endodontology developed, Mannocci et al. 2021, Mannocci, Bitter et al. 2022).

The ferrule is often expressed as the amount of sound dentine above the finish line, but it refers to the bracing of the crown over the prepared tooth.

Various criteria have been used over the years to assess the ferrule effect and they include height, thickness, number of remaining walls, and percentage of remaining walls.

Many studies have classified teeth with varying degrees of tooth surface loss based on the number of coronal dentine walls remaining: one wall remaining, two walls remaining, three walls remaining, all four walls remaining and no walls remaining. (See Figure 1-1)

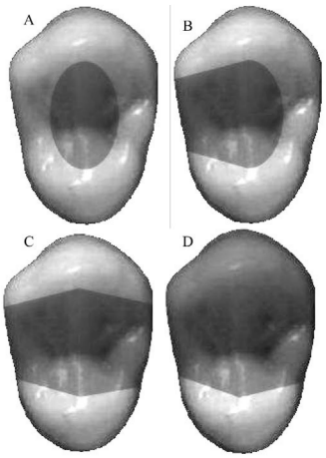


Figure 1-1 Schematic representation of coronal walls remaining shaded light, (from Ferrari et al. 2007) A = four walls remaining, B = three walls remaining, C = two walls remaining, D = one wall remaining

Nagasiri and Chitmongkolsuk reported remaining coronal tooth structures as maximum, moderate, and minimal remaining coronal tooth structures depending on the number of walls present and remaining dentine wall thickness. The authors did not mention how they measured the thickness of the walls (Nagasiri and Chitmongkolsuk 2005).

Naumann et al. used graduated pluggers and periodontal probes to measure remaining crown height, remaining wall thickness, size and flare of the canal orifice to help plan treatment procedures or predict tooth prognosis (Naumann, Blankenstein et al. 2006).

The remaining dentine height of 1.5-2mm was reported to be a significant factor in the survival of post and core restorations (Creugers, Mentink et al. 2005)(Fokkinga, Kreulen et al. 2007). Cagidiaco et al. reported the presence of one, two or three coronal walls had a significantly lower risk of failure compared to teeth without remaining dentine height (Cagidiaco, Garcia-Godoy et al. 2008). In the study by Schmitter et al., the remaining dentine height was not a significant factor, but in their study the mean ferrule height was > 3mm (Schmitter, Rammelsberg et al. 2007). (Fokkinga, Kreulen et al. 2007), emphasised the importance of remaining dentine height for the survival of the tooth. Ferrari et al. reported that the presence of at least one coronal wall significantly reduced the risk of failure, even if the ferrule was absent (Ferrari, Vichi et al. 2012). Most of these studies are on post-retained teeth and may not apply to teeth restored without posts.

A list of studies related to ferrule effect is mentioned in Table 1.2.

Table 1.2 Studies on the ferrule effect

Thickness of residual wall	**Type of teeth (anterior vs molar, premolar)**	**Height**	**Number of remaining walls**	**Volume**	**Missing wall**	**Width of access cavity**	**Remaining supra crestal tooth**
(Nagasiri and Chitmongkolsuk 2005)	(Schmitter, Rammelsberg et al. 2007)	Creugers et al. 2005	Ferrari et al. 2007	Creugers et al. 2005	No studies	Naumann 2006	Seltzer 2011
(Cloet, Debels et al. 2017)		Naumann et al. 2007	Cagidiaco et al. 2008	Fokkinga et al. 2007			
		Schmitter et al. 2007	Ferrari et al. 2012	Schmitter et al. 2007			
		Cagidiaco et al. 2008		Al-Nuaimi et al. 2020			
		Mancebo et al. 2010					
		Juloski et al. 2012					
		Ferrari et al. 2012					
		(Cloet, Debels et al. 2017)					

1.3.5 Silver amalgam

Silver amalgam has been widely used as a direct restorative material because of its various advantages, including good marginal seal, wear resistance, compressive strength, and low cost.

With amalgam, two types of direct techniques are employed for posterior teeth: the “Nayyar core” technique (Nayyar, Walton et al. 1980) and the “amalgam crown” technique (McCabe 1995).

Nayyar et al. (Nayyar, Walton et al. 1980) described an amalgam dowel and core technique for restoring ETT, in which amalgam is placed into 2mm extensions inside the root canal and pulp chamber to act as a dowel and core, and has proven to be very effective in endodontically treated posterior teeth. However, they noticed that with cast restorations contacts, contours and occlusion are best established indirectly.

McCabe (McCabe 1995) modified this technique to an amalgam crown restoration, which he saw as less expensive than a cast restoration, requiring less chair-side time, and relatively easy to re-treat if necessary and as an interim restoration.

Plasmans (Plasmans, Creugers et al. 1998) reported an 88% survival for complex amalgam restorations over a 100-month observation period; however, Smales and Hawthorne (Smales and Hawthorne 1997) reported only a 48% survival for complex cusp covering amalgam restorations compared to the crown which had 89% survival. Martin and Bader (Martin and Bader 1997) also reported a higher

success rate for crowns compared to complex amalgam restorations. However, none of these studies specifically evaluated the use of complex amalgam restorations as an alternative to full crowns for ETT.

1.3.6 Direct composite resins.

Lynch et al. (Lynch, Burke et al. 2004) studied retrospectively the association between the type of coronal restoration and survival of ETT. They concluded that teeth with cast restorations survived the longest (91.7%) followed by amalgam (86.5%) and composite resin (83%), while those with temporary restoration survived the lowest (34.5%) over an average three-year follow-up.

Dammaschke et al. (Dammaschke, Nykiel et al. 2013) investigated the influence of coronal restorations on the fracture resistance of ETT over a mean period of nine years on 676 root-filled and restored posterior teeth. All teeth with gold partial restoration survived without fracture. However, there were only 24 partial gold crowns in the sample. Full crowns survived an average of 15.3 years, composite resin 13.4 years, amalgam 11.8 years and glass ionomer cement 6.6 years. They also reported that teeth with one or two surfaces restored with amalgam, composite or glass ionomer showed lower fracture rates than teeth with three or more restored surfaces. When comparing amalgam, composite resin and GIC, they reported amalgam to have the second highest mean fracture rates after GIC. Indirectly restored ETT survived better than those with direct restoration. However, as this is a retrospective study, its results must be interpreted with caution.

The presence of occlusal stresses decreases the survival of direct resin-based composite restorations on endodontically treated teeth according to studies by Lempel et al. (Lempel, Lovasz et al. 2019). This is also a retrospective study and they assessed occlusal stress through a questionnaire (night or awake grinding, jaw fatigue) and clinical examination (wear facets, masticatory muscle hypertrophy, tongue indentation). They reported that the main reasons for the failure of direct resin restorations in ETT were vertical root fracture, cusp fracture, restoration fracture, secondary caries, and loss of adhesion.

In a systematic review, Suksaphar et al. (Suksaphar, Banomyong et al. 2017) investigated the survival rates of ETT restored with crowns or composite resin restorations. Unlike the Cochrane review (Sequeira-Byron, Fedorowicz et al. 2015), this review paper had three studies included in the review (Cagidiaco, Radovic et al. 2007, Mannocci, Bertelli et al. 2009, Dammaschke, Nykiel et al. 2013). The pooled data showed 94%-100% survival for crowns and 91.9%-100% survival for composite resins. They concluded that in teeth with minimum to moderate loss of tooth structure, survival of ETT with crowns or resin composites was not significantly different. These results suggest that preparing a tooth for a full crown may not be justified any more, especially with the benefits of preservation of the tooth and the ability of modern adhesive materials. If these direct composite resins are substituted with an indirect composite resin like an overlay or onlay, that may provide even better results than a direct resin with far inferior mechanical properties. More studies should be carried out comparing different types of adhesive indirect restoration on ETT.

1.3.7 Cast gold restorations.

Cast gold onlays and crowns have traditionally been considered the gold standard restoration in terms of durability. It is believed that adequately fabricated cast gold restorations provide excellent longevity and that the aesthetic tooth-coloured alternatives have a predicted lifespan that may be shorter.

In a long-term study by Studer et al. (Studer, Wettstein et al. 2000) on cast gold inlays and onlays on vital and ETT, 96% survival was noted at 10 years, 87% at 20 years and 73.5% at 30 years. Out of the 303 cast gold restorations, 274 were on vital teeth and 29 on ETT placed on 166 molar teeth, 131 premolar teeth and six anterior teeth. 12 out of 29 from the ETT failed, while only 30 out of 274 cast gold restorations on vital teeth failed. The main reasons for failure were secondary caries and loss of retention. In this study, the ETT had a three times higher risk of failure after 20 years of function compared to a vital tooth.

1.3.8 Metal ceramic crowns

Metal ceramic crowns particularly porcelain fused to metal are most commonly prescribed for indirect restoration for both anterior and posterior teeth (Christensen 2007). They have been shown to have a survival rate of 100% at three years, 99% at five years and 95% at 11 years (Leempoel, Eschen et al. 1985). Long-term studies have reported dental caries as the main cause of the failure of metal ceramic crowns (Schwartz, Whitsett et al. 1970, Walton, Gardner et al. 1986). There does not appear to be a significant difference between anterior and posterior metal ceramic crowns, in

terms of catastrophic failure, but anterior teeth needed more interventions due to fractures (Walton 1999).

A 25-year survival and clinical performance of 2340 gold-based metal ceramic single crowns were reported by Walton (Walton 2013). The 10-year survival was estimated at 97% and 85% at 25 years.

Metal ceramic crowns may be aesthetically inadequate due to the grey metal framework appearance gingivally, and the layer of opaque porcelain needed to mask the underlying metal framework. This has led to an increase in the provision of metal-free all-ceramic restorations that can be adhesively bonded to tooth.

1.3.9 All-ceramic crowns and overlays

Several methods have been employed to produce all-ceramic restorations including conventional feldspathic porcelain, aluminous porcelain, glass infiltrated alumina, zirconia, glass ceramic, reinforced glass ceramic, densely sintered alumina.

In a systematic review (Pjetursson, Sailer et al. 2007) comparing five-year survival of all-ceramic crowns and metal ceramic crowns from 34 studies, the following observations were noted. Metal ceramic had a five-year survival of 93.3%. For anterior teeth, all-ceramic crowns showed comparable survival rates to metal ceramic crowns.

For posterior teeth, densely sintered alumina (Procera, Nobel Biocare, Zürich-Flughafen, Switzerland) and reinforced glass ceramic crowns (IPS Empress, IPS e.max, Ivoclar Vivadent, Schaan, Liechtenstein) performed similarly to metal ceramic

crowns. Glass ceramic crowns (DICOR; Dentsply Sirona, York, PA, USA) and In Ceram (Vita Zahnfabrik, Bad Säckingen, Germany) crowns had lower survival rates when used for premolars and molars.

Posterior all-ceramic crowns had more failures than anterior all-ceramic crowns. The most common failure of all-ceramic crowns was the fracture of the core resulting in 85% of the losses, indicating a need for a post or adequate ferrule. The most common failures noted with all-ceramic crowns were caries, periodontitis, and abutment tooth fracture. The cumulative failure for metal ceramic crowns after five years was 4.4% while for all-ceramic crowns was 6.7%. These results should be interpreted with caution as this review did not specify the proportion of vital and non-vital teeth.

A further review by the same group (Sailer, Makarov et al. 2015) reviewed 67 studies covering 4663 metal ceramic and 9434 all-ceramic restorations. All-ceramic crowns made of leucite or lithium disilicate reinforced glass ceramic or alumina-based oxide ceramics can be recommended as an alternative to the gold standard metal ceramic crowns for anterior and posterior regions. The feldspathic and silica-based ceramics can only be recommended for the anterior region due to higher odds of fracture.

Layered zirconia-based single crowns should not be considered as primary options. Loss of retention and fracture of the ceramic veneering (layered ceramic) were listed as the technical reasons for the same. These findings are not relevant to monolithic zirconia restorations.

A clinical evaluation of 121 lithium disilicate all-ceramic crowns placed in 35 patients (11 ETT and the rest on vital teeth, 98 anterior and 23 posterior teeth) showed that ETT without post-core restorations exhibited a high failure rate (Toman and Toksavul 2015).

1.3.10 Lithium disilicate

Lithium disilicate was first introduced in 1988 under the name IPS Empress 2 (IvoclarVivadent, Schaan, Principality of Liechtenstein), for use with pressable technology. In 2005, IPS Empress 2, was replaced by a modified version, IPS e.max Press and IPS e.max CAD. The CAD version comes in blocks and can be machined, crystallised by firing, and delivered at the same appointment; it can bond to dentine and any available enamel so that tooth preparations can be more conservative, and it can be used to construct onlays, overlays and full crowns for ETT.

A three-year randomised study on partial crowns using lithium disilicate with or without posts showed a 93.3% survival for premolars without fibre posts and 100% survival for premolars with fibre posts and molars with and without posts (Ferrari, Ferrari Cagidiaco et al. 2019).

1.3.11 Monolithic and layered zirconia

Layered zirconia, as mentioned previously, should not be considered the primary option for single crowns (Sailer, Makarov et al. 2015). Loss of retention and

fracture of the ceramic veneering (layered ceramics) were listed as the technical reasons for the same.

1.3.12 Indirect composite resin

Resin composites consist of a polymeric matrix reinforced by fillers that could be inorganic (ceramic or glass or glass ceramic) or organic or composite (Ferracane 2011). Older resin blocks suffered from increased resin wear, loss of surface polish and colour instability (Douglas 2000).

Chrepa et al. (Chrepa, Konstantinidis et al. 2014) assessed the survival of indirect composite resin onlays on ETT in a retrospective study over a median follow-up of 37 months. The restoration survival was 96.8% at the end of the follow-up period.

1.3.13 Nanohybrid ceramics

Manufacturers have been developing new formulations for chair-side CAD-CAM materials that combine the advantageous properties of ceramics such as colour stability, durability with those of the composite resin such as low abrasiveness and improved flexural properties. Examples of such materials are Cerasmart (GC, Tokyo, Japan) and Enamic (Vita Zahnfabrik) which have improved properties over the old resin bocks. The resin materials are easy to fabricate and easier to repair intra-orally, chair-side. The CAD-CAM burs used to fabricate this restoration can be used for up to 100 restorations compared to 5-10 for ceramic restorations. Cerasmart is a high-density composite resin material containing 71% filler particles by weight.

A list of various materials used for restoring ETT is shown in Table 1.3 . Most of the developments are in the material science related to composite, ceramic and zirconia based restorative materials. Notice the shortage of clinical studies related to ETT with these materials. The other noticeable improvement is in the role of adhesion and bonded restorations.

Table 1.3 Restorative materials used for ETT.

Material	**Type of restoration**	**The main mode of retention**	**Annual failure rate**	**Studies**
Amalgam restoration	Direct restoration	Mechanical	3%	(Manhart, Chen et al. 2004)
Composite resin	Direct restoration	Adhesion	2.2% 1.78%	(Manhart, Chen et al. 2004) (Lempel, Lovasz et al. 2019)
Composite overlay indirect	Onlay / overlay	Adhesion	2.9%	(Manhart, Chen et al. 2004)
Composite overlay CAD-CAM	Onlay / overlay	Adhesion	na	
Ceramic overlay indirect	Onlay / overlay	Adhesion	2%	(Manhart, Chen et al. 2004)
Ceramic overlay-CAD-CAM	Onlay / overlay	Adhesion	1.7%	(Manhart, Chen et al. 2004)

Gold onlay	Onlay / overlay	Cementation	1.4%	(Manhart, Chen et al. 2004)
Metal ceramic crown	Full crown	Cementation	1%	(Pjetursson, Sailer et al. 2007)
Ceramic crown: pressed, layered or CAD-CAM	Full crown	Adhesion	2%	(Pjetursson, Sailer et al. 2007)
Zirconia crown: layered or monolithic	Full crown	Cementation	1%	(Larsson and Wennerberg 2014)
Gold crown	Full crown	Cementation	1%	(Manhart, Chen et al. 2004)

1.4 Concluding remarks

Most studies indicate the need to preserve tooth structure to minimise the risk of fracture and improve the outcome of root canal treatment. There is also strong evidence for a cuspal coverage restoration of posterior teeth.

Loss of vitality followed by endodontic therapy has been shown to affect tooth biomechanical behaviour only to a limited extent. Conversely, tooth strength is reduced in proportion to coronal tissue loss, due to either caries lesion or restorative procedures. Therefore, the best current approach for restoring endodontically treated teeth involves minimising tissue sacrifice, especially in the cervical area, combined with the use of adhesive procedures at both radicular and coronal levels to optimise restoration stability and retention.

1.5 Assessment of outcome of root canal treatment

The assessment of the outcome of the treatment of apical periodontitis is based on clinical, radiographic, and histological findings. Clinical diagnosis utilises signs and symptoms, related clinical tests and imaging systems, including conventional or digital radiography and computed tomography to offer a provisional diagnosis. The histological examination, on the other hand, provides information at the cellular level, which makes it possible to offer a definitive diagnosis (Ricucci, Lin et al. 2009).

Radiographic methods have been a widely accepted alternative for assessing the histologic status of the periapical area. They are based on a positive correlation between histologic and radiographic findings (Brynolf 1967, Kanagasingam, Lim et al. 2017). Brynolf's study found strong agreement between radiographic and histological findings on analysing 318 maxillary incisors in human cadavers.

The outcome of root canal treatment is assessed in most studies using clinical and radiographic methods (Ng, Mann et al. 2011). Although the gold standard is the histologic method of assessing the periapical tissues, this is not feasible for clinical practice. Clinical methods include the absence of pain or swelling, disappearance of the sinus tract, no loss of function and no evidence of tissue destruction (Bender, Seltzer et al. 1966).

Gutman published a list of subjective and objective criteria (Table 1.4) that can be used to evaluate the outcome of endodontic treatment (Gutmann 1992).

Table 1.4 Criteria for the outcome of root canal treatment by Gutmann (Gutmann 1992)

Clinical success	**Clinical questionable**	**Clinical failure**
No tenderness to palpation or percussion	Sporadic vague symptoms, not reproducible	Persistent subjective symptoms
Normal mobility	Pressure sensation of feeling of fullness	Recurrent sinus tract or swelling
No sinus tracts or integrated periodontal disease	Low grade discomfort following palpation, percussion or chewing	Predictable discomfort to percussion or palpation
Tooth function	Discomfort when pressure is applied by the tongue	Evidence of irreparable tooth fracture
No sign of infection or swelling	Superimposed sinusitis with a focus on the treated tooth	Excessive mobility or progressive periodontal breakdown
No evidence of subjective discomfort.	Occasional need for analgesics to relieve minimal discomfort	Inability to function on the tooth

Radiographic success	**Radiographic questionable**	**Radiographic failure**
Normal to slightly thickened pdl space (<1mm)	Increased pdl space (>1mm <2mm)	Increased width of pdl space (>2mm)
Elimination of the previous rarefaction	Stationary rarefaction or slight repair evident	Lack of osseous repair within a periradicular rarefaction or increase in the size of a rarefaction
Normal lamina dura about the adjacent tooth	Increased lamina dura about adjacent teeth	Lack of new lamina dura formation or significant increase in osseous density in the periradicular tissues
No evidence of resorption	Evidence of resorption	The presence of osseous rarefactions in periradicular areas where previously none existed (lateral rarefaction)
Dense 3D obturation of the visible canal space extending to the CDJ (approximately 1mm from the radiographic apex)	Voids in the density of canal obturation, especially in the apical third	Visible patent canal space that is unfilled or represents significant voids in the obturation of the canal

	Extension of filling material beyond the anatomic apex	Excessive overextension of the filling material with obvious voids in the apical third of the canal
		Active resorption coupled with other radiographic signs of failure

Histologic success	Histologic questionable	Histologic failure
Absence of inflammation	Presence of mild inflammation	Presence of a moderate to severe inflammatory infiltrate
Regeneration of periodontal fibres adjacent to or inserted into healthy cementum (Sharpey's fibres)	Areas of cementum undergoing concomitant resorption and repair	Lack of osseous repair with concomitant resorption of the surrounding bone
Layering or repair of cementum with new cementum into or across the apical foramen (rare)	Lack of periodontal fibre organisation	Active resorption of cementum with no evidence of repair
Osseous repair is evident along with healthy osteoblasts surrounding the newly formed bone	Minimal osseous repair along with evidence of osteoclastic activity	Presence of zones of necrotic or foreign tissue remnants
No resorption is present and previous areas or resorption demonstrate cemental deposition		Presence of granulation tissue and possible epithelial proliferation

1.5.1 Radiographic assessment of endodontic outcome

Radiographic assessment involves the use of conventional or digital periapical radiographs and more recently cone beam CT.

The problem with radiographic assessment is that interpretation is a source of errors. Inconsistent interpretation of the same radiograph by the same observer at different time intervals or between different observers has been reported (Goldman, Pearson et al. 1974, Zakariasen, Scott et al. 1984).

Different strategies have been recommended to minimise interpretation errors. Optimal viewing conditions are recommended while assessing the radiographic images including blocking all extraneous light (Welander, McDavid et al. 1983). Also recommended is the use of magnification, the use of a viewing box and masking radiographs (Patel, Rushton et al. 2000, Orafi, Worthington et al. 2010). It has also been suggested to avoid long duration of viewing to avoid fatigue (Goldman, Pearson et al. 1972). Two observers using an index with a joint agreement to the radiographic status reduces observer variations and increases the reliability and validity of the findings (Molven, Halse et al. 2002).

There are two indices for periapical radiographs to help standardise observers' interpretation of periapical status.

The first is the Probability Index **(PRI)** proposed by Reit and Grondahl (Reit and Grondahl 1983). This is not so widely used, and, in this index, the criteria were:

1. Periapical destruction of bone is almost definitely not present.
2. Periapical destruction of bone is almost probably not present.
3. Unsure
4. Periapical destruction of bone is probably present.
5. Periapical destruction of bone is almost definitely present.

The periapical index **(PAI)** developed by Orstavik et al. (Orstavik, Kerekes et al. 1986) used Brynolf's histologic and radiologic correlational study (Brynolf 1967) for calibration of the observers (Figure 1-2). The use of this index is questionable on teeth other than maxillary incisors, as Brynolf's findings were based only on anterior teeth, while other teeth may have varying thicknesses of the cortical plate which creates anatomical noise and do not allow the detection of radiolucencies.

Periapical radiographs are a widely used technique for diagnosing and managing endodontic pathosis. However, the information they yield is affected by geometric distortion, anatomic noise and compression of 3D structure into two-dimensional views (Patel, Dawood et al. 2009).

CBCT scans overcome some of the limitations of periapical radiographs (Lofthag-Hansen, Huumonen et al. 2007, Patel, Dawood et al. 2007, Estrela, Bueno et al. 2008).

Three radiographic CBCT indices have been developed for the assessment of periapical pathosis.

The first of these indices was developed by Estrela et al. and is known as the CBCT PAI index (Estrela, Bueno et al. 2008). This index used a six-point scoring system (0-5) with two additional variables - expansion of cortical bone and destruction of cortical bone (Figure 1-3). This index has been used in many clinical studies (Estrela, Bueno et al. 2008, Fernandez, Cadavid et al. 2013)

Venskutonis et al. (Venskutonis, Plotino et al. 2015) developed the periapical and endodontic status scale (PESS) based on the complex periapical index (COPI) and endodontically treated tooth index (ETTI). The COPI was designed for the identification and classification of periapical diseases, while the ETTI was designed for the endodontic treatment quality evaluation using a CBCT.

The endodontic radiolucency index was developed by Rice et al. (Rice, Abramovitch et al. 2019) as a highly sensitive and reproducible tool for evaluating periapical lesions.

Patel et al. (Patel, Wilson et al. 2012) developed a six-point scoring scale for the radiographic assessment of periapical lesions. This can be used for both periapical and CBCT radiographic images and allows for direct comparison between the two imaging techniques (Figure 1-4). This criterion of assessment has been used in many studies (Zahran, Patel et al. 2021, Patel, Puri et al. 2022)

Figure 1-2 The Periapical Index (PAI) showing a reference set of radiographs with corresponding line drawings and their associated PAI scores (Orstavik, Kerekes et al. 1986)

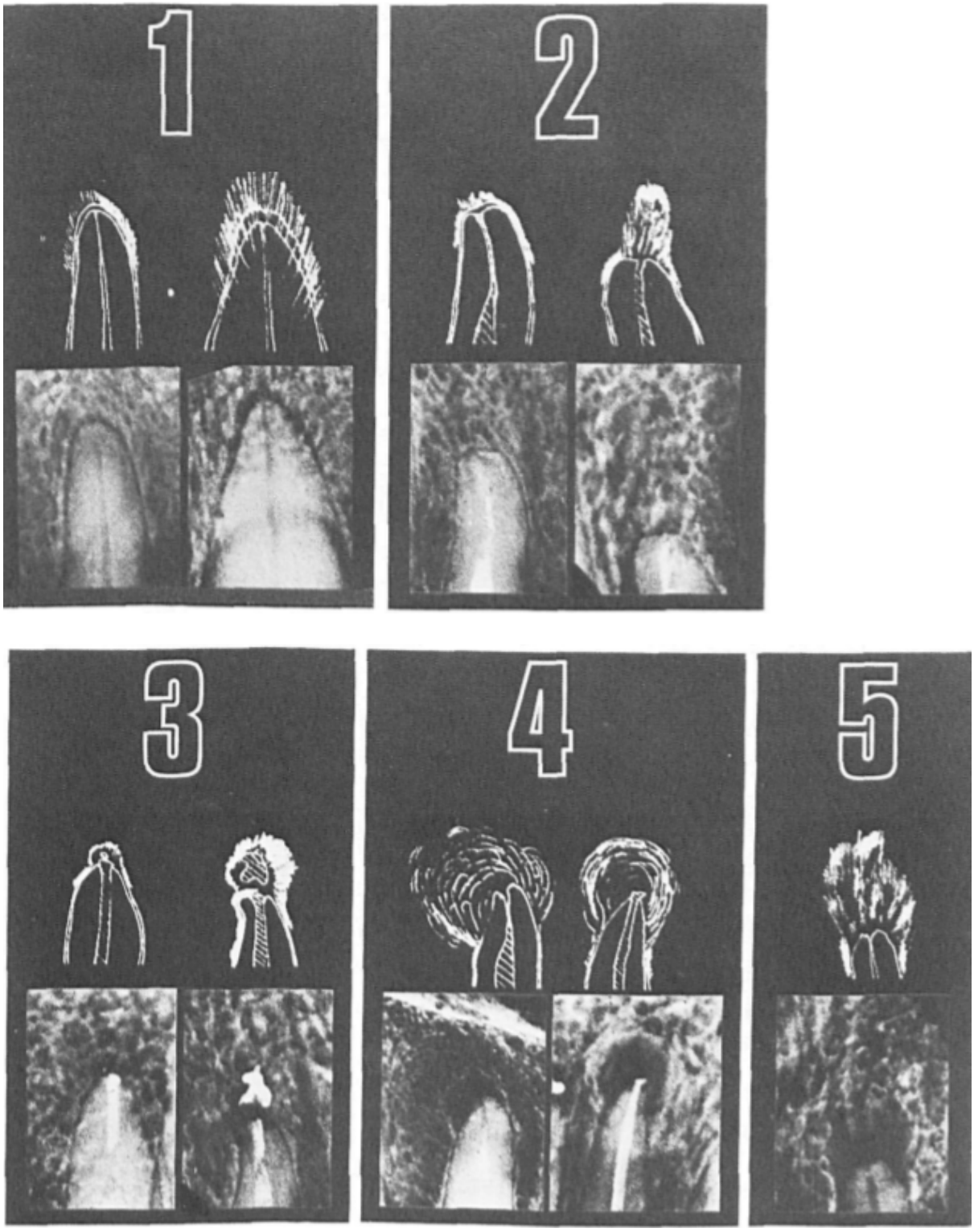


Figure 1-3 CBCTPAI by (Estrela, Bueno et al. 2008)

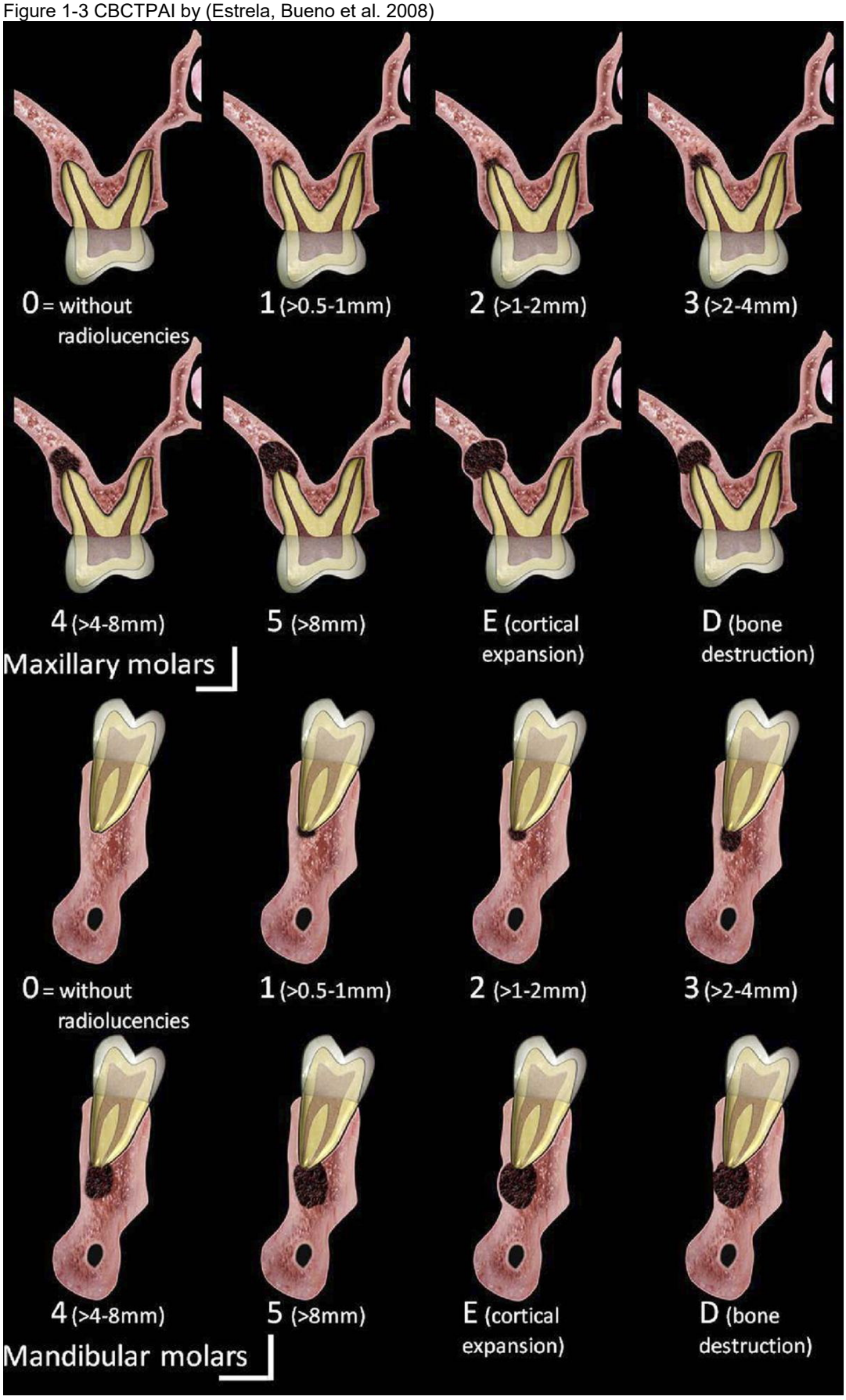
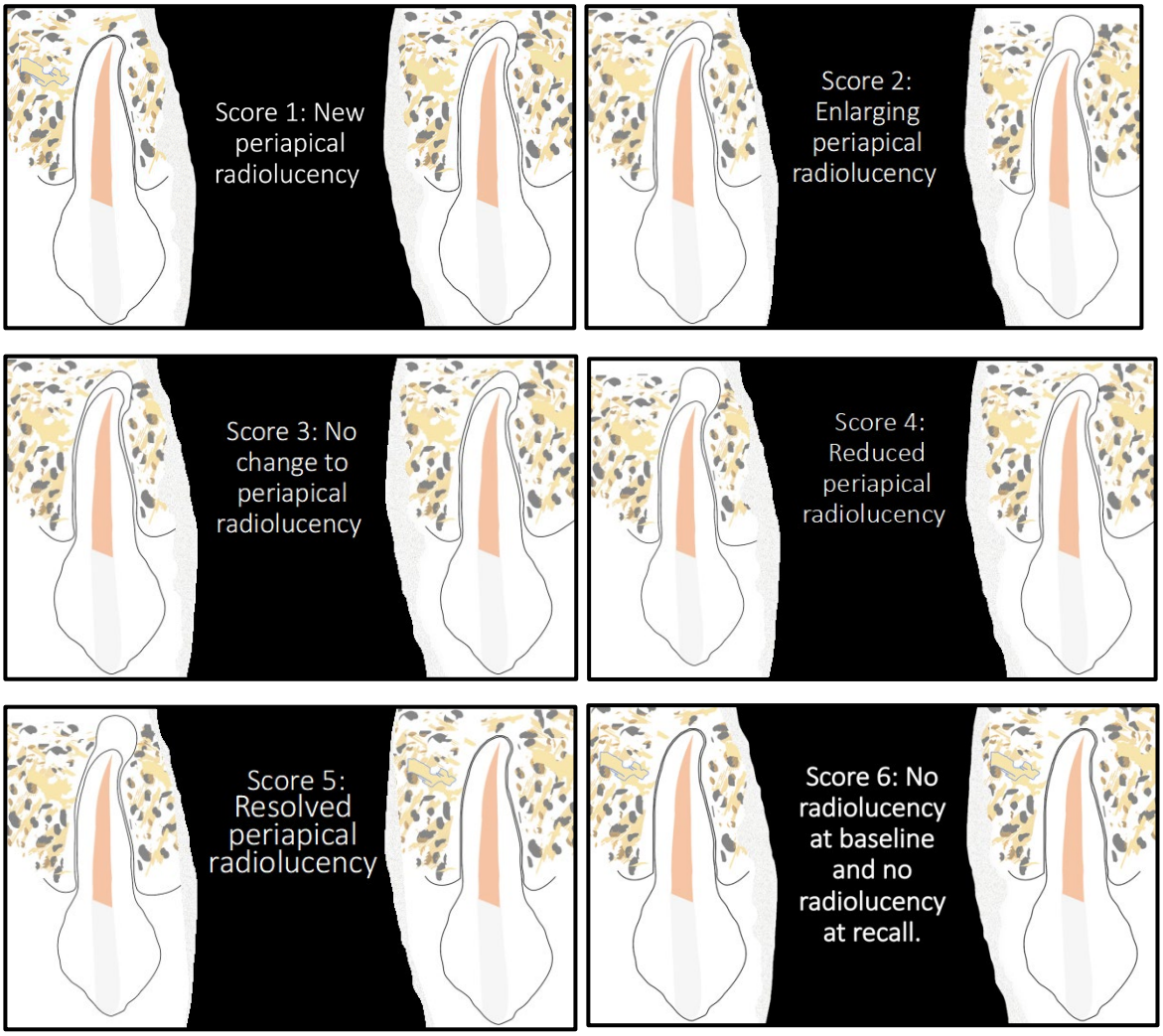


Figure 1-4 An illustration of the six-point radiographic assessment criteria developed by Patel et al. (Patel, Wilson et al. 2012)



1.6 CBCT vs periapical radiographs in outcome assessment

Periapical radiographs are prone to interpretation bias; recall radiographs may be taken at a different angulation, and therefore the radiolucency may appear smaller in size or disappear completely. Conversely, with a change in angulation, a smaller lesion may appear to be enlarged and recorded as a failure. These and other drawbacks of periapical radiographs can be minimised using CBCT (Patel, Dawood et al. 2007).

Preoperative pulp and periapical status have been reported to affect the outcome in most studies. The presence and size of a periapical radiolucency seem to have a detrimental effect on the outcome of root canal treatment in most studies (Sjogren, Hagglund et al. 1990, Friedman, Abitbol et al. 2003, Ng, Mann et al. 2011), while a study by Bystrom et al. did not find any difference in outcome between teeth with and without radiolucencies (Bystrom, Happonen et al. 1987). Ng reports that the odds of success of treatment are reduced by about 14% for every 1mm increase in the size of the preoperative lesion (Ng, Mann et al. 2011).

Liang's study (Liang, Li et al. 2011) assessing outcome predictors identified that 80% of short root fillings on periapical radiographs were flush with the apex on CBCT images. Liang's study also noted that the density of root filling and quality of coronal restoration were prognostic factors influencing the outcome in CBCT scans. However, this study did not have a baseline CBCT scan for meaningful comparisons to be made.

The CBCT outcome study by Patel et al. (Patel, Wilson et al. 2012) showed a higher failure rate for teeth with no preoperative periapical lesions diagnosed using CBCT compared to a periapical radiograph.

The outcome study by Davies et al. (Davies, Patel et al. 2016) showed that the CBCT scans diagnosed a significantly lower proportion of favourable outcomes compared to periapical radiographs in root canal retreatments.

A pooled study by Al-Nuaimi et al. (Al-Nuaimi, Patel et al. 2017), from three CBCT root canal treatment outcome studies undertaken at King's College London, showed a higher proportion of favourable outcomes in anterior teeth and premolars compared to molars. The proportion of favourable outcomes of primary and secondary root canal treatments assessed with CBCT was lower compared to those shown in periapical radiographs.

1.7 Outcome studies

The definition of success can be based on strict criteria or loose criteria (Ng, Mann et al. 2011). In the strict criteria, success was defined as the absence of pain, inflammation or swelling clinically and radiographic evidence of normality. In the loose criteria, success was defined as the absence of pain, inflammation or swelling along with radiographic signs of complete or incomplete healing (normal periodontal ligament width or reduced size of periapical lesion). Table 1.5 summarizes the different criteria used to define periapical status.

Table 1.5 Different studies and different terminologies used.

Studies	**Outcome terminology used and criteria for determining periapical status**		
(Strindberg 1956)	**Success** **Clinical:** No symptoms **Radiographic:** The contours, width and structure of the periodontal margin were normal OR the periodontal contours were widened mainly around the excess filling.	**Uncertain** **Radiographic:** The tooth was extracted prior to the three-year follow-up due to unsuccessful treatment of another root of the tooth. There were ambiguous radiographs which for some reason could not be repeated.	**Failure** **Clinical:** Presence of symptoms **Radiographic:** A decrease in the periapical rarefaction OR unchanged periapical rarefaction OR the appearance of a new rarefaction or an increase in the initial rarefaction

(Bender, Seltzer et al. 1966, Bender, Seltzer et al. 1966)	**Success** **Clinical:** Absence of pain / swelling Absence of sinus / fistula No loss of function No evidence of tissue destruction **Radiographic:** An eliminated or arrested area of rarefaction after a post-treatment interval of six months to two years		
(Friedman and Mor 2004)	**Healed** Clinical: Normal Presentation Radiographic: Normal presentation	**Healing** Clinical: Normal presentation Radiographic: Reduced radiolucency	**Diseased** Clinical signs or symptoms are present, even if the radiographic presentation is normal. Radiolucency has emerged or persisted without change, even when the clinical presentation is normal.
(Gorni and Gagliani 2004)	**Complete healing** No clinical signs and symptoms,	**Incomplete healing** Reduced periapical lesion on cases that had a pre-	**Unsatisfactory healing** Persistence of clinical signs and symptoms and periapical radiolucency

	normal periodontal ligament width though slight sealer extrusion was accepted	existing lesion without any clinical signs and symptoms	was still present, unchanged or increased in size at the 24-month recall.
(European Society of 2006)	**Favourable** Clinically: Absence of pain, swelling or other symptoms No sinus tract No loss of function Radiographic: Normal periodontal ligament space around the root	**Unfavourable** Clinically: The tooth is associated with signs and symptoms of infection. Radiographic: A new lesion is visible, or the pre-existing lesion has increased in size	**Uncertain** Radiographic: The lesion has remained the same size or only diminished in size. In such cases a follow-up up to four years is recommended and after four years, if the lesion persists, it is to be considered associated with post-treatment disease.

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More than 60 clinical trials have assessed the outcome of primary root canal treatment over the past 80 years using periapical radiographs (Friedman, Abitbol et al. 2003). The limitations of periapical radiographs in detecting periapical radiolucencies have been well documented (Bender 1997, de Paula-Silva, Wu et al. 2009, Patel, Dawood et al. 2009).

The limitations of previously published systematic reviews evaluating the outcome of root canal treatment have been described (de Paula-Silva, Wu et al. 2009). A high number of cases confirmed as healthy by periapical radiographs revealed apical periodontitis on CBCT and histology (de Paula-Silva, Santamaria et al. 2009, Kanagasingam, Lim et al. 2017).

A few outcome studies have already been published that incorporated CBCT in the radiographic evaluation of endodontic outcomes (Liang, Li et al. 2011, Patel, Wilson et al. 2012, Al-Nuaimi, Patel et al. 2017).

The primary objective of outcome assessment is to monitor the healing or development of apical periodontitis. A minimum observation period of one year is recommended with a clinical and radiographic follow-up, but a longer period may be needed when the healing is incomplete or trauma is involved (European Society of 2006).

Table 1.6 below shows a comparison of endodontic studies that used CBCT and PA for outcome assessment.

1.8 Comparing the results of outcome studies undertaken using CBCT and periapical radiographs

Table 1.6 Table summarising the results of outcome studies using CBCT and periapical radiographs for the assessment of the outcome of endodontic treatments.

	Patel 2012	**Van der Borden 2013**	**Liang 2013**	**Davies 2015**	**Al-Nuaimi 2017**	**Zavattini 2020**	**Gudac et al. 2022**	**Zahran 2022**	**Rahim 2023***
Operators & qualification	Single specialist	Single endodontic department	Four dentists	Multiple specialists and postgraduates	Multiple postgraduates	Multiple specialists and postgraduates	Single specialist	Multiple Specialists and postgraduates	Multiple Specialists and postgraduates
Location	UK	Holland	China	UK	UK	UK	Lithuania	UK	UK
Publication year	2012	2013	2013	2015	2017	2020	2022	2022	*
Type of study	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective
Study duration	1 year	10-37 months	1 year	11-18 months	1 year	1 year	2 years	1 year	1 year
Recall	75%	75%	82%	86%	88% teeth (86% patients)	83.2%	100%	80%	81.6%
Sample size	123	50 teeth 71 roots	84	114 teeth 206 roots	137	104	176	144	131
1° or 2° RCT	1°	1°or 2°	1°	2°	2°	1°	1°or 2°	1°	1°or 2°
Anterior	30	9	na	13	Nil	No details	No details	Nil	Nil
Premolar	19	6	na	18	28	No details	No details	Nil	7
Molar	69	35	nil	67	109	No details	No details	115	100

Comparison	Compared CBCT and digital PA before treatment and at one-year recall	Compared volume and area of lesion assessed by CBCT and PA	The outcome of root canal treatment with and without ultrasonic activation of irrigant.	Compared single PA, parallax, and CBCT to detect periapical lesions		Calcium silicate sealer single cone vs non calcium silicate cement and warm vertical		Compared standard and enhanced infection control protocol on root canal treatment outcomes	Compared tooth preservation factors on outcome of root canal treatment.
Outcome	**By roots** Healed by PA: 92.7% CBCT: 73.9% Healing by PA: 97.2% CBCT: 89.4% **By tooth** Healed by CBCT 62.5% PA 87% Healing by PA 95.1% CBCT 84.7%	CBCT and PA Healing (favourable) (undetected or reduced) PA 63/71 (88.7%) CBCT 55/71 (77.5%) Outcome: Disagreement 45.1% (32/71 roots) Agreement 54.9% (39/71 roots)	PA showed more teeth without radiolucency. However favourable outcomes (Absence of radiolucency and reduction in size) were similar between both.	PA: favourable By tooth: 93% By Root: 96% CBCT: favourable By tooth: 77% By root: 87% Maxillary molar Unfavourable PA: 5%; CBCT: 14% Healed PA: 90%; CBCT: 78% Mandibular molars Unfavourable PA: 2%; CBCT: 13%	Favourable outcome PA 88% CBCT 82%	Success rate AH plus and warm vertical. PA 89% CBCT 80% Calcium silicate cement and single cone PA 90% CBCT 84%	Healed PA 89% CBCT 83% Favourable PA 96% CBCT 94%	Favourable outcome Overall CBCT 76.5% PA 92.2% Standard infection control protocol CBCT 66.7% PA 87%	Favourable outcome CBCT 78.5% PA 88.8%

				Healed PA: 83%; CBCT: 66%				Enhanced infection control protocol CBCT 85.2% PA 96.7%	
Conclusion	CBCT revealed lower healing compared to PA	Changes in lesion size determined by PA and CBCT are different. The outcome determined by PA may not be correct		CBCT detected more periapical lesions than single PA or parallax PA	The percentage of unfavourable outcomes was significantly higher when less than 30% of the original tooth structure was present at baseline	No difference between CBCT and PA or between AH plus and Bioroot RCS	Most disagreement between the two methods is seen at periapical lesion size 3mm and greater (inability to agree on actual size in mm)	Enhanced infection control protocol resulted in a more successful outcome after 1 year	Please See Ch 3

Rahim 2023* is unpublished data from our clinical trial (Chapter 3)

Table 1.7 Table showing pooled data of unfavourable and favourable outcomes from studies comparing PA and CBCT.

Study	Imaging	Unfavourable	Favourable	Total Number of teeth
Patel 2012	PA	6	117	123
	CBCT	19	104	
Davies 2016	PA	7	91	98
	CBCT	23	75	
Al-Nuaimi 2017	PA	10	122	132
	CBCT	20	112	
Zavattini 2020	PA	11	93	104
	CBCT	18	86	
Liang 2013	PA	5	79	84
	CBCT	7	77	
Van der Borden 2013	PA	8	63	71
	CBCT	16	55	
Zahran 2022	PA	9	106	115
	CBCT	27	88	
N Rahim* 2023	PA	12	95	107
	CBCT	23	84	
Total	**PA**	**68**	**766**	834
	CBCT	**153**	**681**	834

Table 1.8 Pooled data comparing PA and CBCT, highlighting the categories where there is a disagreement between the two techniques.

		Teeth with new lesions	**Teeth with enlarged lesions**	**Teeth with unchanged lesions**	**Teeth with reduced lesions**	**Teeth with resolved lesions**	**Teeth with no new lesions (no lesion before or after)**	**Total Number of teeth**
	SCORE	**1**	**2**	**3**	**4**	**5**	**6**	
		Unfavourable			**Favourable**			
Patel 2012								
	PA	1	5	0	43	0	74	123
	CBCT	9	10	0	62	0	42	123
Davies 2016								
	PA	0	2	5	16	40	35	98
	CBCT	2	8	13	15	50	10	98
Al-Nuaimi 2017								
	PA	0	4	6	24	48	50	132
	CBCT	0	9	11	45	48	19	132
Zahran 2021								
	PA	5	4	0	20	26	60	115
	CBCT	9	8	10	20	25	43	115
Rahim 2023*								
	PA	4	5	3	14	20	61	107
	CBCT	2	12	9	20	29	34	107
Zavattini 2020								
	PA	11			93			104
	CBCT	18			86			104
Liang 2013			**Enlarged lesions**	**Uncertain**	**Reduced lesions**		**Absence of radiolucency**	

	PA		1	4	52		27	84
	CBCT		2	5	61		16	84
Van der Borden 2013			**The volume of lesions increased**	**changed**	**The volume of lesions reduced**	**Complete absence of PA lesion**	**Undetected**	**Total number of teeth**
	PA (area)		5	3	31		32	71
	CBCT (volume)		6	10	44		11	71

The pooled data above (Table 1.7, Table 1.8) shows that periapical radiographs are largely overestimating the success of root canal treatments compared to a cone beam CT. PA results display a much higher number of teeth scoring no radiolucency preoperatively and at recall due to the large number of undetected radiolucencies at baseline. These results agree with the systematic review by Aminoshariae et al. (Aminoshariae, Kulild et al. 2018).

1.9 Concluding remarks

Endodontically treated teeth are more prone to fracture and the survival of post-endodontic restorations are inferior to those of vital teeth. Preservation of tooth structure has been proven to improve the survival of endodontically re-treated teeth. There are no papers assessing the factors affecting preservation of tooth structure on the outcome of restorations and endodontic outcome of primary root canal treatments.

Previous work on endodontic outcome assessed by CBCT and PA showed an underestimation of the number of periapical lesions detected in PA and a consequent overestimation of the success rate of root canal treatments.

There are limited studies assessing outcome of root canal treatment using CBCT. No work has been conducted assessing the outcome of root canal treatment, using CBCT, in relation to factors such as ferrule effect, and conservative cuspal coverage restorations such as onlays; the findings of this literature review provided the justification for the systematic review, laboratory study and clinical studies described in the following chapters.

Chapter 2 : The survival of tooth-coloured onlays used for the restoration of root canal treated teeth: a systematic review and meta-analysis.

2.1 Abstract

2.1.1 Background:

Full coverage crowns are the most widely used post-endodontic restorations. Partial coverage restorations for ETT, such as onlays, which preserve more tooth structure, are not so well investigated, and lack data from clinical trials.

2.1.2 Aim:

This systematic review aimed to examine the literature to assess the survival of ceramic or composite onlays on root canal treated teeth compared to tooth-coloured onlays on vital teeth.

2.1.3 Data source:

The protocol for the review was developed and registered in the PROSPERO database. The reviewers searched the database in PUBMED, EMBASE, and COCHRANE Central Register of Controlled Trials for articles from 1980 – 2022, with no language restriction. This was followed up by a search on selected journals.

2.1.4 Study eligibility criteria, participants, and intervention:

The inclusion criteria were: Clinical studies related to ceramic inlays, onlays or overlays placed on root canal treated teeth; Composite inlays, onlays or overlays on endodontically treated teeth; prospective, retrospective, or randomised clinical trials conducted in humans; Studies with a dropout less than 30%; Studies with a follow-up more than two years. Clinical trials evaluating the

success and survival of onlays on vital and non-vital teeth were included; studies with no onlay restorations on endodontically treated teeth were excluded.

2.1.5 Study appraisal and synthesis methods:

The quality of the included studies was assessed using Cochrane criteria.

2.1.6 Results:

We included nine clinical trials that compared tooth-coloured onlay restorations on vital and non-vital teeth. A total of 99 articles were evaluated, of which nine met the inclusion criteria and eight provided data for the meta-analysis. The results showed that ceramic onlays failed more in non-vital teeth compared to vital teeth. The main mode of failure appears to be chipping or fracture of the restoration. In view of the relatively high rate of clinical success, onlays may be considered as a treatment option for restoring endodontically treated teeth.

2.1.7 Limitations, conclusions, and implications of key findings:

Tooth-coloured onlays offer an acceptable survival as post-endodontic restoration. Tooth-coloured onlays survive longer in vital teeth compared to ETT. The main mode of failure appears to be the fracture of the restoration.

2.1.8 Funding:

None.

2.1.9 Registration:

This systematic review was registered in PROSPERO-CRD42020176880.

2.2 Introduction

There is not enough evidence for direct restorations nor onlays on ETT in the posterior dentition. Based on previous work, full crowns are routinely provided for ETT (Sorensen and Martinoff 1984, Aquilino and Caplan 2002, Salehrabi and Rotstein 2004, Ng, Mann et al. 2011, Fransson, Dawson et al. 2016). Full crowns have long been considered the gold standard for restoring endodontically treated teeth (Aquilino and Caplan 2002).

Preservation of sound tooth structure is known to affect the outcome of root canal procedures (Al-Nuaimi, Patel et al. 2017). Al-Nuaimi et al. determined that teeth with less than 30% tooth structure remaining had a significantly more unfavourable outcome of root canal retreatments assessed using CBCT.

The percentage of remaining tooth structure depends on the extent of caries, existing restorations, non-carious tooth structure loss and tooth structure loss during access and root canal preparation (Reeh, Messer et al. 1989, Ikram, Patel et al. 2009). The choice of post-endodontic restoration also affects the degree of tooth structure loss, varying significantly from direct fillings to onlays and full crowns. Onlays are partial or complete occlusal coverage restorations that are a conservative alternative to full crowns. An additional benefit is that they can be adhesively bonded to the tooth, thereby preserving more tooth structure. Edelhoff and Sorensen (Edelhoff and Sorensen 2002) showed in an ex-vivo study that inlay and onlay preparation only resulted in 5-27% tooth structure removal, while full crowns resulted in 67-75% tooth structure removal. If we then consider that ETT survival is significantly affected by the remaining tooth structure

(Nagasiri and Chitmongkolsuk 2005, Al-Nuaimi, Patel et al. 2017), then it is imperative that clinicians do their best to preserve tooth structure.

However, there are limited studies on onlays as a post-endodontic restoration for ETT. This is primarily due to the preferential teaching of full crowns in dental schools. This has resulted in a generation of dentists still providing full crowns (Bomfim, Rahim et al. 2020). There are very limited well-designed clinical trials assessing post-endodontic restorations and materials on ETT (Mannocci 2013, Sequeira-Byron, Fedorowicz et al. 2015).

The tooth-coloured indirect restorative materials widely used now are lithium disilicate-based glass ceramic, zirconia-based all-ceramic material and nanohybrid ceramic materials. These materials, especially etchable glass ceramic and nanohybrid ceramics, can be adhesively bonded to the tooth and hence do not require the retentive features needed for cemented restorations.

2.3 Aims and objectives.

This systematic review aims to compare the survival of tooth-coloured onlays and overlays on ETT with those on vital teeth and to determine the most frequent causes of failure reported in retrospective studies, prospective studies, or randomised clinical trials.

2.4 Materials and methods

This systematic review conforms to the PRISMA guidelines (Moher, Liberati et al. 2009). The PICOS strategy was used to develop the literature search strategies. The study was registered in the Prospero database (CRD42020176880). See Appendix F.

2.4.1 Objectives

The aim of this review is to evaluate by means of a systematic review and meta-analysis the hypothesis of no difference in failure rates of ceramic or composite onlays in vital and endodontically treated teeth.

2.4.2 Focused question

“What is the longevity of tooth-coloured onlays on endodontically treated teeth compared to vital teeth?”

2.4.3 Search strategies

Two independent reviewers searched the following databases for articles on the survival of tooth-coloured onlays on root canal treated teeth: MEDLINE/ PUBMED, EMBASE, COCHRANE Central Register of Controlled Trials, Web of Science, Scopus, Scielo, Lilacs and Ibecs. The articles were sourced from 1983 up to April 2022. References of the pieces were further checked manually. The eligibility criteria were based on the PICOS strategy described in (Table 2.1).

Table 2.1 PICOS search strategy

PICOS strategy	
Patient (P)	Patients of any age, gender, or ethnicity had endodontically treated permanent posterior teeth restored using ceramic or resin onlays.
Intervention (I)	Composite or ceramic onlays to restore endodontically treated teeth.
Comparison (C)	Compared with composite or ceramic onlays in vital teeth.
The outcome measured (O)	The primary outcome is the survival of the tooth and restoration. The secondary product is the assessment of the mode of failure between crown and onlays in vital and endodontically treated teeth.
Study design (S)	Randomised clinical trials or prospective/ retrospective non-randomised cohort studies on humans will be included, with a follow-up at least two years and less than 30% dropout.

The search strategy is described in (Table 2.2). A combination of keywords and mesh terms was used. All titles and abstracts were first studied to rule out studies that did not fit the inclusion criteria.

Table 2.2 Search strategy used in an electronic database (PubMed, Web of Science, Scopus, Scielo, Lilacs and Ibecs)

PubMed (Medline)	(dental onlay[MeSH Terms])) OR (dental onlays[MeSH Terms])) OR (onlay[MeSH Terms])) OR (onlay, dental [MeSH Terms])) OR (onlays[MeSH Terms]))) + (endodontics[MeSH Terms])) OR (root canal therapy[MeSH Terms])) + (assessment, outcomes[MeSH Terms]) OR (outcome)	PubMed= 2,114,836 PMC = 2,000,822 Mesh = 66
Web of Science	(dental onlay OR dental onlays OR onlay OR onlay dental OR onlays + endodontics root canal therapy + assessment, outcomes OR outcome)	2,555,162
Scopus	(dental onlay OR dental onlays OR onlay OR onlay dental OR onlays + endodontics root canal therapy + assessment, outcomes OR outcome)	19,524

2.4.4 Selection criteria

The inclusion and exclusion criteria as well as measured outcomes are listed in (Table 2.3).

Table 2.3 Inclusion criteria, exclusion criteria and outcome measured.

Inclusion criteria	**Exclusion criteria**	**Outcome measured**
Clinical studies related to ceramic inlays, onlays or overlays placed on adult human root canal treated teeth in private practice, hospitals, or universities	In-vitro studies, studies on animals, previous reviews of the literature	Survival of restoration, survival of tooth
Prospective, retrospective, or randomised clinical trials	Ceramic restorations of part of an abutment tooth used as a retainer for fixed or removable prosthesis were also excluded	Mode of failure of restoration and tooth
No restriction on the type of resin or ceramic material, method of fabrication, preparation, or cementation	Post retained restorations.	Comparison of failure between vital and endodontically treated teeth
More than two years of follow-up	Endocrowns	
Less than 30% dropout		

2.4.5 Screening process

Two review authors (NR and RA) screened independently the titles and/or abstracts of studies retrieved from the searches and those from additional sources (manual searching, reference lists). The full text of all potentially eligible studies was retrieved and assessed independently by the two reviewers. In case of disagreement regarding the inclusion or exclusion of a study, FM reviewed the articles and acted as arbiter if there was a discrepancy in the selected studies. MA provided the statistical analysis. NR, RA, FF, SP and FM reviewed the final edition (Figure 2-1).

2.4.6 Quality assessment

The quality of the selected articles was assessed by two authors (NR and RA), and in case of disagreement, it was resolved with a third reviewer (FM). The risk of bias in the selected studies was assessed using the modified Cochrane Collaboration tool, which included the following domains: selection bias randomisation, allocation concealment, unit of randomisation issues, performance bias (blinding of participants, operators, examiners), detection bias (blinding of outcome assessment), attrition bias (loss to follow-up and missing values or participants), and reporting bias (unclear withdrawals, or reported outcomes). Bias was assessed as a high, low, or unclear judgement. RevMan 5.4 (RevMan 5.4, The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) was used to obtain a risk of bias summary and graph for the selected studies (Figure 2-4).

2.4.7 Data extraction

The data were extracted on MS Excel. The reviewers tabulated the collected data, which included the following data: authors, year, number of patients, age range, location, study setting, number of operators, type of study, follow-up period, dropout and restorative material used.

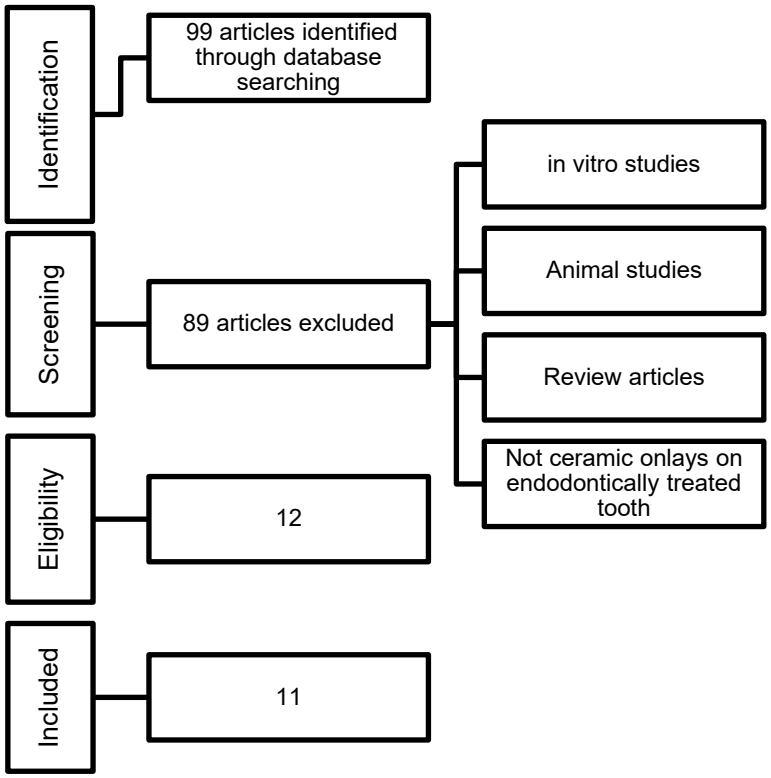


Figure 2-1 Search flow as described in the PRISMA statement.

2.4.8 Literature search

The search yielded 99 articles, from which nine were included in the study following evaluation of the titles, abstracts, and the inclusion criteria. The studies were published from 2006-2020. The collected data are presented in Table 2.4 and Table 2.5 below.

Table 2.4 Characteristics of the selected studies

Clinical study	Study setting	Number of operators	Inclusion period and follow-up	Dropout	Material	Number of patients	Age range	Country
Shulte et al. 2005	University	244 (students and dentists)	1993-2002 retrospective	Not applicable	Leucite-reinforced pressed glass ceramic (IPS Empress)	390	17-64	Germany
Reiss et al. 2006 I J Comp Dent	Private practice	1	1987-1990 18 years follow-up		Feldspar blanks using Cerec 1	299	12-70	Germany

Stoll et al. 2007	University	909 students and 715 dentists	1991-2001 Ten years follow-up Prospective study examined in retrospect	346/1624 restorations 21.3%	Leucite-reinforced pressed glass ceramic (IPS Empress)	643	16-76	Germany
Naeselius et al. 2008	Private practice	2	1997-2000 Four years Prospective	29/91 patients plus three excluded	Leucite-reinforced pressed glass ceramic (IPS Empress)	59	Mean 50.3	Sweden

Van Dijken et al. 2010	University / public health service clinic	4	1992-1998 15 years Prospective	16/121 patients 24/252 restorations	Leucite-reinforced pressed glass ceramic (IPS Empress)	105	26-81	Sweden
Murgueitio and Bernal 2011	Private clinic	1	2003-2010 Three years	210 restorations	Leucite-reinforced pressed glass ceramic (IPS Empress)	99	Mean age 42	Colombia
Beier et al. 2012	University	2	1987-2009 Up to 20 years		Leucite-reinforced pressed glass	302	33-59	Austria

			Retrospective study		ceramic (IPS Empress)			
Nejatidanesha et al. 2015	Private practice	1	March 2009 - September 2009 Five years follow-up Retrospective study	3	Glass ceramic (IPS Empress)	106	18-70	Iran
Collares et al. 2016	Private practice	167	1994-2014 15-year period	192/5791 were excluded	Monolithic feldspathic	5523	Not Specified	161 from Germany

			Prospective		porcelain 77.3% Glass ceramic 18%			Two from Chile and one from China, Spain, France, USA
Huettig and Gehrke 2016	University	Not mentioned	Four years	45/48 patients 327/ 375 restorations	Lithium disilicate (IPS Empress)	45	17-73	Germany
Lu et al. 2018	University	3	2013-2016 Three years prospective	2/93 patients	Vita Enamic and Vita Mark II	91	18-71	China

Table 2.5 Table showing the selected studies and the failure of ceramic restorations.

Clinical study	Number of ceramic restorations	Restorations on vital teeth	Restorations on non-vital teeth	Evaluation criteria	Failures	The main reason for failure
Shulte et al. 2005	810 inlays and onlays	764	46	Failure assessment: fracture, caries, extraction endo treatment etc.	26 in vital One in non-vital	Ceramic fracture five Adhesive failure 10 Pulpitis 10 Tooth fracture one Extraction one
Reiss et al. 2006 I J Comp Dent	1011	934	77	Not specified	122 failures, mostly fractures	122 events

					(28 on non-vital teeth)	Ceramic and tooth fractures 39% in total (16 non-vital) Caries 21 cases
Stoll et al. 2007	1624	1588	36	Not specified	53/1624. Seven failed on non-vital teeth; 36 failed on vital teeth	Fractures 18 Margin defect eight Endodontic complications seven Cementation errors five

						Loss of adhesion six Caries four
Naeselius et al. 2008	81	63	18	CDA	6/81. One in non-vital teeth	Non-vital: one fracture Vital: five cases: three fracture, one caries, one secondary fracture
Van Dijken et al. 2010	252	187	41	Modified USPHS	55/228 restorations. 16	Lost restoration Ceramic fracture Secondary caries Extraction

	24 dropped out, so it became 228				failed in non-vital teeth	Crown fracture Pulp involvement Root fracture
Murgueitio and Bernal 2011	210	101	109	Modified USPHS	Seven failures, six on non-vital teeth	Ceramic fracture
Beier et al. 2012	University	2	1987-2009 Up to 20 years Retrospective study		Leucite-reinforced pressed glass ceramic (IPS Empress)	302

Nejatidanesha et al. 2015	159	92 restorations None fractured	67 restorations Three fractured	CDA	Three failures. All on non-vital teeth	Ceramic fracture
Collares et al. 2016	5791	5400	391	Not Specified	220/5791	Ceramic or tooth fracture Endodontic complications Caries
Huettig and Gehrke 2016	327	na	na	CDA	15	Chipping and. debonding
Lu et al. 2018	101	No vital teeth	101	Modified USPHS	Two vita Enamic (hybrid ceramic)	Three debonding: two

	94 after three years				Three Vitablocs Mark II (feldspar)	Vitablocs and one Enamic One ceramic fracture Vitabloc Mark II One tooth fracture: Vita Enamic

2.5 Results

2.5.1 Study characteristics

The main characteristics of the included studies are shown in the table above (Table 2.4).

Five studies (Reiss 2006, Naeselius, Arnelund et al. 2008, Murgueitio and Bernal 2012, Nejatidanesh, Amjadi et al. 2015, Collares, Correa et al. 2016) were conducted in a private practice setting while the other studies (Stoll, Cappel et al. 2007, van Dijken and Hasselrot 2010, Beier, Kapferer et al. 2012) were conducted in a university setting.

Four studies were from Germany, two from Sweden and one each from Austria, Colombia, China, and Iran. One study was multi-centred. The patients' age ranged from 18 to 81 years. The number of patients ranged from 34 to 5523. The study duration ranged from five years to 20 years.

Leucite-reinforced glass ceramic (IPS Empress, Ivoclar, Vivadent) was the most used ceramic in the studies.

As Table 2.6, Table 2.7 and Table 2.8 below show, there was a higher failure of ceramic onlays on endodontically treated teeth compared to vital teeth. The main mode of failure on both vital and non-vital teeth was ceramic fracture. In Beier's study (2012), 62% of failures were related to ceramic, either a fracture, crack, or chipping. 15% of failures were the development of caries, and 5% were tooth fractures. Van

Dijken et al. (2010) reported the main failures to be debonding and ceramic fracture, followed by caries.

Table 2.6 Survival of ceramic onlays in vital and non-vital teeth

Study	**Year**	**Failed ceramic onlays in ETT n (%)**	**Total cases in ETT**	**Failed ceramic onlays in vital teeth n (%)**	**Total cases in vital teeth**
Nejatidanesha et al.	2015	3 (4.5%)	67	0 (0%)	92
Beier et al.	2012	6 (5.7%)	106	89 (7.2%)	1229
Murgueitio and Bernal	2011	6 (5.5%)	109	1 (1%)	101
Van Dijken et al.	2010	16 (39%)	41	39 (20.9%)	187
Naeselius et al.	2008	1 (5.6%)	18	5 (7.9%)	63
Stoll et al.	2007	7 (19.4%)	36	46 (2.9%)	1588
Reiss	2006	28 (36.3%)	77	93 (10%)	934
Shulte et al.	2005	1 (2.2%)	46	26 (3.4%)	764

Table 2.7 Percentage of failed onlays

	% of failure	Time span
Failed in non-vital cases	9.85%	5-20 years span
Failed in vital cases	6.03%	

Table 2.8 Mode of failure of onlays in vital and ETT

Study	Mode of failure	Combined failures in vital and ETT where it is not separated	Mode of failure in vital teeth	Mode of failure in ETT
(Collares, Correa et al. 2016)	Fracture of restoration Fracture of tooth Caries Sensitivity / endodontic debonding	98 (both restoration and tooth) 18 36 2	NA	NA

	Total failures / cases	20/5791		
(Beier, Kapferer et al. 2012)	Fracture of restoration Fracture of tooth Caries Sensitivity / endodontic debonding **Total failures / cases**	60 4 14 3 95/1335	NA	NA
Murgueitio and Bernal 2011(Murgueitio and Bernal 2012)	Fracture of restoration Fracture of tooth Caries Sensitivity / endodontic debonding **Total failures / cases**		1 1/101	6 6/109
(van Dijken and Hasselrot 2010)	Fracture of restoration	16		

	Fracture of tooth Caries Sensitivity / endodontic debonding Total failures / cases	1 11 3 18 55/228	39/187	16/41
(Naeselius, Arnelund et al. 2008)	Fracture of restoration Fracture of tooth Caries Sensitivity / endodontic debonding Total failures / cases		4 1 5/63	1 1/18
(Stoll, Cappel et al. 2007)	Fracture of restoration Fracture of tooth Caries Sensitivity / endodontic	18 (tooth and rest) 4 7		

	debonding Total failures / cases	6 53/1624	46/1588	7/36
(Reiss 2006)	Fracture of restoration Fracture of tooth Caries Sensitivity / endodontic debonding Total failures / cases	Mostly ceramic and tooth fracture 121/1011	NA	NA
Shulte et al. 2005	Fracture of restoration Fracture of tooth Caries Sensitivity / endodontic debonding Total failures / cases	5 1 10 10 26	NA	NA

2.5.2 Meta-analysis

Eight studies were used for the meta-analysis presented in Table 8. The result of the meta-analysis is shown in the forest plot in Figure 2-2 below.

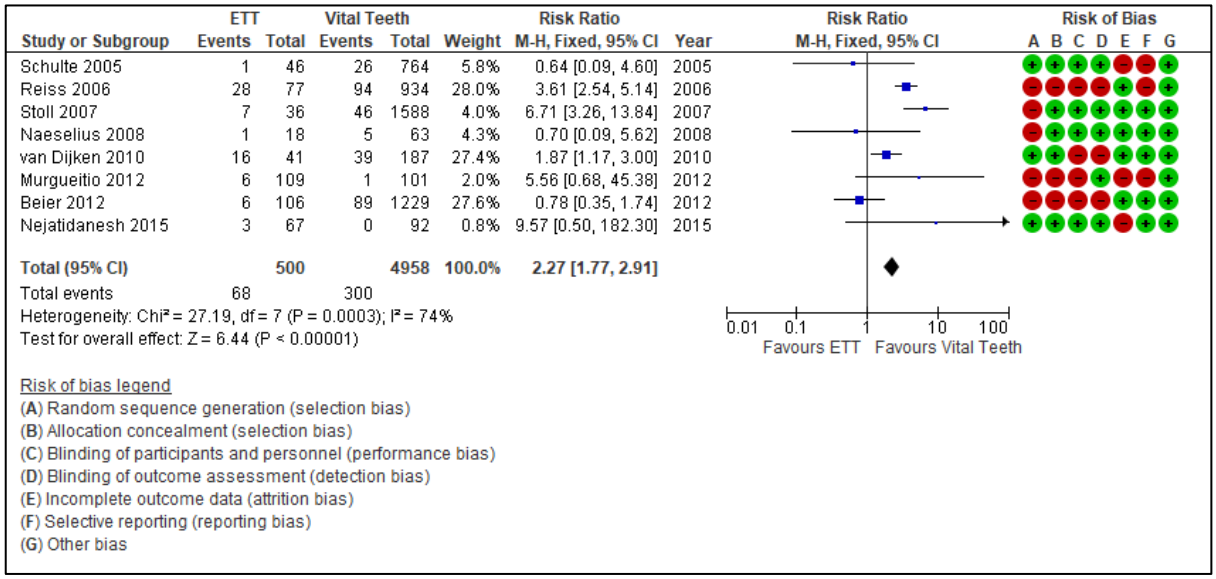


Figure 2-2 Forest plot summarizing the results of the meta-analysis.

The study which provided the largest contribution to the meta-analysis was Reiss (2006) with 28%. The pooled relative risk of failure in the root canal treated teeth was 2.27 with 95% confidence interval from 1.77 to 2.91, indicating more frequent failures in root canal treated teeth compared to vital teeth. The null hypothesis is rejected ($p<0.00001$).

The eight studies used in the meta-analysis are heterogeneous, and the heterogeneity was statistically significant ($p=0.0003$). The variation in relative risk measured as I^2 was 74%. The I^2 of 74% (>50%) suggests great heterogeneity among the studies.

2.5.3 Risk of bias within studies

Bias introduced due to the small studies that were included in the analyses was tested using Begg's, Egger's and Peters test. All three tests showed no evidence for the bias due to small study effect (p=0.81, 0.52 and 0.81 respectively). The publication bias was assessed using funnel plots with 95% pseudo-CI (Figure 2-3).

Visual inspection of the funnel plot indicates no asymmetry and hence the absence of publication bias. However, as only eight studies are involved in the analysis, no conclusion could be reached on publication bias.

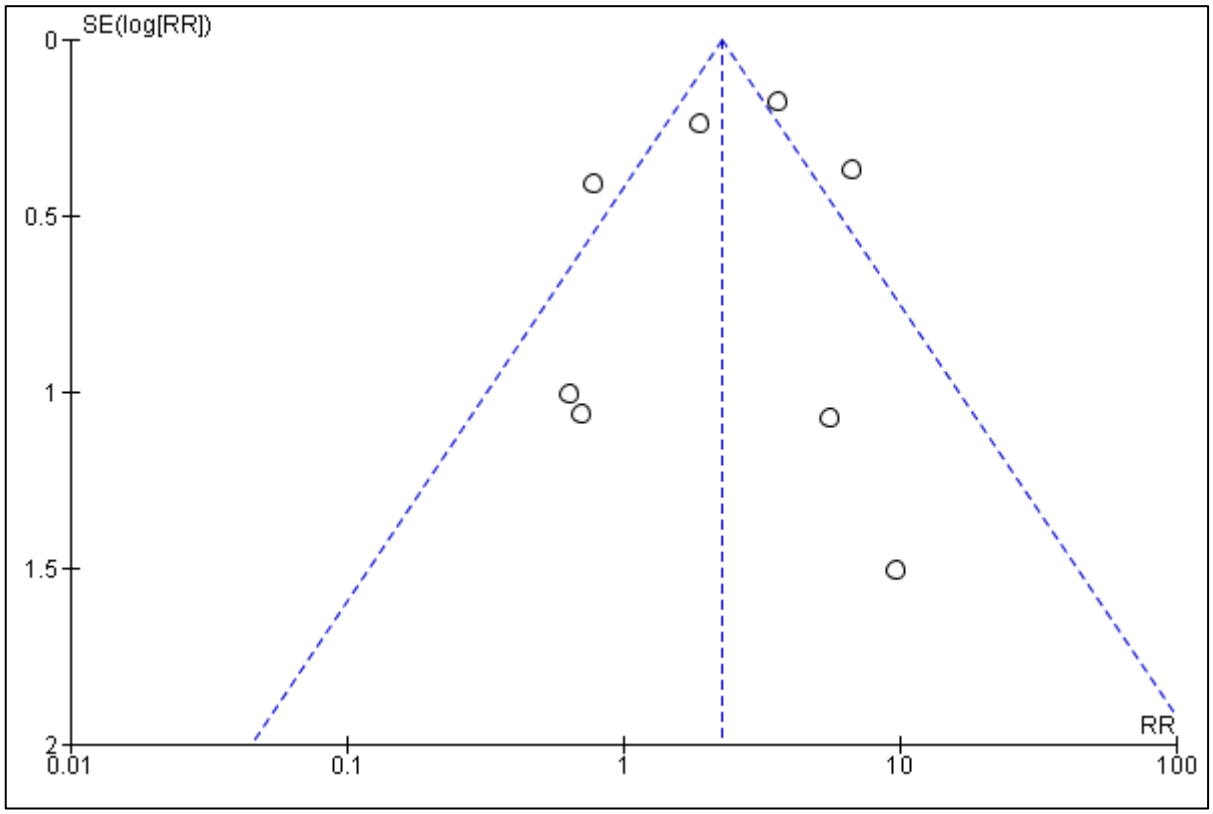
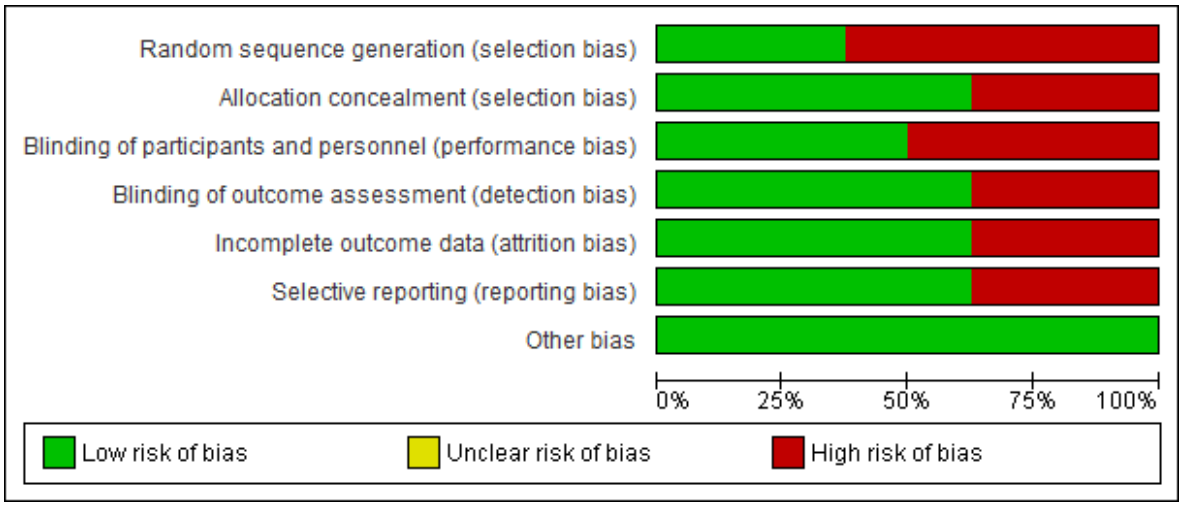
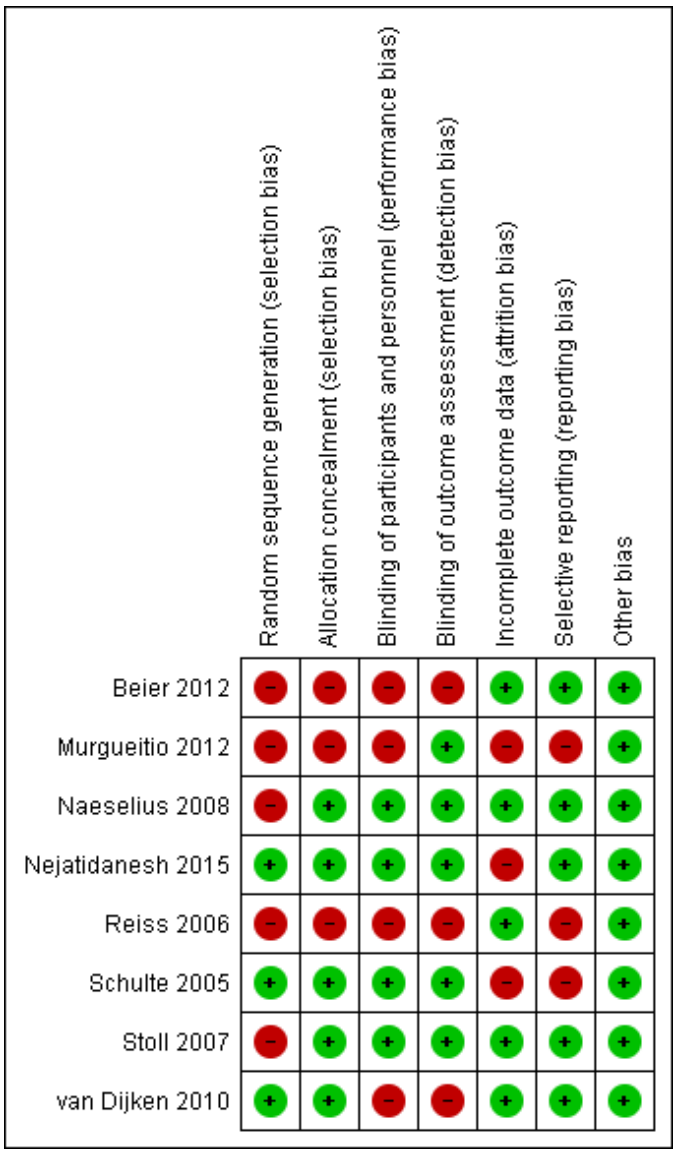


Figure 2-3 Funnel plot with pseudo 95% confidence limits

Figure 2-4 Risk of Bias





2.6 Discussion

This systematic review and meta-analysis analysed the clinical survival of tooth-coloured partial crowns (onlays and overlays) on ETT compared to vital teeth. In our review, the pooled results include 500 partial crowns on ETT and 4958 partial crowns on vital teeth. 68 failed in ETT, while 300 cases failed in vital teeth. The results of this study suggest that the survival of tooth-coloured onlays is significantly higher in vital teeth compared to ETT ($p<0.01$).

It has been established (see Chapter 1) that there is a difference in the dentine of vital teeth and ETT that results in the ETT being more prone to fractures. Among the most widely accepted reasons for tooth fracture is the loss of tooth structure which arises from access cavity preparations, removal of carious dentine, or defective and leaking restorations, which makes these teeth more prone to fracture.

However, that does not explain the higher incidence of fracture of restorations on ETT. It has been postulated that the dentine in vital teeth is hydrophilic and more compatible with the hydrophilic primer than the more sclerotic water-containing dentine in ETT. This could result in bond failures and subsequent chipping of the brittle ceramic material.

Ceramics are, naturally, a very brittle material and prone to fracture under tension (Qualtrough and Piddock 1997). Numerous approaches have been introduced to reduce the fracture rate and this has resulted in the development of metal ceramics and, finally, all-ceramic materials. Two of the most widely used all-ceramic materials

currently are lithium disilicate and zirconia. Most of the studies noted in this review are from leucite-reinforced glass ceramic, which is the earlier version of the lithium disilicate marketed by IPS Empress.

The results of this systematic review are inferred from pooled studies that used leucite-reinforced glass ceramic the most. Currently, the most widely used all-ceramic materials are lithium disilicate, which was introduced in 2005, and zirconia, which was introduced in 2009. The nanohybrid ceramics are a more recent introduction. Despite more than two decades of clinical acceptance globally, there are very few clinical trials reporting the survival of these groups of materials for restoring ETT. Currently available studies with lithium disilicate suggest caution when using on ETT (Brandt, Winter et al. 2019). There are hardly any clinical trials on nanohybrid ceramics.

The most frequent mode of failure in this systematic review was the fracture of the ceramic. This has been previously reported in the literature (Beier, Kapferer et al. 2012). The next most common reason was debonding, followed by caries (van Dijken and Hasselrot 2010, Beier, Kapferer et al. 2012).

In our review, significantly higher failure rates were found in ETT. Only in studies by Schulte (2005), Naeselius (2008) and Beier (2005) was the outcome favourable in ETT over vital teeth.

The meta-analysis comparing the survival of restorations in vital and ETT shows a significant difference between the two types, with more fractures seen in ETT.

The overall success rate for ceramic onlays on vital teeth was 93.97%, while on endodontically treated teeth it was 90.15%.

2.7 Implication for research

Currently, the most popular ceramic restorative materials are lithium disilicate and zirconia. The striking observation from this systematic review and meta-analysis is that there are hardly any clinical trials with the newer lithium disilicate and zirconia-based materials in restoring ETT. Very few clinical studies are available on nanohybrid ceramic, lithium disilicate and zirconia as ceramic material for restoring ETT, or for using CAD-CAM systems for restoring ETT or using onlays instead of full crowns for ETT. Most of the data used by the industry are from laboratory studies.

The importance of remaining tooth structure that can affect the survival of tooth onlays in non-vital teeth has not been investigated. The improvements in enamel and dentine adhesion over the years also must be factored into survival studies at the present time compared to old research papers. Another area of research is computer-aided design and computer-aided manufacture (CAD-CAM) of dental restorations. There are not many clinical trials on the use of CAD-CAM systems on ETT, while they have been clinically proven to be a successful restorative option in vital teeth. It is pertinent for clinical studies to validate their use in endodontically treated teeth as a viable alternative to the present gold-standard post-endodontic restoration on posterior teeth, which is the full crown.

2.8 Implications for clinical practice

Numerous ceramic materials and nanohybrid ceramics have flooded the market, partly due to increasing demand for highly aesthetic restorations. Due to inadequate standards criteria, the industry has introduced to the market materials that have not had been adequately tested in clinical trials.

This meta-analysis indicates that the survival of ceramic onlays is very high irrespective of the study design, follow-up period, and ceramic material used. However, these restorations survived longer on vital teeth than ETT. The main failure seems to be a fracture of the restoration. This kind of fracture offers the clinician with another opportunity to salvage the tooth or even provide a full crown if indicated. It is hoped that further advances in materials, especially zirconia-based materials would offer more resistance to fracture.

When using tooth-coloured restorative materials for restoring ETT, clinicians must be aware that many materials are available in the market, each with differing properties. There are only short-term studies with the more popular materials such as lithium disilicate and zirconia on ETT.

2.9 Conclusions

Tooth-coloured onlays have a good survival rate as post-endodontic restorations. The survival of these restorations, however, is higher in vital teeth. The main mode of failure appears to be a fracture of restoration followed by secondary caries. More clinical trials with follow-up of five years are needed to make a more accurate analysis.

Chapter 3 : A CBCT study assessing the outcome of endodontically treated teeth restored using CAD-CAM generated nanohybrid ceramics.

3.1 Introduction

The goal of root canal therapy is to prevent and eliminate apical periodontitis (Ford 2008). Apical periodontitis is caused by bacteria within the root canal system (Kakehashi, Stanley et al. 1965, Moller, Fabricius et al. 1981). Elimination of this causative factor through chemo-mechanical means can help prevent and treat apical periodontitis.

Root canal treatment outcomes can be measured as patient-centred outcomes, clinician-centred outcomes, and research-centred outcomes (Duncan, Nagendrababu et al. 2021, Azarpazhooh, Sgro et al. 2022, Kirkevang, El Karim et al. 2022).

Researcher-centred studies are interested in prognostic factors and depend on clinical and radiographic examination to evaluate the resolution of the periapical disease (Ng, Mann et al. 2007).

Clinician-centred outcome measures use these data to offer patients with high-quality and predictable treatment modalities.

Patient-centred outcomes on the other hand refer to tooth survival and function, resolution of symptoms, cost and quality of life. In endodontics, patient-centred outcomes are rarely reported.

Few studies have investigated the effects of restorability, and restoration on the outcome of root canal treatment assessed using CBCT (Tifooni, Al-Nuaimi et al. 2019).

3.1.1 Assessment of endodontic treatment outcome

In 1956, Strindberg reported on the strict criteria that involved complete resolution of the apical lesion radiographically (Strindberg 1956). Orstavik, in 1996, showed from a sample of 599 endodontically treated roots that the peak incidence of healing of apical periodontitis was one year after treatment (Orstavik 1996). In some cases, he noted that it could take 4 years or more for radiographic evidence of complete healing. This formed the basis for the ESE recommendation that the first follow-up should be done 1 year after treatment, and that if a lesion fails to resolve, further follow-ups must be done every year for a period of 4 years (European Society of 2006).

Periapical radiography and clinical assessment have been used as the recommended method for assessing treatment outcomes of endodontic disease (European Society of 2006, Nair and Nair 2007, Ford 2008).

However, periapical radiographs have certain limitations as a two-dimensional representation of a three-dimensional object and are also affected by anatomic noise

(Figure 3-1,Figure 3-2) and geometric distortion (Bender and Seltzer 1961, Patel, Dawood et al. 2009), for example, apical lesions confined to the cancellous bone are not easily visualised on periapical radiographs in posterior teeth due to the dense cortical plate overlying it (Bender 1997) (Figure 3-3).

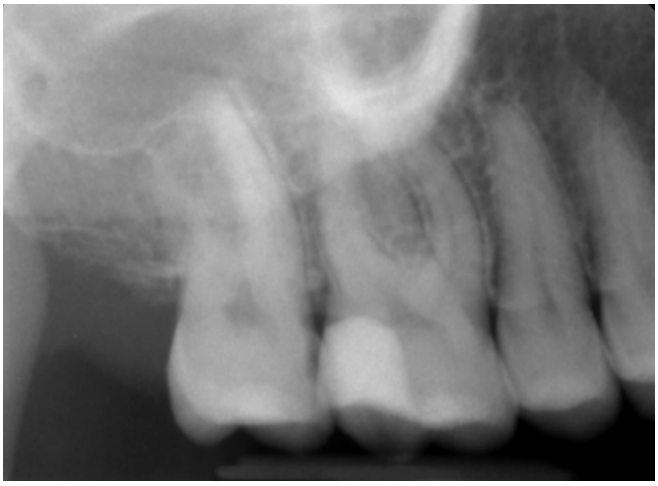


Figure 3-1 PA radiograph showing its limitations: Anatomic noise from the zygomatic arch impairs the clear vision of any periapical changes.

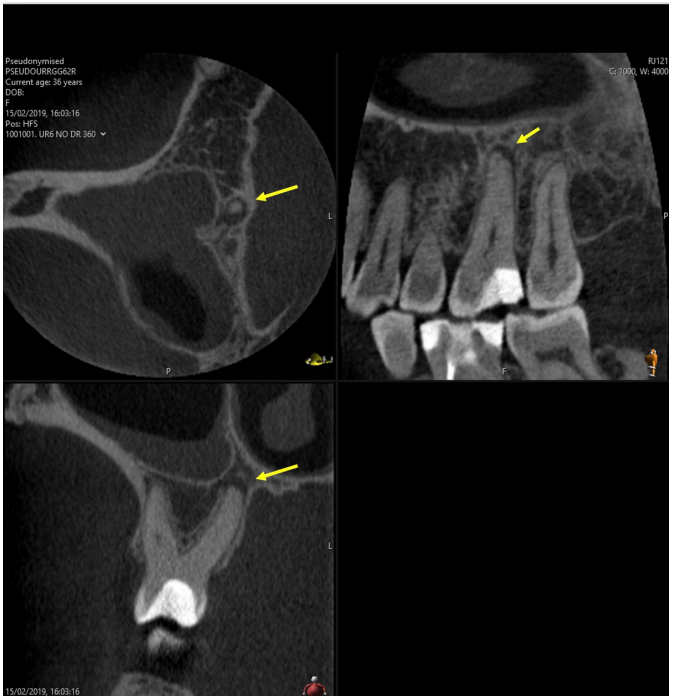


Figure 3-2 The reconstructed image of the palatal root of the UR6 in axial, coronal and sagittal planes reveals the periapical lesion associated with the root. (yellow arrow).

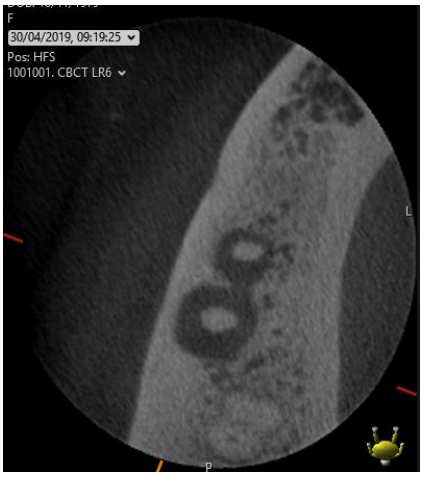


Figure 3-3 Thick and dense cortical bone making lesions in cancellous bone to be not seen as readily in periapical radiographs compared to axial views on CBCT scan

In recent years, the use of CBCT has increased for endodontic diagnosis and assessment of outcomes as it can overcome the deficiencies of periapical radiographs. Studies have shown that CBCT is more sensitive in detecting apical periodontitis than periapical radiographs. (Lofthag-Hansen, Huumonen et al. 2007, Estrela, Bueno et al. 2008, Low, Dula et al. 2008, Abella, Patel et al. 2012, Patel, Wilson et al. 2012, Davies, Mannocci et al. 2015, Al-Nuaimi, Patel et al. 2017). Paula-Silva et al compared the outcome of root canal treatment in dogs using PA and CBCT and showed a favourable outcome of 79% using PAs but only 35% with CBCT, whereas the specificity of the two techniques was similar (de Paula-Silva, Santamaria et al. 2009).

Kanagasingam et al used histopathology to assess radiolucencies detected in cadavers by CBCT and PA and found almost complete agreement between CBCT and histopathologic diagnosis and that the CBCT had a higher diagnostic accuracy than the PA (Kanagasingam, Lim et al. 2017). The accuracy of detecting apical

radiolucencies in root canal-treated teeth has been questioned by another histopathologic study (Kruse, Spin-Neto et al. 2017).

Despite the benefits of CBCT over PA shown in studies from 2007(de Paula-Silva, Wu et al. 2009, Patel, Dawood et al. 2009), and CBCT units being in use in dentistry, since 2001, (Scarfe, Levin et al. 2009), there are very few outcome studies comparing CBCT with the PA (Liang, Li et al. 2011, Patel, Wilson et al. 2012, Fernández, Cadavid et al. 2013, Liang, Jiang et al. 2013, van der Borden, Wang et al. 2013, Davies, Patel et al. 2016, Al-Nuaimi, Patel et al. 2017) or using CBCT alone (Zahran, Patel et al. 2021).

The studies by (Liang, Li et al. 2011, Fernandez, Cadavid et al. 2013, Torabinejad, Rice et al. 2018), did not utilise a pre-op scan to have a significant comparison with the post-op CBCT scan and therefore their results are irrelevant in terms of comparisons of accuracy between the two techniques.

A systematic review and meta-analysis by Dutra et al showed digital (0.72 accuracy value) and periapical radiographs (0.73 accuracy value) to have good accuracy while CBCT scans had excellent accuracy (0.96 accuracy value) in detecting radiographic signs of apical periodontitis (Leonardi Dutra, Haas et al. 2016).

3.1.2 Factors affecting outcome.

3.1.2.1 Age, gender, ethnicity, and systemic health of the patient

Several studies investigated the effect of age on the outcome of root canal treatments and found no significant effect (Kerekes and Tronstad 1979, Sjogren, Hagglund et al. 1990, Smith, Setchell et al. 1993) only a few papers (Besse, Woda et al. 1985, Van Nieuwenhuysen, Aouar et al. 1994)reported a lower success rate for older patients.

Similar to age, no correlation has been attached to gender in the outcome of root canal treatments (Barbakow, Cleaton-Jones et al. 1980, Sjogren, Hagglund et al. 1990, Ng, Mann et al. 2008), though Swartz et al had shown a higher incidence of a favourable outcome in women, (Swartz, Skidmore et al. 1983) while Smith et al showed a higher incidence in men (Smith, Setchell et al. 1993). No possible explanation for the difference has been mentioned yet.

General medical health has been investigated as part of outcome studies. Amongst the many medical conditions, Mindiola et al found a higher incidence of failures of ETT in patients with hypertension and diabetes (Mindiola, Mickel et al. 2006) (Fouad and Burleson 2003, Doyle, Hodges et al. 2006). Severely immune-compromised patients showed delayed healing or more unfavourable outcomes. (Marending, Peters et al. 2005, Azim, Griggs et al. 2016) .

3.1.2.2 Presence of apical periodontitis

The presence of periapical lesions has been reported in many studies as one of the most important factors affecting the outcome of the treatment. The presence of periapical lesions reduced the success rate from 96 to 86% when it was present preoperatively (Sjogren, Hagglund et al. 1990). Similarly, significantly lower success rates were reported in other studies both by PA (Swartz, Skidmore et al. 1983, Friedman, Abitbol et al. 2003, Ng, Mann et al. 2011, Ricucci, Russo et al. 2011) and CBCT(Patel, Wilson et al. 2012, Fernandez, Cadavid et al. 2013, Davies, Patel et al. 2016, Al-Nuaimi, Patel et al. 2017, Fernández, Cardona et al. 2017, Zahran, Patel et al. 2021).

A study by Bystrom et al (Bystrom, Happonen et al. 1987) however, did not find any difference.

3.1.2.3 Size and volume of the periapical lesion

Outcome studies with PA used the size of the lesion while some CBCT-based studies have reported volume measurements using dedicated software. It is interesting to note that most maxilla-facial radiologists still provide reports of periapical lesions as an area when in reality it is a three-dimensional lesion and perhaps should be reported as a volume. Periapical lesions have been measured in 2 dimensions on both periapical radiographs and CBCT scans. Radiologists report CBCT scans by giving a linear measurement of the periapical lesion.

Some studies have reported that lesions less than 5mm in diameter heal better following root canal therapy than those that are larger in size (Sjogren, Hagglund et al. 1990) (Friedman, Abitbol et al. 2003, Ng, Mann et al. 2011) while studies by Bystrom et al did not find any difference (Bystrom, Happonen et al. 1987). Ng reports that the odds of success of treatment are reduced by about 14% for every 1mm increase in the size of the preoperative lesion (Ng, Mann et al. 2011).

Most studies based on PA have shown that teeth with smaller lesions had a higher success rate than teeth with larger lesions.

3.1.3 Assessment of bone loss in 3D

3.1.3.1 Fenestrations and Dehiscence

The 3D viewing capability of the CBCT enables us to assess if the periapical bone loss has led to a fenestration or dehiscence.

Dehiscence is defined as a narrow vertical defect in the alveolar plate of bone over a root extending from the crestal area apically (Figure 3-4). Fenestration, on the other hand, is defined as a window-like opening or defect in the alveolar plate of bone frequently exposing a portion of the root (Figure 3-5).

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The clinical implications are not fully understood as there are very limited studies investigating this type of bone loss on ETT. However, it is assumed that for

placing implants, a dehiscence is likely to be more unfavourable than a fenestration (Sumanth, Savitha et al. 2014).

Loss of crestal bone may introduce more pathologic bacteria into the periodontal space thus potentially worsening the endodontic-periodontal prognosis.

Our restorative outcome study appears to show that the success of post endodontic restorations is favourable when there is cortical bone loss (Chapter 4 results).

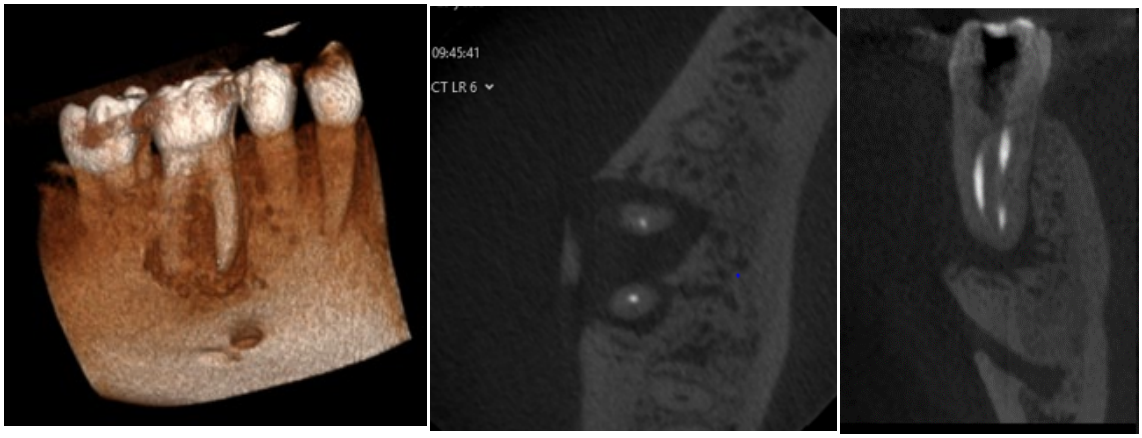


Figure 3-4 Dehiscence type bone loss on CBCT Scan.

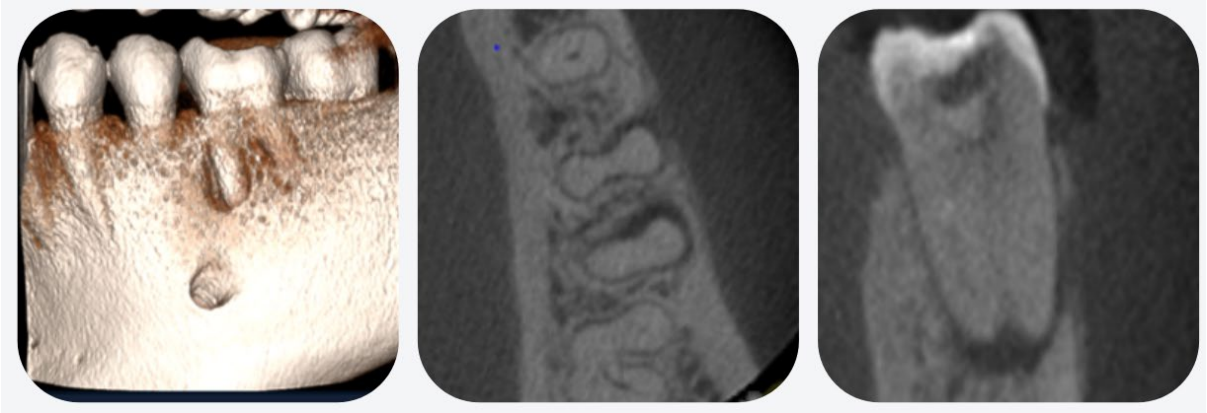


Figure 3-5 Fenestration type bone loss

3.1.3.2 Furcation bone loss

Another benefit of having a 3D view of the root and neighbouring structures is the ability to assess furcation bone loss, in sagittal, coronal and axial slices. Normally in a periapical radiograph, only the sagittal view is seen and the bone loss between the roots bucco lingually is missed out (Figure 3-6).

To our knowledge, there are no papers investigating the effect of furcation bone loss in (Figure 3-7) on the outcome of root canal treatment. There are also hardly any clinical papers on endodontic-periodontic interrelationship that investigates the use of CBCT in furcation bone loss assessment.

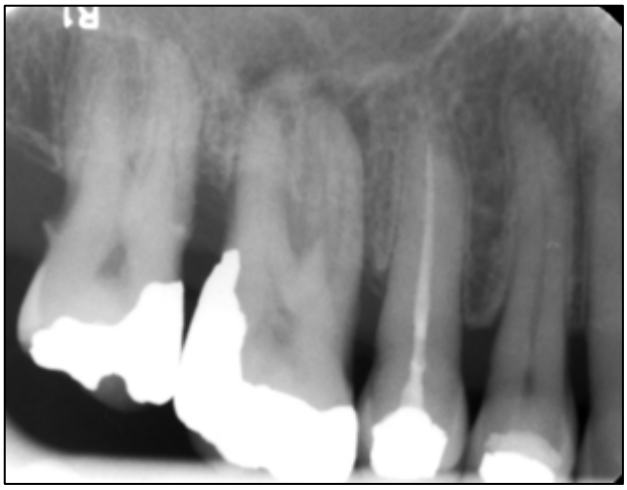


Figure 3-6 Periapical radiograph showing expected difficulty in assessing bone loss between the roots.

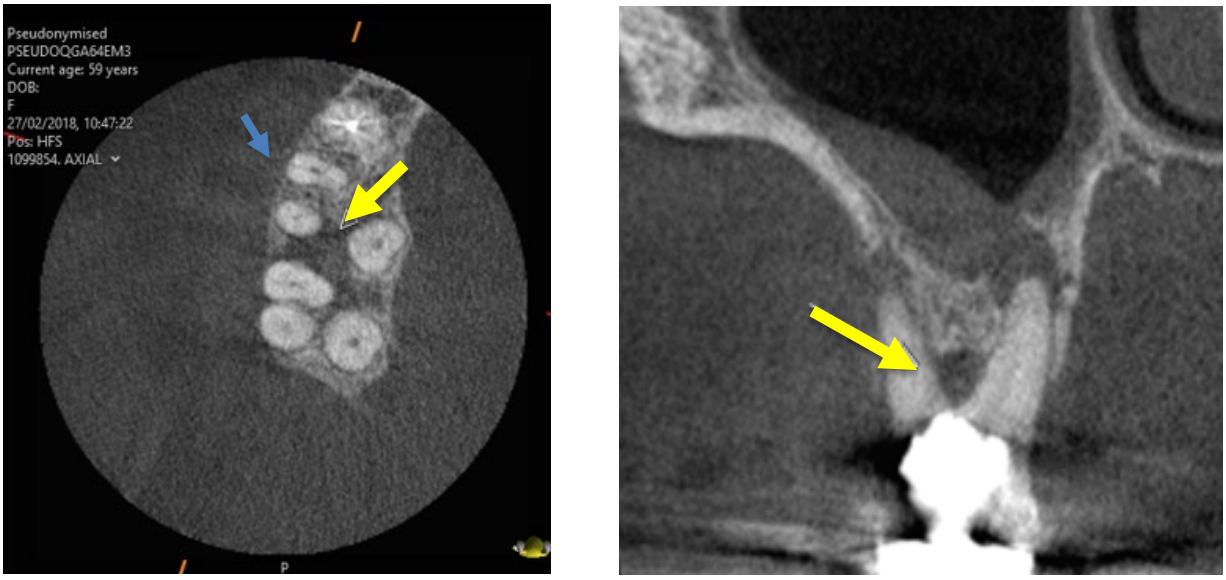


Figure 3-7 The reconstructed image showing intact cortical bone in the buccal furcation area (blue arrow) and significant bone loss in the distal aspect between disto -buccal and palatal root (Yellow arrow).

3.2 Aims and Objectives

The aim of this prospective CBCT based outcome study is to assess the outcome of root canal treatment of posterior teeth restored using CAD-CAM generated onlays and crowns.

The objectives were to assess the effect of several restorative factors including loss of marginal ridge, width of access cavity, thickness and height of dentine wall, quality of restoration, type of restoration and endodontic factors including presence and size of periapical lesion, quality of root canal treatment, length of root canal filling on the outcome of endodontic treatments of posterior teeth restored using CAD-CAM generated onlays and crowns.

3.3 Materials and Methods

3.3.1 Study design

This was a prospective cohort study investigating the outcome of endodontically treated teeth that were restored using CAD CAM generated onlays made of a nanohybrid ceramic material. Both the endodontic outcome and the clinical performance of the restorations were assessed and analysed, in this chapter, we are reporting the results of the outcome study.

3.3.2 Ethical approval and trial registration

This prospective cohort study followed the Preferred Reporting Items for Observational studies in Endodontics (PROBE) guidelines (Nagendrababu, Duncan et al. 2020) (See Appendix G) and received ethical approval from the North West-Greater Manchester Central Research Ethics Committee, the Health Research Authority (IRAS Project ID 224248, Protocol Number IRAS 95221, REC reference 17/NW/0594) (See Appendix H).

The study was conducted in compliance with the principles of the Declaration of Helsinki (2008) and good clinical practice.

The clinical trial was registered in the ClinicalTrial.gov registry (Identifier: NCT03378778). See Appendix I

3.3.3 Patient selection, inclusion, and exclusion criteria

Patients who needed endodontic treatment for a posterior tooth (Premolar or molar) were included in the trial. Patients were excluded if they were pregnant, immunosuppressed, non-ambulatory, extremely anxious, if teeth were deemed unrestorable, or with periodontal probing depths greater than 3mm. (Table 3.1).

Table 3.1 Inclusion and exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
Age range 18 -80 years	Young patients under 18
Healthy or patients with systemic disease but are ambulatory	Pregnant, Immunosuppressed, non-ambulatory, extremely nervous
Premolar or molar	Anterior teeth
Teeth requiring endodontic treatment: Primary, secondary or surgical endodontics	Cracked tooth deemed with guarded prognosis under magnification (Split tooth, cracks extending into the root canals, furcation, vertical root fracture)
Restorable teeth	Unrestorable teeth
Mature root apices	Mobile teeth
	Periodontal pockets > 3mm

A total of 150 patients met the inclusion criteria and were approached to participate in the study.

3.3.4 Invitation to study and Consent Process

Patients attending the endodontic postgraduate clinics were approached if they satisfied the inclusion criteria and were invited to participate in the study.

All patients were informed about the details of the clinical procedures, the potential complications of the endodontic treatment, the number of visits, and follow-up visits.

They were then invited to take part in the study and explained the nature and objectives of the study. They were also informed about the additional radiation dose associated with participation in the study.

All participants were provided with an Invitation Letter, Patient Information Sheet and Informed Consent form (See Appendix K, L ,M)

They were not aware of what specific restoration the tooth under evaluation received (onlay or crown). The patients were given time till their next appointment to decide if they wished to take part in the study and written informed consents were obtained if they consented to take part in the study.

Two patients did not consent to the study, one did not return after the consultation appointment, and two were deemed unrestorable during restorability assessment, one had a visible crack, these patients were therefore excluded from the study.

3.3.5 Pre-operative assessment, Clinical and radiographic evaluation

The patients were recruited and treated at Guy's Hospital. Kings College, London from January 2018 to December 2020.

All patients participating in the study were assessed in the Consultant clinics to provide the baseline status (T0).

Routine diagnosis and treatment planning procedures were followed that included a detailed history taking with special emphasis on pain history, routine dental, medical and social history. These were documented in the electronic dental management software (Salud, Titanium Oral Health Solutions, Ireland).

Clinical examinations included routine extraoral and intraoral examinations and special tests for the endodontically involved tooth and control teeth. These included inspection (swelling, sinus tracts), palpation (pain, swelling), percussion (tenderness), periodontal probing (pocket depth), mobility, and special tests: Pulp sensibility test using cotton pellet and cold spray (Roeko Endo-Frost, Coltene/ Whaledent, Germany) for the cold test, electric pulp test (Kerr Vitality Scanner 2006; SybronEndo, Orange, CA, USA).

The data were then recorded in an electronic data sheet (Microsoft Excel, Microsoft) on the Edge NHS software (www.edge.nhs.uk) which is a cloud-based clinical trial management system (Clinical Informatics Research Unit, Edge Program, Southampton).

The radiographic examination included the periapical radiograph and a small field of view (FOV) CBCT scan.

Periapical radiographs were taken using a size 2 phosphor plate digital imaging system (Digora Optime, Soredex, Tuusula, Finland) alongside a beam aiming device (Dentsply Rinn, Elgin, IL, USA). Periapical radiographs were taken using a dental x-ray machine (Heliodent, Sirona, Bensheim, Germany). The exposure settings were 65 kV, 7mA and an exposure of 0.16-0.32 seconds. The exposed phosphor plates were processed using the Digora Optime scanner, with a scanning resolution of 400 dpi. The images were processed using the Digora default software.

A CBCT scanner(3D Accuitomo, J Morita MFG. Corp, Kyoto, Japan) was used to obtain the image of the area of interest. with a 4x4 cm FOV and 0.125 mm of voxel size. The exposure settings were 90 kV, 4 mA, and 17.5 seconds. The degree of beam angulation was set according to the manufacturer's instructions and the tooth under investigation was positioned at the centre of the FOV. The CBCT scans were reconstructed using the proprietary software of Accuitomo (i-Dixel images, J Morita)

3.3.6 Clinical intervention

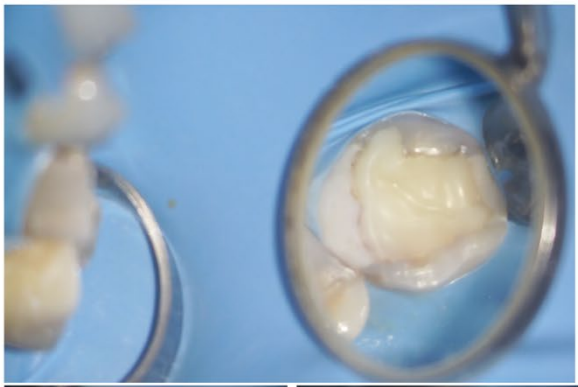
The root canal procedures were undertaken by the main author, one specialist endodontist and five endodontic residents. The operators were trained and standardized to follow a structured treatment protocol, which was consistent with the European Society of Endodontology Guidelines.

Root canal treatment was carried out in one or two visits. All treatments were undertaken under local anaesthesia with rubber dam isolation and magnification using an operating microscope (3-step entrée, Global, St Louis, MO, USA) (Figure 3-8). Restorability assessment was carried out first by removing all caries and existing restorations. Following access cavity preparation, the root canals were negotiated using hand files (K flexofile, Readysteel, Dentsply, Sirona) sizes 06,08,10, and 15. The working length was determined using an electrical apex locator (Root ZX, J. Morita Corp., Kyoto, Japan) and confirmed with a digital periapical radiograph. The canals were prepared using a crown down technique using Protaper Gold Universal rotary files (Dentsply Sirona) at a constant speed of 300 rpm and a torque of 4N to at least a size F2 using. Canals were copiously irrigated with 2.5% sodium hypochlorite (Milton Laboratories, Rivadis, Louzy, France) using a side vented 27-gauge needle and luer-lock syringe (Monoject endodontic irrigation needle 27G, Cardinal Health, Dublin, OH, USA).

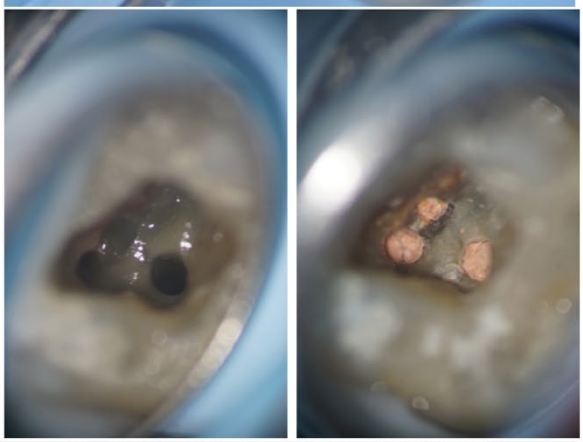
If two visits were required, a dressing of calcium hydroxide (Hypocal, Ellman International, Oceanside, New York, USA) was applied into the root canals followed by a dry cotton pellet and glass ionomer cement to seal the access cavity (Fuji IX, GC Corp, Japan).

In the final visit or once root canal preparation was complete, the canals were irrigated with sodium hypochlorite and sonically activated using Endoactivator (Dentsply, Sirona) with the medium activator tips (25/04) short of the apex by 1mm for 30 seconds. A penultimate irrigation with 17% ethylene diamine tetra acetic acid (EDTA, Pulpdent, Watertown, Massachusetts, USA) was performed to remove the

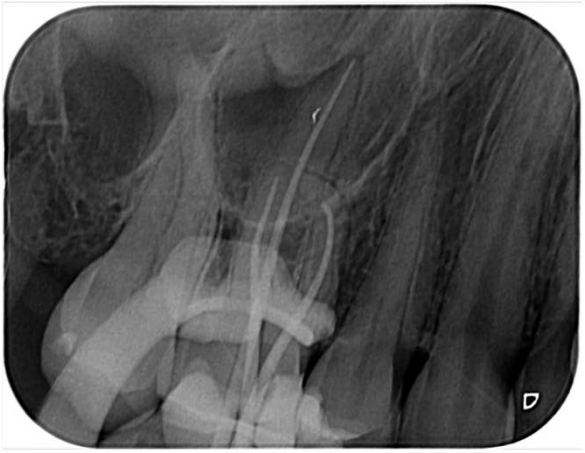
smear layer followed by another rinse with sodium hypochlorite. The canals were dried with sterile paper points (Dentsply, Sirona). All canals were filled with gutta-percha (Dentsply Sirona) and AH plus sealer (Dentsply Sirona) using a continuous wave of condensation and followed by backfill with thermoplasticized gutta-percha (Figure 3-8). The access cavities were restored using a flowable hybrid composite (Corecem, RTD, Saint-Egrève, France). A radiograph of the obturated tooth was taken and the patients were then scheduled for post-endodontic restoration (See Ch4 Material and Methods Section).



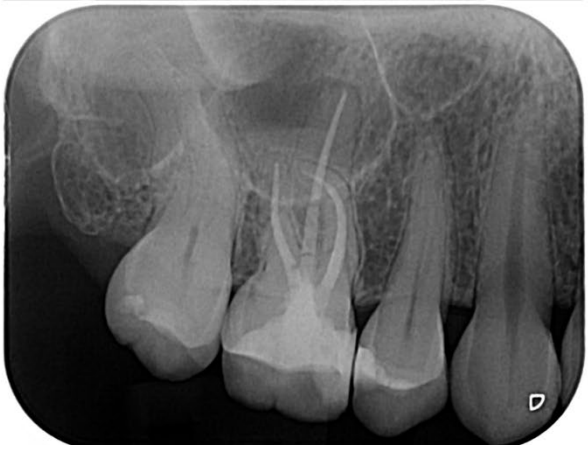
Root canal treatment was done in 1 or 2 visits. All treatments were done under rubber dam isolation with magnification using an operating microscope (3 Step entrée, Global, St Louis, MO, USA)



Following access cavity preparation, the root canals were negotiated using hand files and prepared using a crown down technique using the protaper gold universal rotary files to at least a size F2.



A master cone radiograph was taken to check the cone fit and adjustments made, if necessary, prior to obturation.



All canals were filled with gutta percha and AH plus sealer using a continuous wave of condensation followed by backfill using thermoplasticised gutta percha. The access cavities were restored with a flowable hybrid composite resin.

Figure 3-8 Images of Clinical procedure showing the treatment sequence.

3.3.7 Patient recall

The completion of root canal treatment was considered the baseline for the endodontic outcome study. The recall appointments were scheduled 1 year after treatment. All patients were initially contacted by phone and if they did not respond after another 2 attempts, they were sent a letter to attend the recall. (See Appendix N)

3.3.8 Follow up Clinical and Radiographical assessment.

The follow-up examinations were carried out by one investigator for documenting the clinical and radiographic findings. Medical and dental history was updated on Salud; clinical examination included the presence of pain, swelling, sinus tract, tenderness to percussion and palpation, mobility and periodontal probing. All information was transferred from the clinical records to the database.

A periapical radiograph and a small FOV CBCT scan were taken using the same settings used for the pre-operative scan.

3.3.9 Assessment of the Endodontic Outcome

One investigator who was not part of the radiological assessment collected all the scans, anonymised them, and identified the images that showed the presence or absence of periapical radiolucency, or the largest periapical radiolucency seen in the axial, coronal and sagittal views at baseline and 1-year recall. They were displayed together by root as a PowerPoint (Microsoft) presentation on a Dell laptop with a

resolution of 1680 x1050. The raw CBCT data was available to the examiners if needed.

A consensus panel of 2 experienced and calibrated specialist endodontists assessed the outcome as suggested by Molven et al (Molven, Halse et al. 2002). The examiners were not involved in carrying out the treatments. All radiographs were pseudo-anonymised. To minimise interpretation errors, all extraneous light was blocked (Welander, McDavid et al. 1983) and possible operator fatigue (Goldman, Pearson et al. 1972) was reduced by assessing the radiographic and CBCT images over 5 sessions with at least a week's gap in between. Disagreements were resolved by discussion.

A periapical radiolucency was defined as a radiolucency associated with the root apex that was twice the width of the periodontal ligament space (Low, Dula et al. 2008, Bornstein, Lauber et al. 2011). The radiographic outcome was scored using the 6-point radiographic assessment criteria proposed by Patel et al (Patel, Wilson et al. 2012) comparing baseline and 1 year recall (Figure 3-9).

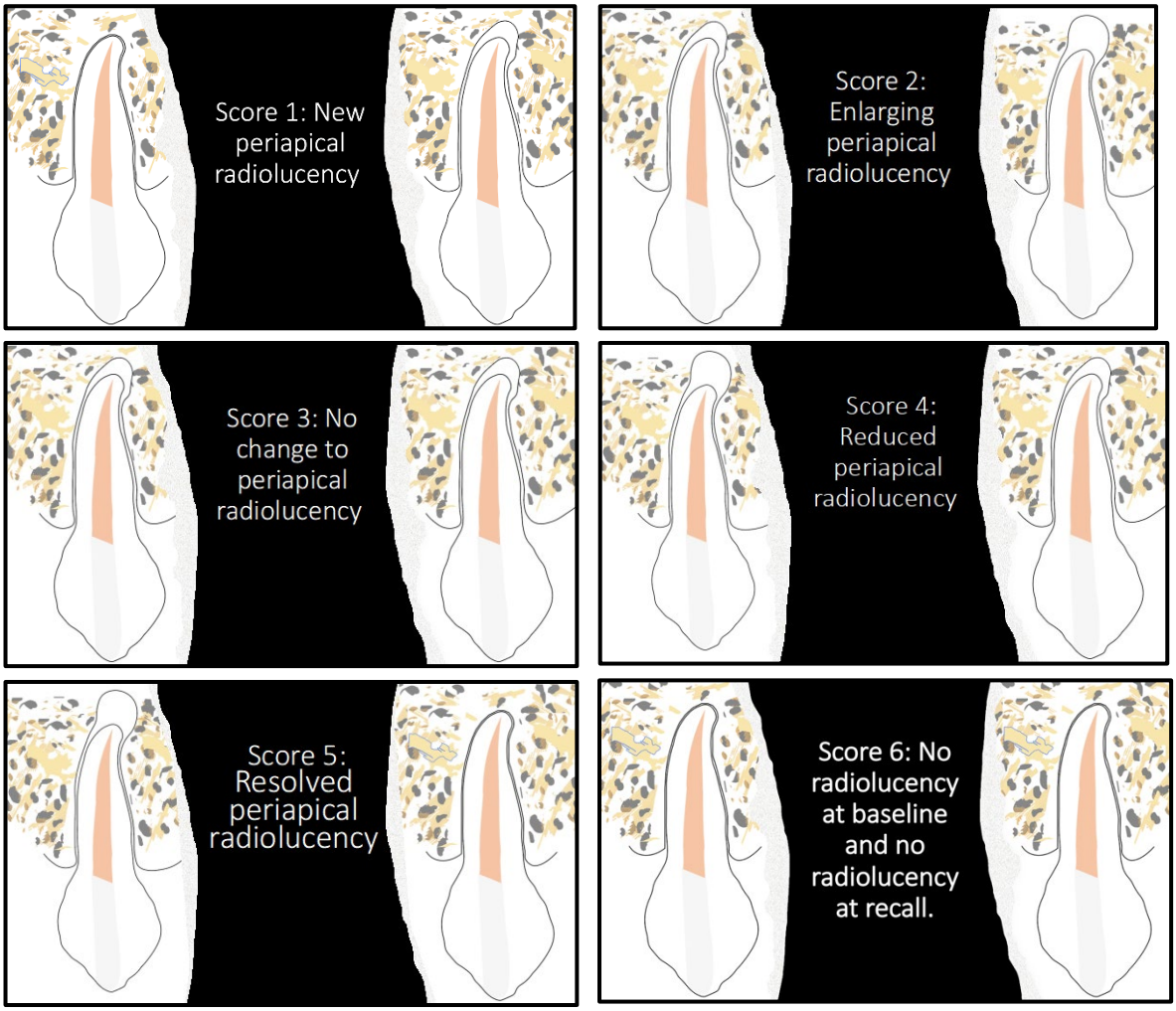


Figure 3-9 An illustration of the 6-point radiographic assessment criteria developed by Patel et al (Patel, Wilson et al. 2012)

Table 3.2 Scoring criteria.

Score	Description	Outcome
1	New periapical radiolucency	Unfavourable
2	Enlarged periapical radiolucency	
3	Unchanged periapical radiolucency	
4	Reduced periapical radiolucency	Favourable
5	Resolved periapical radiolucency	
6	Unchanged healthy periapical status (No radiolucency at baseline and nothing at recall)	

The intra examiner reliability was assessed by re-evaluating 50 pairs of randomly selected PA and CBCT scans 3 weeks after the first evaluation.

The CBCT scans were also assessed for size of periapical lesion, cortical bone loss (dehiscence and fenestration), furcation involvement, quality of root canal obturation and terminus of root canal obturation.

3.3.10 Clinical signs and symptoms.

If the teeth presented with pain or tenderness to percussion, palpation or with swelling or draining sinus the outcome was classified as unfavourable along with scores 1,2,3.

Multirooted teeth were assessed by root and the root with the worst treatment outcome determined the outcome of the tooth.

3.3.11 Assessment of post endodontic restorations

See Chapter 4.

3.4 Statistical analysis

Endodontic outcome was assessed as favourable or unfavourable, both outcomes were considered as the dependent variables in this research.

Statistical analysis consisted of a general descriptive analysis for categorical variables by means of absolute and relative frequencies. Quantitative variables were described using mean, standard deviation, range, median and interquartile range (IQR)

The inferential analysis included:

Simple binary logistic regression models using GEE (generalized estimation equations) were performed to study probability of success (favourable) of root canal treatment. This model was fitted separately for each of the predictor variables (age, gender, ethnicity, jaw, type of restoration, size of lesion etc.) with favourable outcome as the dependent variable. Non-adjusted odds ratio (OR) and 95% confidence intervals were obtained. Variables that were significant at a liberal 10% level were considered for the multivariate logistic regression. GEE is the suitable approach to handle multiplicity of teeth per patient. For all the models, statistical significance was assumed at 5% level.

Power calculation

In order to detect differences of success rate between independent groups (e.g., upper vs. lower maxilla), the power was estimated at 86.2% for rates 75%-95% for 125 independent teeth at 95% confidence, However, the power was corrected because of the within-subject dependence of observations. Considering ratio=1.25 teeth per patient and assuming a moderate intra-class correlation (ICC=0.5), effective power was set at 81.2% under the same conditions.

Intra examiner agreement was assessed using linear weighted Kappas’s index.

3.5 Results

3.5.1 Demographic characteristics of teeth

A total of 150 patients were approached between February 2018 and February 2020 at the postgraduate endodontic clinic of Guy's Hospital, Kings College London. Root canal treatment and post endodontic restoration a (onlay or crowns) were provided to 143 patients. (See flow chart in Figure 3-10).

Table 3.3 Reasons for No Shows

Reason for Leaving study before completion	**Number of patients**
Withdrawal of consent (no longer interested)	2
Did not attend the appointments	2
Unrestorable tooth on assessment	2
A cracked tooth with guarded prognosis	1

Two patients did not consent to the study, one did not return after the consultation appointment, and two were deemed unrestorable during restorability assessment, one had a visible crack, these patients were therefore excluded from the study (Table 3.3).

143 teeth were provided with root canal treatment, and retreatment and followed up with an onlay or crown. 107 patients attended the recall for the endodontic outcome assessment.

Table 3.4 Reasons for no shows at recall.

Reason for Drop out at recall	Number of patients
Withdrawal of consent (no longer interested)	8
Loss of contact (Changed address/ phone number)	5
Pregnancy	2
Work-related issues	1
Babysitting/ childcare related	2
Health issues	2
Covid related	5

3.5.2 Clinical assessment.

Two teeth had to be extracted due to restorative failure as the tooth and restoration fractured off, leaving the remaining tooth structure unrestorable.

Four patients developed clinical signs of failure (tenderness to percussion). The CBCT scans also showed an unfavourable outcome in these four cases. They have been scheduled for endodontic retreatment.

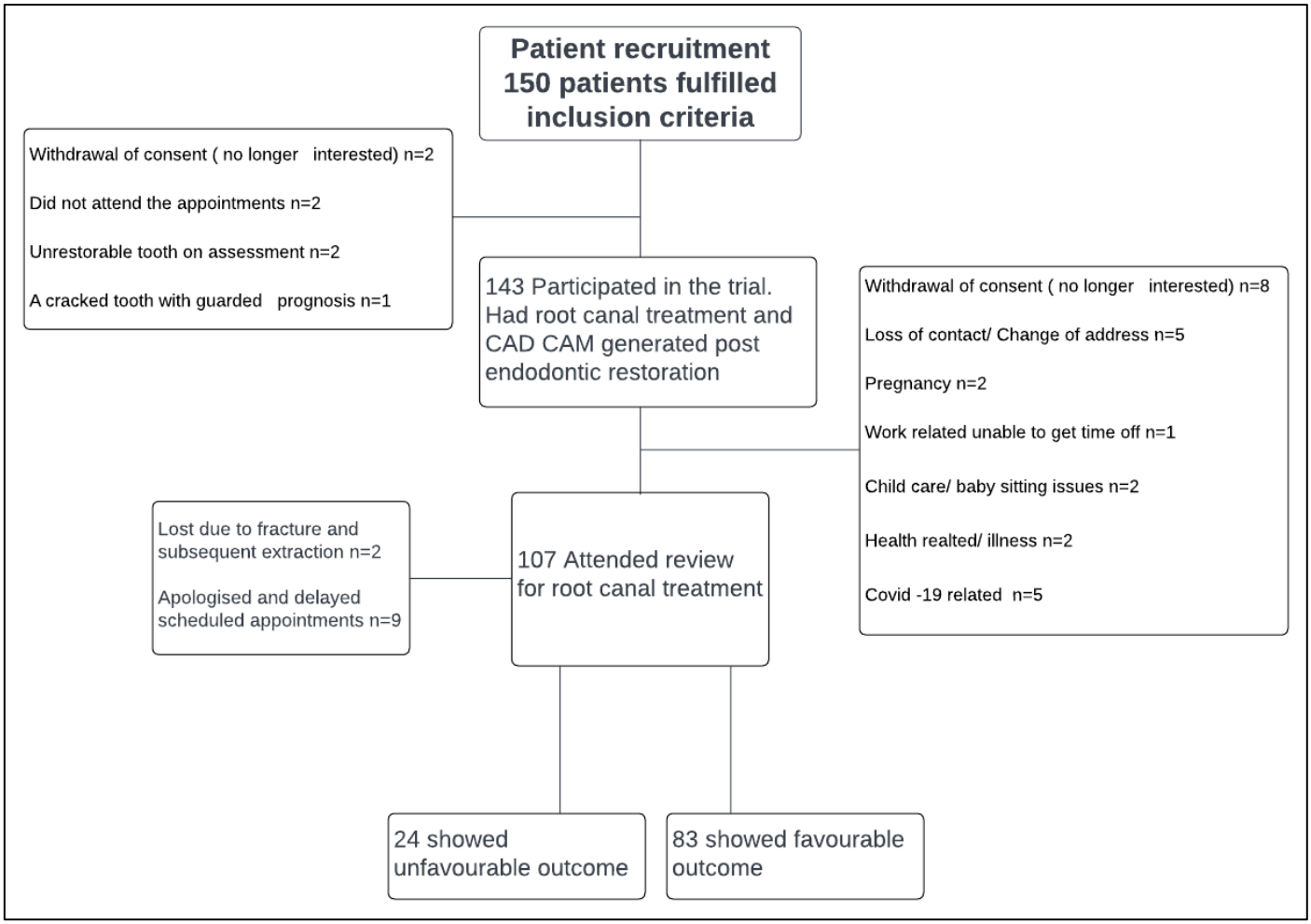
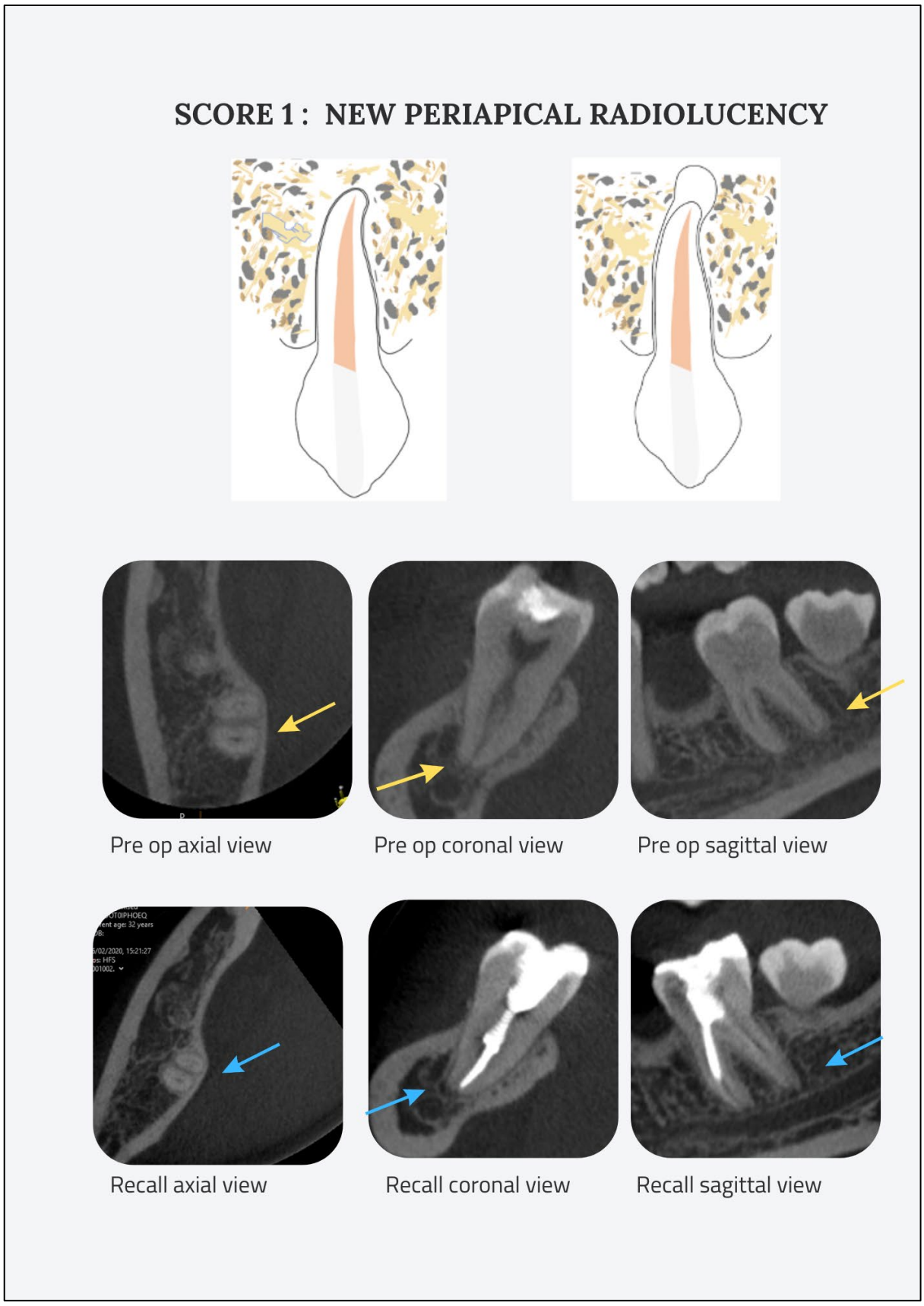
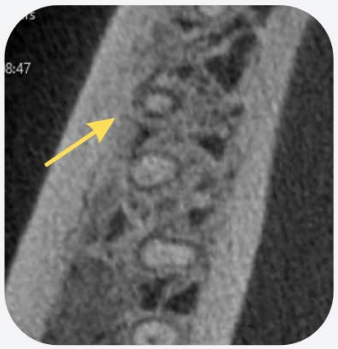


Figure 3-10 Flow Chart

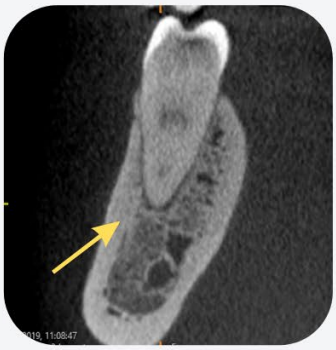
3.5.3 Radiographic Assessment (CBCT)



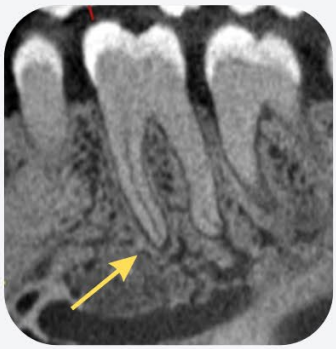
SCORE 2 : ENLARGING PERIAPICAL RADIOLUCENCY



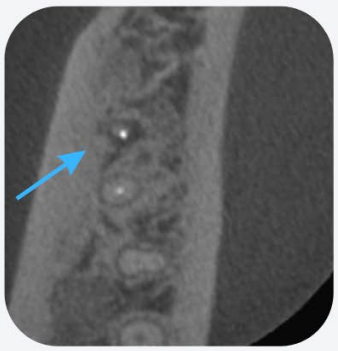
Pre op axial view



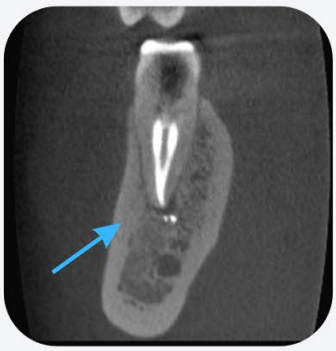
Pre op coronal view



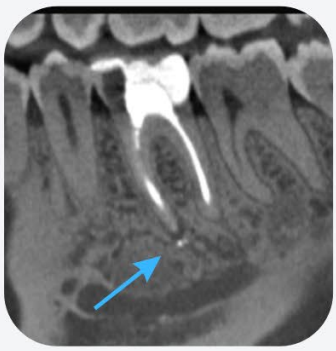
Pre op sagittal view



Recall axial view

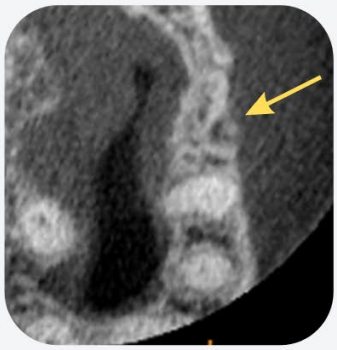


Recall coronal view

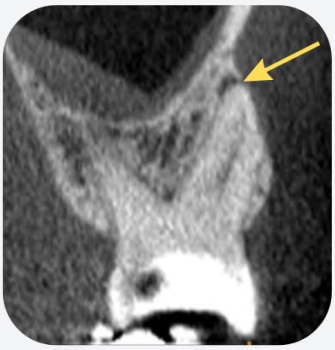


Recall sagittal view

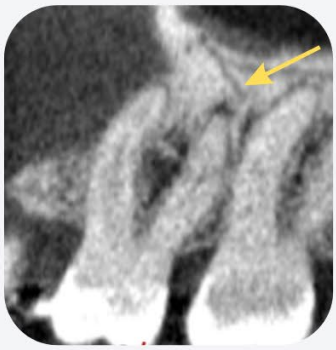
SCORE 3 : NO CHANGE TO PERIAPICAL RADIOLUCENCY



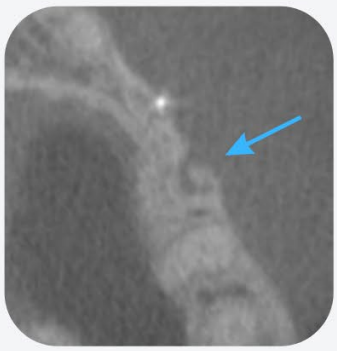
Pre op axial view



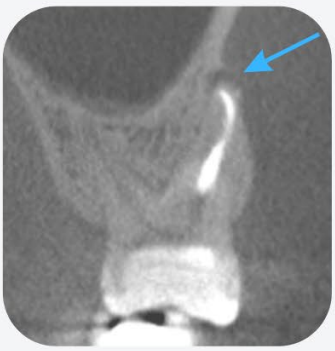
Pre op coronal view



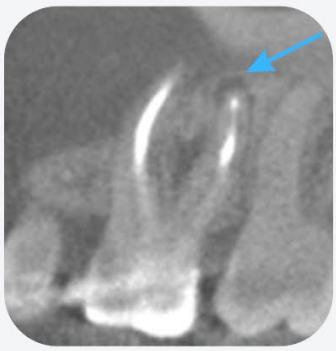
Pre op sagittal view



Recall axial view

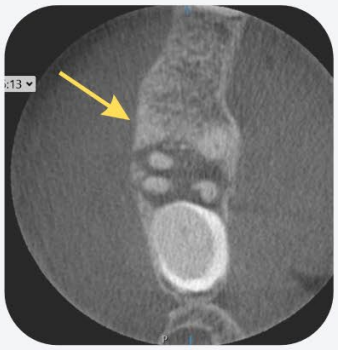


Recall coronal view

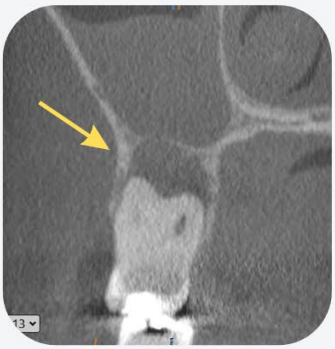


Recall sagittal view

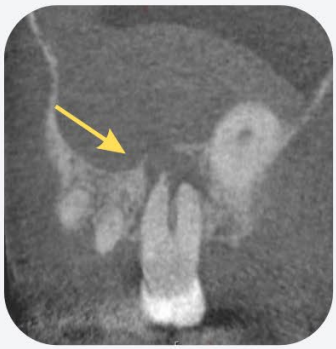
SCORE 4 : REDUCED PERIAPICAL RADIOLUCENCY



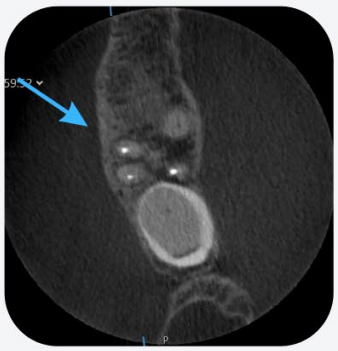
Pre op axial view



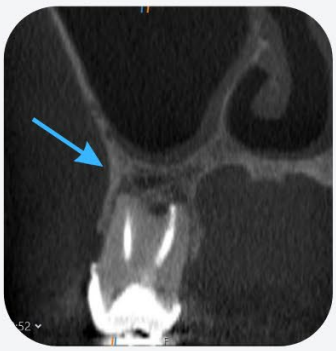
Pre op coronal view



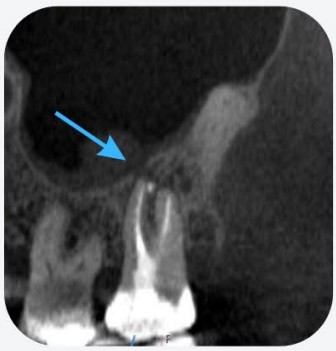
Pre op sagittal view



Recall axial view

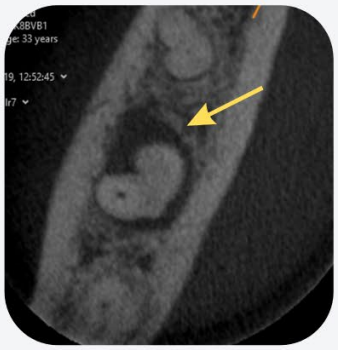


Recall coronal view

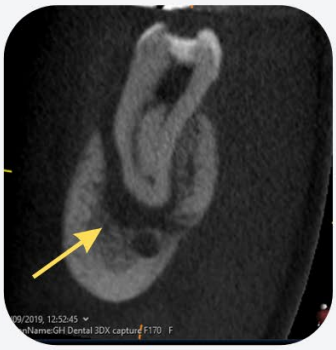


Recall sagittal view

SCORE 5 : RESOLVED PERIAPICAL RADIOLUCENCY



Pre op axial view



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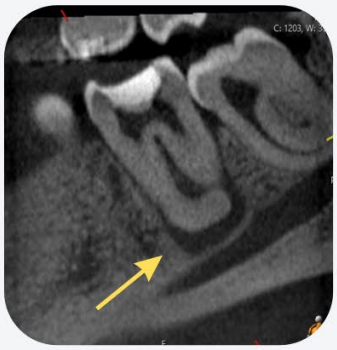
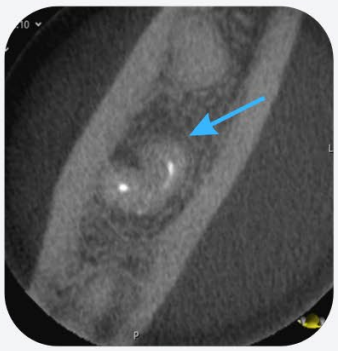
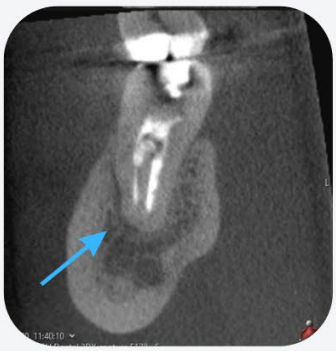


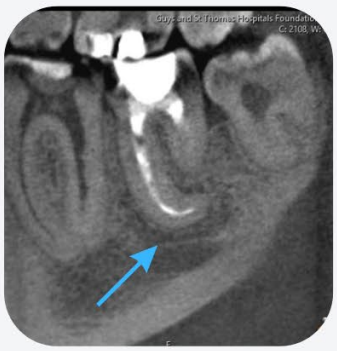
Pre op sagittal view



Recall axial view

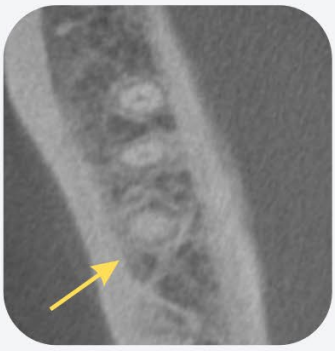


Recall coronal view

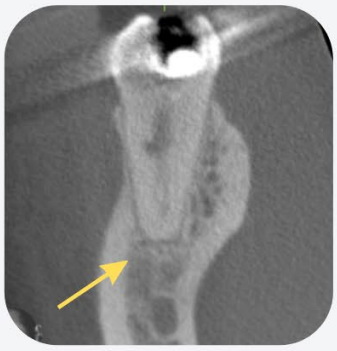


Recall sagittal view

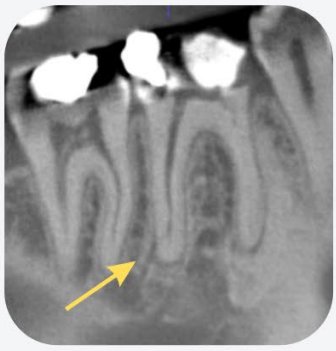
Score 6 : No radiolucency at baseline and no radiolucency at recall



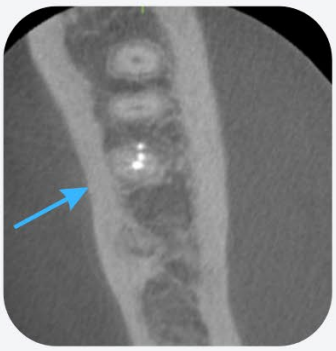
Pre op axial view



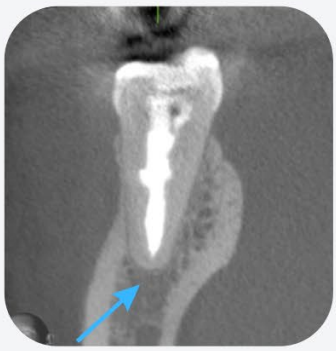
Pre op coronal view



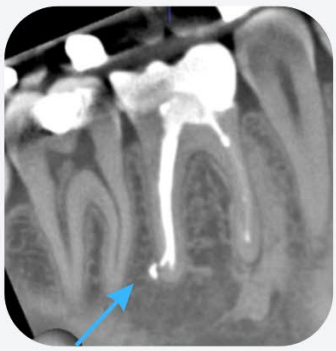
Pre op sagittal view



Recall axial view

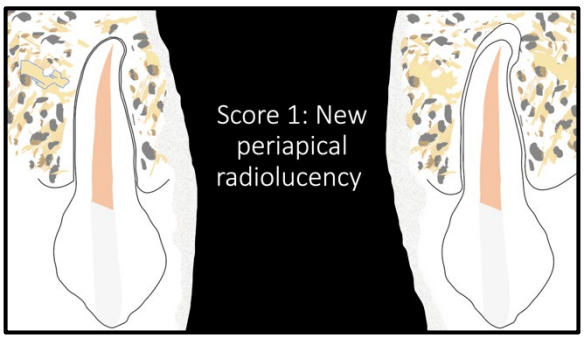


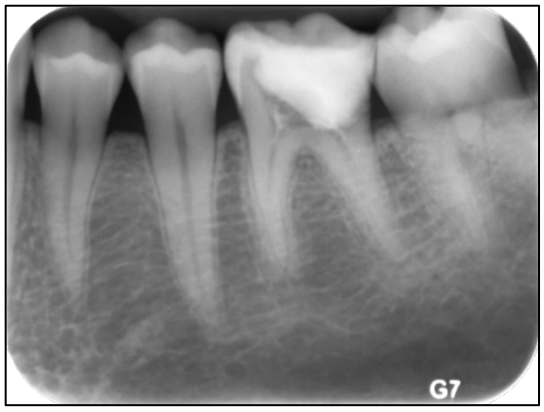
Recall coronal view

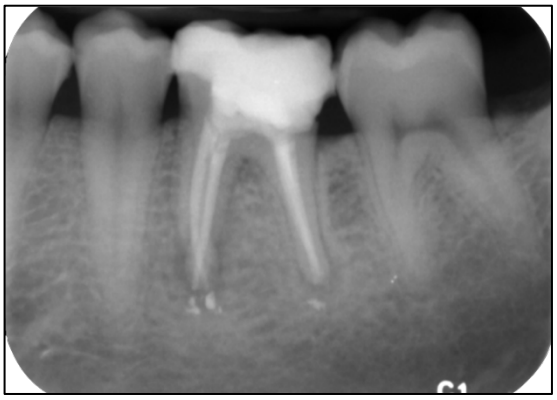


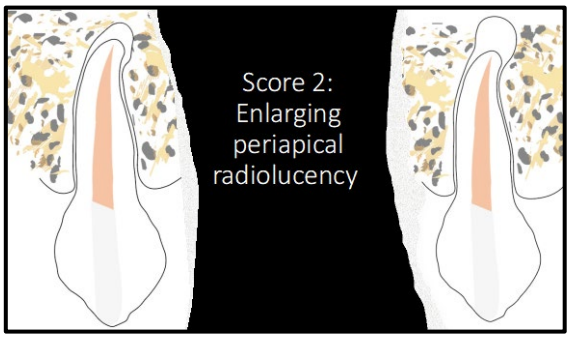
Recall sagittal view

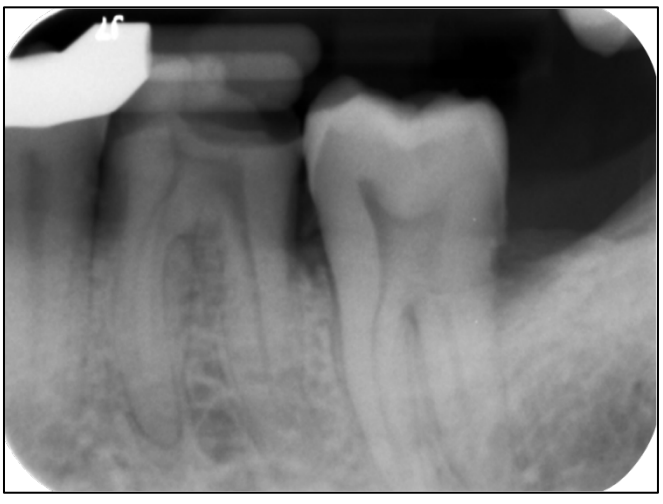
3.5.4 Radiographic outcome by PA

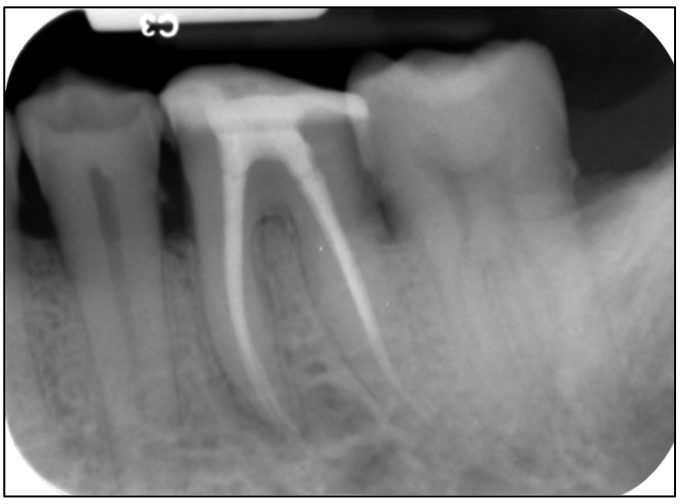


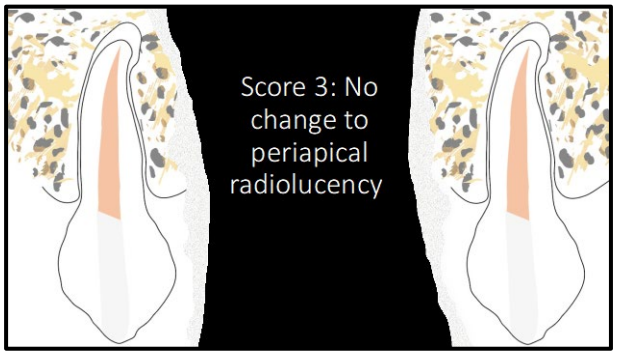


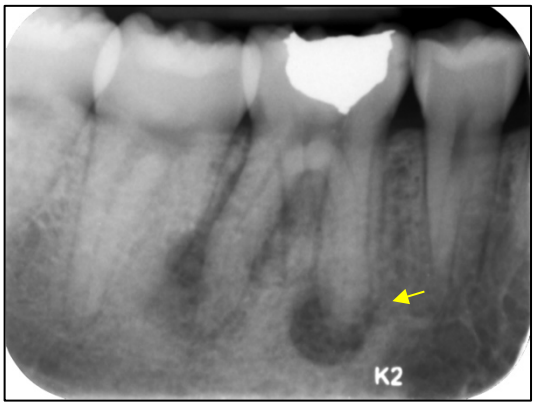


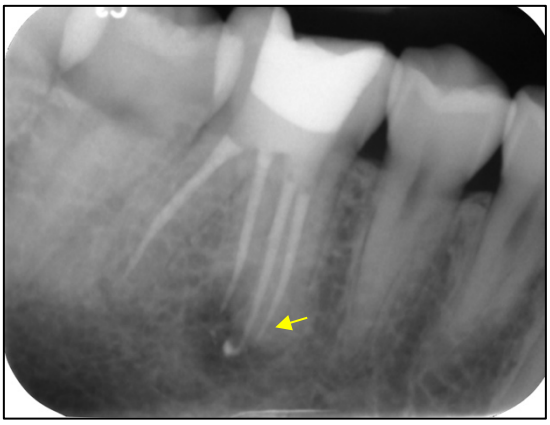


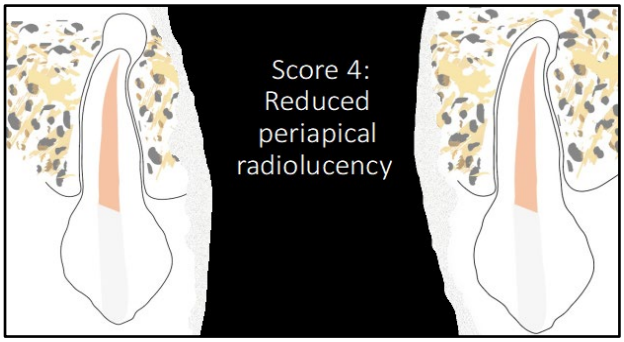


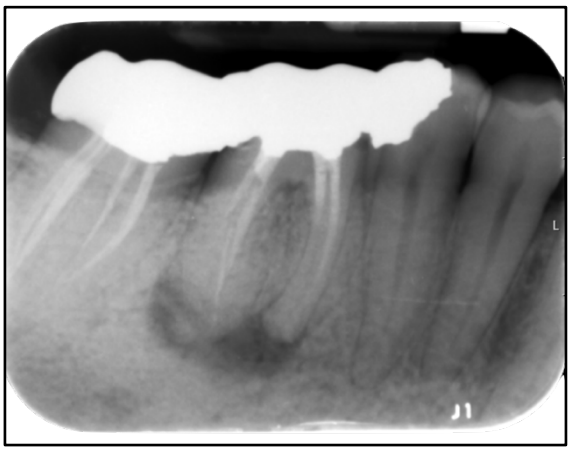


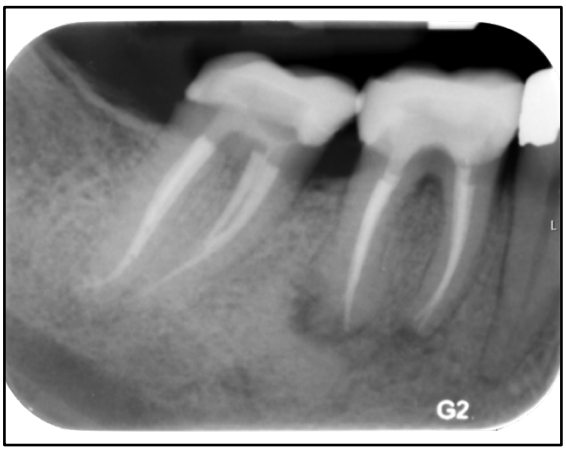

Score 3: No change to periapical radiolucency

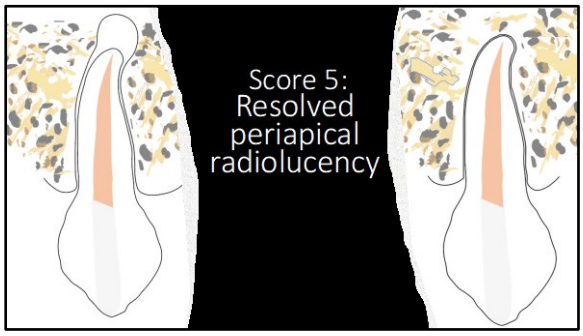

K2

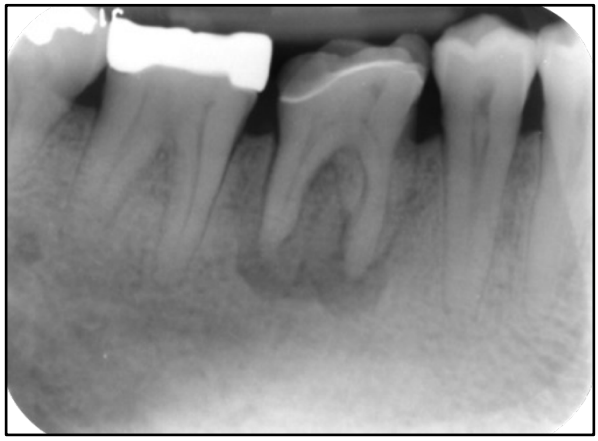


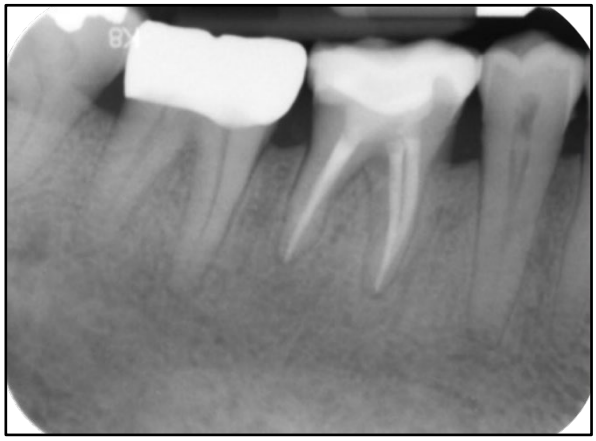

Score 4: Reduced periapical radiolucency

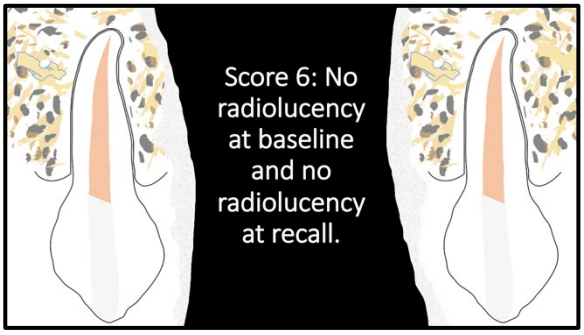

J1

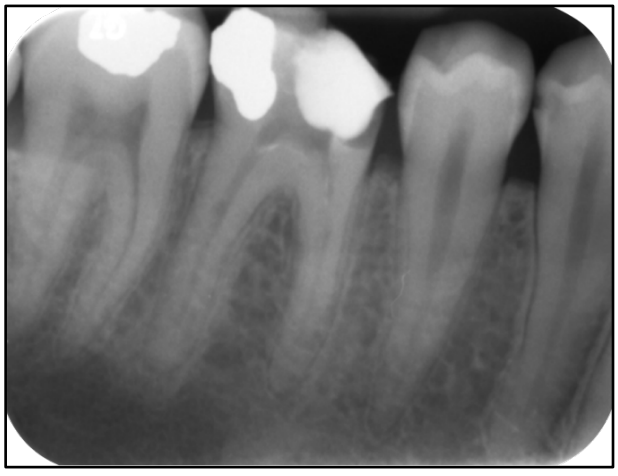

G2

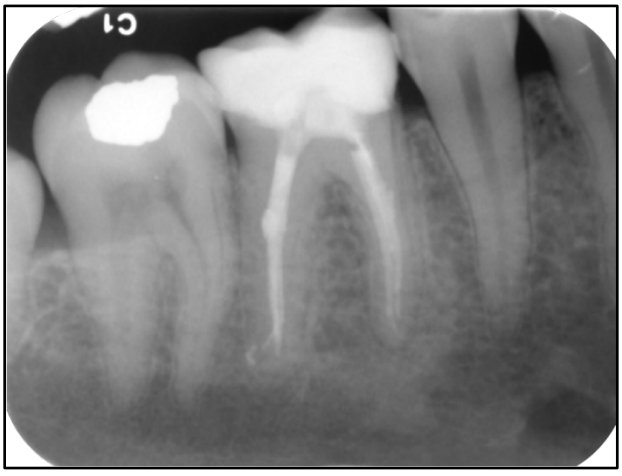

Score 5:
Resolved
periapical
radiolucency






Score 6: No
radiolucency
at baseline
and no
radiolucency
at recall.





3.5.5 Endodontic Outcome

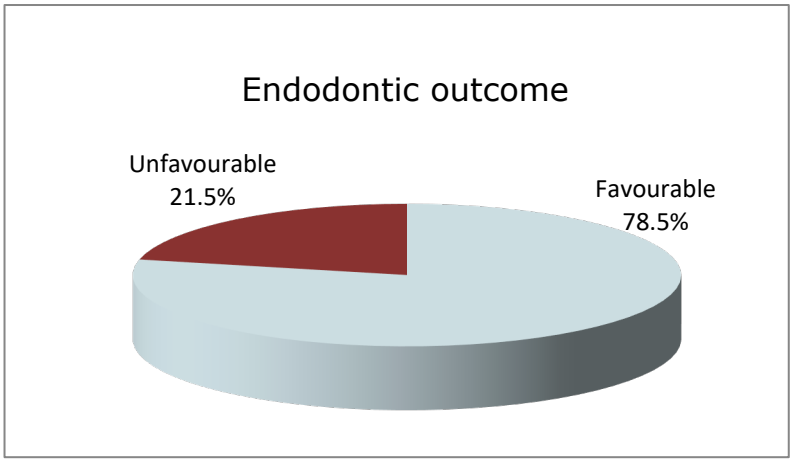


Figure 3-11 Endodontic outcome by CBCT

The overall percentage of favourable outcomes was 78.5% by the CBCT and 88.8% by the PA. (Figure 3-11, Table 3.5).

Table 3.5 Comparison of outcome by PA and CBCT and distribution by Score

Score	Description	Periapical Outcome		CBCT Outcome	
1	New periapical radiolucency	4	Unfavourable 12 (11.2%)	2	Unfavourable 23 (21.5%)
2	Enlarged periapical radiolucency	5		12	
3	Unchanged periapical radiolucency	3		9	
4	Reduced periapical radiolucency	14	Favourable 95 **(88.8%)**	20	Favourable 84 **(78.5%)**
5	Resolved periapical radiolucency	20		29	
6	Unchanged healthy periapical status (No radiolucency at baseline and no radiolucency at recall)	61		34	
		107		107	

Table 3.6 Percentage of success by loose and strict criteria

Criteria	**Successful outcome**	
	PA n (%)	CBCT n (%)
Loose Criteria (Scores 4,5,6)	95 (88.8%)	81 (78.5%)
Strict criteria (Scores 5,6)	81 (75.7%)	63 (58.9%)

When strict criteria were applied (scores 5 and 6), the success of root canal treatment assessed by CBCT dropped to 58.9%, while with PA it was 75.7% (Table 3.6).

Endodontic and restorative variables potentially affecting the endodontic outcome are reported from Table 3.7 to Table 3.16

3.5.6 Identification of Prognostic factors predicting success rate using logistic regression: A CBCT based assessment.

A simple binary logistic regression model is presented below for each independent variable using a GEE approach.

3.5.6.1 Patient factors

Table 3.7 Unadjusted effects of patient characteristics using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Gender	107	23 (21.5%)	84 (78.5%)			
Male	48	11 (23.9%)	35(76.1)	1		
Female	63	12 (19.7%)	11 (82.5)	1.04	0.88-1.24	0.624
Age	42.9±13.3	23 (21.5%	84(78.5%)	0.99	0.99-1.00	**0.047***
Ethnicity	106	23 (21.7%)	83 (78.3%)			0.501
Caucasian	55	11 (20%)	44 (80%)	1		
Afro-caribbean	26	5 (19.2%)	21 (80.8%)	1.01	0.82-1.24	0.942
Asian	21	7 (33.3%)	14(66.7)	0.88	0.69-1.11	0.262
Others	4	0 (0%)	4(100%)			
Tooth type	107	23 (21.5%)	84 (78.5%)			
Premolar	7	0 (0%)	7 (100%)			
Molar	100	23 (23%)	77 (77%)			0.152(Chi^2)
Arch	107	23 (21.5%)	84 (78.5%)			
Maxilla	50	10 (20%)	40 (80%)	1		
Mandible	57	13 (22.8%)	44 (77.2%)	0.97	0.83-1.14	0.735
Medical history	103	20 (19.4%)	83 (80.6%)			
Healthy	59	13 (22%)	46 (78%)	1		
Systemic involvement	44	7 (15.9%)	37 (84.1%)	1.06	0.91-1.25	0.448
Smoking	105	21	84			0.634
No	83	17	66	1		
Yes, current	13	3	10	0.97	0.77-1.23	0.829
Previously	9	1	8	1.09	0.89-1.36	0.381

The patient's gender, ethnicity, general medical status, or smoking status did not have any significant effect on the success of primary or secondary root canal treatment. (Table 3.7)

Age however had a significant effect. Age with an OR of 0.99 and p=0.047 showed that for every 1-year increase in age, the likelihood of a favourable outcome decreased by 1 %.

Female patients had a higher success rate, although this was not statistically significant. Medical conditions like systemic involvement nor smoking status did not have a significant effect on the outcome of root canal treatment.

3.5.6.2 Tooth and morphology

Table 3.8 Unadjusted effects of tooth characteristics using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Tooth type	107	23 (21.5%)	84 (78.5%)			
Premolar	7	0 (0%)	7 (100%)			
Molar	100	23 (23%)	77 (77%)			0.152(Chi^2)
Lower first molar	39	11 (28%)	28(71.8%)	1		
Lower second molar	18	3 (16.7%)	15(83.3%)	1.12	0.90-1.40	0.313
Upper first molar	35	7 (15.8%)	28	1.08	0.88-1.31	0.466
Upper second molar	8	0	8			
Arch	107	23 (21.5%)	84 (78.5%)			
Maxilla	50	10 (20%)	40 (80%)	1		
Mandible	57	13 (22.8%)	44 (77.2%)	0.97	0.83-1.14	0.735

Both the upper jaw or lower jaw as well as whether it was the first, or second molar also did not affect outcome of root canal treatment (Table 3.8).

The mandibular first molar were associated with higher odds of failure than the other sets of teeth (Maxillary first, second molar, mandibular second molar, upper and lower premolars). However, this was not statistically significant.

3.5.7 Tooth restorability factors and CBCT based endodontic outcome.

Table 3.9 Unadjusted effects of factors affect restorability using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Number of walls remaining	84	19 (22.6%)	65 (77.4%)			0.796
No	3	1 (33.3%)	2 (66.7%)	1		
1	8	3 (37.5%)	5 (62.5%)	0.96	0.51-1.80	0.897
2	22	5 (22.7%)	17 (77.3%)	1.11	0.67-1.84	0.680
3	37	8 (21.6%)	29 (78.4%)	1.12	0.65-1.95	0.676
4	14	2 (14.3%)	12 (85.7)	1.21	0.69-2.13	0.510
Mesial wall	84	19 (22.6%)	65 (77.4%)			
Missing	42	13 (31%)	29 (69%)	1		
Remaining	42	6 (14.3%)	36 (85.7%)	1.18	0.98-1.43	0.088
Distal wall	84	19 (22.6%)	65 (77.4%)			
Missing	50	11 (22%)	39 (78%)	1		
Remaining	34	8 (23.5%)	26 (76.5%)	0.99	0.81-1.20	0.877
Buccal wall	84	19 (22.6%)	65 (77.4%)			
Missing	9	1 (11.1%)	8 (88.9%)	1		
Remaining	75	18 (24%)	57 (76%)	0.88	0.71-1.09	0.238
Lingual wall	84	19 (22.6%)	65 (77.4%)			
Missing	19	6 (31.6%)	13 (68.4%)	1		
Remaining	65	13 (20%)	52 (80%)	1.12	0.89-1.42	0.333
Marginal ridge missing	67	16 (23.9%)	51 (76.1%)			0.296
Mesial	20	6 (30%)	14 (70%)	1		
Distal	28	4 (14.3%)	24 (85.7%)	1.17	0.91-1.50	0.216
Both	19	6 (31.6%)	13 (68.4%)	0.98	0.74-1.50	0.915
Dentine Wall Thickness (WT)						
WT Mesial	39	5	34	1.01	0.94-1.08	0.847
WT Mesio buccal	75	18	57	0.96	0.85-1.09	0.537

WT Disto buccal	73	18	55	0.96	0.85-1.09	0.526
WT Distal	34	9	25	1.08	1.01-1.16	**0.018***
WT Disto lingual	71	15	56	0.92	0.85-1.00	0.056
WT Mesio lingual	74	16	58	0.92	0.81-1.04	0.177
Dentine Wall Height (WH)						
WH Mesio buccal	75	18	57	1.04	0.97-1.11	0.264
WH Mesio lingual	74	15	68	0.96	0.90-1.01	0.115
WH Disto buccal	72	18	54	1.04	0.97-1.10	0.294
WH Disto lingual	71	15	56	0.96	0.92-1.01	0.118
Width of access cavity	75	17	58	1.05	0.99-1.12	0.100
Volume of remaining tooth	82	17	65	1.00	0.99-1.01	0.961

An increase in the thickness of the distal wall was significantly associated with a favourable outcome (OR=1.18; p=0.088). None of the other factors affecting tooth restorability had any significant effect on the outcome.(Table 3.9)

3.5.8 Direct and indirect restorations and CBCT based endodontic outcome.

Table 3.10 Unadjusted effects of onlays and crowns using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Type of Post Endo Restoration	107	23 (21.5%)	84 (78.5%)			0.295
Direct filling	6	3 (50%)	3 (50%)	1		
Onlay	76	16 (21.1%)	60 (78.9%)	1.34	0.89-2.01	0.164
Full crown	25	4 (16%)	21 (84%)	1.41	0.92-2.15	0.119

There was no statistical significance between onlays and crowns in relation to the outcome of root canal treatment ($p>0.05$) (Table 3.10)

3.5.9 Contact points and CBCT based Endodontic outcome.

Table 3.11 Unadjusted effects of patient characteristics using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Proximal contacts	107					
One side on mesial	19	4 (21.1%)	15 (78.9%)	1		
On both sides	86	18 (20.9%)	68 (79.1%)	1.00	0.82-1.23	0.991
	2	1 (50%)	1 (50%)			
Time interval between root canal obturation and crown/onlay	105 4.9 ± 6.3	23 5.6 ± 7.4	82 4.7 ± 6.0	0.99	0.98-1.01	0.595

The presence or absence of proximal contacts did not show any statistical significance to the outcome of root canal treatment at one year recall.

Similarly, time interval between obturation and placement of cuspal coverage restoration did not show statistical significance at one year recall. (Table 3.11)

3.5.10 Pulpal-periapical diagnosis and CBCT based endodontic outcome.

Table 3.12 Unadjusted effects of pulpo-periapical diagnosis using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Pulp diagnosis	107	23 (21.5%)	84 (78.5%)			0.171
Irreversible pulpitis	42	11 (26.2%)	31 (73.8%)	1		
Pulp necrosis	37	9 (24.3%)	28 (75.7%)	1.02	0.84-1.23	0.848
Previously extirpated	28	3 (10.7%)	25 (89.3%)	1.17	0.98-1.39	0.088
Periapical diagnosis	107	23 (21.5%)	84 (78.5%)			0.575
Normal	27	5 (18.5%)	22 (81.5%)	1		
Chronic AP	48	9 (18.8%)	39 (81.3%)	0.99	0.82-1.22	0.982
Acute AP	32	9 (28.1%)	23 (71.9%)	0.91	0.73-1.14	0.401

There was no statistically significant effect of the pulpal-periapical diagnosis on endodontic outcome. (Table 3.12).

3.5.11 Primary vs secondary root canal treatment outcome assessed by CBCT.

Table 3.13 Unadjusted effects of patient characteristics using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Non-surgical root canal treatment	103	21 (20.4%)	82 (79.6%)			
Primary	85	20 (23.5%)	65 (76.5%)	1		
Retreatment	17	1 (5.9%)	16 (94.1%)	1.19	1.03-1.38	**0.019***
Apical surgery	**1**	0 (0%)	1 (100%)			

Retreatments had a significantly more favourable outcome compared to primary root canal treatments (OR = 1.19, p=0.019) (Table 3.13).

3.5.12 Preoperative status

Table 3.14 Unadjusted effects of preoperative status using logistic regression analysis

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
Cortical bone loss	99	19 (19.2%)	80 (80.8%)			0.175
No bone loss	74	16 (21.6%)	58 (78.4%)	1		
Fenestration	15	1 (6.7%)	14 (93.3%)	1.16	0.99-1.36	0.066
Dehiscence	10	2 (20%)	8 (80%)	1.02	0.76-1.35	0.912
Furcation bone loss	104	21 (20.2%)	83 (79.8%)			
No	80	17(21.2%)	(78.8%)	1		
Yes	18	4 (22.2%)	14 (77.8%)	1.00	0.81-1.24	0.979
Periapical Lesion	105	22 (21%)	83 (79%)			
Absent	36	5 (13.9%)	31 (86.1%)	1		
Present	69	17 (24.6%)	52 (75.4%)	0.90	0.76-1.06	0.203
Size of lesion	105	22 (21%)	83 (79%)			**0.044***
Absent	36	5 (13.9%)	31 (86.1%)			
<2mm	25	9 (36%)	16 (64%)	1		
2-5mm	11	4 (36.4%)	7 (63.6%)	1.00	0.71-1.39	0.983
>5mm	33	4 (12.1%)	29 (87.9%)	1.27	1.03-1.57	**0.028***

Teeth with periapical lesions with a diameter above 5mm had a significantly higher probability of favourable outcomes compared to teeth with lesions less than 5 mm in size(p=0.028). (Table 3.14)

3.5.13 Quality of root canal treatment

Table 3.15 Unadjusted effects of patient characteristics using logistic regression analysis.

Category	Total	Unfavourable n(%)	Favourable n(%)	OR	CI 95%	p-value
		Unfavourable n(%)	Favourable n(%)			
Length of root canal filling	105	22 (21%)	83 (79%)			**0.039***
Adequate	48	6 (12.5%)	42 (87.5%)	1		
Underfilled/short	11	5 (45.5%)	6 (54.5%)	0.72	0.55-0.95	**0.020***
Overfilled	46	11 (23.9%)	35 (76.1%)	0.89	0.76-1.04	0.154
Root filling voids	105	22 (21%)	83 (79%)			
No	55	6 (10.9%)	49 (89.1%)	1		
Yes	50	16 (32%)	34 (68%)	0.81	0.70-0.94	**0.006****
Quality of restoration	105	22 (21%)	83 (79%)			
Adequate	89	17 (19.1%)	72 (80.9%)	1		
Inadequate	16	5 (31.3%)	11 (68.8%)	0.89	0.69-1.13	0.328
Procedural complications	105	22 (21%)	83 (79%)			
No	93	17 (18.3%)	76 (81.7%)	1		
Yes	12			0.79	0.59-1.07	0.124
Missed canal	9	5 (55.6%)	4 (44.4%)			
Perforation	1	0	1			
Other	**2**	**0**	**2**			

Teeth with root canal fillings that were less than 2mm from the apex in all three planes, had a statistically significant reduced probability of favourable outcome compared to root fillings of adequate length (OR =0.78, p= 0.02). Overfilling also resulted in a lower success rate compared to adequate length. The presence of voids in the root canal obturation was also associated with a poorer prognosis (OR =0.81, p=0.006)

3.5.14 Multivariate regression Analysis

The factors which were included into the multivariate regression analysis were: age, primary or secondary root canal treatment, Presence and size of periapical lesion, length of root canal filling, density (voids) of root canal filling.

Table 3.16 Association between Endodontic outcome and independent variables: Results of multiple binary logistic regression model using GEE for probability of favourable. Adjusted odds ratio (OR) and 95% confidence interval.

	Category	**OR**	**CI 95%**	p-value
Age		1.01	0.96-1.06	0.698
Non-surgical root canal treatment				
	Primary	1		
	Retreatment	4.67	0.45-48.4	0.196
Lesion size				**0.043***
	Absent	1		
	<2mm	0.14	0.03-0.65	**0.012***
	2-5mm	0.18	0.03-1.31	0.090
	>5mm	0.75	0.13-4.32	0.749
Root filling length				**0.019***
	Adequate	1		
	Short	0.08	0.01-0.47	**0.005****
	Overfilled	0.51	0.14-1.91	0.317
Root filling voids	No	1		
	Yes	0.20	0.06-0.74	**0.016***

The presence of a periapical lesion significantly reduced the likelihood of a favourable outcome (p=0.043). When the periapical lesions were 2 mm or less in diameter, the probability of a favourable outcome decreased compared to lesions that were more than 2mm (OR 0.14, 95% CI= 0.03-1.31, p=0.012).

The root canal filling length significantly predicts the success of root canal treatment (p=0.019). When this filling is shorter than an adequate filling, then the probability of a favourable outcome was significantly lower than adequate filling (OR =0.08, 95% CI= 0.01-0.47, p=0.005). However no significant difference was noted between overfilled and adequate root fillings (p=0.317).

The presence of voids into the root canal obturations was also associated with a likelihood of unfavourable outcome (OR= 0.20, 95% CI= 0.06-0.74, p=0.016).

3.6 Discussion

In this prospective cohort study, factors which significantly affected the outcome of root canal treatments included the length of the obturations, the presence of voids, the presence and size of the periapical radiolucency.

None of the restorative factors taken into consideration (volume of residual tooth structure, missing marginal ridges, access cavity width, dentine wall thickness and height) was found to significantly affect the endodontic treatment outcome, this is due to the small sample size available.

The most surprising finding was that teeth with periapical lesions >2mm in size had a significantly higher probability of favourable outcomes compared to teeth with lesions less than 2 mm in diameter (p=0.028). This was based on loose criteria (Score 4,5,6) where healing and healed are considered favourable (See Figure 3-12 and Figure 3-13).

This is not in agreement with previous studies (Friedman, Abitbol et al. 2003, Ng, Mann et al. 2011), again the limited sample size is the most likely explanation for this finding.

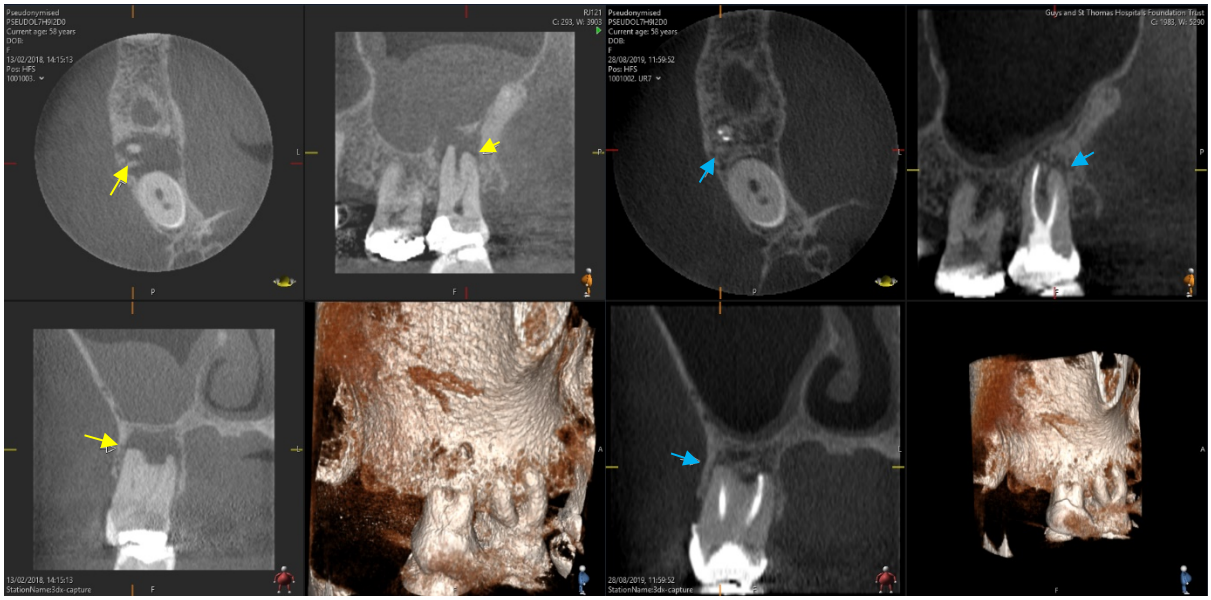


Figure 3-12 Favourable outcome for a tooth with large lesion. Pre op marked with yellow arrow and 1 year recall with blue arrow.

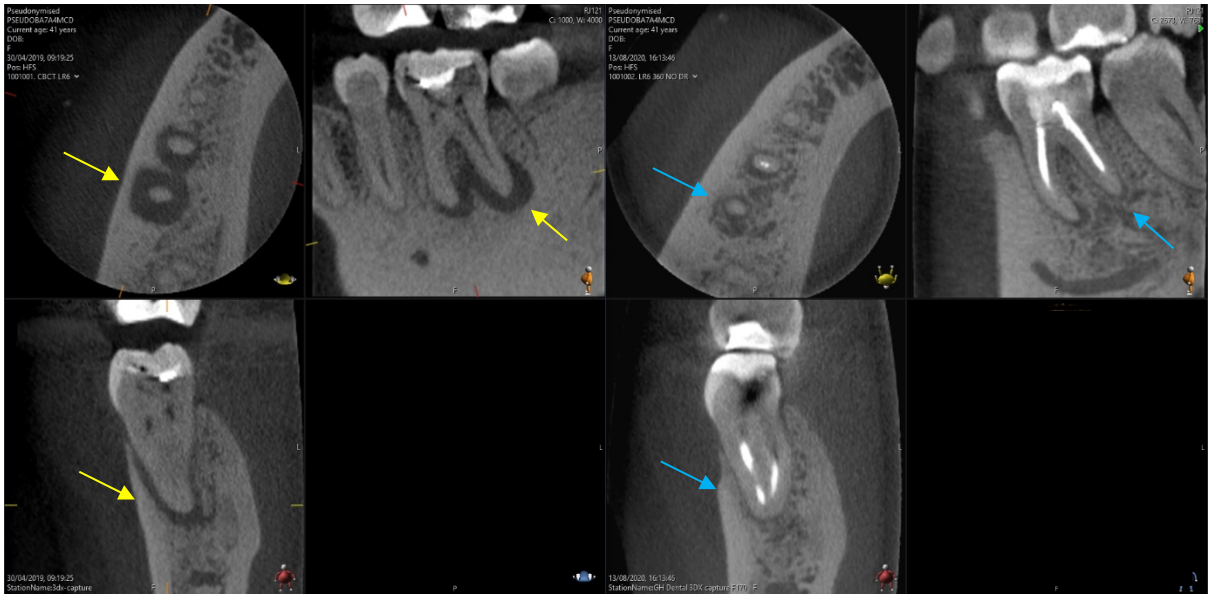


Figure 3-13 One year follow up showing a favourable outcome (Pre op shown in yellow and 1 year recall in blue arrows)

3.6.1 Voids in the root canal filling.

Another significant finding from this prospective study was that root canal treated teeth that had voids. This has already been reported in other periapical and CBCT based studies (Liang, Li et al. 2011, Lee, Cheung et al. 2012). One area where significant numbers of voids were detected was the interface between gutta percha and composite resin (Figure 3-14) and along the root canal walls in this study (Figure 3-15). CBCT scans were used to score presence or absence of voids. There has been concerns about artefacts affecting the ability of CBCT scans to determine the quality of root canal treatment.

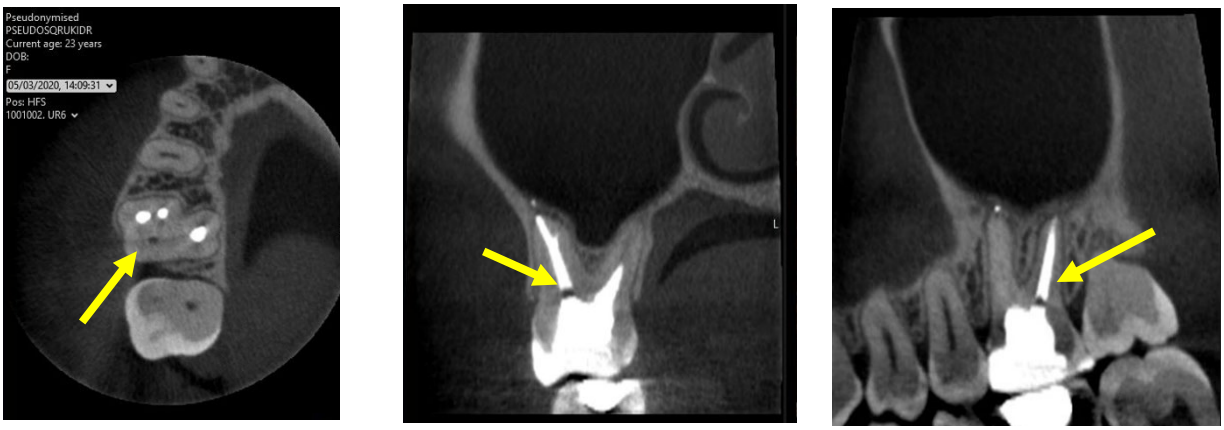


Figure 3-14 CBCT scan showing voids at the interface between gutta percha and composite resin (Yellow arrow)

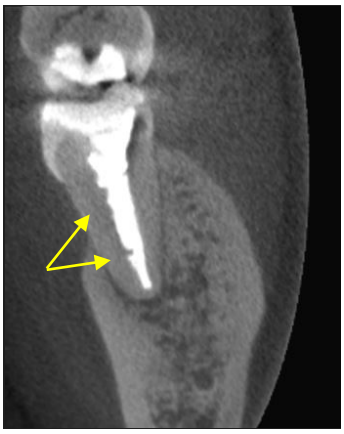


Figure 3-15 CBCT scan showing voids along the root canal walls (yellow arrow).

3.6.2 Length of root canal filling

Underfilling (more than 2mm from the radiographic apex) resulted in a significantly more unfavourable outcome than adequate (within 0-2mm) or overfilling. This is similar to previously reported studies (Liang, Li et al. 2011, Ng, Mann et al. 2011) with both CBCT based outcome studies agreeing with the 2D periapical outcome studies (Ingle JI 1985).

The type of coronal restoration did not have a significant effect on the outcome of endodontic treatment. Onlays therefore appear to be an evidence-based option for restoring ETT both from an endodontic and from a restorative point of view (based on results from Chapter 4). The fact that onlays preserve more tooth structure should encourage practitioners to provide this option instead of a full crown whenever possible.

The success rate of non-surgical root canal retreatment was surprisingly very high in our cohort of cases. Admittedly the sample size of retreatment cases was very low, and for this reason no statistical significance was derived comparing to primary root canal treatment.

3.6.3 Study Design

In this study multiple teeth were used per patient. Most studies use one tooth per patient. Having more than one tooth per patient complicates and confounds the

analysis without special measures. In this study we used the Generalised Equation Methods (GEE) as the approach to handle multiple teeth per patient.

Previous studies had resolved this problem by randomly selecting one tooth per patient but this is associated with the risk of losing valuable information (Polycarpou, Ng et al. 2005).

The recall rate for the study was 75% (107 from 143 who received the treatment). The recall period was during the Covid -19 pandemic, and this may have contributed directly or indirectly to the relatively low recall rate, however similar studies ran in our and other institutions pre-covid showed similar recall rates; in Patel et al (2012) the recall was 75%. Reasons for not attending recalls include taking time off work, expenses in transportation. (Friedman, Abitbol et al. 2003, Ng, Mann et al. 2011) The study is ongoing, and patients are being recalled on a periodic basis and data will be analyzed. This study has ethical approval for a second year CBCT scan and is being followed up.

The assessment of outcome was done a panel of two experienced specialist endodontists who have been involved with similar research for many years and directly involved in the formulation of the 6-point classification.(Patel, Wilson et al. 2012). It has been reported that two observers using an index with a joint agreement to the radiographic status reduces observer variations and increases the reliability and validity of the findings (Molven, Halse et al. 2002), something followed in our study. Other strategies to minimise interpretation errors include blocking all extraneous light (Welander, McDavid et al. 1983) and use of magnification, a viewing box and masking

radiographs(Patel, Rushton et al. 2000, Orafi, Worthington et al. 2010). It has also been suggested to avoid long duration of viewing to avoid fatigue (Goldman, Pearson et al. 1972).

The favorable outcome of this study assessed by CBCT was 78.5% which compares to similar CBCT based outcome studies (Zahran, Patel et al. 2021) 76.5%, (Patel, Wilson et al. 2012) 73.9%.

Two patients with symptomatic teeth were scheduled for endodontic retreatment. Another two patients with radiographic signs of enlarging periapical radiolucency had no symptoms from and were unwilling to have their teeth re-treated. One concern with this decision is the impact periapical bone loss may have on placement of implants. But as we have seen in some of our own cases, large lesions have shown signs of healing and endodontic retreatments also had a favourable outcome.

3.7 Conclusion

This prospective study identified no difference in endodontic outcome between onlays and full crowns. Short root canal fillings and presence of voids were found to be significant prognostic factors that can affect the outcome of root canal treatment. Size of the lesion was also a significant prognostic factor but, in our study, lesions less than 2 mm had significantly increased unfavourable outcome, when assessed using the CBCT.

Chapter 4 : Clinical evaluation of posterior nanohybrid ceramic onlays as post-endodontic restorations and digital assessment of restorability.

4.1 Introduction

One of the most critical factors that affect the survival of an endodontically treated tooth is a good post-endodontic restoration (Ng, Mann et al. 2010) and the absence of restorative complications (Vire 1991, Fuss, Lustig et al. 1999). There is also increasing evidence that the remaining tooth structure influences the survival of a root-filled tooth (Nagasiri and Chitmongkolsuk 2005, Al-Nuaimi, Patel et al. 2017).

Restoring a tooth to form and function is an integral part of restorative dentistry. Deciding which teeth are restorable and which are best extracted is critical in successfully managing a badly broken-down tooth. With advances in implant dentistry, it becomes even more imperative that the right decision is made whether to save or extract. Guidelines for tooth restorability and case complexity assessment using different restorative indices have been produced by the American Association of Endodontists, British Endodontic Society, Dutch Endodontic Treatment Index, Canadian Academy of Endodontics case classification system, Tooth Restorability Index, and dental practicality index (McDonald and Setchell 2005, Dawood and Patel 2017). However, tooth restorability decision-making remains tricky even for experienced dentists (Alani, Bishop et al. 2011), and also when advanced imaging systems are used (Rodriguez, Abella et al. 2017).

Intra-oral scanners have been developed in digital dentistry to take the impressions of the oral cavity. Their use has since evolved for various other purposes such as monitoring and assessing the clinical status of teeth during check-ups, assessing restorations and tooth wear. To our knowledge, there is no previous work in which restorability has been assessed using intra-oral scanners.

One of the attractions of advances in dentistry is the way it has embraced digital technology. One such technology is the CAD-CAM system for fabricating dental restorations. The concept has been in place since the 1970s and for routine dental use since 1989(Mörmann, Brandestini et al. 1989, Duret and Preston 1991). It has developed significantly over the years from the Sopha System and the Cerec 1 to the more recent E4D Dentist system (D4D Technologies) and the Cerec 3 (Dentsply Sirona).

ETT are usually restored using full crowns. There are no prospective clinical studies assessing the clinical performance of onlays compared to full crown on ETT. Although there are a few studies investigating inlays, onlays and full crowns, on vital teeth with some ETT among the samples (see Chapter 2), there are hardly any prospective clinical studies assessing onlay restorations only on ETT apart from a retrospective study by Chrepa et al. (Chrepa, Konstantinidis et al. 2014). In this study, an indirect composite was used to fabricate the onlays. The clinical records and radiographs were used to score the modified USPHS criteria, which is not how they were meant to be scored and only once during a follow-up examination, hence the results may not be entirely reliable in this study.

4.1.1 Assessment of factors affecting restorability

4.1.1.1 Tooth restorability Indices

Several indices and guidelines have been formulated to help in treatment planning. These include the AAE case assessment form, the Dutch endodontic treatment index (Ree, Timmerman et al. 2003), the tooth restorability index (McDonald and Setchell 2005, Bandlish, McDonald et al. 2006), and the dental practicality index (Dawood and Patel 2017).

4.1.1.1.1 Tooth restorability index (TRI)

Among the numerous indices, one of the widely used is the tooth restorability index proposed by McDonald and Setchell (McDonald and Setchell 2005).

A tooth is divided into six sextants: mesial, mesio-lingual, disto-lingual, distal, disto-buccal and mesio-buccal (Figure 4-1). A score from 0-3 is given for each sextant based on the height and thickness of the wall of the dentine (Figure 4-1, Table 4.1). The scores of each sextant are added up to give a tooth restorability index score ranging from 0-18 and then a clinical decision can be made (Table 4.2). A subsequent paper showed moderate to good agreement between examiners (Bandlish, McDonald et al. 2006), but clinical validation of TRI is still lacking. Traditionally the measurements of height and width are made using measuring forceps and graduated periodontal probes. There is also an inability to “visually” explain to the patient why the treatment option is to save or extract the tooth.

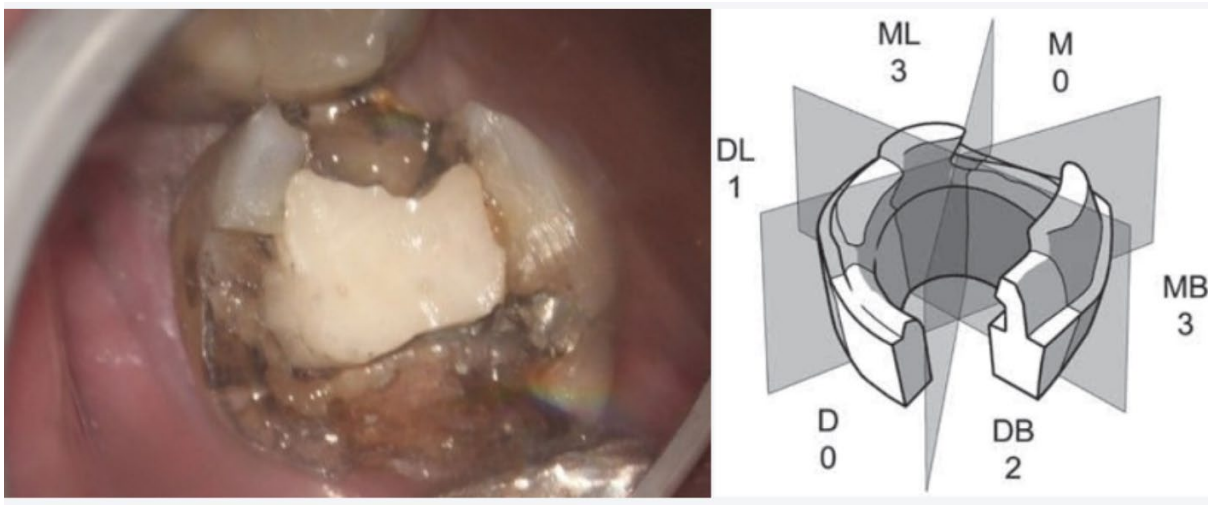


Figure 4-1 Image showing a broken-down tooth where emergency treatment has been provided and scoring the six segments according to the criteria.

Table 4.1 Scores given to each sextant and scoring criteria.

Score		**Height and width / axial wall of dentine**
0	None	No axial wall of dentine
1	Inadequate	<1.5 mm
2	Questionable	Slightly more dentine than score 1 but between 1 and 3
3	Adequate	Sufficient coronal dentine

Table 4.2 Total score by adding scores of each sextant and resulting clinical decision.

Tooth structure remaining	**Clinical decision**
Tooth with TRI of 12 and greater	Restorable
Tooth with scores of 9-12	Questionable and dependent on number of sextants with a score of 3. Acceptable if 2-3 sextants have achieved a comfortable score of 3.
Score <9	Unacceptable to retain a plastic core. Consider: Crown lengthening or a post and core

With the help of an intra-oral scanner and associated software, these measurements can be made digitally. This index has not been validated by clinical studies assessing the success and survival of restorations on endodontically treated teeth.

There are also no studies investigating the use of an intra-oral scanner for assessing restorability. With the visual impact of digital dentistry provided by intra-oral

scanners and software, they can be a good tool for use in dental education and patient education, as well as to clinicians while assessing restorability.

4.1.1.1.2 DPI Index

Another popular index that has been clinically validated is the DPI proposed by Dawood and Patel (Dawood and Patel 2017). This index aimed to include many determinants of tooth function and survival by accounting for structural integrity, periodontal and endodontic status, as well as the patient's oral and health status.

The DPI index has been validated by two studies including a four-year recall study looking at the effect of coronal tooth structure loss on the survival of ETT (Tifooni, Al-Nuaimi et al. 2019, Al-Nuaimi, Ciapryna et al. 2020).

A recent paper showed the use of DPI on treatment planning decisions of undergraduate and post-graduate dental students (Hamer, Kanagasingam et al. 2021).

4.1.1.2 Digital assessment of the residual amount of tooth structure

4.1.1.2.1 Intra-oral scanner

Intra-oral scanners have been developed in digital dentistry as an alternative method of making "dental impressions" of the oral cavity. Conventionally, alginate or elastomeric impression materials were used to make impressions. This had the drawbacks of poor quality of impressions, poor stability, inability to top up or correct inaccuracies, patient discomfort, and need for disinfecting before storage and parcel.

The intra-oral scanner can overcome these disadvantages as images can be stored indefinitely. The clinician can evaluate the anatomic structures better, and discuss treatment plans with patients, other dentists and technicians. Currently, the main drawback of digital impressions is probably the difficulty in detecting deep margins; good retraction and haemostasis may be needed to detect these margins. As the technology develops, this drawback may be expected to reduce.

Digital scanners have been used for various other purposes such as monitoring and assessing the clinical status of teeth and restoration at check-ups and assessing tooth wear (Kumar, Keeling et al. 2019, O'Toole, Osnes et al. 2019, Charalambous, O'Toole et al. 2022).

Intra-oral scanners have also been used for shade taking (Czigola, Róth et al. 2021), planning stents for use in implant surgery (Yang, Hu et al. 2022), endodontic access cavity (Zehnder, Connert et al. 2016) and endodontic surgery (Strbac, Schnappauf et al. 2017).

Some of the studies describing the advantages and disadvantages of the intra-oral scanner are listed in Table 4.3 and Table 4.4 below.

Table 4.3 Advantages of IO Scanner.

Advantages	**Studies**
Less patient discomfort	(Zimmermann, Mehl et al. 2015) (Schepke, Meijer et al. 2015) (Yuzbasioglu, Kurt et al. 2014)
Quicker and time-efficient	(Yuzbasioglu, Kurt et al. 2014, Schepke, Meijer et al. 2015)
Simplified clinical procedure	(Lee and Gallucci 2013, Zimmermann, Mehl et al. 2015)
Eliminate the need for plaster casts	(Lee and Gallucci 2013)
Improved communication with patients	(Zimmermann, Mehl et al. 2015)
Improved communication with dental technicians	(Zimmermann, Mehl et al. 2015)
Digital images can be stored indefinitely	

Table 4.4 Disadvantages of IO Scanner.

Disadvantages	**Studies**
Difficulty detecting deep margins	(Zimmermann, Mehl et al. 2015, Mandelli, Ferrini et al. 2017)
Learning curve	(Lee and Gallucci 2013, Mandelli, Ferrini et al. 2017)
Purchasing and managing costs	(Zimmermann, Mehl et al. 2015)
Some scanners need powder application onto the teeth	
Some scanner heads are large	

4.1.1.3 Digital measurements of the residual tooth structure using the intra-oral scanner

4.1.1.3.1 Number of walls remaining

Teeth can be classified as having one, two, three, four or no walls remaining, depending on the presence or absence of the mesial, distal, buccal / labial or palatal / lingual wall. Shown below is a representative image using Geomagic software (Geomagic, USA), after exporting the intra-oral scanned image to an .STL file.

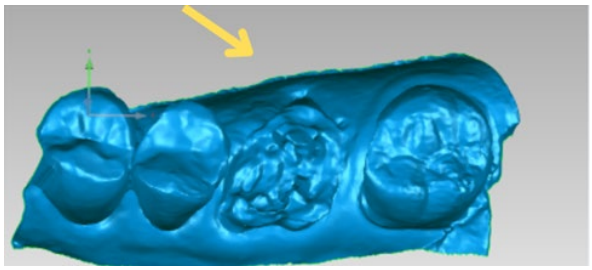


Figure 4-2 No walls remaining.

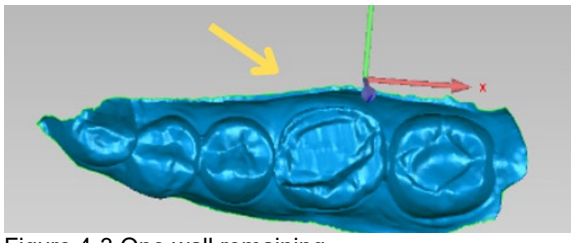


Figure 4-3 One wall remaining.

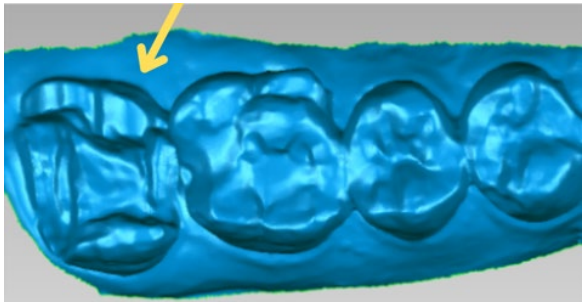


Figure 4-4 Two walls remaining.

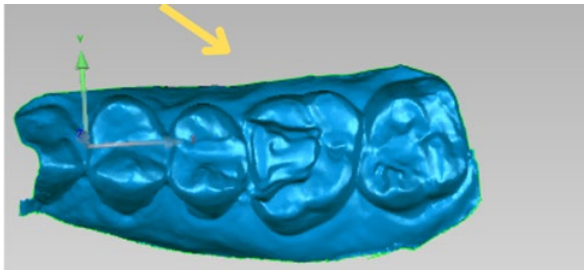
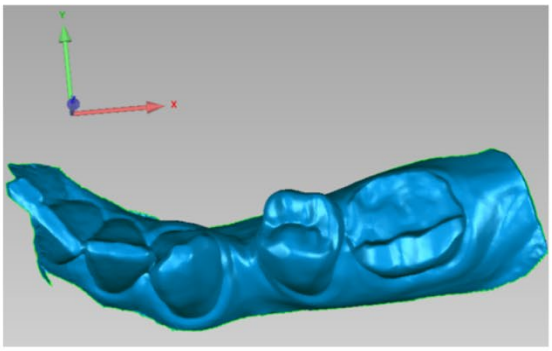


Figure 4-5 Three walls remaining.

4.1.1.3.2 Remaining dentine wall height, thickness and width of the access cavity preparation



Scanned image of a prepared tooth with one wall remaining

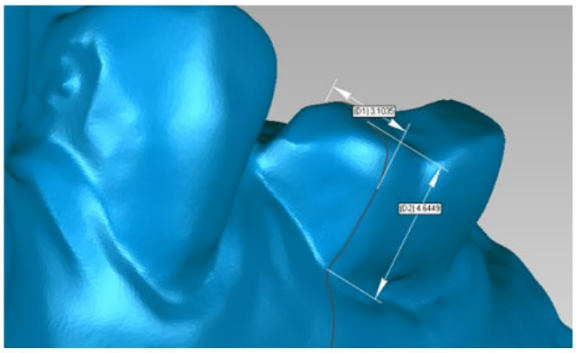


Figure shows measurements of the coronal wall height as well as wall thickness

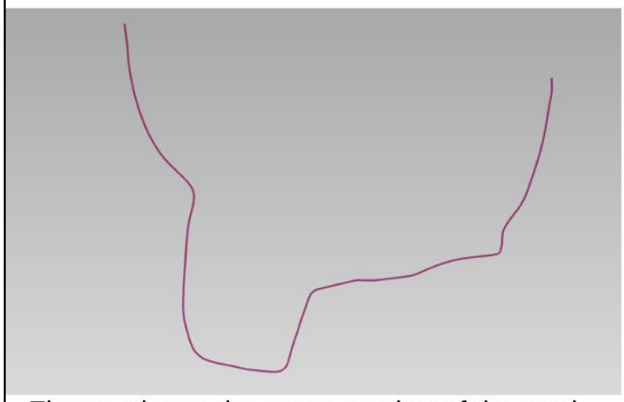


Figure shows the cross section of the tooth revealing the remaining coronal wall, wall thickness

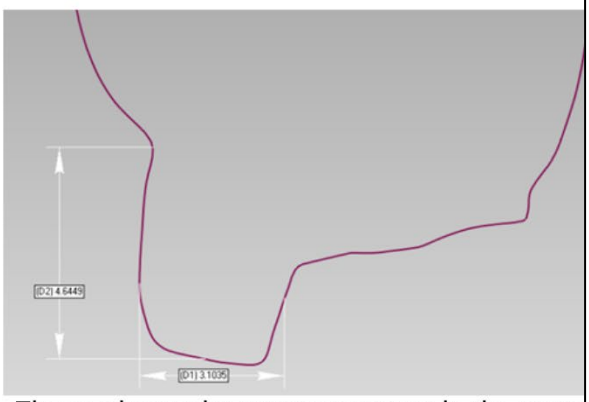


Figure shows the measurements in the cross section

QR code of animation showing digital measurements using Geomagic software

Figure 4-6 Images showing digital measurement of wall height and thickness. If the QR code is viewed though a smartphone, a video of the method of measuring wall height, thickness can be seen.

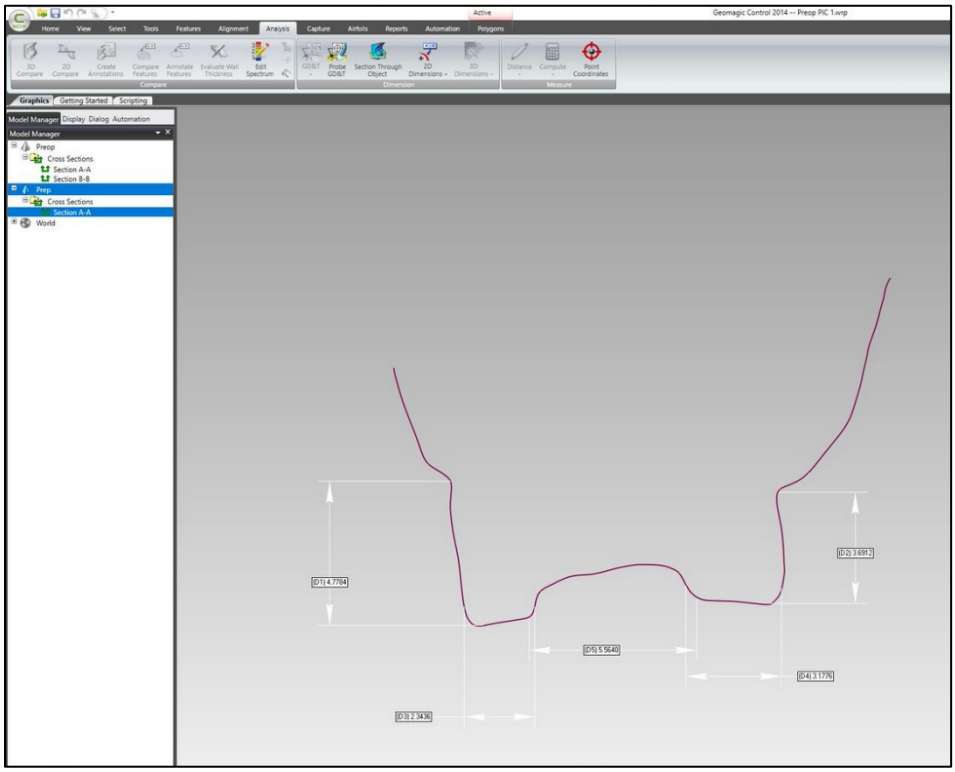


Figure 4-7 Image showing a cross-section of a scanned tooth through Geomagic software, allowing measurements of the height and width of the remaining dentine.

The importance of height and width of ferrule has been previously described (see Chapter 1) The Geomagic software allows this to be measured digitally from an intra-oral scan of the tooth (Figure 4-6,Figure 4-7). Currently we would do this using graduated probes or callipers.

4.1.1.3.3 Volume of the remaining tooth

Clinical studies assessing the volume of remaining tooth structure suggest a strong relationship between remaining tooth tissue and survival. Al-Nuaimi et al. have used digital technology in measuring residual tooth structure volume, and this was used to show that endodontically retreated teeth with less than 29.5% of remaining tooth structure were three times more likely to be extracted compared with teeth that had greater than 29.5% residual tooth structure (Al-Nuaimi, Patel et al. 2017).

4.1.2 Assessment of restorations

Studies assessing various restorations should use standardised methods and report results clearly and in a transparent manner to reduce bias. Clinical indices such as the United States Public Health Service (USPHS, Ryge) criteria, California Dental Association (CDA criteria) and Federation Dentaire Internationale (FDI criteria) have been developed to standardise the criteria for outcome measurement of dental restorations (Cvar and Ryge 2005, Hickel, Roulet et al. 2007, Hickel, Mesinger et al. 2022). The USPHS criteria and FDI criteria are the most used and will be used in our study.

4.1.3 Criteria for assessing dental restorations.

4.1.3.1.1 USPHS criteria

The USPHS evaluation system is the most widely used method for assessing the quality of dental restorations. This was developed in 1971 by Cvar and Ryge, who proposed five criteria for clinical assessment of dental restorations - colour match, cavosurface marginal discolouration, anatomic form, marginal adaptation and caries (Cvar and Ryge 2005). These criteria were developed more than 50 years ago when the longevity of restorations other than amalgam was limited. Since then, many researchers modified the USPHS criteria to compensate for the newer materials with the result we now have many versions of the modified USPHS criteria (Modified Ryge criteria). New categories such as retention, post-operative sensitivity, fracture, occlusion and others were added by different researchers and were all known as modified USPHS criteria (See Appendix P) and (Table 4.5).

For each category, score Alpha (A) is ideal, Bravo (B) is clinically acceptable, Charlie (C) indicates replacement for prevention and Delta (D) advocates the immediate replacement. Scores Alpha and Bravo are considered favourable while Charlie and Delta are considered unfavourable.

Table 4.5 Modified USPHS criteria for clinical evaluation of dental restorations.

Category	Rating and characteristics A: Alpha, B: Bravo, C: Charlie, D: Delta	Baseline	One-year follow-up
Anatomical form	A: Restoration's contour is continuous with existing anatomical form and margins B: Restoration is slightly over-contoured or under-contoured C: Marginal overhang or tooth structure (dentine or enamel) is exposed D: Restoration is missing, traumatic occlusion or restoration causes pain in the tooth or adjacent tissue		
Secondary caries	A: No visible caries C: Caries contiguous with the margin of the restoration		
Retention	A: Present B: Partial loss C: Absent		
Marginal adaptation	A: Excellent continuity at resin–enamel interface; no ledge formation, no discolouration B: Slight discolouration at resin–enamel interface; ledge at the interface C: Moderate discolouration at resin–enamel interface measuring 1mm or greater D: Recurrent decay at the margin		
Polishability	A: Smooth and highly shiny, similar to enamel B: Smooth and satin, highly reflective C: Rough and shiny, satin, somewhat reflective D: Rough and dull or satin, not reflective		
Surface staining	A: Absent C: Present		
Sensitivity	Pre-operative sensitivity (yes/no) Post-operative sensitivity (yes/no)		
Soft tissue health	A: Excellent response, no inflammation B: Slight inflammation of gingival tissue C: Moderate to severe gingival inflammation		
Proximal contact points	A: Present C: Absent		

Most of the restorations using these criteria received alpha scores at six-, 12- and 18-month follow-ups. In many cases, the lack of sensitivity of the USPHS criteria is misinterpreted as good clinical performance. Thus, the lack of sensitivity, continuous modifications of the USPHS criteria, non-standardised categories, scales and reporting have led to a volume of studies that are difficult to interpret. There was thus a need for more sensitive criteria for assessing early deteriorations and differences between restorations and techniques.

4.1.3.1.2 FDI criteria

To detect early deterioration and signs of failure, a more sensitive scale than the modified USPHS scale was required. This led to the development of the FDI criteria developed by Hickel et al.(Hickel, Roulet et al. 2007) , based on three criteria: aesthetic, functional and biological (see Appendix R). Each category is subdivided into sub-categories that allow detailed description and analysis. Each sub-category is scored according to five-step grading of the restoration with scores one to three being clinically acceptable, scores four and five unacceptable, with score four requiring at least repair and score five a complete replacement. There are a total of 16 evaluation criteria.

The FDI criteria were recommended for clinical trials to assess restorations, and restorative techniques, and as a clinical guideline to determine if restoration can be maintained, repaired or replaced. The authors have outlined investigators do not need to use all 16 categories and instead select the appropriate criteria for their study and that the scoring could be reduced from five steps to a lower scale, even up to a favourable and unfavourable restoration.

The FDI criteria has since been revised first in 2010 and then again in 2022 (Hickel, Mesinger et al. 2022). A review paper highlighted an increased use of FDI assessment in clinical trials jumping from 4.5% use in 2016 to 50% in 2020.

4.2 Aims and objectives.

The aim of this prospective restorative outcome study is:

- to assess the success and survival of CAD-CAM-generated onlays and crowns after one year of clinical service.

The objectives of the study are:

- to use digital 3D data using intraoral scanner to compare success with different measures of residual tooth structure.
- to assess the clinical performance of CAD CAM generated nanohybrid ceramic onlays and full crown on endodontically treated teeth using the modified USPHS and FDI criteria.

4.3 Materials and methods

4.3.1 Study design

This was a prospective cohort study investigating the outcome of endodontically treated teeth that were restored using CAD-CAM-generated onlays and crowns made of a nanohybrid ceramic material (Cerasmart, GC, Japan). Both the endodontic outcome (Chapter 3) and clinical performance of the restoration were assessed and analysed (Chapter 4).

4.3.2 Ethical approval and trial registration

See Chapter 3 (section 3.3.2)

4.3.3 Sample size and power calculation

Sample size and power calculations were described in Chapter 3 (section 3.4)

4.3.4 Patient selection

See Chapter 3 (section 3.3.3)

4.3.5 Inclusion and exclusion criteria

See Chapter 3 (section 3.3.3)

4.3.6 Restorative procedure

All the teeth underwent root canal treatment in one or two visits (see Chapter 3). The teeth were then restored using a CAD-CAM (Planmeca, Finland) system to manufacture onlays and crowns made of Cerasmart (GC, Europe).

One operator prepared, fabricated, and placed all the restorations in one appointment. The tooth was prepared for a nanohybrid ceramic onlay or crown (Cerasmart, GC Europe) with about 1.5-2.0 mm occlusal depth, 1.0 mm to 1.5mm axial thickness, rounded internal line angles, the divergence of 12 degrees (six for each wall). The functional cusp was reduced by 2mm and the non-functional cusp by 1.5mm. When the remaining wall thickness was less than 1.5mm, it was reduced. The gingival margin was placed in enamel whenever possible. The most conservative preparation possible was done.

The decision when to prepare for an onlay and when to prepare for a crown was made clinically. In general, preference was given to the most conservative solution (onlay).

After preparation, the tooth was isolated using optragate (Ivoclar Vivadent, Schaan, Liechtenstein).

Retraction cord (Ultrapak, Ultradent) or paste (3M astringent paste) were used for tissue retraction and haemostasis (Figure 4-8, Figure 4-9).

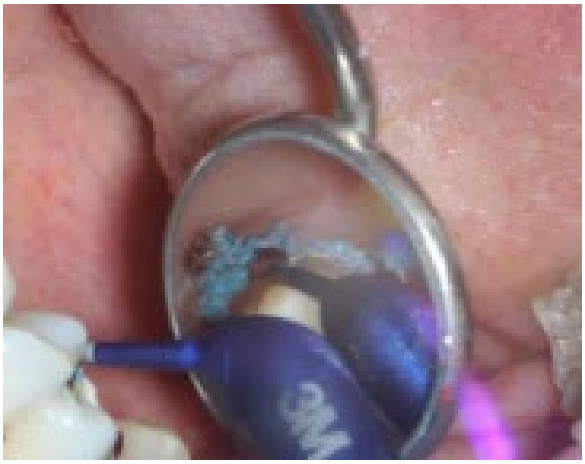


Figure 4-8 Tissue retraction, haemostasis using astringent paste. (3M Astringent Paste)

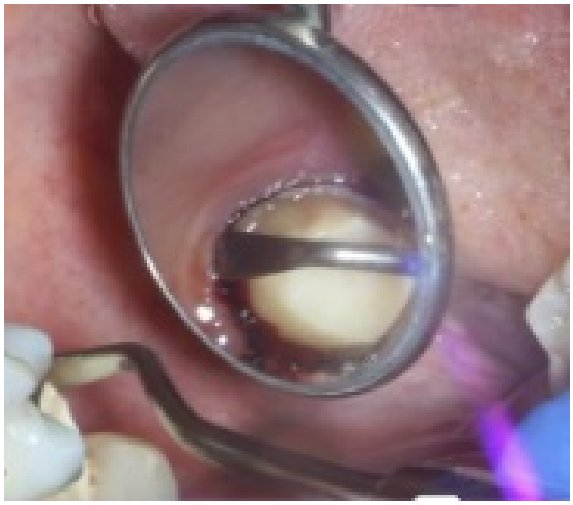


Figure 4-9 Tissue retraction, haemostasis using retraction cord. (Ultradent)

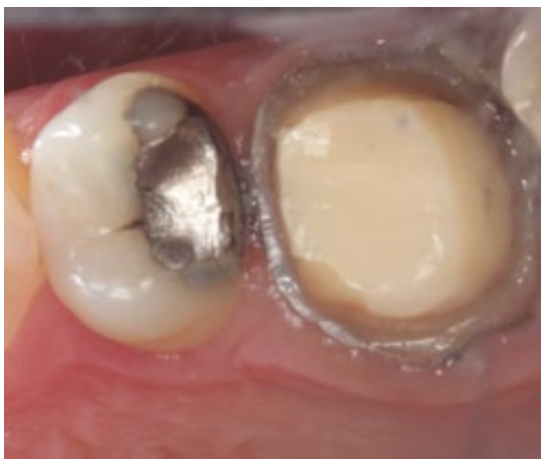


Figure 4-10 Prepared tooth ready for intra oral scan

The prepared tooth and corresponding antagonists were scanned using Planscan (Planmeca, Finland) (Figure 4-10, Figure 4-11).

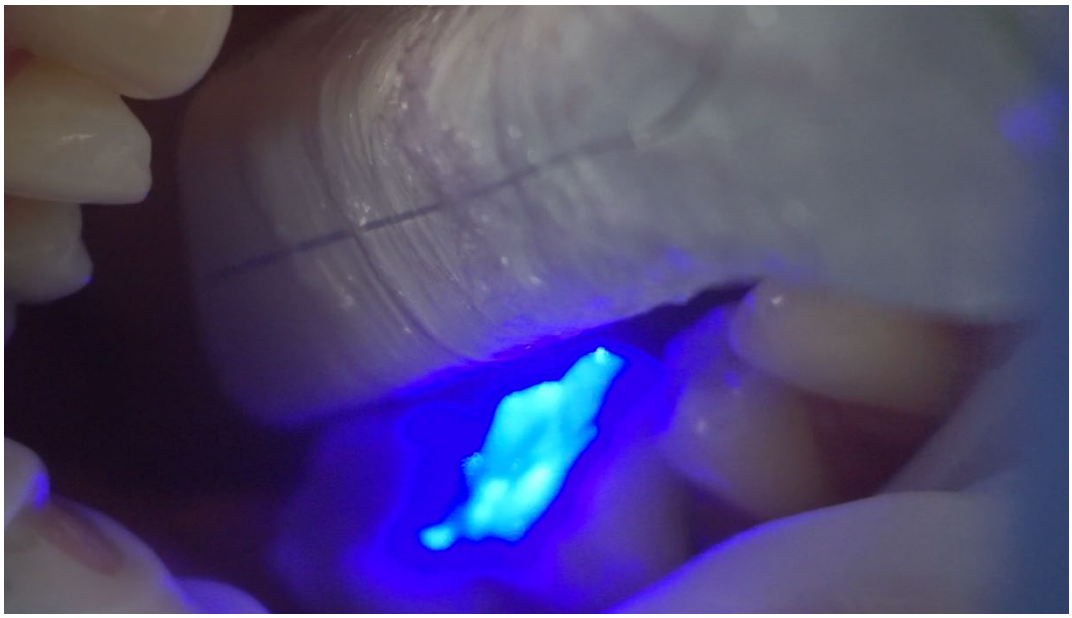


Figure 4-11 Lower teeth being scanned by the intraoral scanner.

The buccal bite was scanned for the registration of the occlusal relationship (Figure 4-12).

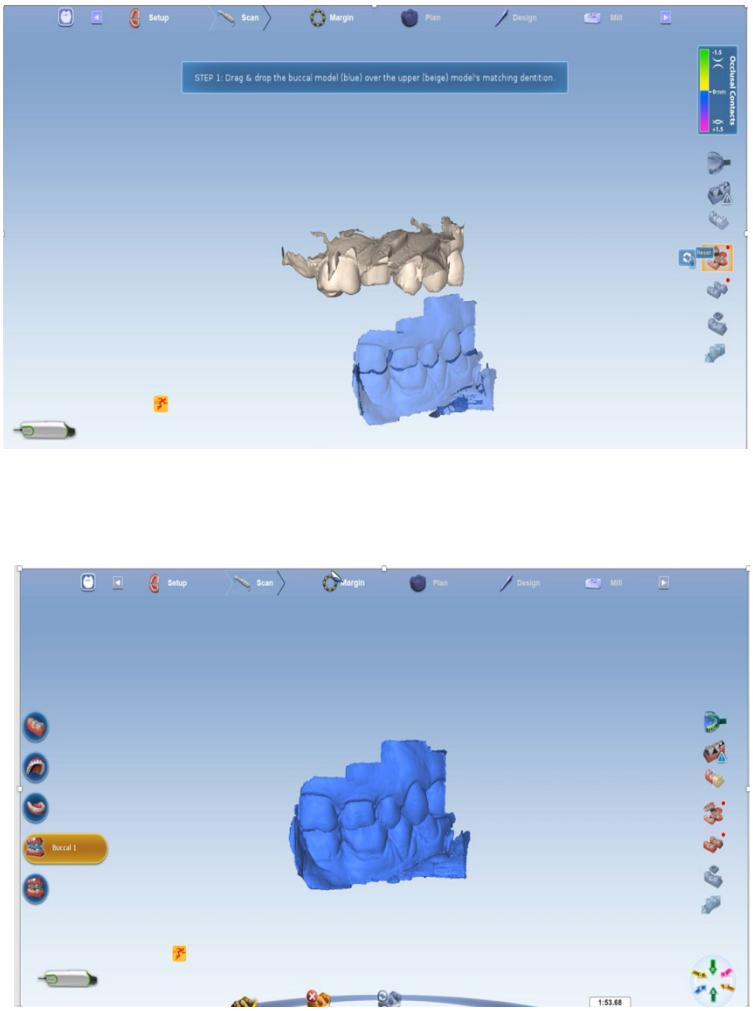


Figure 4-12 Buccal bite registration

The restorations were designed using Romexis and milled using Planmill from Cerasmart blocks (Figure 4-13).

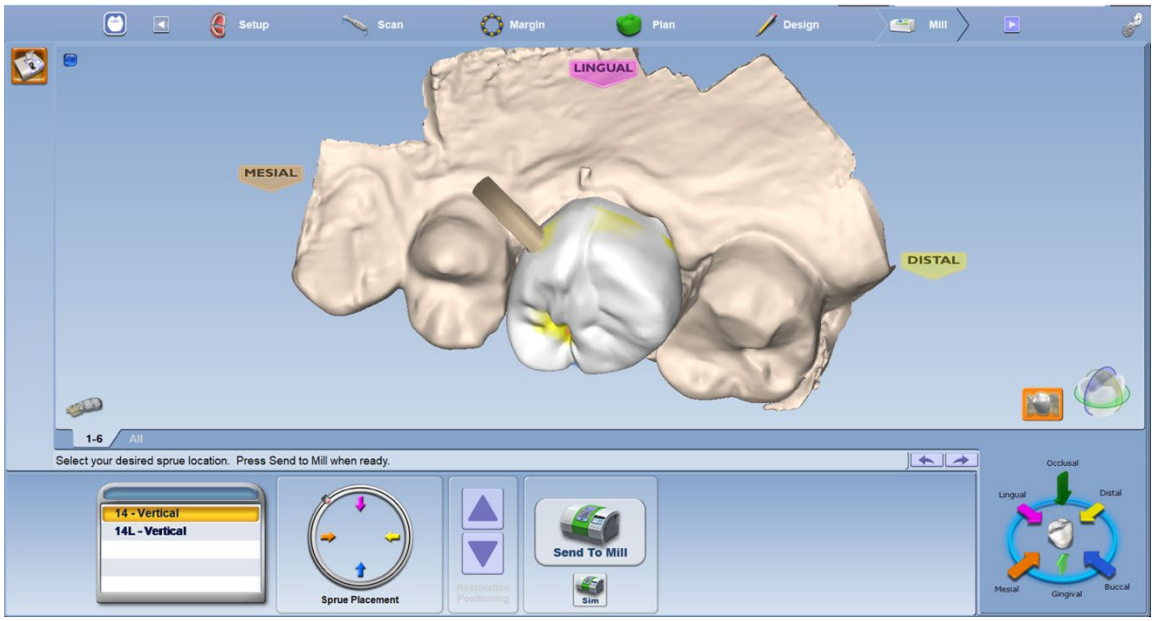
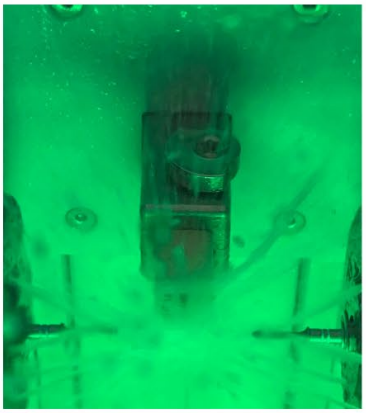
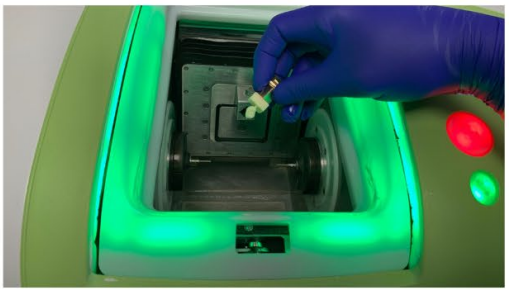


Figure 4-13 CAD CAM designed crown ready to be milled.

Using the Romexis software for computer aided design of the restoration



Computer aided manufacture of the restoration (above and below left) and the milled restoration (below right)



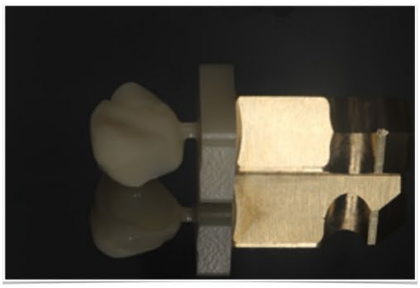


Figure 4-14 Designing and milling the CAD-CAM restoration.

After procuring the restoration from the milling chamber (Figure 4-14), the sprue was trimmed off, and proximal contacts and the fit were checked, corrected, and polished. A bitewing radiograph was taken to check the fit (Figure 4-17).

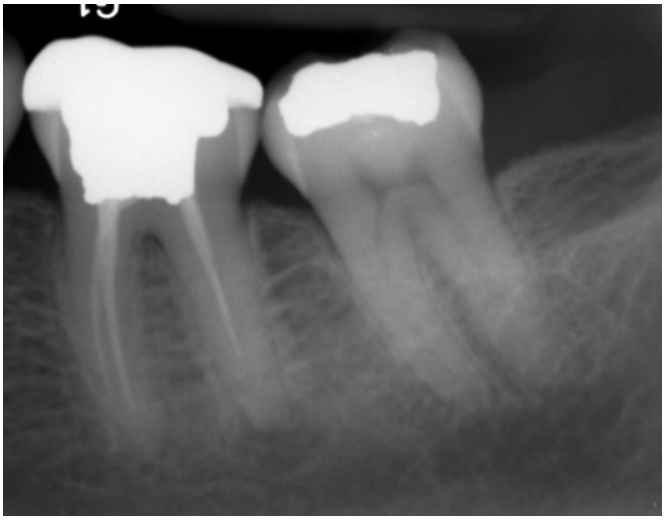


Figure 4-15 Pre-op radiograph of a failing root canal treatment with an amalgam core.

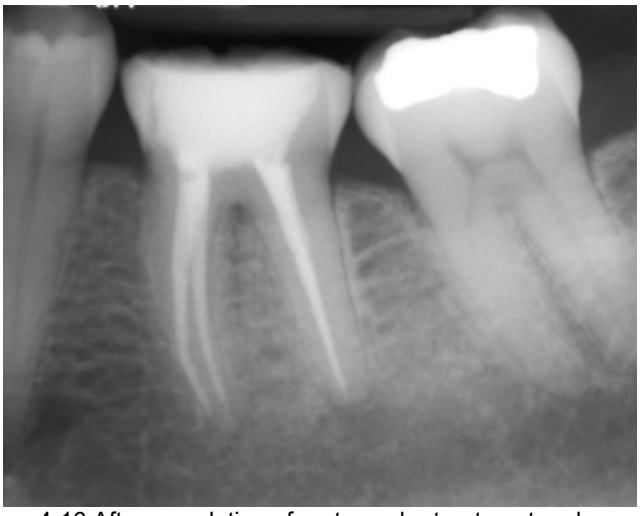


Figure 4-16 After completion of root canal retreatment and a composite core.

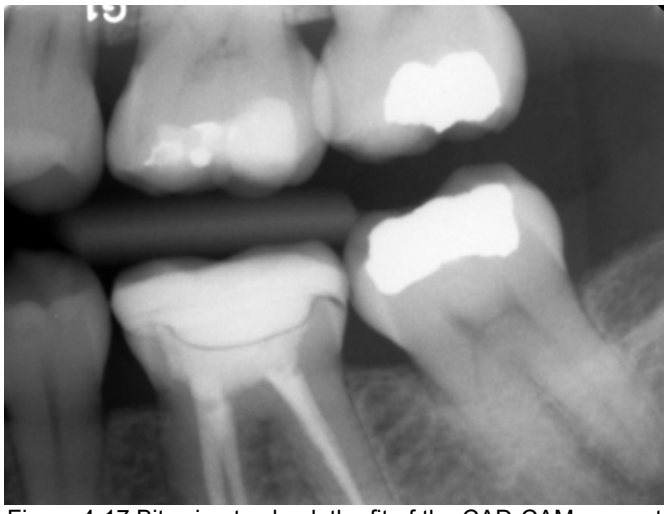


Figure 4-17 Bitewing to check the fit of the CAD-CAM generated onlay.

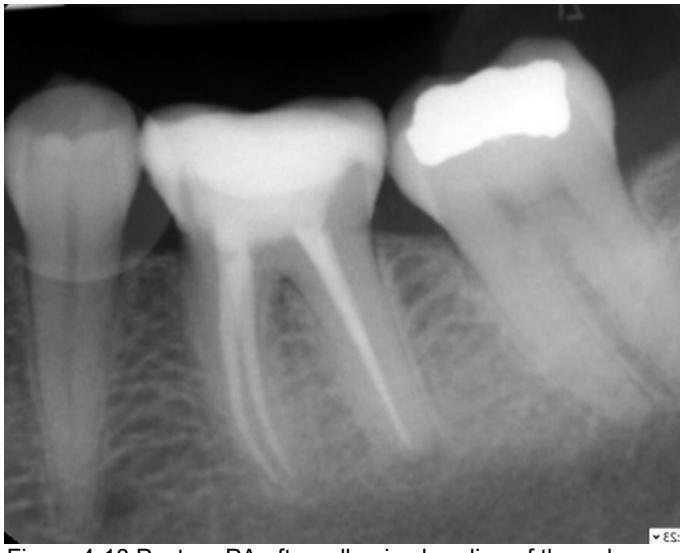


Figure 4-18 Post-op PA after adhesive bonding of the onlay

4.3.7 Luting procedure

After try in, the restorations were wiped clean, the fitting surface was sandblasted using a chair-side sandblaster using alumina oxide particles, and then silanated. The tooth was isolated using Optragate (Ivoclar Vivadent, Schaan, Liechtenstein), its surface was cleaned using 32% phosphoric acid, etched for 10 seconds, rinsed with water and gently dried. The prepared surfaces were treated with enamel-dentine adhesive. Relyx Unicem, a self-adhesive resin cement was used to bond the restoration to tooth (Figure 4-19).

The excess resin cement was removed using a micro brush and dental floss. The restorations were light polymerised for two seconds with occlusal directed pressure. The remaining excess cement was removed, and light polymerised for 40 seconds. The occlusion was checked and refined if needed; the surfaces were polished.

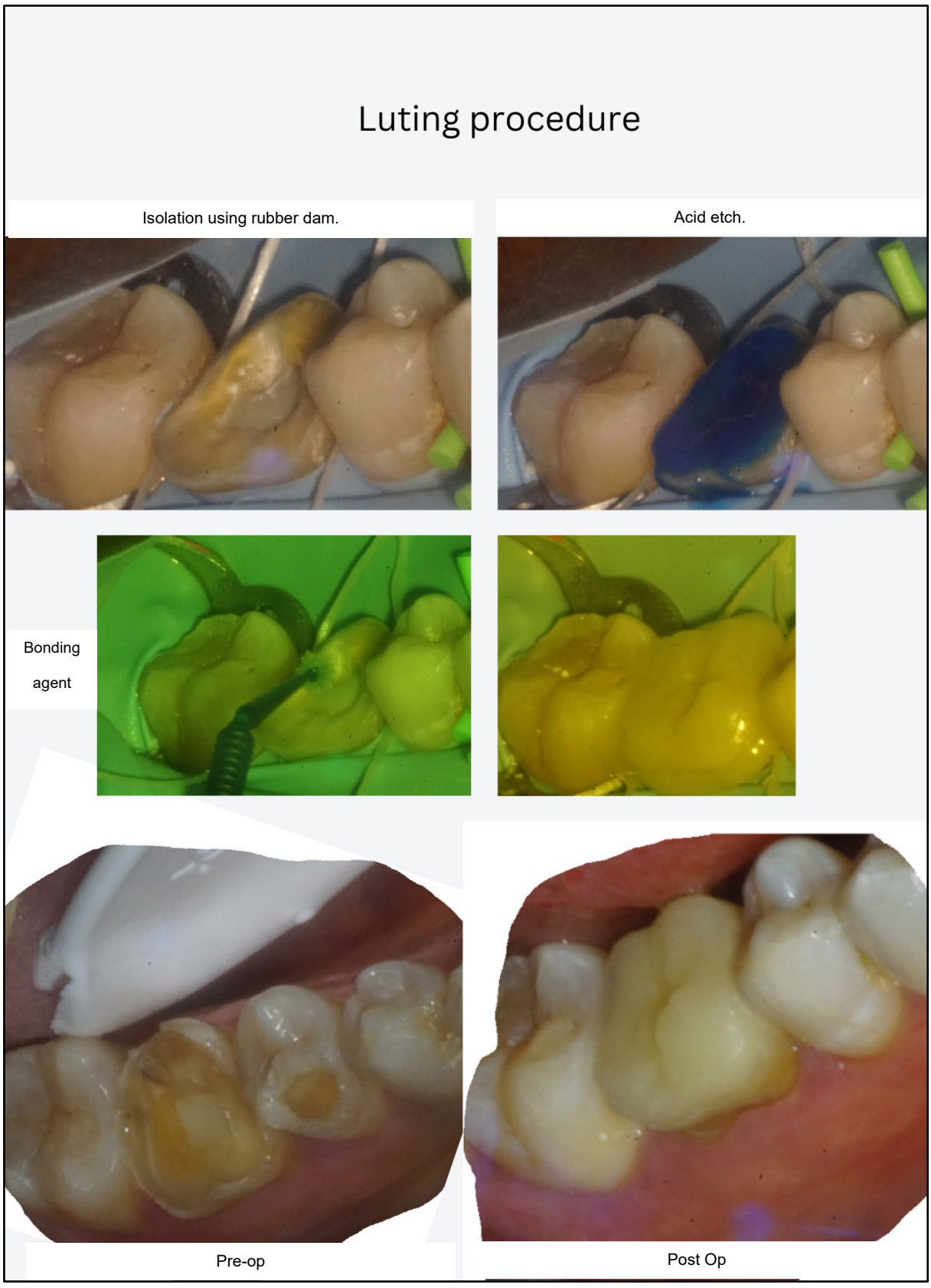
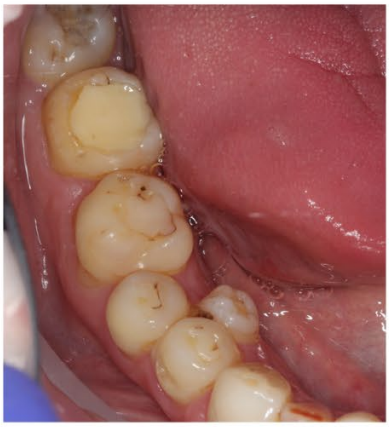
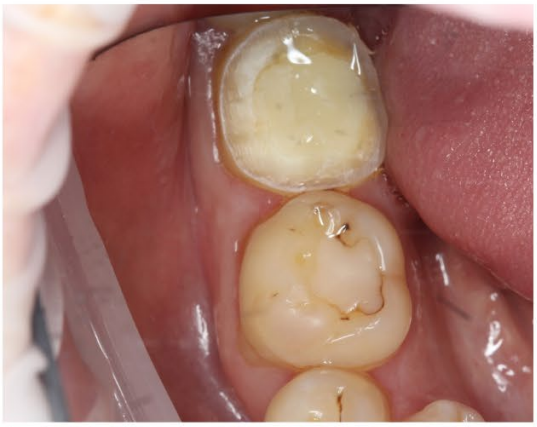


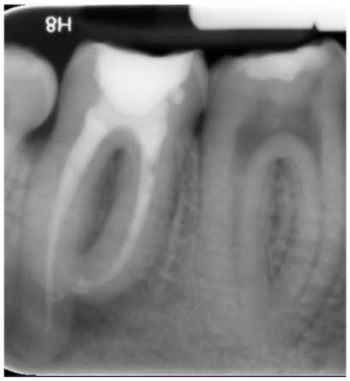
Figure 4-19 Luting procedure.

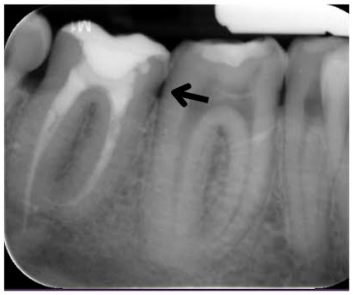


a. Pre op view LR7



b. LR7 prepared for an onlay





d. Before and after radiographs showing the bonded onlay. Notice the preservation of the cervical dentine (arrow)

c. Milled out onlay (above) and bonded to the tooth (below)

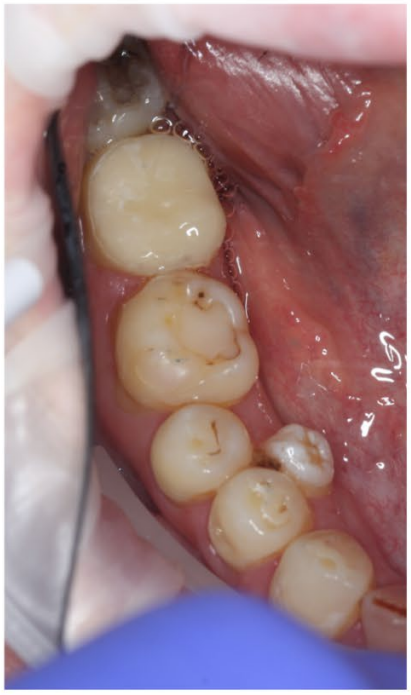


Figure 4-20 Images from an onlay restoration for LR7

4.3.8 Clinical and radiologic examination

A post-operative intra-oral scan was recorded and a baseline assessment of the restoration using modified USPHS and FDI criteria was made.

The intra and postoperative radiographs of the intraoperative procedures are shown in (Figure 4-15, Figure 4-16, Figure 4-17, Figure 4-18).

4.3.9 Patient recall

All patients were scheduled for recall one year after placement of the restoration. They were also provided with contact details in case of issues such as restoration fracture, debonding or pain. All patients were contacted by telephone. In case there was no response after three repeated attempts, a letter was mailed to the patients informing them of the need for the follow-up and to attend the same.

4.3.10 Follow-up assessment

All patients who attended the recall were examined by two specialists: one in prosthodontics and one in endodontics. At the recall appointment, the restorations were assessed using the modified USPHS and FDI criteria.

4.3.11 Evaluation

4.3.12 Digital evaluation of restorability parameters using an intra-oral scanner

The teeth were scanned using an intra-oral scanner (Planscan, Planmeca, Finland) at baseline (after removal of caries and restoration), after preparation for onlay or crown and after the fit of the restoration. The recall scans were undertaken at one-year.

The scans were exported as .STL files to Geomagic software (Geomagic, USA) and the analysis was done using this software (see section 4.1.1.3 for a description of the methods of digital measurements).

The following variables were digitally measured:

Number of walls remaining

Width of dentine wall

Height of dentine wall

Width of access cavity preparation

Volume of the remaining tooth

4.3.13 Evaluation of restorations using modified USPHS and FDI criteria

The restorations were evaluated using the modified USPHS criteria as well as the FDI criteria.

Two calibrated examiners other than the operator assessed the restoration and a consensus score was provided for each category.

The modified USPHS system has 10 criteria, but only eight were applied for the present sample. Colour match (only Shade A2 blocks were used) and sensitivity (not relevant on ETT) were not scored.

The scale for modified USPHS ranged through Alpha, Bravo, Charlie and Delta.

A: Alpha: represented the ideal clinical situation.

B: Bravo was considered clinically acceptable.

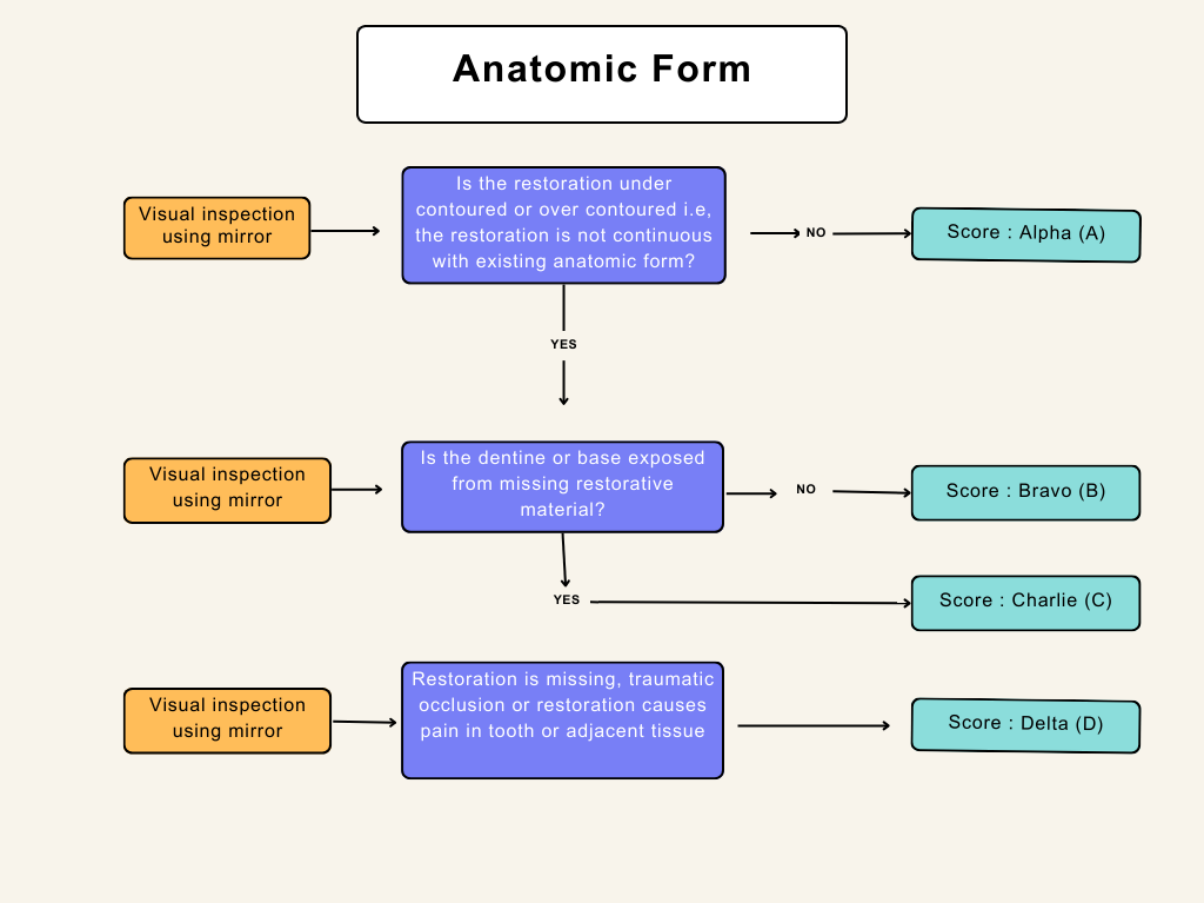
C: Charlie: restorations were recommended to be replaced for preventing further breakdown.

D: Delta: restorations were recommended for immediate replacement.

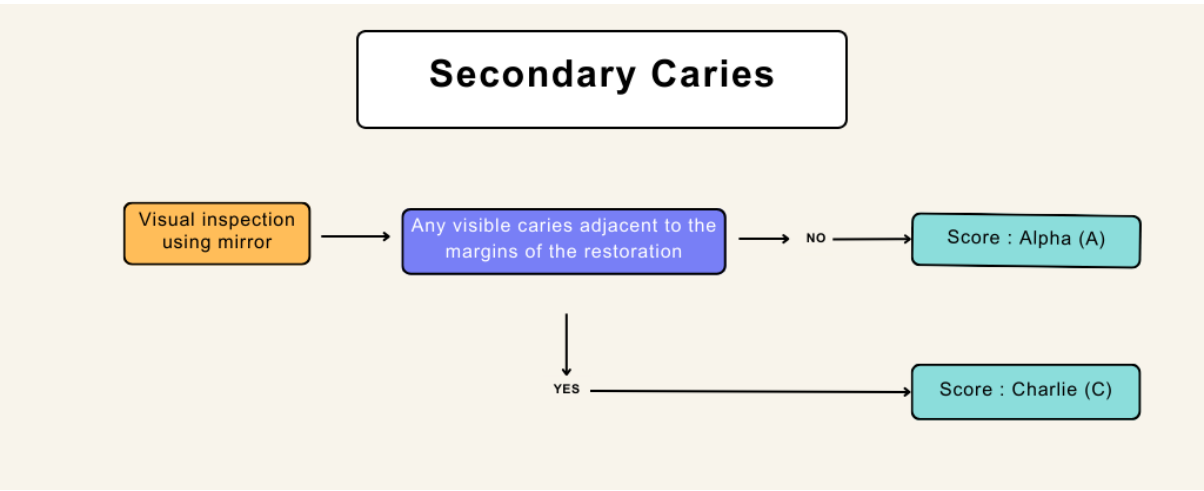
Scores A and B were considered favourable outcomes while scores C and D were considered unfavourable outcomes.

4.3.14 Method of evaluation using USPHS

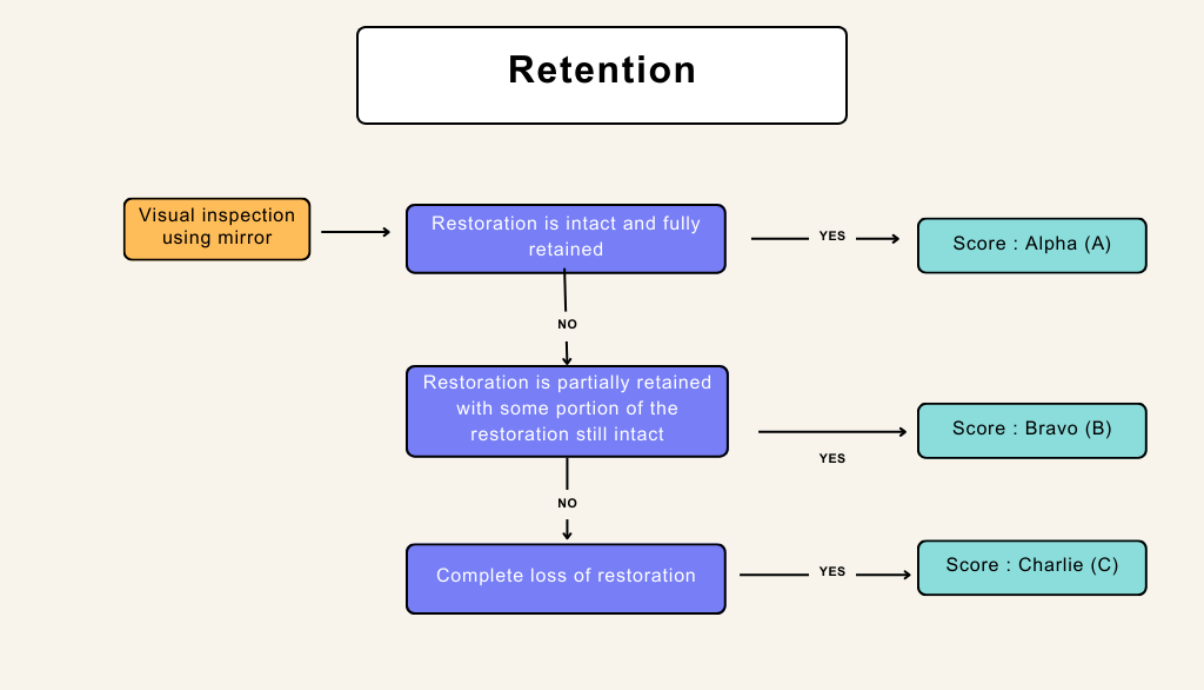
4.3.14.1 Anatomic form



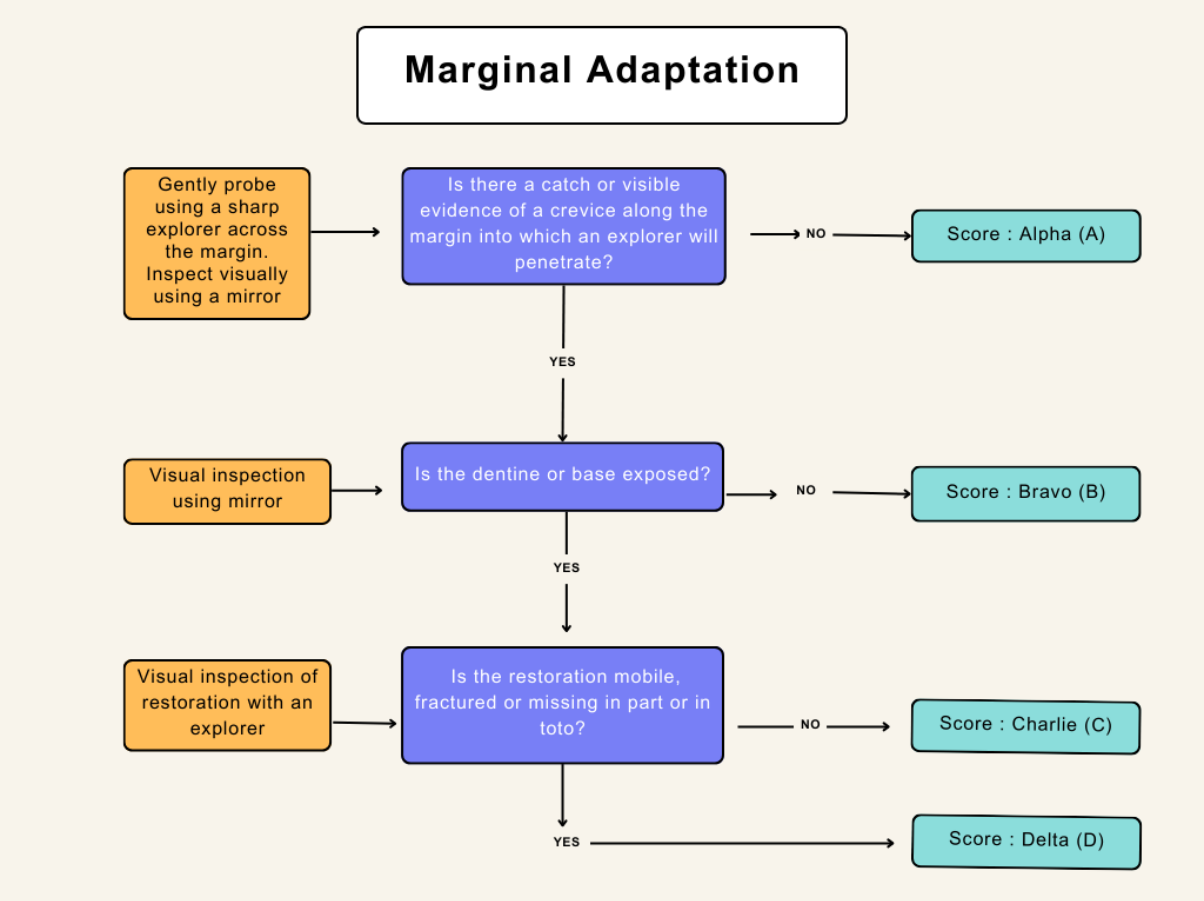
4.3.14.2 Secondary caries



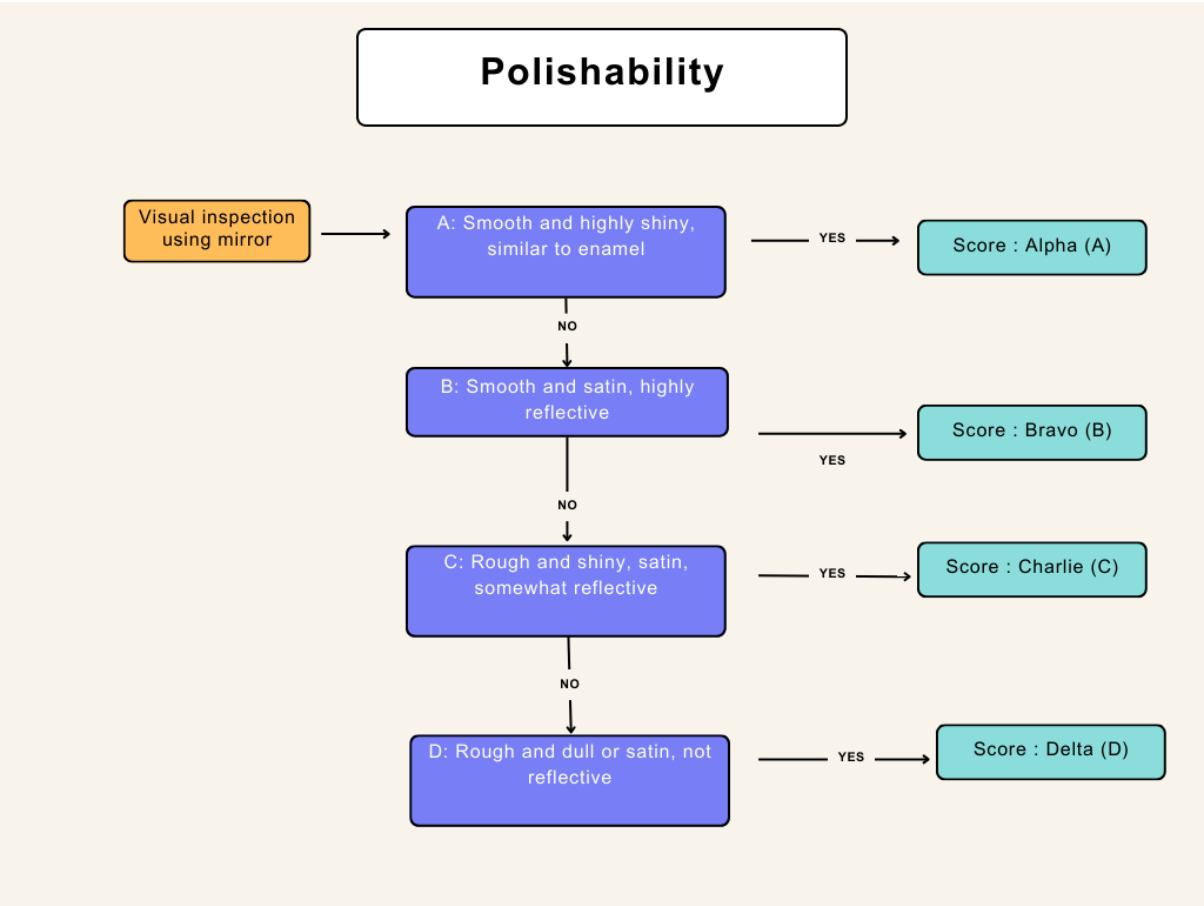
4.3.14.3 Retention



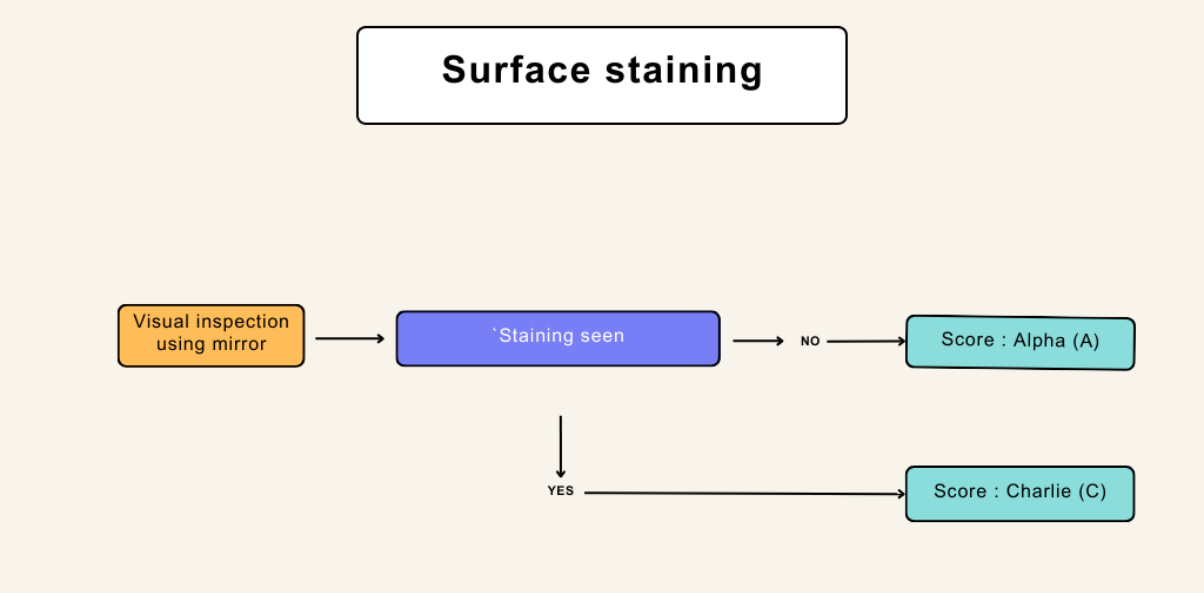
4.3.14.4 Marginal adaptation



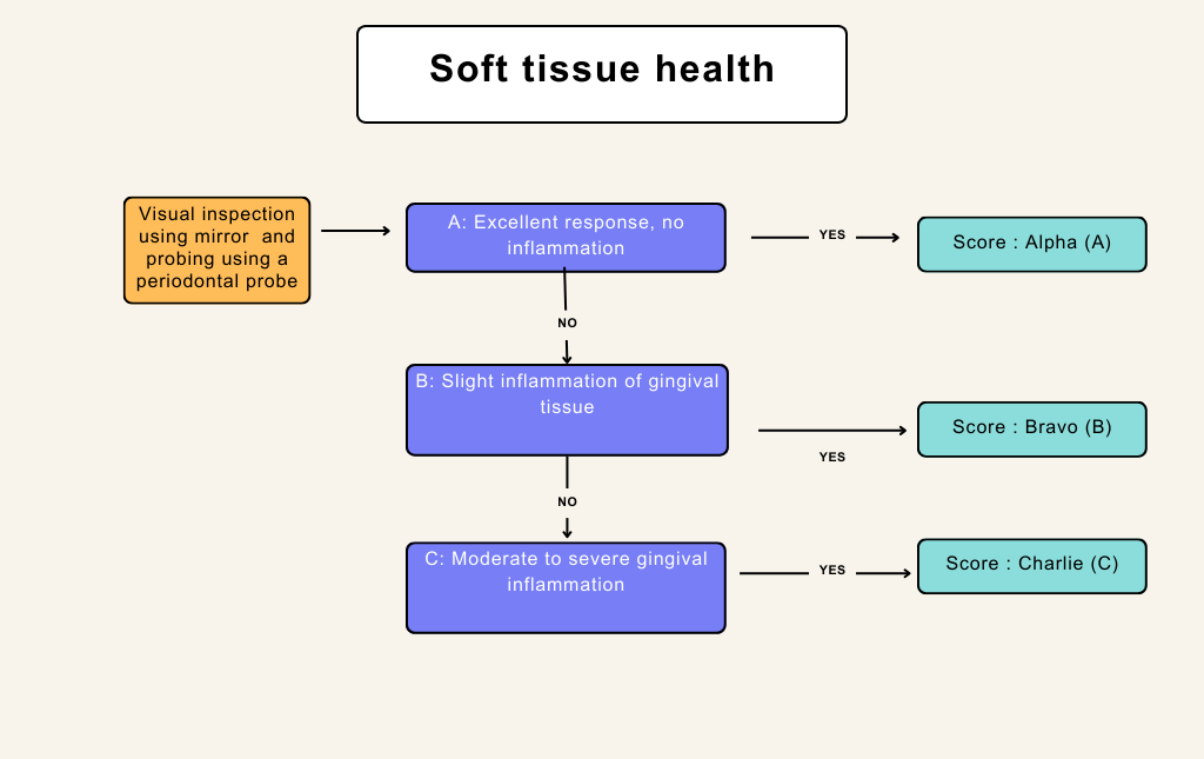
4.3.14.5 Polishability



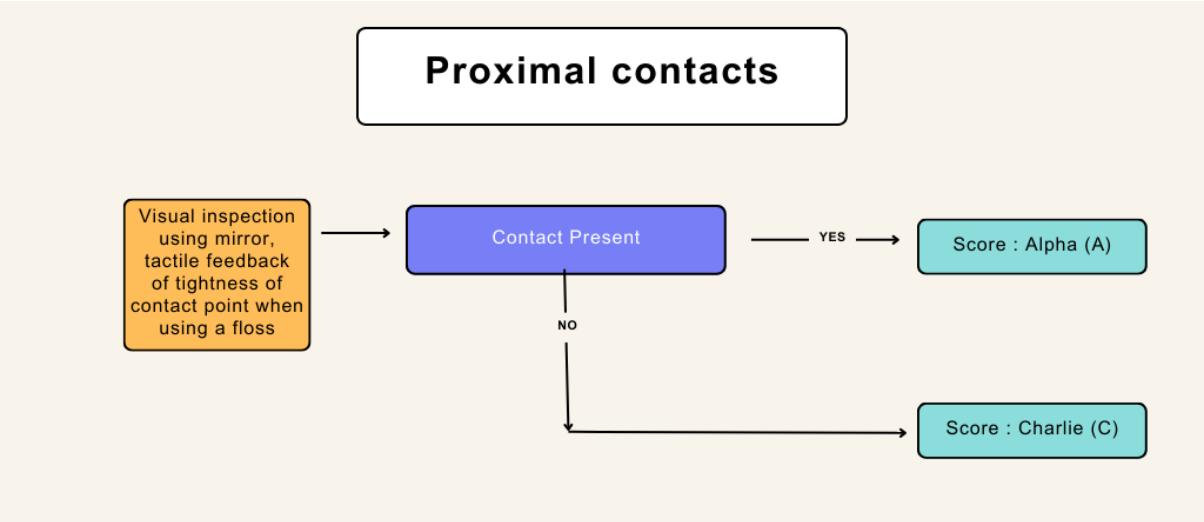
4.3.14.6 Surface staining



4.3.14.7 Soft tissue health



4.3.14.8 Proximal contact points



4.3.15 Method of evaluation using the FDI criteria

Similarly, the scoring was done for the same group using the FDI criteria. (See Appendix R).

4.4 Statistical analysis

4.4.1 Statistical analysis of factors assessment restorability

All the analysis was carried out using IBM SPSS software (SPSS Version 23, IBM). The significance level was set at 5% ($\alpha = 0.05$).

Statistical analysis for restorability assessment consisted of a descriptive analysis of categorical and ordinal variables using absolute and relative frequencies.

The inferential statistics used a simple binary logistic regression. The association between the different independent variables and outcome was assessed using binary logistic regression models. Non-adjusted odd ratio (OR) and 95% confidence interval were obtained. This was followed by a multivariate binary logistic regression model selecting the significant variables ($p<0.1$) obtaining adjusted OR.

4.4.2 Statistical analysis of restorations

Statistical analysis of restorations consisted of a descriptive analysis that described the categorical and ordinal variables using absolute and relative frequencies.

The inferential analysis used Wilcoxon's test to compare the distribution of scores for each criterion at baseline and one-year recall for the overall samples and then for onlays and crowns.

Mann-Whitney's U-test was used to compare the distribution of scores between onlays and crowns at baseline and at one-year recall.

McNemar's test was used to assess the proportion of favourable and unfavourable outcomes from baseline to one-year recall for all the samples and then for onlays and crowns.

Fisher's Exact test was used to assess if any relationship existed between unfavourable and favourable outcomes comparing onlays and crowns at one-year recall.

The level of significance was set at 5% (α=0.05).

All two-pair comparisons between baseline and one-year recall as well as between overlays and crowns were adjusted by Bonferroni's criteria.

4.4.3 Definition of success, failure, survival

The restorative outcome was classed as: -

Absolute failure if the tooth had been extracted.

Relative failure if the tooth could be restored following the fracture of the restoration.

Success if the tooth and restoration were intact.

4.5 Results

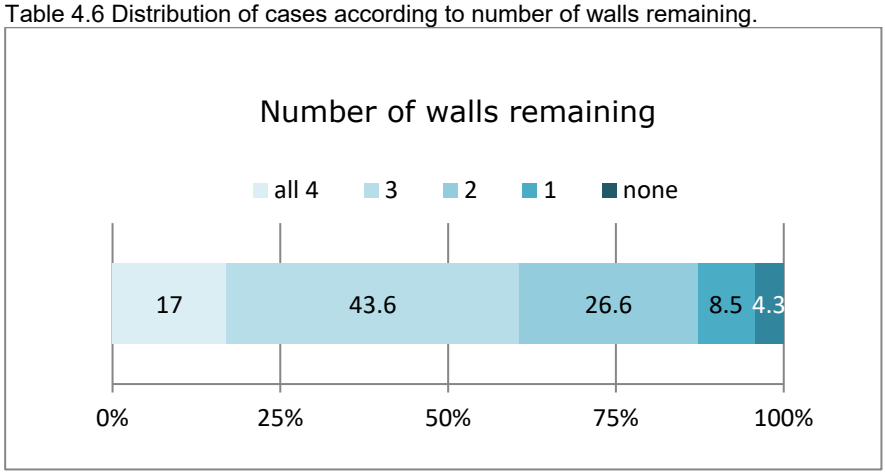
4.5.1 Results for digital assessment of restorability

A total of 124 ETT were restored in 99 patients using a CAD-CAM-generated onlay or full crown. Six teeth were not restored using onlays or crowns and had to be left with a direct composite filling restoration due to the closure of clinics because of Covid-19.

There was a total of 38 male patients (38.4%) and 61 female patients (61.6%), with an average age of 42.7±13.1 years and a range of 22-77 years. 56 of these patients were Caucasians (57.1%), 19 of Afro-Caribbean origin (19.4%), and 20 were of Asian origin (20.4%).

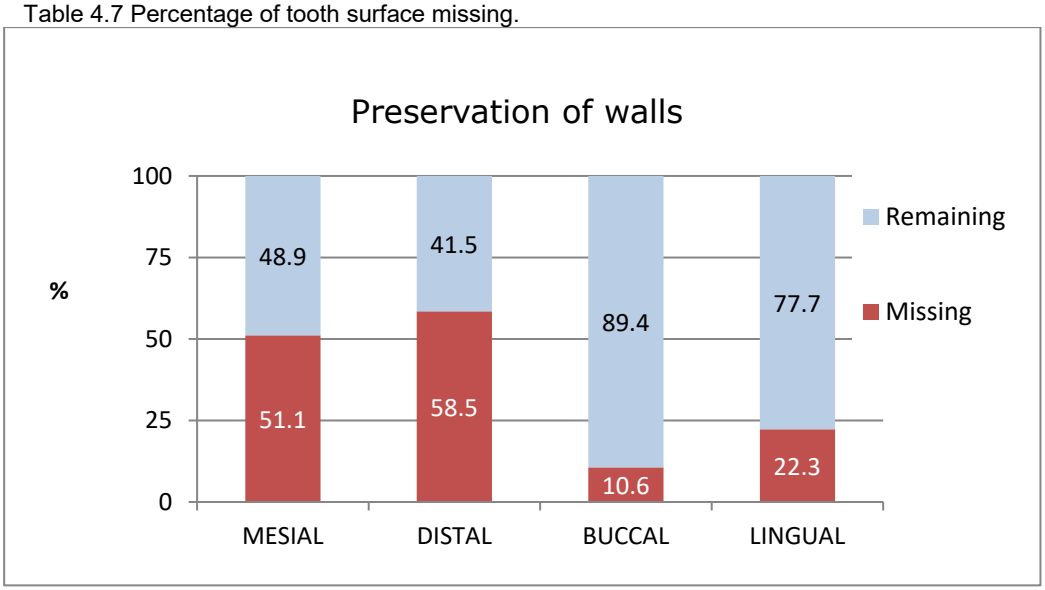
Of the 124 teeth, 62 teeth (50%) were on the upper jaw and 62 teeth (50%) were on the lower jaw. There were eight pre-molars (6.4%) and 116 molars (93.6%). 89 teeth were first molars, 28 teeth (22.4%) were second molars, seven teeth (5.6%) were second pre-molars, and one was a first premolar (0.8%).

Table 4.6 Distribution of cases according to number of walls remaining.



There were 17% of teeth with all four walls remaining, 43.6% with three walls remaining, 26.6% with two walls remaining, 8.5% with one wall remaining and 4.3% with no walls remaining (Table 4.6).

Table 4.7 Percentage of tooth surface missing.



From the analysed samples, 51.1% of the samples had missing mesial marginal ridge, 58.5% distal marginal ridge, 10.6% buccal wall and 22.3% palatal or lingual wall (Table 4.7).

4.5.1.1 Restorative Outcome

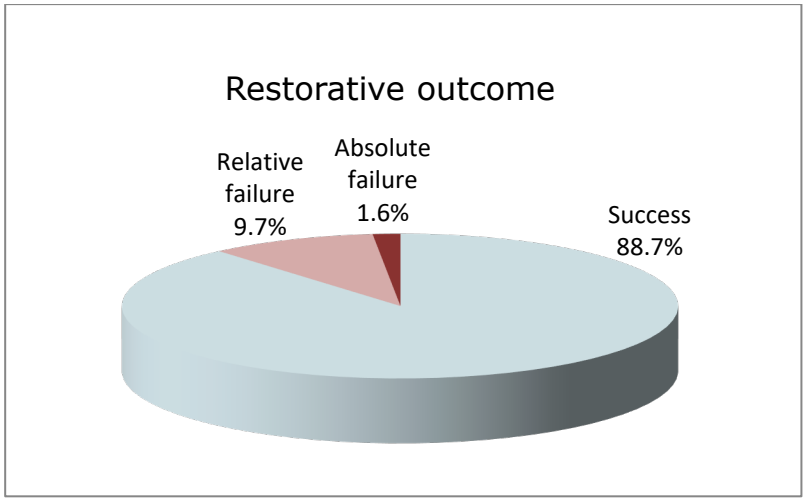


Figure 4-21 Restorative outcome.

The overall survival of teeth and restorations was 98.4%. The success rate was 88.7% (95%CI: 83.1-94.3%). Eleven teeth (9.7%) had a relative failure as the restorations displayed minor fractures and could be repaired (Figure 4-21).

Two teeth (1.6%) restored with full crowns were extracted following a catastrophic fracture of the tooth and were classified as absolute failures.

4.5.1.2 Effect of variables on the outcome of restoration and tooth

The restorative outcome was dichotomised as success or failure (absolute plus relative). Demographic and clinical variables were assessed using a simple binary logistic regression analysis. (Table 4.8).

Table 4.8 Association between restorative outcome and independent variables: Results of simple binary logistic regression model using GEE for the probability of success. Non-adjusted odds ratio (OR) and 95% confidence interval. Chi 2 test or Mann-Whitney test when OR was not computable.

Independent variables	Number of samples by the patient (%) or mean ± standard deviation	Number of samples by teeth (%) or mean ± standard deviation	Failure	Success	OR	CI 95%	p-value
Gender	99	124	14 (11.3)	110 (88.7)			
Male	38 (38.4)	52	8	44	1		
Female	61	72	6	66	1.09	0.97-1.23	0.151
Age	42.7 ± 13.1	14		110	1.00	0.99-1.01	0.742
Ethnicity	98	124	14	110			0.757
Caucasian	56	66	6	60	1		
Afro-Caribbean	19	27	4	23	0.95	0.82-1.10	0.471
Asian	20	26	4	22	0.97	0.84-1.13	0.721
Others	3	5	0	5			
Medical history	94	120	14	106			
Healthy	55(58.5)	70	8	62	1		
Systemic involvement	39 (41.5)	50	6	44	0.97	0.86-1.08	0.546
Smoking	97	122	14	108			0.481 (Chi^2)
No	79 (81.4)	96	12	84			
Yes, current	11 (11.3)	15	2	13			
Former	7(7.2)	11	0				
Tooth type	124	124					
Premolar	8	8(6.4)	0				
Molar	116	116(93.6)	14	110			0.305 (Chi^2)
Arch	124	124					
Maxilla	62	62 (50)			1		
Mandible	62	62(50)			0.92	0.82-1.03	0.128
Number of walls remaining	89	94	14	80			0.254 (Chi^2)
No walls remaining	4 (4.5)	4	0	4			
One wall remaining	8 (9)	8	2	6			
Two walls remaining	23 (25.8)	25	3	22			
Three walls remaining	38 (42.7)	41	9	32			

Four walls remaining	16 (18)	16	0	16			
Mesial wall		94	14	80			
Missing	46 (51.7)	48	5	43	1		
Remaining	43 (48.3)	46	9	37	0.98	0.86-1.12	0.729
Distal wall		94	14	80			
Missing	50 (56.2)	55	13	42	1		
Remaining	39 (43.8)	39	1	38	1.15	1.02-1.29	**0.021***
Buccal wall		94	14	80			
Missing	10 (11.2)	10	0	10			
Remaining	79 (88.8)	84	14	70			0.278 (Chi^2)
Lingual wall		94	14	80			
Missing	21 (23.6)	21	4	17	1		
Remaining	68 (76.4)	73	10	63	1.13	0.94-1.37	0.199
Marginal ridge missing		74	14	60			0.204
Mesial missing	23 (33.3)	23	1	22	1		
Distal	27 (39.1)	30	9	21	0.87	0.73-1.04	0.121
MOD	19 (27.5)	21	4	17	0.89	0.73-1.08	0.234
Wall thickness							
WTM	2.15 ± 0.92	43	8	35	0.93	0.86-1.01	0.079
WTMB	2.90 ± 0.71	85	13	72	0.98	0.89-1.08	0.643
WTDB	2.97 ± 0.93	83	13	70			0.344 (MW)
WTD	2.35 ± 1.11	39	2	37	1.02	0.99-1.04	0.148
WTDL	2.53 ± 0.85	81	12	69			0.318 (MW)
WTML	2.85 ± 0.85	84	14	70	1.05	0.99-1.11	0.093
WHMB	5.68 ± 1.43	85	13	72	0.97	0.95-0.99	**0.003****
WHML	4.72 ± 1.42	84	14	70	1.04	1.01-1.06	**0.001****
WHDB	5.35 ± 1.59	82	13	69	0.99	0.96-1.02	0.369
WHDL	4.23 ± 1.53	81	12	69			0.174 (MW)
Width of access cavity	5.68 ± 1.69	84	13	71	0.98	0.97-0.99	**0.003****

Vol remaining	60.9 ± 12.6	90	11	79			0.150 (MW)
Restoration	124		14	109			
Onlay	87		10	77	1		
Full crown	31		5	26	0.97	0.85-1.11	0.652
Filling	6		0				
Proximal contacts							
Only on mesial	21		4		1		
On both sides	101		10		1.11	0.92-1.34	0.269
Only on distal	2		0				
The time interval between root canal obturation and placement of onlay or crown	4.7 ± 5.9	121	14	107			0.726 (MW)
Cortical bone loss			14	101			
No bone loss	85 (73.9)		13	72	1		
Fenestration / dehiscence	30 (26.1)		1	29	1.10	1.00-1.21	**0.045***

4.5.1.3 Results of non-adjusted bivariate analysis (Table 4.8)

The presence of the distal marginal ridge significantly improved the restorative outcome (OR=1.24; p=0.001). The presence of the distal wall increased the odds of a successful outcome by 24%. This computes to a 19% probability of failure if the distal wall is missing.

Also, when compared to a missing mesial wall, the odds of success reduced significantly if the distal wall was missing as compared to a missing mesial wall (OR= 0.77; p=0.006).

The disto-buccal dentine wall thickness was significantly associated with a likelihood of a successful outcome (p=0.019).

Using CBCT to assess cortical bone loss, it was seen that the presence of cortical bone loss was associated with a statistically significant probability of success (OR=1.12, p=0.026). 29 out of 30 restorations with fenestrations and dehiscence had a statistically significant successful outcome (96%) compared to teeth with no cortical bone loss (72 success out of 84 restorations=85.7% failed restorations).

4.5.1.4 Adjusted Multivariate analysis.

Following this, a multivariate regression model was carried out to identify the prognostic factors that influenced the success of tooth and restorations at one-year recall. None of the prognostic variables was significantly associated with a successful outcome (Table 4.9).

Table 4.9 Multivariate analysis

	Category	**OR**	**CI 95%**	**p-value**
Distal wall	Missing	1		
	Remaining	9.32	0.90-96.2	0.061
Wall thickness disto-buccal		0.82	0.29-2.28	0.700
Wall height disto-lingual		1.83	0.96-3.46	0.065
Cortical bone loss	No bone loss	1		
	Fenestration / dehiscence	4.11	0.38-44.5	0.245

4.5.2 Results for clinical assessment of restorations

A total of 124 teeth were followed up one year after placement from a total of 131 restorations. These restorations were assessed using the modified USPHS criteria and the FDI criteria for assessing restorations. 87 teeth were restored using onlays for cuspal coverage of the endodontically treated teeth, while 31 were restored using full crowns. Six teeth only had a direct composite resin restoration, as they could not be restored because of clinic closure during Covid-19. Not all teeth could provide data for the different independent variables.

4.5.2.1 Anatomic form of restorations

Table 4.10 Results of the USPHS clinical evaluation of anatomic form (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and at one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Anatomic form	Favourable	A	70 (87.5)	79 (98.8)	25 (86.2)	28 (96.5)	107 (98.2)	65 (81.3)	74 (92.6)	22 (75.9)	25 (86.2)	99 (90.8)
		B	9 (11.3)		3 (10.3)			9 (11.3)		3 (10.3)		
	Unfavourable	C	1 (1.3)	1 (1.3)	1 (3.4)	1 (3.4)	2 (1.8)	1 (1.3)	6 (7.6)	1 (3.4)	3 (10.3)	9 (8.2)
		D	0 (0)		0 (0)			5 (6.3)		2 (6.9)		

Table 4.11 Results of the FDI clinical evaluation of anatomic form (favourable vs. unfavourable) of the onlays and crowns (%) at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Anatomic form	Favourable	1	68 (85)	79 (98.8)	23 (79.3)	29 (100)	108 (99.1)	64 (80)	76 (95)	22 (75.9)	28 (96.6)	104 (95.4)
		2	11 (13.8)		6 (20.7)			12 (15)		6 (20.7)		
		3	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	4	0 (0)	1 (1.3)	0 (0)	0 (0)	1 (0.9)	1 (1.3)	4 (5.1)	0 (0)	0 (0)	4 (3.7)
		5	1 (1.3)		0 (0)			3 (3.8)		0 (0)		

The USPHS assessment of anatomic form is shown in Table 4.10. The anatomic form for combined onlays and crowns made of CAD-CAM-generated nanohybrid ceramic material scored 87.2% alpha and 98.2% favourable at baseline under the modified USPHS criteria, and 79.8% alpha and 90.8% favourable at one-year recall. Wilcoxon's test, which tests for statistical significance among all the restorations for changes in clinical performance between T0 and T1 revealed the changes for the overall samples to be statistically significant (p=0.008).

Within the samples but grouped as onlays (73.4% of the total sample) and crowns, the changes in anatomic form were tested using Wilcoxon's test. The onlays did not show statistically significant changes in anatomic form from T0 to T1, under the modified USPHS criteria. The crowns also did not show any statistically significant changes from T0 to T1.

Using the Mann-Whitney's test, with Bonferroni's correction, there were no statistically significant changes in anatomic form between onlays and crowns under the modified USPHS criteria, both at T0 and at T1.

The analysis of the outcome between T0 and T1 (favourable vs unfavourable) using McNemar's test on the overall samples (onlays and crowns) showed there were statistically significant changes in anatomic form (p=0.016). However, when the McNemar's test was used to assess the anatomic form where the samples were now grouped as onlays and crowns, there were no statistically significant differences between T0 and T1 in either the onlays assessed separately together or crowns assessed separately together between T0 and T1 (comparing groups by time).

The results of the Fisher's Exact test comparing the outcome between onlays, and crowns revealed no statistically significant difference.

The FDI assessment of anatomic form is shown in Table 4.11. The Wilcoxon's test for the total samples of crowns and onlays revealed only a marginal significance (p=0.066) for anatomic form between T0 and T1. 83.5% of restorations scored 1 and 99.1% were favourable at baseline, while 78.9% scored 1 and 95.4% were favourable at T1.

The Wilcoxon's test by time comparing all onlays from T0 to T1 did not show any statistical significance (p=0.132), while the crowns also did not show any statistically significant changes in anatomic form from T0 to T1 (p=1.000)

The Mann-Whitney test did not reveal any statistically significant changes between onlays and crowns at T0 as well as at T1.

McNemar's test on the outcome of the overall sample between T0 and T1 of the overall sample did not reveal any statistical significance. McNemar's test assessing the outcome at T0 and T1 for onlays as well as separately for crowns revealed no statistically significant changes.

The Fishers Exact test comparing the outcome of anatomic form on onlays, and crowns revealed no statistically significant difference.

4.5.2.2 Retention of restoration

Table 4.12 Results of the USPHS clinical evaluation of retention (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Retention	Favourable	A	79 (98.8)	80 (100)	29 (100)	29 (100)	109 (100)	69 (86.3)	77 (96.3)	25 (86.2)	27 (93.1)	104 (95.4)
		B	1 (1.3)		0 (0)			8 (10)		2 (6.9)		
	Unfavourable	C	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3.8)	3 (3.8)	2 (6.9)	2 (6.9)	5 (4.6)
		D	0 (0)		0 (0)			0 (0)		0 (0)		

Table 4.13 Results of the FDI clinical evaluation of retention (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Fracture of restorative material and retention	Favourable	1	79 (98.8)	79 (98.8)	29 (100)	29 (100)	108 (99.1)	68 (85)	74 (92.5)	25 (86.2)	25 (86.2)	99 (90.8)
		2	0 (0)		0 (0)			0 (0)		0 (0)		
		3	0 (0)		0 (0)			6 (7.5)		0 (0)		
	Unfavourable	4	0 (0)	1 (1.3)	0 (0)	0 (0)	1 (0.9)	1 (1.3)	6 (7.6)	0 (0)	4 (13.8)	10 (9.2)
		5	1 (1.3)		0 (0)			5 (6.3)		4 (13.8)		

The USPHS assessment of retention is shown in (Table 4.12). The retention of restoration assessment under modified USPHS criteria for combined onlays and crowns made of CAD-CAM-generated nanohybrid ceramic material was 95.4% at one-year recall. The Wilcoxon's test, which tests for statistical significance among all the restorations for changes in retention of restoration between T0 and T1, revealed the changes for the overall samples to be statistically significant ($p<0.001$).

The Wilcoxon's test by time comparing all onlays from T0 to T1 still showed significant changes in retention from T0 to T1 ($p=0.006$) while the crowns did not show any statistically significant changes in retention of restoration from T0 to T1.

There were no statistically significant changes between crowns and onlays in relation to retention of restoration, using the Mann-Whitney's test, both at baseline and one-year recall ($p>0.05$).

The McNemars test revealed no significant changes in the outcome of retention of the restorations separately or as crowns and onlays at T0 and T1.

The Fishers Exact test revealed no statistical difference in the outcome between crowns and onlays regarding retention of the restoration.

Table 4.13, representing the FDI assessment of fracture of restorative material and retention, showed a statistically significant difference between baseline and one-year recall in the number of unfavourable fracture and retention of restorations. This had significantly increased from one (0.9%) restoration at baseline to 10 (9.2%) at one-year recall (P< 0.001).

When the type of restorations was considered, there was no statistically significant difference for crowns between baseline and one year, while it was a statistically significant difference for onlays between baseline and one-year recall (P=0.006).

The McNamar's test revealed significant changes in the outcome of the restorations for the overall sample for fracture of restoration (p=0.004), but not separately as crowns and onlays at T0 and T1.

The Fishers Exact test revealed no statistical difference between onlays and crowns in the fracture of the restorative material or the retention of the restoration.

4.5.2.3 Marginal adaptation of restorations

Table 4.14 Results of the USPHS clinical evaluation of marginal adaptation (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Marginal adaptation	Favourable	A	74 (92.5)	79 (98.8)	28 (96.6)	29 (100)	108 (99.1)	69 (86.3)	77 (96.3)	25 (86.2)	27 (93.1)	104 (95.4)
		B	5 (6.3)		1 (3.4)			8 (10)		2 (6.9)		
	Unfavourable	C	1 (1.3)	1 (1.3)	0 (0)	0 (0)	1 (0.9)	1 (1.3)	3 (3.8)	0 (0)	0 (0)	3 (2.8)
		D	0 (0)		0 (0)			2 (2.5)		0 (0)		

Table 4.15 Results of the FDI clinical evaluation of marginal adaptation (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One-year**				
Criteria		FDI Scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Marginal adaptation	Favourable	1	74 (92.5)	79 (98.8)	28 (96.6)	29 (100)	108 (99.1)	67 (83.8)	78 (97.6)	25 (86.2)	26 (89.6)	104 (95.4)
		2	4 (5)		1 (3.4)			10 (12.5)		1 (3.4)		
		3	1 (1.3)		0 (0)			1 (1.3)		0 (0)		
	Unfavourable	4	1 (1.3)	1 (1.3)	0 (0)	0 (0)	1 (0.9)	2 (2.5)	2 (2.5)	2 (6.9)	2 (6.9)	4 (3.7)
		5	0 (0)		0 (0)			0 (0)		0 (0)		

The USPHS assessment of marginal adaptation, showed a statistically significant difference between baseline and one-year recall in the number of unfavourable marginal adaptation for the overall sample. This had significantly increased from one (0.9%) restoration at baseline to three (2.8 %) at one-year recall (P=0.023) (Table 4.14).

When the type of restorations was considered, there was no statistically significant difference for crowns between baseline and one year or for onlays regarding marginal adaptation (p>0.05).

The McNamar's test revealed no significant changes in the outcome of the marginal adaptation of restorations separately or as crowns and onlays between T0 and T1. The Fishers Exact test revealed no statistical difference between onlays and crowns in the marginal adaptation of the restoration at T0 and T1.

FDI assessment of marginal adaptation, showed a statistically significant difference between baseline and one-year recall in the number of unfavourable marginal adaptations of restorations for the overall samples. This had significantly increased from one (0.9%) restoration at baseline to four (3.7%) at one-year recall (P=0.006) (Table 4.15).

When the type of restoration was considered, there was no statistically significant difference for crowns between baseline and one year, while there was a statistically significant difference for onlays between baseline and one-year recall (P=0.022).

There was a statistically significant difference between onlays and crowns at baseline or one-year recall regarding marginal adaptation. The McNamar's test revealed no significant changes in the outcome of the marginal adaptation of restorations separately, or as crowns and onlays between T0 and T1.

Fishers Exact test revealed no statistical difference between onlays and crowns in the marginal adaptation of the restorations at T0 and T1.

4.5.2.4 Secondary caries assessment

Table 4.16 Results of the USPHS clinical evaluation of secondary caries (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Secondary caries	Favourable	A	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)	79 (98.8)	79 (98.8)	28 (96.6)	28 (96.6)	107 (98.2)
		B	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	C	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.3)	1 (1.3)	0 (0)	0 (0)	1 (0.9)
		D	0 (0)		0 (0)			0 (0)		0 (0)		

Table 4.17 Results of the FDI clinical evaluation of secondary caries (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Secondary caries	Favourable	1	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)	80 (100)	80 (100)	28 (96.6)	28 (96.6)	104 (95.4)
		2	0 (0)		0 (0)			0 (0)		0 (0)		
		3	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		5	0 (0)		0 (0)			0 (0)		0 (0)		

There was no statistically significant difference in either USPHS or the FDI criteria of assessment of secondary caries of restorations between baseline and one-year recalls (Table 4.16, Table 4.17)

4.5.2.5 Polishability (modified USPHS)

Table 4.18 Results of the USPHS clinical evaluation of polishability (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Polishability	Favourable	A	79 (98.8)	80 (100)	26 (89.7)	29 (100)	109 (100)	78 (97.5)	79 (98.8)	24 (82.8)	27 (93.1)	106 (97.2)
		B	1 (1.3)		3 (10.3)			1 (1.3)		3 (10.3)		
	Unfavourable	C	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.3)	0 (0)	0 (0)	1 (0.9)
		D	0 (0)		0 (0)			1 (1.3)		0 (0)		

There was no significant difference between baseline assessment and 1 year recall assessment for polishability of restorations (Table 4.18).

4.5.2.6 Surface staining of restorations

Table 4.19 Results of the USPHS clinical evaluation of surface staining (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			Baseline					One year				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Surface staining	Favourable	A	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)	79 (98.8)	79 (98.8)	27 (93.1)	27 (93.1)	106 (97.2)
		B	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	C	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.3)	0 (0)	0 (0)	1 (0.9)
		D	0 (0)		0 (0)			1 (1.3)		0 (0)		

Table 4.20 Results of the FDI clinical evaluation of surface staining (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			Baseline					One year				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Surface staining	Favourable	1	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)	78 (97.5)	79 (98.8)	28 (96.6)	28 (96.6)	107 (98.2)
		2	0 (0)		0 (0)			1 (1.3)		0 (0)		
		3	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.3)	1 (1.3)	0 (0)	0 (0)	1 (0.9)
		5	0 (0)		0 (0)			0 (0)		0 (0)		

There was no significant difference between the baseline assessment and one-year recall assessment for surface staining under the modified USPHS criteria or the FDI criteria (Table 4.19, Table 4.20).

4.5.2.7 Soft tissue health

Table 4.21 Results of the USPHS clinical evaluation of soft tissue health (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			Baseline					One year				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Soft tissue health	Favourable	A	72 (90)	80 (100)	24 (82.8)	29 (100)	109 (100)	60 (75)	79 (98.8)	22 (75.9)	28 (96.6)	107 (98.2)
		B	8 (0)		5 (17.2)			19 (23.8)		6 (20.7)		
	Unfavourable	C	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.3)	1 (1.3)	0 (0)	0 (0)	1 (0.9)
		D	0 (0)		0 (0)			0 (0)		0 (0)		

There was a statistically significant difference in the modified USPHS criteria of assessment of soft tissue health between baseline and one-year recall ($p<0.001$), and among the restorations, onlays show a statistically significant unfavourable soft tissue health at one-year recall. There was no statistically significant difference in the crown group of restoration (Table 4.21).

4.5.2.8 Proximal contact

Table 4.22 Results of the USPHS clinical evaluation of proximal contact (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		USPHS scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Proximal contact	Favourable	A	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)	78 (97.5)	79 (98.8)	27 (93.1)	27 (93.1)	106 (97.2)
		B	0 (0)		0 (0)			1 (1.3)		0 (0)		
	Unfavourable	C	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.3)	1 (1.3)	0 (0)	0 (0)	1 (0.9)
		D	0 (0)		0 (0)			0 (0)		0 (0)		

Table 4.23 Results of the FDI clinical evaluation of proximal contact (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Proximal contact	Favourable	1	70 (87.5)	80 (100)	25 (86.2)	29 (100)	109 (100)	68 (85)	79 (98.8)	23 (79.3)	28 (96.6)	107 (98.2)
		2	2 (2.5)		2 (6.9)			3 (3.8)		3 (10.3)		
		3	8 (10)		2 (6.9)			8 (10)		2 (6.9)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.3)	0 (0)	0 (0)	1 (0.9)
		5	0 (0)		0 (0)			1 (1.3)		0 (0)		

There was no statistically significant difference in the modified USPHS or FDI criteria of assessment of overall proximal contact between baseline and one-year recall (Table 4.22, Table 4.23).

4.5.2.9 Surface lustre

Table 4.24 Results of the FDI scores of the assessment of the surface lustre of the restorations (favourable vs. unfavourable) at baseline and one-year recall.

Clinical evaluation			Baseline					One year				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Surface lustre	Favourable	1	74 (92.5)	80 (100)	24 (82.8)	29 (100)	109 (100)	73 (91.3)	80 (100)	23 (79.3)	28 (96.5)	108 (99.1)
		2	6 (7.5)		5 (17.2)			7 (8.8)		5 (17.2)		
		3	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		5	0 (0)		0 (0)			0 (0)		0 (0)		

There was no statistically significant difference in the FDI criteria of assessment of surface lustre between baseline and one-year recall (Table 4.24).

4.5.2.10 Patient's view

Table 4.25 Results of the FDI clinical evaluation of patients' view (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			Baseline					One year				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Patient's view	Favourable	1	67 (83.8)	80 (100)	28 (96.6)	29 (100)	109 (100)	61 (76.3)	76 (95)	27 (93.1)	28 (96.6)	104 (95.4)
		2	13 (16.3)		1 (3.4)			15 (18.8)		1 (3.4)		
		3	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (5)	4 (5)	0 (0)	1 (3.4)	5 (4.6)
		5	0 (0)		0 (0)			0 (0)		1 (3.4)		

There was a statistically significant difference in the FDI criteria of assessment of patient's view between baseline and one-year recall (p=0.016) (Table 4.25).

4.5.2.11 Tooth cracks and fractures

Table 4.26 Results of the FDI clinical evaluation of tooth cracks and fractures (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Tooth cracks and fractures	Favourable	1	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)	80 (100)	80 (100)	27 (93.1)	27 (93.1)	107 (98.2)
		2	0 (0)		0 (0)			0 (0)		0 (0)		
		3	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6.9)	2 (1.8)
		5	0 (0)		0 (0)			0 (0)		2 (6.9)		

There was a statistically significant difference in the FDI criteria of assessment of tooth fracture between baseline and one-year recall (p=0.016) (Table 4.26).

4.5.2.12 Periodontal response

Table 4.27 Results of the FDI clinical evaluation of periodontal response (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			**Baseline**					**One year**				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Periodontal response	Favourable	1	69 (86.3)	80 (100)	21 (72.4)	29 (100)	109 (100)	58 (72.5)	80 (100)	21 (72.4)	29 (100)	109 (100)
		2	11 (13.8)		8 (27.6)			21 (26.3)		8 (27.6)		
		3	0 (0)		0 (0)			1 (1.3)		0 (0)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		5	0 (0)		0 (0)			0 (0)		0 (0)		

There was a statistically significant difference in the FDI criteria of assessment of periodontal response between baseline and one-year recall (p=0.001) (Table 4.27).

4.5.2.13 Adjacent mucosa

Table 4.28 Results of the FDI clinical evaluation of adjacent mucosa (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and at one year.

Clinical evaluation			Baseline					One year				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Adjacent mucosa	Favourable	1	76 (95)	80 (100)	25 (86.2)	29 (100)	109 (100)	75 (93.8)	80 (100)	25 (86.2)	29 (100)	109 (100)
		2	4 (5)		2 (6.9)			5 (6.3)		2 (6.9)		
		3	0 (0)		2 (6.9)			0 (0)		2 (6.9)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		5	0 (0)		0 (0)			0 (0)		0 (0)		

There was no statistically significant difference in the FDI criteria of assessment of adjacent mucosa between baseline and one-year recall (Table 4.28).

4.5.2.14 Oral and general health

Table 4.29 Results of the FDI clinical evaluation of patients' view (favourable vs. unfavourable) of the number of onlays and crowns (%) assessed at baseline and one year.

Clinical evaluation			Baseline					One year				
Criteria		FDI scores	Onlay (%)		Crown (%)		Total (%)	Onlay (%)		Crown (%)		Total (%)
Oral and general health	Favourable	1	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)	80 (100)	80 (100)	29 (100)	29 (100)	109 (100)
		2	0 (0)		0 (0)			0 (0)		0 (0)		
		3	0 (0)		0 (0)			0 (0)		0 (0)		
	Unfavourable	4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		5	0 (0)		0 (0)			0 (0)		0 (0)		

There was no statistically significant difference in the FDI criteria of assessment of overall oral and general health between baseline and one-year recall (Table 4.29).

4.6 Discussion

In this cohort study on the clinical performance of CAD-CAM restorations the performance of onlays and crowns was not statistically different. This must be accepted with caution as long-term follow-up is planned to validate these results, also randomized clinical trials are needed as in the present study the decision to restore a tooth with an onlay or a crown was made by the clinicians, and it is reasonable to assume that teeth considered to be “weaker” were more often restored with crowns.

The clinical performance of onlays and crowns were evaluated using the modified USPHS criteria and the FDI criteria. The US Public Health Services (USPHS) is the most used method for assessing clinical performance of restoration. It has been reported that the USPHS criteria are not sensitive enough to detect early changes, however, at one-year the results were substantially similar using FDI and USPHS criteria.

Using the FDI assessment at one year, the restorations showed some fractures of the restorative material ($p<0.001$), loss of marginal adaptation ($p=0.006$), a worse patient view of the restoration ($p=0.016$) and some periodontal problems ($p=0.001$).

Similarly, when assessed under the modified USPHS criteria the restorations showed a worse retention ($p<0.001$), marginal adaptation ($p=0.023$), soft tissue health ($p<0,001$) and anatomic form ($p=0.008$)

All the other criteria did not show any significant changes from T0 to T1 under FDI and modified USPHS criteria.

When the samples were assessed separately as onlays and crowns, for changes from T0 to T1, only the onlay samples (73.4% of the overall samples) showed significant changes under FDI assessment regarding “fracture of restorative material and retention” (p=0.006), “marginal adaptation” (p=0.022), “patients’ view” (p=0.046) and “periodontal response” (p=0.002).

There was no significant change in the crown samples from T0 to T1 under the FDI criteria for changes in assessment criteria.

Under the modified USPHS criteria for the above changes, comparing onlays and crowns, from T0 to T1, only the onlay group showed significant changes ($p<0.05$) from T0 to T1 regarding “retention” (p=0.004) and “soft tissue health” (p=0.002). In the crown samples group, no changes were detected.

It must also be noted that two teeth restored with full crowns had to be extracted due to a crown/root fracture whereas all chipping and fractures in the onlay samples were repairable, this might be due to the fact that crowned teeth were originally more broken down than teeth restored with onlays or to the unnecessary loss of tooth structure associated with a full crown preparation.

4.6.1 Patient satisfaction

Many studies and clinical trials are now changing emphasis from a clinician centred outcome to patient centred outcomes. The study participants were asked to indicate their level of satisfaction, and this was only possible on the FDI assessment. Most patients were extremely pleased with the treatment, possibly from having

received a cuspal coverage restoration at no expense. However, when the restoration chipped, their level of satisfaction understandably dipped.

4.6.2 Intra examiner reliability

Determination of the intra-examiner reliability between the two ratings showed values above 0.75 for Cohen's kappa. This indicates high agreement between the examiners during assessment and supports an unbiased rating. In this type of clinical study, it is not possible to blind the operators as they evaluate using visual examination with a mirror and probe. However, they were not involved in the placement of the restorations and had no prior information as to what they would evaluate. Some degree of bias cannot be excluded.

4.6.3 Study design

Clinical trials assessing restorations can be short-term or long-term. Long-term studies are usually conducted by specialists or general dental practice, where the patients can be followed up during their regular check-ups. Long-term studies provide invaluable evidence regarding the clinical performance of restorative materials, and techniques regarding the success and survival of teeth and restorations.

As an example, a study by Mannocci, Qualtrough et al. showed that at one-year and three-years recalls there was no significant difference between amalgam and composite in root-filled pre-molars, but at five years, amalgam showed higher fracture and composite showed more secondary caries (Mannocci, Qualtrough et al. 2005). So clearly recalls of one to three years may not be sufficient for a meaningful interpretation of the results.

Another factor to be considered is that the manufacturers introduce many new materials into the market based on ex-vivo studies. It would be expensive and not viable to have long-term clinical trials on each of these materials. Very few restorative materials remain unaltered after three years. Despite a lot of resources spent on laboratory testing, there are no tests that are truly predictive of long-term clinical performance. The material we used in our study was Cerasmart (GC, Europe) a nanohybrid ceramic material, that has now been replaced with Cerasmart 270; as it often happens, the evolution of dental materials is faster than the clinical research assessing the existing materials.

Randomised clinical trials (RCTs)have been favoured in the past, being widely considered to be the best design to answer specific questions in clinical research. However RCTs are resource intensive, and oftentimes performed under artificial conditions with limited external validity (Opdam, Collares et al. 2018). Also, RCTs in dentistry are often undertaken with small sample sizes and suffer from very low recall rates in the long term; hence the demand for randomised clinical trials with longer observation periods is perhaps unrealistic and alternate designs should be taken into consideration, especially considering that restorative materials are quickly removed from the market and replaced by newer versions.

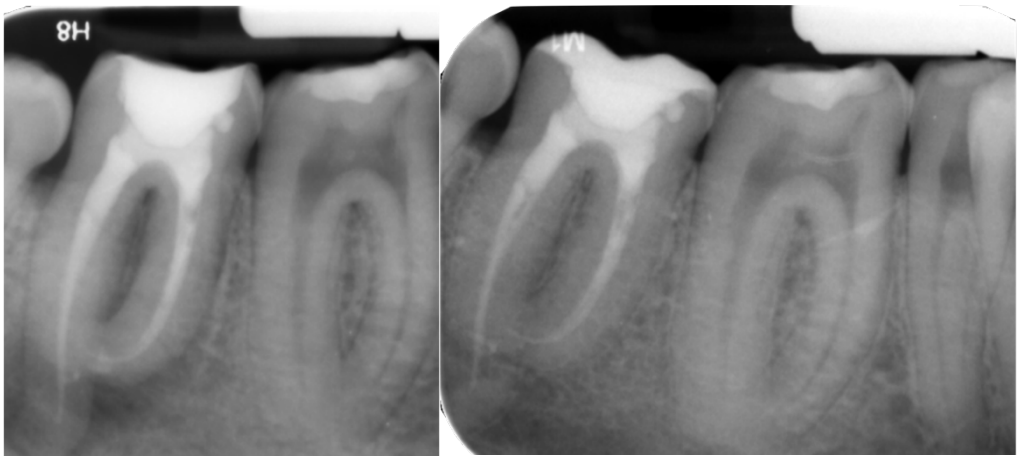


Figure 4-22 Radiographs of. preoperative and post operative cuspal coverage restoration using an onlay which provides both cuspal protection and preservation at the cervical area.

4.6.4 Success and survival of onlays and crowns with nanohybrid ceramics

Almost all the failures we noted were due to chipping or bulk fracture of the nanohybrid ceramic. This mode of failure appears to be similar to that of ceramic inlays (van Dijken, Hasselrot et al. 2001). Important factors such as the design of the cavity preparation, shape and thickness of the restoration, internal fit of the restoration was not analysed in this study.

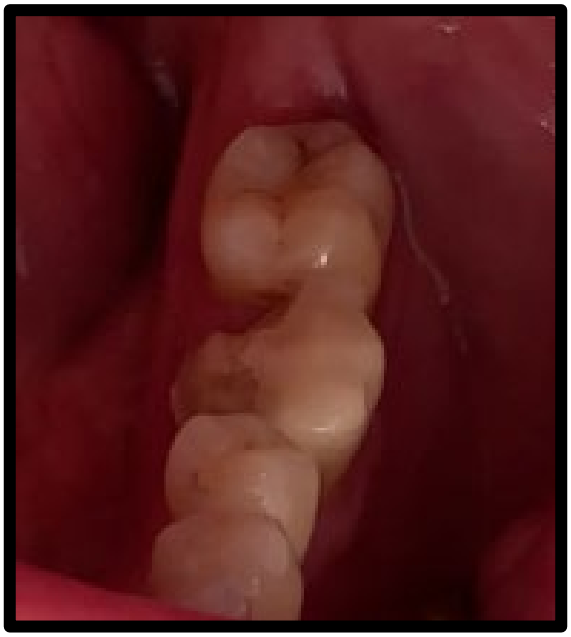


Figure 4-23 A fractured full crown from what is believed to be Hoop's stress concentration at the lingual and occlusal transition.

A very specific type of fracture reported to be due to Hoops stress concentration at the occlusal and axial transition has been reported in the literature based on finite element analysis(Shembish, Tong et al. 2016) . We noticed this type of fracture with full crowns, and these appear to be the first clinical images validating the findings of the ex-vivo Hoop's stress concentration theory. (Figure 4-23)

This type of fracture risk may be the reason why some manufacturers are not recommending novel hybrid ceramic materials as full-coverage crowns (Lava Ultimate, 3M). There are many factors in play though which could result in restoration fracture which were not analysed in this study, namely bruxism and diet.

4.6.5 Choice of restorative material

It has been reported that for single tooth restorations most of the currently available ceramic materials will perform well (Sailer, Makarov et al. 2015). The material we used is a nanohybrid ceramic which consists of a resin-like matrix with ceramic fillers, making it less rigid compared to porcelain materials (Figure 4-22).

As mentioned before one advantage of this material is that the lifespan of the burs used in the milling machine is much longer when milling nanohybrids compared to lithium disilicate or zirconia blocks. Finally, if retreatment was required in the future, it would be easier to revise the treatment through a nanohybrid material than through lithium disilicate or zirconia. Nanohybrids may also allow a small degree of flexibility compared to more rigid ceramics and this may be beneficial to an ETT. They also allow simple repair of the access cavity in many situations such as after root canal

retreatment or after pulpotomy, if full root canal treatment is required later. They are also easier to adjust and polish.

Other materials we could have considered are lithium disilicate and zirconia. Lithium disilicate (IPS, e.max) is one of the most popular and widely used ceramic materials. It has high translucency and bonds to the tooth. With some brands of lithium disilicate namely, IPS e.max CAD (Ivovclar, Lichenstein), the restoration is milled followed by crystallization. This would increase the required chair-side time. Other brands of lithium disilicate CAD block (GC Initial LiSi Block, GC, Europe) does not require firing because it comes fully crystalized while Cerec Tessera (Dentsply Sirona, Europe) comes partially crystallized and therefore reduces chairside time.

Zirconia is also rivalling lithium disilicate in terms of popularity. The ideal material would be one in between, combining the aesthetics and bondability of lithium disilicate with the high strength and resistance to fracture of zirconia. Zirconia onlays and crowns could be made with a thickness of 0.5mm, have very high strength and are very resistant to fracture. However, they are not as translucent as glass ceramics and therefore not as aesthetic. They also can cause a significant wear of antagonistic teeth and are challenging to bond to the tooth. A significant body of research is ongoing in zirconia with 3Y, 4Y and 5Y group of zirconia. Y refers to yttria and an increase in the proportion of yttria is associated with an increase in the translucency and with a reduction of flexural strength. The layered zirconia used for improving aesthetics cannot be recommended due to high number of fractures.(Rosentritt, Preis et al. 2020)

As discussed in the review of literature, there is a general preference for tooth-coloured restorations despite excellent survival of cast gold restorations. Compared to other posterior teeth restorations, cast gold restorations are costly but long lasting.

4.7 Conclusion

Within the limitations of our study, CAD CAM generated nanohybrid materials appear to have a good survival rate. Onlays and crowns appear to show similar clinical performance at one year recall. Results from both the modified USPHS and the FDI criteria appear to show similar performance at one year recall. Caution should be exercised in the interpretation of these results as further follow up is needed.

Chapter 5 : Comparison of wear of enamel and nanohybrid ceramic restorations after one year of simulated chewing with *in vivo* wear from a one-year clinical trial.

5.1 Introduction

Erosive Tooth Wear, also referred to as non-carious tooth surface loss is defined as the irreversible loss of tooth tissue due to acids of non-bacterial origin. Erosive Tooth Wear is often multifactorial in nature and is often subdivided into attrition, erosion, abrasion and abfraction. Attrition is the loss of tooth structure or restoration because of mastication or contact between occluding surfaces of approximal surfaces. Erosion is the loss of tooth tissue by chemical process not involving bacterial action. Abrasion is the physical wear caused by materials other than tooth contact while abfraction is the tooth wear located in the cervical area caused by flexural forces during function and parafunction. Wear of teeth can be a normal physiological process as part of the ageing process or pathological due erosion, abrasion, attrition or abfraction (Lussi, Megert et al. 2012). It is often difficult to determine when tooth wear becomes pathological. The estimated wear rate of enamel from physiological processes is estimated to be between 20-38 μm per annum (Eccles 1982).

Similar to tooth tissue, dental materials that are utilised to restore form and function of teeth are also exposed to similar physiological or pathological process that result in material wear. Wear of any materials in the oral cavity are often influenced by

thickness of enamel or restorative material, patient's diet, use of abrasive food, parafunctional habits and although manufacturers calculate the likely wear of materials using *in vitro* simulations, the *in vivo* performance of many materials when it comes to wear is relatively poorly understood (Wang, Zhu et al. 2022).

Composite resins, due to their excellent aesthetic properties, have slowly replaced dental amalgam as the restorative material of choice for almost all cavities. However, their wear resistance is considered as a factor that contributes to their failure (Hickel and Manhart 2001). Ceramic materials are widely reported to cause to excessive wear of opposite dentition (Hmaidouch and Weigl 2013). Nanohybrid ceramics are a novel group of materials that aim to combine the features of both composite resin and ceramics. They are made of a highly polymerised resin matrix with nano ceramic particles embedded within. Materials combining resin matrix with ceramic fillers have been reported to cause less wear on opposing teeth and their wear rate is considered close to natural teeth however there is very little clinical data in the literature on nanohybrid ceramic wear performance *in vivo* (Baldi, Carossa et al. 2022).

Various wear simulation testing devices are available to test the wear characteristics restorative materials and enamel *in vitro.* These devices consist of a specific medium, a movement type, and a method of loading which is either electromechanical, hydraulic, or spring loaded (Wang, Zhu et al. 2022). Valid wear simulation is thought to require three components, firstly control over the sliding component as well as the vertical component of the testing device, secondly constant irrigation to ensure two-body wear is being simulated and thirdly generation of results

which have a co-efficient of variation around 10 %. Measurement of wear *in vivo* is conducted using either direct scanning of the dentition using an intraoral scanners or indirect scanning of dental models using a profilometer (Charalambous, O'Toole et al. 2021). The software for measurement of wear *in vivo* is still emerging and there are known issues with superimposition software if reference-based alignment is not used, however reference-based alignment is not always possible *in vivo* if there are areas which are not able to be identified as having not worn (Charalambous, O'Toole et al. 2021). Recently, surface subtraction has been proposed to provide a solution to the known issues with superimposition however clinically there are still unresolved issues with measurement of tooth wear *in vivo* (Charalambous, O'Toole et al. 2021, Mylonas, Moazzez et al. 2022) . Therefore, there is a need for further clinical studies with reference to *in vitro* and *in vivo* data on wear performance of novel materials.

5.2 Aims and objectives:

The primary objective of this study was to evaluate the wear of Nano hybrid ceramic (Cerasmart, GC, Europe) using an intra-oral scanner, in comparison to the wear of human enamel *in vitro,* opposing a nanohybrid ceramic antagonist under 80N loading in the presence of water for 250,000 cycles (corresponding to one year of clinical use).

The secondary objective of this study was to evaluate the wear of nanohybrid ceramic and human enamel *in vivo* after 1 year of clinical use using an intra-oral scanner (Figure 5-1).

5.3 Materials and Methods

5.3.1 Materials

The materials used in the study are listed in Table 5.1, and the equipment in Table 5.2

Table 5.1 Materials used.

Product	Manufacturer	Specifications
Nano hybrid ceramic	Cerasmart Universal blocks GC Corporation, EU, Leuven	Shade A2, HT size 14

Table 5.2 Equipment used.

Testing Equipment and Analysis Software	Manufacturer
Bose Enduratec ElectroForce Wear testing Machine	TA Instruments, Minnesota, USA
Intra Oral Scanner	True Definition, 3M ESPE
Geomagic Freeform X	Oqton, San Francisco USA
MountainsMap 9	Digital Surf, Besancon, France

5.3.2 Methodology

The *in vitro* part of the study investigated the effect of attrition forces under constant deionized water irrigation at 37°C. Two materials were used in the wear testing machine, human enamel and Cerasmart (GC, Europe),

The samples were divided into two groups: 1 Human Dental Enamel and 2: Resin Hybrid Nano-ceramic.

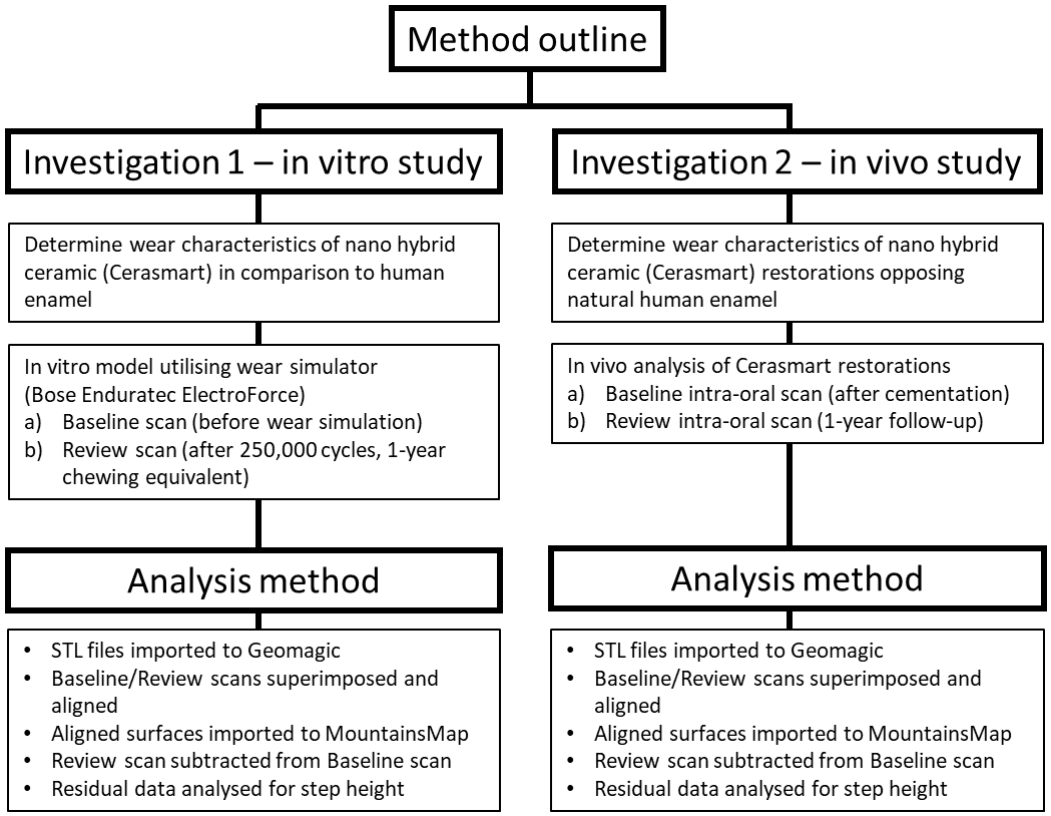


Figure 5-1 Flow chart of the experiments.

5.3.2.1 Investigation 1 - Study Design

In this *in vitro* study the samples were subjected to attrition with no media other than deionized water. The following steps were involved:

1. Sample preparation
2. Baseline IO scanner
3. Wear simulation cycles 0-250,000 cycles
4. IO scan at 250,000 cycles
5. Repeated for each sample.
6. Analysis

5.3.2.2 Sample Preparation

Ethical approval

Ethical approval was required and obtained for this study since human tissues (extracted teeth) were used in this study (REC: 12/LO/1836). An informed consent was given by the patient prior to collection of samples. Careful observation was paid to observing the Human Tissue Act (2004), which controls appropriate usage, storage and disposal of human tissues.

The samples were disinfected using 2% sodium hypochlorite (Miltons Sterilising fluid, Proctor and Gamble, UK), rinsed with deionised water and stored in deionised water at 4 degree Celsius until needed.

Investigation 1 – in vitro wear determination and analysis

Tooth Sample Preparation

Each tooth was embedded in an impression compound (Impression compound, Kerr, UK) and then sectioned using a water-cooled diamond wafering blade (Buehler Isomet GmbH, Germany) to obtain a restoration and pathology free buccal surface. The wear was conducted on unpolished enamel sections, which were duplicated into resin hybrid ceramic to allow a paired testing to be conducted. The enamel section was scanned using the IO scanner, uploaded to the Romexis software for design and milling the duplicated enamel sample (Figure 5-2)

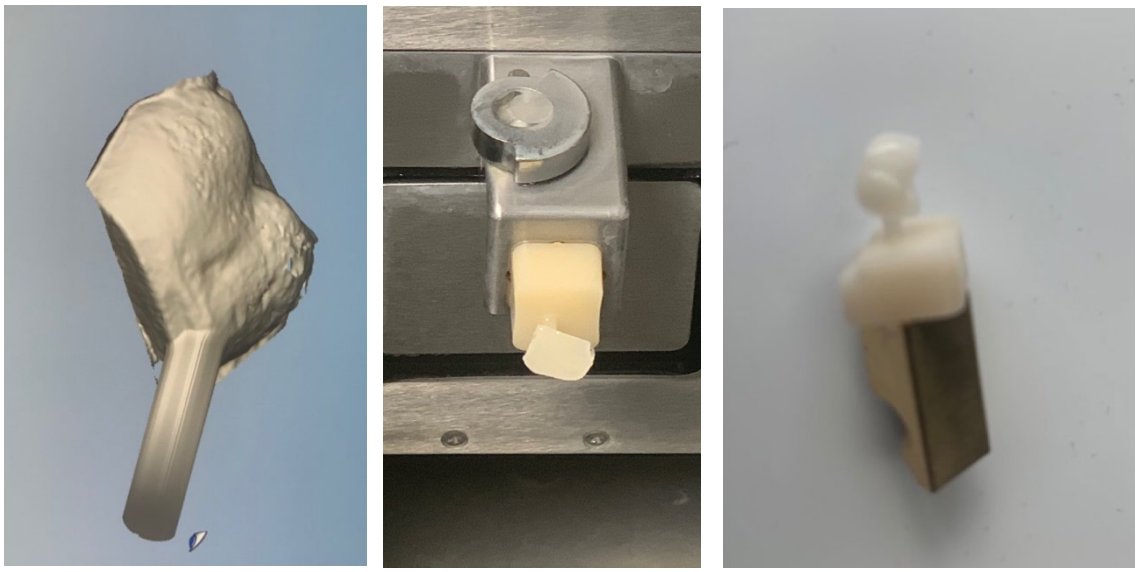


Figure 5-2 Milling a copy of the enamel sample.

Milling of the nano hybrid ceramic analogue to human molar cusps

Following previously published protocols, which describe the use of leucite-reinforced ceramic as an enamel analogue for fabrication of antagonists in simulation of attrition *in vitro*, 2.36 mm diameter nanohybrid ceramic antagonists (GC Cerasmart, Europe) were milled using a 3-axis water cooled milling machine (Planmeca PlanMill 40, Planmeca, Finland) (Heintze, 2019). The CAD file for the antagonists was provided by Ivoclar R&D as an .stl file and represented a single molar cusp of 2.36 mm diameter which is the most internationally accepted geometry for a wear antagonist. To maximise the number of antagonists produced from each block the CAD file was mirrored into a double- headed antagonist which was then sectioned after milling.

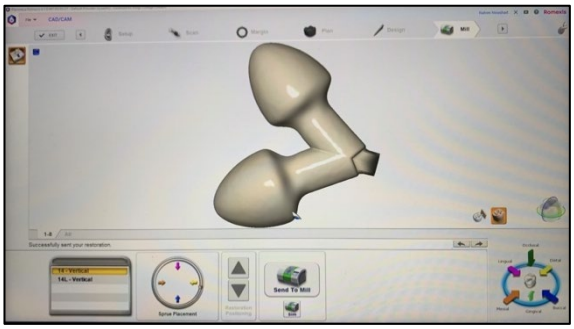


Figure 5-3 Image shows the milling file with two antagonists.

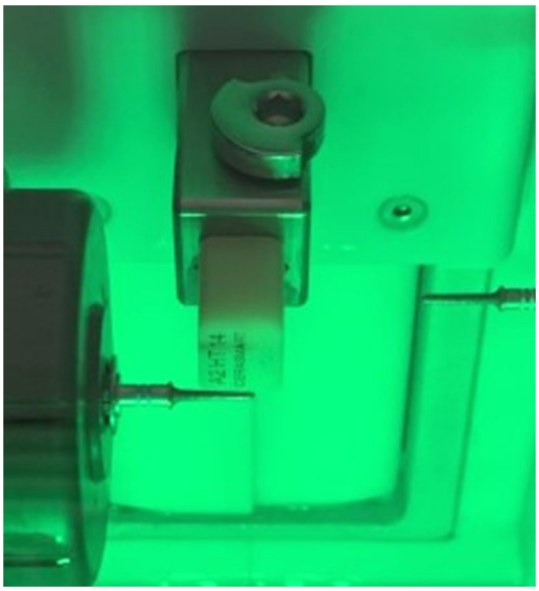


Figure 5-4 Block milled to manufacture the nano-resin ceramic antagonists

Figure 5-5 The milled-out antagonists - two per block which were separated after milling.

Following milling, as per the manufacturer's instructions, the antagonists were and embedded in a custom-made resin holder to allow them to be mounted into the wear simulation machine.

Mounting of samples

The samples were mounted with the buccal surface facing outwards in bis-acrylic resin (Protemp 4, 3M ESPE, Germany). To achieve this, a customised silicone mould was constructed to match the dimensions of the holder of the wear simulator. The enamel samples were placed facing downwards into each individual well and cold cure acrylic resin was poured into it. Next, flat glass slabs of 500 mg weight were placed on top of the matrix to ensure a smooth and horizontal surface. The cold cure acrylic resin (Oracryl Self-Cure Acrylic, Bracon Dental Laboratory Products, UK) was produced according to the manufacturer's instructions' mixing powder and liquid components under the fume cupboard in the research laboratory. Once set, the blocks were removed from the matrix and inspected for any faults, such as incorrect thickness of the block. At the end of the process, one would have produced 7 enamel samples embedded in rectangular acrylic blocks of length (12mm), width (9mm) and height (2mm).

Scanning with Intraoral scanner at baseline

The mounted samples were scanned for the baseline scan measurement. The samples were first scanned using the scan spray powder (High-Definition Scan Spray, 3M ESPE, USA) and then using an intra-oral scanning (True Definition Scanner, 3M ESPE, USA)

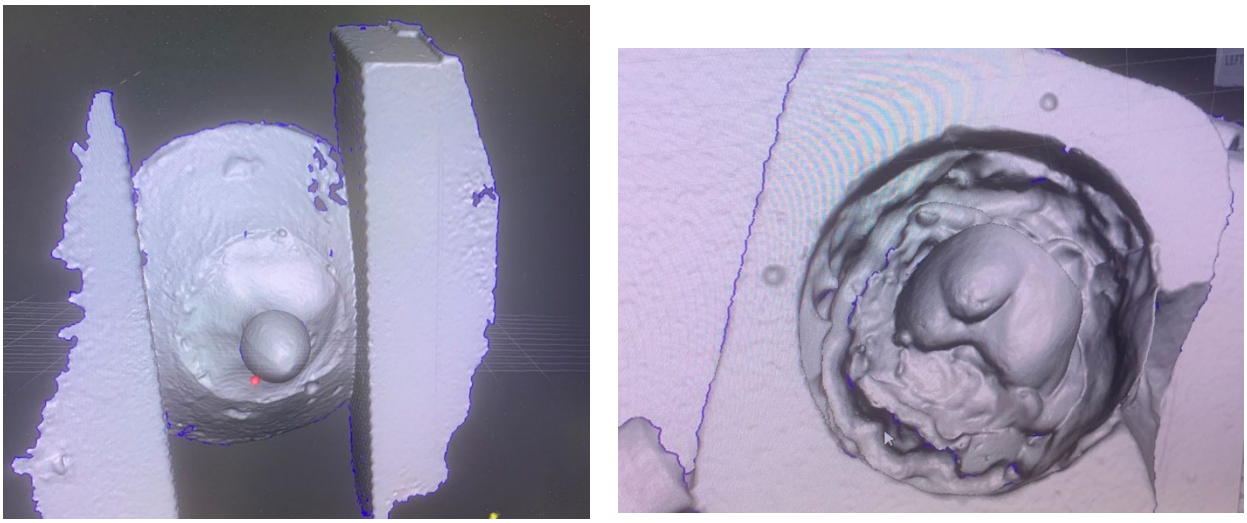


Figure 5-6 The sample and the antagonist were scanned at baseline.

In vitro wear simulation

For the wear simulation a Bose Enduratec ElectroForce Series II 3330 *device* was used. The machine consists of an upper chamber moves vertically (vertical actuator) to which the antagonist was attached, and a lower chamber moves horizontally (horizontal actuator) carrying the sample.

Figure 5-7 Bose Enduratec ElectroForce Series II 3330

The lower chamber rested on a 3-axis load cell which gives the Bose machine it's characteristic ability to control force applied through a sensitive feedback loop.

Water passes through a tube into the chamber at 37 degrees and is then let out through another tube during the chewing cycle (Figure 5-8).

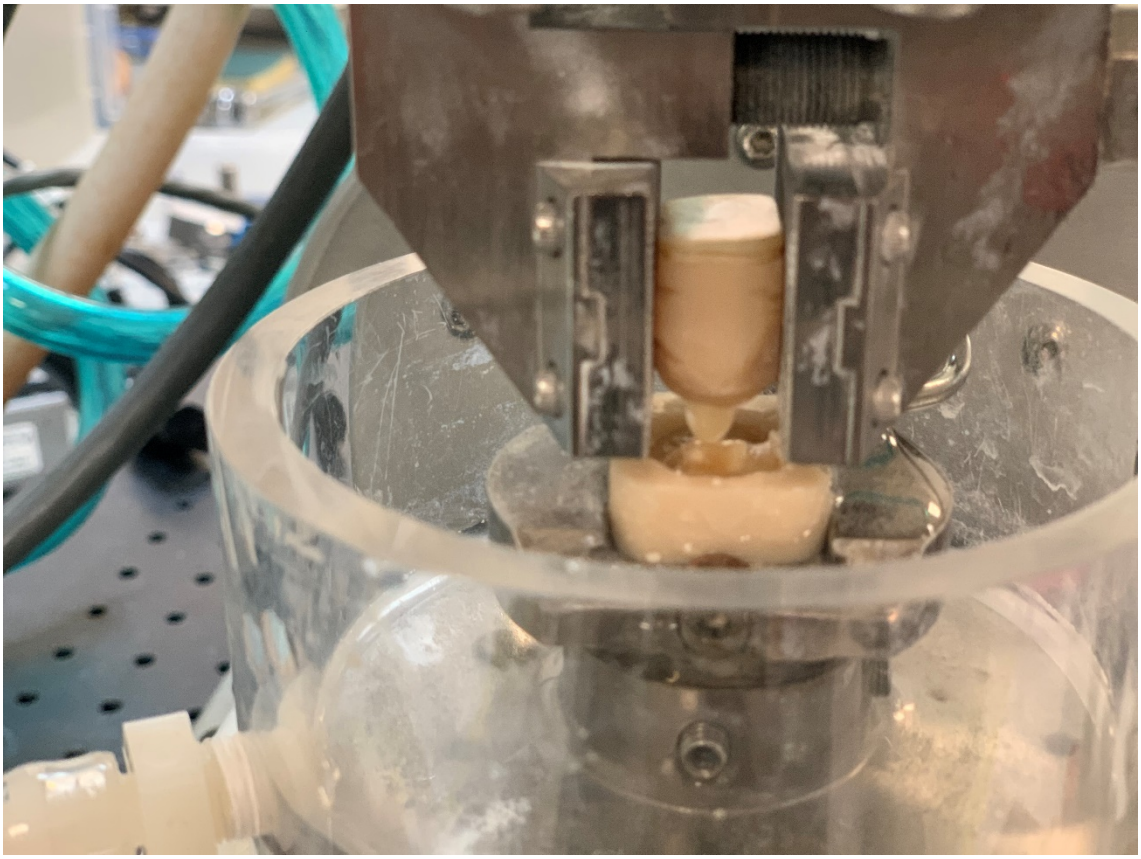


Figure 5-8 Water connection on the side; Antagonist and the sample seen during a wear cycle.

The wear simulator is connected to a computer running Wintest7 software. For each test the device had to be tuned according to the different parameters used and samples under investigation. It was a process of trial and errors until we reached the parameters achieving the most stable and reproducible wear cycle. A few settings needed to be settled before adjusting the wear simulation parameters including the test limits which ensure the protection of the device; in case of any error causing an excessive unpredictable load beyond the limits, the device automatically safely goes to a stop.

After adjusting, the limits the chewing tab is opened, and the basic test parameters are determined which are (Figure 5-9).

- Vertical holding load: The maximum holding load required for the test.
- Retract height: the return height of the vertical actuator. It is an absolute value.
- Cycle count: the number of cycles required to complete.
- Start point: initial position of the horizontal actuator.
- Start - retract begin retracting vertical actuator at this point in the horizontal stroke
- End point: End position of the horizontal actuator.

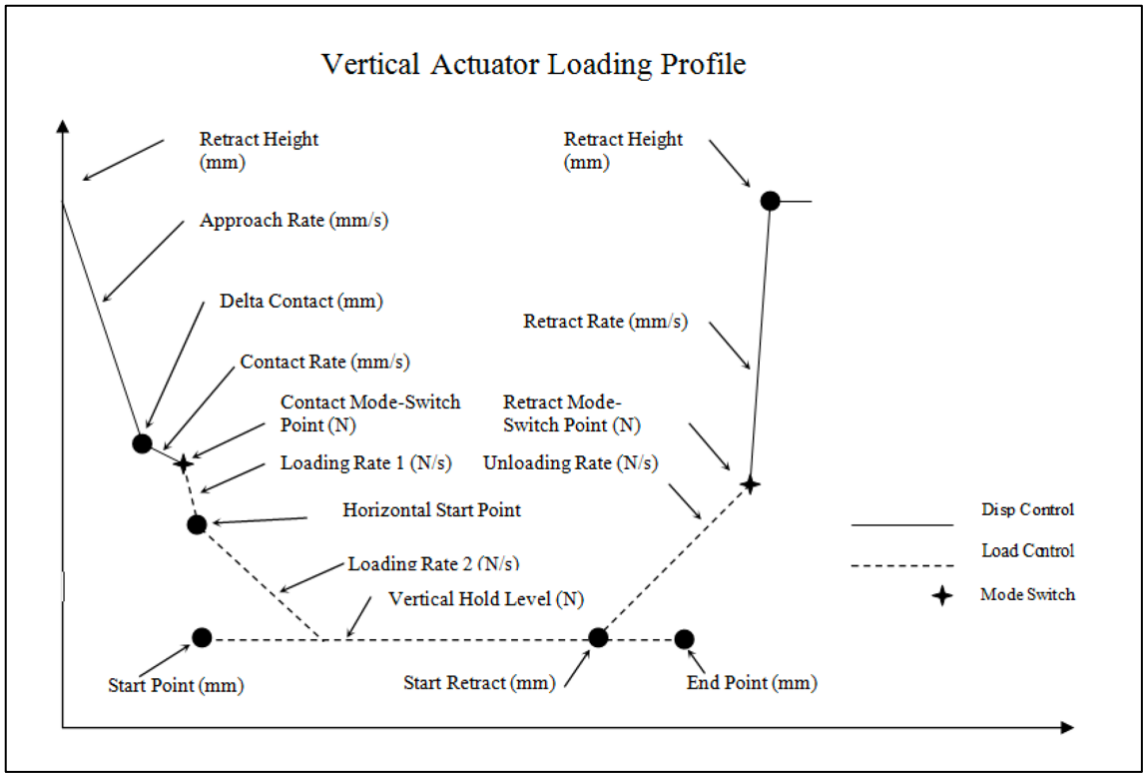


Figure 5-9 Vertical loading profile

To start the chewing cycle, the sample and antagonists are mounted in place. Water is allowed to run and the chewing application from the main test window is opened. Parameters are checked before continuing.

The antagonist lowers until it touches the sample at the previously specified location and starts dragging according to the drag rate previously determined. The

maximum load is reach and is verified for each cycle by the readings from the load cell. The vertical actuator finishes its cycle goes back to its resting position and the cycle starts over again.

The simulator can be run for a maximum of 150,000 cycles. Once it reaches 150,000 cycles it automatically shuts down. The set-up is then increased by 100,000 to provide the remaining chewing. It takes 250,000 cycles to simulate one year chewing. This process takes about a week of continuous use of the wear simulator for one sample to complete 250,000 cycles.

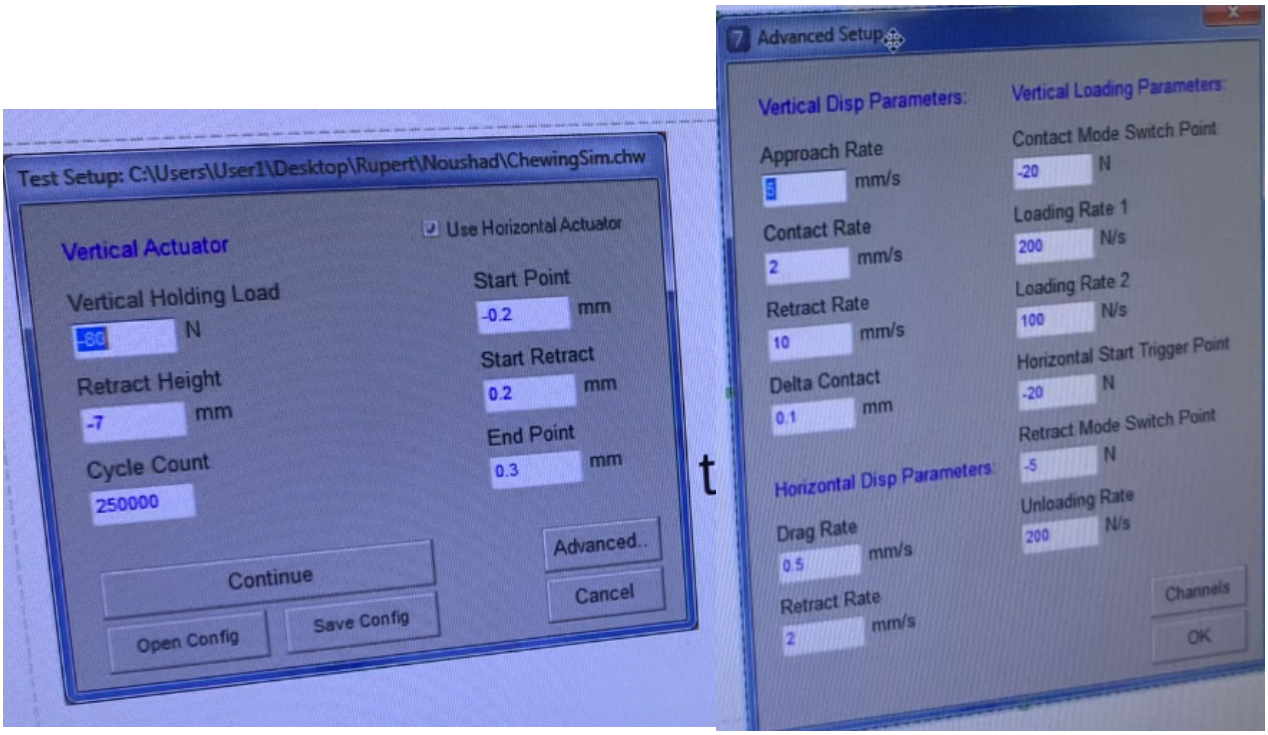


Figure 5-10 Basic and advanced test parameters for the chewing cycle

After-wear scanning with IOS

The samples were scanned again with the Intraoral scanner after the chewing cycle. 3M True Definition scanner was used. This was repeated for each set of samples. The samples and the antagonists were then subjected to further analysis. During the wear simulation, one Cerasmart antagonist fractured, and that group was not evaluated.

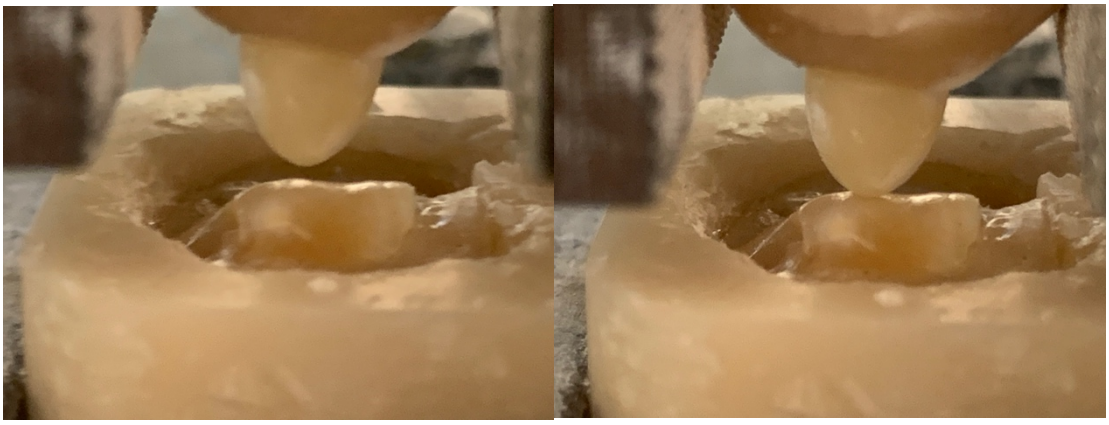


Figure 5-11 Close up of the chewing cycle

Investigation 2 – in vivo wear determination and analysis

See Chapter 4 for Study design, Ethics Approval, Patient selection, Clinical Procedure.

In our clinical study (Chapter 4), an intra oral scan of the restoration was taken after fit and then again after 1 year when they came back for the review. Only opposing teeth that had enamel occlusally were selected. A total of 15 samples were selected for the analysis.

The upper and lower intra oral scans were imported as .stl files to the analysis PC. Either the upper or lower posterior tooth would be the nanohybrid restoration and the opposing would be the enamel surface. The files were uploaded to Geomagic software.

Analysis of the scanned digital 3D images:

The scanned images taken by the intraoral scanner were exported and saved as a stereolithography file (.stl). The successive scans were all imported into a reverse engineering 3D analysing software Geomagic. For wear analysis, scans had to be superimposed and compared to each other. For each sample and antagonist, a separate folder was created, and the corresponding files were imported and renamed according to the number of cycles. Files were then highlighted so all scans appeared together and initially the best fit alignment feature was selected to ensure they were positioned in one common coordinate system with the least possible mean deviation. The scans were then re-segmented according to planes to obtain a more precise superimposition. The area of interest was selected, and images superimposed to a more accurate alignment.

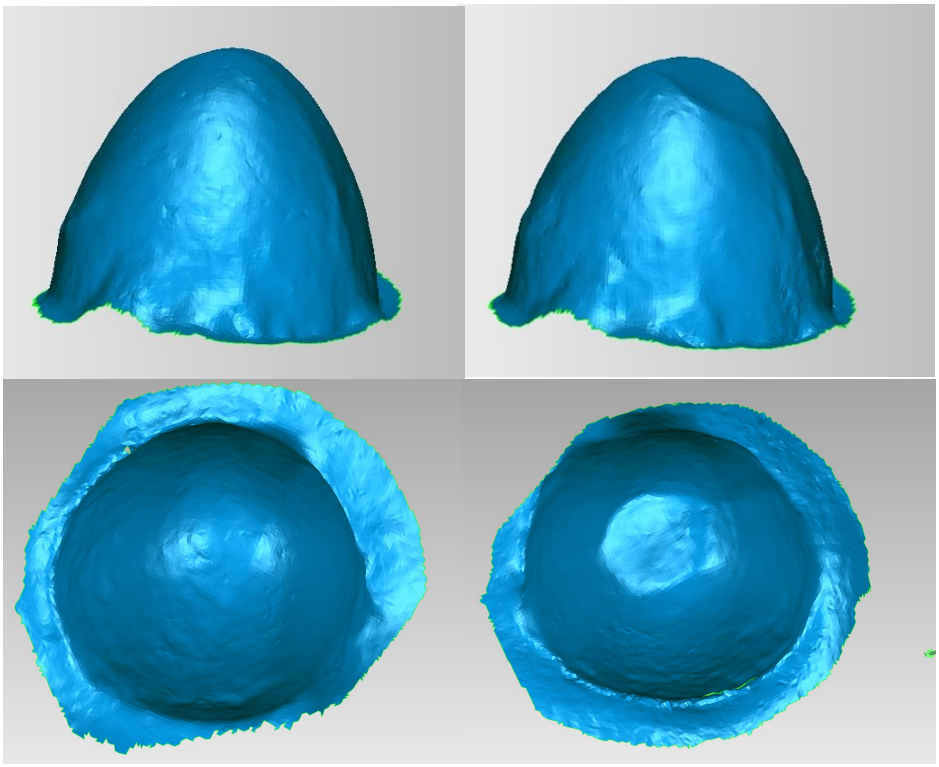


Figure 5-12 Wear on the antagonist after 2500,000 cycles. Preop on the left and post op on the right

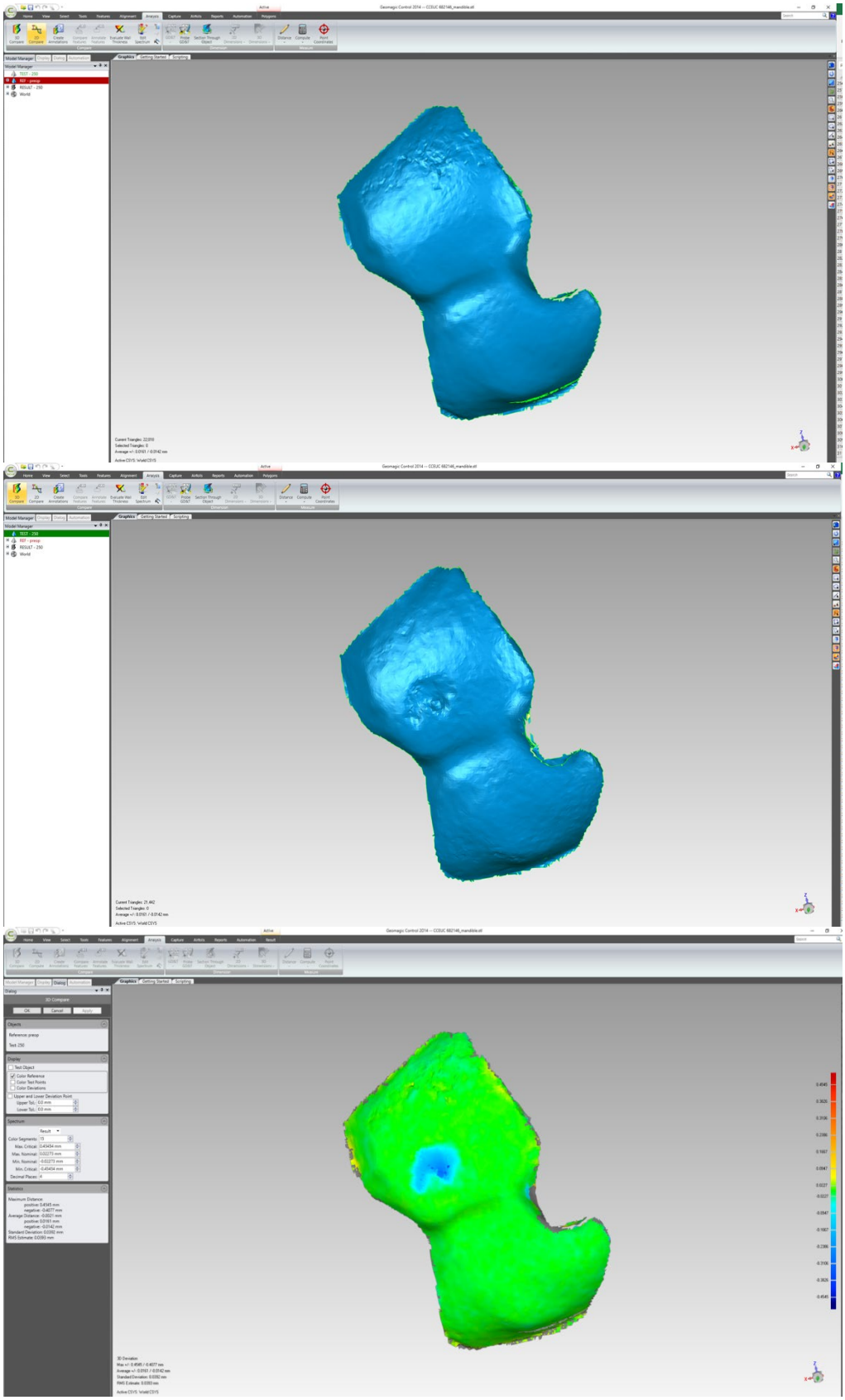


Figure 5-13 Wear on the enamel sample along with 3D rendering.

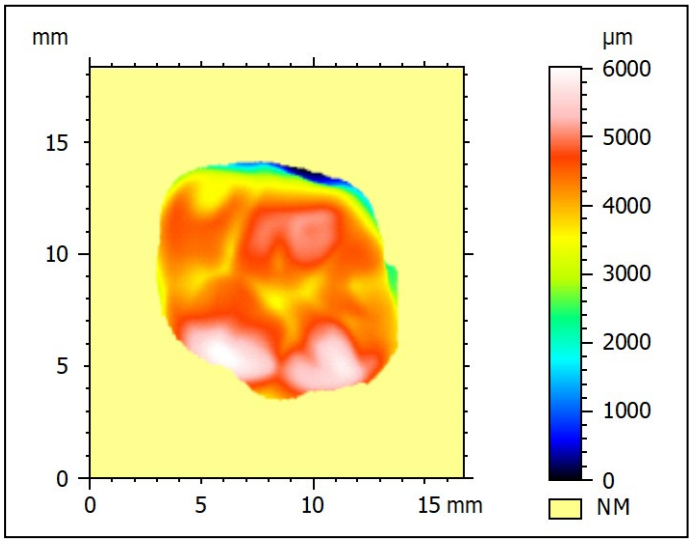
The next step was to import the Geomagic images to MountainsMap software. The analysis for the samples and antagonists followed steps as follows:

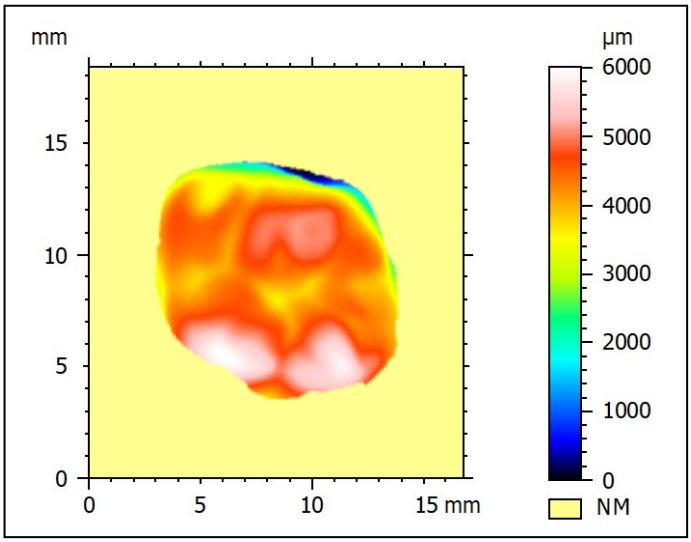
a) For sample analysis:

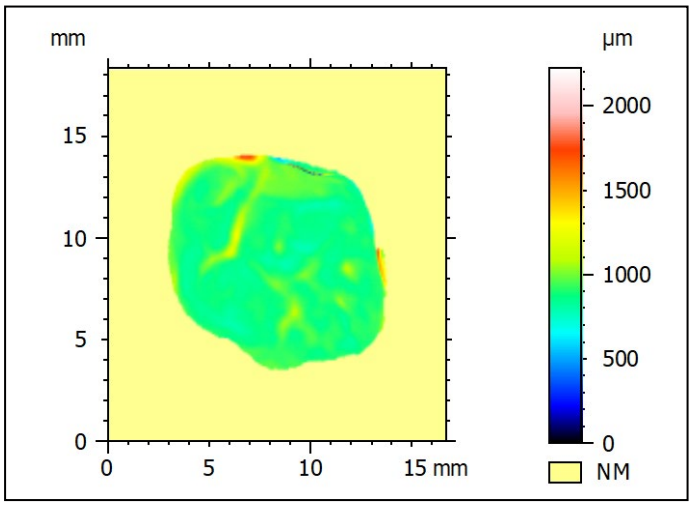
Mean 3D step height was calculated using MountainsMap where the software measured the mean depth of the wear scar at each scan imported (Mylonas et al 2022). These values were then exported as a Microsoft excel sheet for analysis.

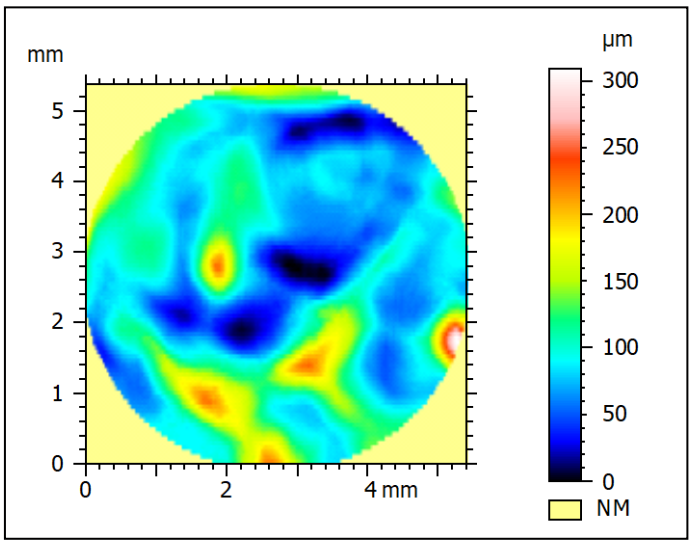
b) For the antagonist analysis:

The antagonist were also analysed the same way as the samples using Geomagic and Mountains Map software. We carried out surface subtraction following previous protocols to create a residual data set which was used to calculate step height surface loss μm.









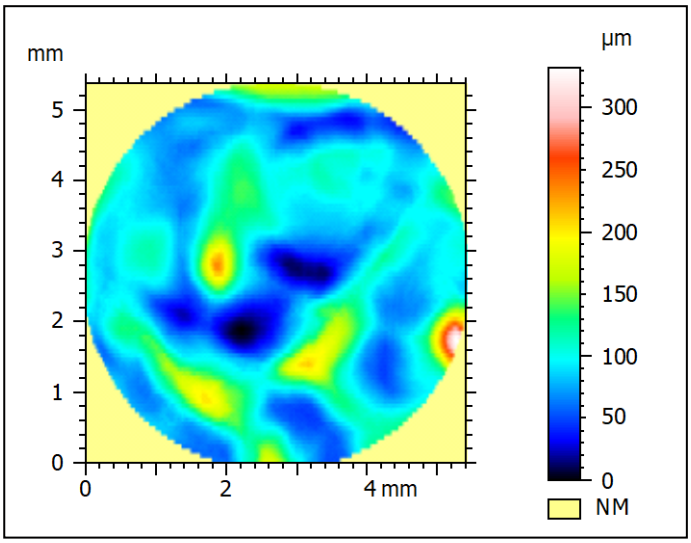


Figure 5-14 Screen shots from Mountainsmap

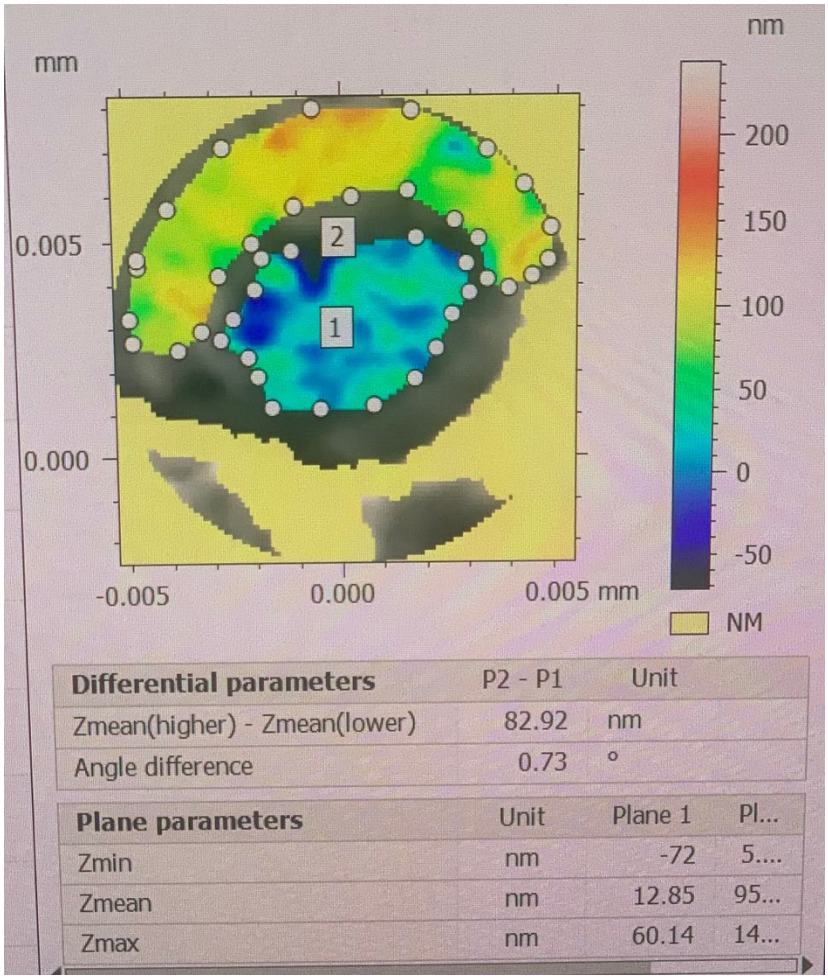


Figure 5-15 Screen shots from MountainsMap

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics Version 2.1 for Windows. Normality testing was performed using histograms, box plots, Q-Q plots, Kolmogorov- Smirnov and Shapiro-Wilk tests. The data was determined as normally distributed and therefore presented as mean and standard deviation (SD). The significance level was set at $P \leq 0.05$.

Three-Way ANOVA was conducted to investigate the effect of study variables and their interaction on wear – post-hoc Scheff's test to determine differences between different groups.

5.4 Results

Table 5.3 Descriptive data of the in vitro and invio samples

Material	**Mean 3D Step Height (µm)**	**Std Dev (µm)**	**Median Step Height (µm)**	**Min Step Height (µm)**	**Max Step Height (µm)**
Investigation 1					
Enamel (*in vitro*)	36.9	5.7	35	27.8	45.2
Cerasmart Antagonist	92.1	10.6	94.2	75	105
Cerasmart sample	122.6	20.6	115.7	98.2	154.4
Cerasmart antagonist	62.4	15	59.4	47.2	92.6
Investigation 2					
Cerasmart restoration (in vivo)	95.7	52.1	93.3	25.1	207
Enamel (in vivo)	61.1	40.8	49.7	25	151.5

Investigation 1

The tests of normality showed that the samples were normally distributed. The mean wear of all the materials tested using One-way ANOVA. It showed that the mean wear differs significantly between the materials ($P<0.001$).

Further Post hoc analysis using Scheffis test showed that the mean wear differs significantly between groups Enamel (*in vitro*) and Cerasmart (*in vitro*) ($p=0.003$) and also between groups Enamel (*in vitro*) and group Cerasmart (in vivo). However, this analysis must be considered in the context that in vitro and in vivo wear cannot be compared due to dietary factors, using different scanners and methodology and so the results may not be comparable statistically.

There were no significant differences between the rest of the groups and between the laboratory tested materials and the clinically tested materials.

Investigation 2

The mean wear of Cerasmart in vivo was 95.7μm, while for enamel it was 61.1μm. There was no statistical significance in wear between enamel in vivo and the *in vitro* samples.

5.5 Discussion

Wear is an active process occurring in the oral cavity, which can affect both the dentition and the restorative materials. In the oral cavity, salivary fluid offers one of the main protective mechanisms due to its lubricating action, and this helps to reduce wear reducing friction.

Profilometry is the gold standard for step height analysis of materials (dental tissue or dental material) that have undergone laboratory-based or in-vivo testing (Mylonas, Moazzez et al. 2022). This technique however is limited for use in laboratory-based scanning and analysis of wear and cannot be used for direct intra-oral evaluation of wear unless analogues are produced for scanning; these can include impressions and study models (Rodriguez and Bartlett 2010). Recently, several studies have been using intra oral scanners for direct wear scar evaluation both in vitro and intra orally. Owing to the ease, shorter time needed and clinical applicability of this method, it had become of rising interest. Michou et al. used intra oral scanner (Trios, 3 shape) to detect early erosive tooth wear showing good performance in early detection and promising use in vivo as well (Michou, Vannahme et al. 2020).

In the present study, enamel in vitro showed a mean attrition wear of 36.9 μm while in the oral cavity, enamel showed a mean wear of 61.1 μm. The Cerasmart sample in vitro showed a mean wear of 122.6 μm while the restoration in vivo showed a mean wear of 95.7 μm.

However, recent work has shown the measurement threshold of an intra oral scanner (3M True Definition) was calculated to 73 microns at the single tooth level, and full arch scans may be limited by detection of depths of 120 microns (Charalambous, O'Toole et al. 2022). Therefore, the findings of this present study need to be interpreted with caution as the values obtained range between these two values. However, direct comparison between the values of measurement threshold and the present study should itself be treated with caution because the full arch accuracy data was obtained from scanning typodont models – whilst the present study scanned whole human arches.

The evaluation of wear is not an easy process due to its high subjectivity. Several devices, mechanical and electro-optical sensors, are used to quantify clinical wear. But for the clinical situation, physical impressions are needed, and their quality may affect the accuracy of wear measurements. To avoid this draw back, it has been suggested to use intraoral scanners. These scanners have the primary use of designing and fabricating CAD/CAM restorations rather than wear detection; thus, their software is not as user friendly as laboratory scanners designed for this purpose. However, some scanners have provided sufficiently accurate results together with ease of use and more time saving.

Many antagonist shapes and materials have been suggested in previous studies. In our study, antagonists were standardized with the aim of proper comparison and prepared according to Ivoclar Vivadent Method by (Heintze, Cavalleri et al. 2008).

5.6 Conclusion

This study suggested no significant difference in wear of antagonist between standardized and non-standardized enamel cusps.

The result of this experiment seems to suggest that the Cerasmart is a gentle restoration to the enamel.

Chapter 6 : Summary and Future work

6.1 Summary

The largest part of this PhD was undertaken using intra oral scanners which allowed us to measure factors affecting restorability, to measure wear of enamel and nano hybrid ceramic both ex-vivo and in-vivo, to make digital impressions and then fabricate conservative post endodontic restorations, such as an onlay using CAD CAM technology.

The systematic review explored the research question as to whether onlays would be suitable as a post endodontic restoration. We had evidence from our previous research group that the volume of tooth remaining affected the survival of endodontically retreated teeth (Al-Nuaimi, Patel et al. 2017). Although it didn't reach statistical significance, the loss of the distal margin could possibly have an impact on the survival of restorations. Further follow up will be required to verify this. At 1 year recall, the survival of onlays on ETT was 98.4% and the success rate was 88.7%. The clinical performance was assessed using the modified USPHS and FDI criteria and both onlays and full crowns performed equally without any statistical significance. The main mode of failure was chipping or fracture of the restoration.

The presence of onlay or crown did not affect the outcome of root canal treatment at one year recall. It is interesting to note that we were not able to provide cuspal coverage restorations to 6 patients due to a break for the Covid 19 pandemic, and at follow up 3 of them had an unfavorable outcome.

The prospective study assessing endodontic outcome did not reveal any prognostic factors based on restorability, but it did reveal that presence of a lesion, size of lesion, length of root canal filling and voids in root canal filling affected the outcome of root canal treatment. Assessing endodontic outcome by CBCT is still not considered appropriate by the endodontic societies and positions statements. As more data becomes available from prospective studies, these practices may change especially on molar teeth.

Branching off from the main clinical trial, we were able to compare the wear of human enamel and nanohybrid ceramic ex vivo with that assessed in the patients enrolled in the clinical trial and the results showed that the wear of nanohybrid ceramics is similar to human enamel.

In conclusion, providing an onlay instead of a full crown can be considered as a conservative option for root filled posterior teeth, and this may influence future prescription patterns for restoration of ETT.

6.2 Future work

This thesis has been able to provide clinical evidence for the use of onlays on endodontically treated teeth. To have a proper validation, the study must be followed up for at least 5 years. Attrition of the cohort size is to be expected and the material has already been modified by the manufacturer, as is common for novel CAD/CAM materials. Prospective clinical trials are in shortage in assessing post endodontic

restorations, and this study is being followed up. One important aspect which needs to be studied is the effect of occlusion and para functional activity on CAD-CAM and conventional restoration of endodontically treated.

As most of the work has been digitally driven, we have seen the potential in research, education and clinical practice using digital technology. A large number of digital applications are being introduced at a rapid pace, some of these techniques are already available in practice including guided access cavity and apical surgery.

Related to my work, there is potential to do further work on fracture analysis as this was the main mode of failure of the restoration. Cerasmart is already upgraded to a potentially stronger material as marketed by the manufacturer, however clinical trials remain lacking.

Appendices

Appendix A: Personal work

Awards		Appendix B
CPD for British Endodontic Society	Post Endodontic restoration	Appendix C
Publication	(Bhuva, Giovarruscio et al. 2021)	Appendix D
Publication	(Bomfim, Rahim et al. 2020)	Appendix E
Lectures	1. EPA meeting Sienna 2. ESE meeting Budapest 3. ESE meeting Vienna 4. BSSPD meeting Aberdeen. 5.FoDOCS Research Day	
Posters	1. BES meeting 2. ESE Meeting	
Teaching	1. Clinical Tutor undergraduate students 2. Seminar for BDS “Pulp Dentine Complex” 3. Case discussion with Post graduate students 4.Hands on training for MSc. Endodontics students	

Appendix B: Awards

1. BSSPD Schottlander Oral award 2022

BSSPD Oral Awards 2022
British Dental Journal **233**(6): 452-452. (2022)

2. Best Poster (2022) British Endodontic Society

(2022 Awards & Prizes | British Endodontic Society)
https://britishendodonticsociety.org.uk/news/42/2022_awards_prizes

3. Certificate of Compassionate practice by Guy's and St Thomas NHS Foundation Trust

4. Finalist ESE Education Prize Presentation

Digital endodontics: Endodontic education in the third dimension

Abstracts. Int Endod J, 56: 3-47. https://doi.org/10.1111/iej.13875 (2023)

INTERNATIONAL ENDODONTIC JOURNAL
The official journal of the British Endodontic Society and the European Society of Endodontology

ABSTRACT | Full Access

Abstracts

First published: 03 January 2023 | https://doi.org/10.1111/iej.13875

Get it at King's

Education Prize

Thursday, 8th September

EP01

Digital endodontics: Endodontic education in the third dimension

N Rahim, S Patel, F Foschi, R Austin, F Mannocci

King's College, London, United Kingdom

Cone beam CT was first introduced to dentistry in Europe in 1998. Over the years, CBCT has proved to be a valuable tool in diagnosis and treatment planning. The impact of CBCT is that we can visualize the radiographic image of the tooth in 3 dimensions.

The Intraoral scanner has been introduced for digital impressions but its use has evolved and is already being used for clinical assessment of the dentition during regular check-ups.

CAD CAM technology can be employed for "root to crown" approaches in endodontics, where the post endodontic restoration can be designed, milled and fitted at the same appointment. The digital workflow appears to be very useful during student education in assessing occlusion, tooth preparation and also discussing treatment with the patient.

Education in a classroom has evolved from blackboards to LCD projector or the overhead projector to visualizers, document camera, video projectors and interactive whiteboards. Endodontic treatments have also evolved with the use of CBCT, digital radiographs, operating microscopes, electronic apex locators and thermoplastic obturation systems. These resources are important for the training of future endodontists. However, the general infrastructure of many institutions does not allow the use of these technologies.

The aim of this presentation is to highlight the growing importance of digital technology in the delivery of endodontic education to compliment the technological developments taking place in endodontics. The objective is to use CBCT and its associated software, intraoral scanner and CAD CAM systems to highlight improved methods of endodontic care that can be applied in an educational setting by both early career dentists and experienced dentists to evolve and utilize the benefits of digital dentistry.

Appendix C: CPD for British Endodontic Society

< Endodontics: Basic Principles and Application in Practice

Post Endodontic Restorations

Post Endodontic Restorations

☆ Add to favourites

By watching this video you should:

- A) Be able to outline the criteria upon which restoration of a root filled tooth must be judged
- B) Be able to identify options available for restoration of anterior and posterior root filled teeth
- C) Be able to choose when to provide an indirect or direct restoration based upon current evidence
- D) Be able to demonstrate core build up

Video

Appendix D: Publication

INTERNATIONAL ENDODONTIC JOURNAL

doi:10.1111/iej.13438

REVIEW

The restoration of root filled teeth: a review of the clinical literature

B. Bhuva[1], M. Giovarruscio[1,2], N. Rahim[1], K. Bitter[3] & F. Mannocci[1]

[1]Department of Endodontics, Faculty of Dentistry, Oral & Craniofacial Sciences, King's College London, London, UK; [2]Department of Therapeutic Dentistry, I.M. Sechenov First Moscow State Medical University, Moscow, Russia; and [3]Department of Operative and Preventive Dentistry, Charité – University Medicine, Berlin, Germany

Abstract

Bhuva B, Giovarruscio M, Rahim N, Bitter K, Mannocci F. The restoration of root filled teeth: a review of the clinical literature. *International Endodontic Journal*, **54**, 509–535, 2021.

Clinicians often face dilemmas regarding the most appropriate way to restore a tooth following root canal treatment. Whilst there is established consensus on the importance of the ferrule effect on the predictable restoration of root filled teeth, other factors, such as residual tooth volume, tooth location, number of proximal contacts, timing of the definitive restoration and the presence of cracks, have been reported to influence restoration and tooth survival. The continued evolution of dental materials and techniques, combined with a trend towards more conservative endodontic-restorative procedures, prompts re-evaluation of the scientific literature. The aim of this literature review was to provide an updated overview of the existing clinical literature relating to the restoration of root filled teeth. An electronic literature search of the PubMed, Ovid (via EMBASE) and MEDLINE (via EMBASE) databases up to July 2020 was performed to identify articles that related the survival of root filled teeth and/or restoration type. The following and other terms were searched: restoration, crown, onlay, root canal, root filled, post, clinical, survival, success. Wherever possible, only clinical studies were selected for the literature review. Full texts of the identified articles were independently screened by two reviewers according to pre-defined criteria. This review identifies the main clinical factors influencing the survival of teeth and restorations following root canal treatment *in vivo* and discusses the data related to specific restoration type on clinical survival.

Keywords: crown, cuspal coverage restoration, endodontic-restorative treatment, restoration of root filled teeth, root canal post, tooth survival.

Received 4 May 2020; accepted 27 October 2020

Introduction

Root filled teeth may be lost due to post-treatment endodontic disease, unrestorable caries, restorative failure, irretrievable cusp or crown fracture, vertical root fracture, periodontal disease or other less common causes. Whilst much of the research relating to post-treatment failure of root filled teeth focuses on the factors leading to the persistence and emergence of endodontic disease, numerous studies have clearly demonstrated that restorative complications are the most common reason for teeth to be extracted (Vire 1991, Fuss *et al.* 1999).

The emergence of research relating to the survival, rather than success (clinical and radiographic), of root filled teeth has highlighted the importance of the

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F Mannocci and K Bitter have contributed equally as senior authors and are joint last named authors.

Appendix E: Publication

Biomechanical planning for minimally invasive indirect restorations

Deborah I. Bomfim,[1] Noushad M. Rahim[2] and Rupert S. Austin*[3]

Key points

- Partial coverage indirect restorations are less commonly prescribed by dental practitioners compared to full-coverage crowns.
- Improvements in material science and digital technologies are opening increased possibilities for aesthetic adhesive partial-coverage indirect restorations.
- This article highlights recent developments in the evidence base for these restorations as well as an algorithm supporting decision-making in fixed prosthodontics.

Abstract

This paper explores the planning and execution of indirect partial-coverage restorations and will outline practical recommendations for maximising the outcomes for minimally invasive (MI) approaches to indirect restorations, with a special focus on vital teeth, endodontically-treated teeth and worn dentitions. Throughout the paper, the supporting evidence for each rationale for partial-coverage restorations will be considered, as well as the risks and benefits of adopting an MI approach to indirect restorations.

Introduction

Increasingly, a worldwide consensus exists towards minimally invasive (MI) approaches for managing dental caries,[1] which for non-cavitated carious lesions often involves non-invasive or micro-invasive management.[2] In contrast, no such consensus yet exists for the prescription, design and preparation of indirect restorations. The majority of the half-a-billion dental restorations placed worldwide every year are direct composite resin restorations (which are more conservative than amalgam restorations), whereas, in contrast, the majority of indirect restorations placed are still full-coverage crowns, which are less conservative than biomimetic partial-coverage indirect restorations.[3]

This suggests that biomechanical preparations which allow for a more conservative biomimetic approach to planning restorations are still not popular when it comes to indirect restorations.

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Refereed Paper.
Accepted 12 August 2020
https://doi.org/10.1038/s41415-020-2170-x

Indeed, in the United States, 95% of indirect restorations are still full-coverage crowns rather than partial-coverage indirect restorations.[4] Moreover, surveys of UK general dental practice reveal that the most used methods for planning and designing tooth preparation are the dimensions of the preparation burs and the form of the opposing/adjacent teeth,[5] as opposed to MI partial-coverage designs. This is a missed opportunity, given the technological advances for planning restorative treatments, including the ability for digital planning of MI endodontic access cavities and digital diagnostic wax-ups having potential to be more precise than conventional wax-ups.

This paper will review the principles behind biomechanical planning for MI indirect restorations, such as the case shown in Figure 1, and consider the many different variables influencing their outcome.[6,7,8] This paper will also explore the planning and execution of indirect partial-coverage restorations and outline practical recommendations for maximising the outcomes for MI approaches to indirect restorations, with a special focus on vital teeth, endodontically-treated teeth and worn dentitions. Throughout the paper, the supporting evidence for each rationale for partial-coverage restorations will be considered, as well as the risks and benefits of adopting an MI approach to indirect restorations.

Planning indirect restorations in vital teeth, non-vital teeth and worn dentitions

What does the evidence say on direct vs indirect restorations for vital teeth?

The most important consideration regarding MI indirect dentistry is to consider whether to provide a direct restoration as opposed to an indirect restoration. Each clinician reading this article will have developed a personal threshold for provision of indirect restorations. This is based on the clinician's own expertise, personal protocols and practice setting, balanced by the available scientific literature, on one hand, and patient values and expectations, on the other.[9] Provision of indirect restorations sacrifices healthier tooth tissue than direct restorations, and moreover, full-coverage crown restorations require more tooth tissue removal than partial-coverage restorations.[10]

Online evidence-based syntheses algorithms are emerging to help resolve this dilemma. To date, more than ten systemic reviews with meta-analyses[11,12,13,14,15,16,17,18,19,20] provide data from prospective clinical outcome studies looking into indirect restorations, which are summarised by online clinical decision-supporting applications; for example 'Crown-or-fill' (www.crownorfill.com).[21] The Crown-or-fill application summarises

Appendix F: Prospero Registration for the Systematic Review

A systematic review and meta-analysis of survival of ceramic onlays on root filled teeth

Citation

Noushad Rahim, Rupert Austin, Federico Foschi, Shanon Patel, Francesco Mannocci. A systematic review and meta-analysis of survival of ceramic onlays on root filled teeth. PROSPERO 2020 CRD42020176880 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020176880

Review question

What is the success and survival of tooth and restoration on endodontically treated teeth that have been restored using onlays?

Searches

We will search the following electronic general, open access, regional and grey literature, bibliographic databases: MEDLINE (searched via PubMed), The Cochrane Library (CDSR, Cochrane Central Register of Controlled Trials (CENTRAL), and DARE), Virtual Health Library (including Bibliography Brazilian Dentistry and LILACS), Scopus, ISI Web of Knowledge, Embase, and ClinicalTrials.gov.

Additionally, Directory of Open Access Journals (DOAJ), Digital Dissertations (searched via UMI Proquest), metaRegister of Controlled Trials, WHO trials search portal, and Google Scholar will be searched manually. No search filters will be applied other than trials on humans and dentistry, where available. Hand searching will also be performed from the reference/citation lists of the full text articles that will be eligible for inclusion and relevant systematic reviews. Non English articles will not be included.

Search date: to be expected: April 2020

Types of study to be included

Randomized clinical trials or prospective/ retrospective non-randomized cohort studies on humans will be included. Nonrandomized cohort studies with unclear design, cross-sectional studies, case reports/series,

non-clinical studies, review articles, letters, opinion pieces, in-vitro and animal studies will be excluded.

Condition or domain being studied

The aim of this systematic review is to evaluate the survival of onlays on root canal treated teeth and to determine the most frequent causes of failure reported in retrospective, prospective studies or randomised clinical trials.

Participants/population

Patients of any age, gender, ethnicity who had endodontically treated permanent posterior teeth restored using onlays or overlays.

Exclusion criteria included in vitro studies, studies on animals or review of literature. Participants that had post retained restorations were excluded

Intervention(s), exposure(s)

Non surgical root canal treatment performed on premolars or molars that are restored using onlays.

Comparator(s)/control

Compared to root treated teeth that are restored using full crowns.

Context

Any clinical setting will be included in order to increase the applicability of the results.

Main outcome(s)

Survival of restoration and/or tooth.

Measures of effect

Survival of the restoration will be measure by any cracks, chipping or fracture.

Survival of the tooth will be measured by its presence in a functional state.

Additional outcome(s)

Mode of failure, longevity, failure of restoration among vital and non vital teeth will be assessed

Measures of effect

Statistical pooling of data using a meta-analysis is planned if the studies are combinable and relatively homogeneous concerning the design, interventions, and outcomes.

Data extraction (selection and coding) [1 change]

Two review authors (NR and RA) will screen independently the titles and/or abstracts of studies retrieved from the searches and those from additional sources (manual searching, reference lists) to identify articles that potentially meet the inclusion criteria. The full text of all potentially eligible studies will be retrieved and assessed independently by the two reviewers.

In case of disagreement regarding the inclusion or exclusion of a study, it will be resolved by discussion with a third reviewer (FM). All potentially relevant papers excluded from the review at this stage will be listed as excluded studies, with reasons provided in the 'Characteristics of excluded studies' appendix table.

FM will review the articles and act as arbiters if there is a discrepancy in the selected studies. MA will provided the statistical analysis. NR, RA, FF, SP and FM will review the final edition.

The following data will be extracted from the studies and captured in an Excel sheet.

General data: Publication year, country, study setting, number of operators, specialist or general dentist, age and number of patients, follow up period, drop outs, number of restorations

Tooth and Restoration related: Material used, type of restoration, Pulpal status of tooth

Outcome: Criteria for assessment, survival, number and mode of failure.

Data extraction will be done by one researcher (NR) and the second (RA) will be contacted in case of doubt.

Risk of bias (quality) assessment

The risk of bias will be assessed using the Cochrane Collaboration's tool for assessing risk of bias of RCTs, while a modified checklist from the one originally proposed by Downs and Black will be used for the non-RCTs. The overall risk of bias will be judged as "high", "low" or "unclear" for randomized studies, while serious methodological limitations will be judged to exist when a non-RCT collected less than 17 points on the modified checklist.

The risk of bias will be incorporated in the results of the meta-analysis (a) in formulating clinical recommendations and (b) by conducting appropriate sensitivity analysis.

The reporting biases (small-study effects or publication bias) will be assessed with a funnel plot and Egger's weighted regression test. When the test hinted towards the existence of publication bias, further assessments are planned.

Strategy for data synthesis

For the primary outcome of the meta-analysis, onlay failure according to their characteristics (pulpal status, onlay material), risk ratios and their corresponding 95% Confidence Intervals will be calculated. The extent and impact of between-study heterogeneity will be assessed by inspecting the forest plots. We will assess reporting biases via contour-enhanced funnel-plots. If hints of bias are identified, we will try to explain them and will we perform sensitivity analyses by including only bias free and/or the most precise studies.

Analysis of subgroups or subsets

Possible sources of heterogeneity in meta-analyses will be sought through pre-specified mixed-effects

subgroup analyses and random-effects meta-regression, if at least 5 studies are included for a specific

comparison.

Subsets according to pulpal status: Vital or non vital teeth

Subsets according to onlay material used.

Contact details for further information

Mohamed Noushad Rahim

mohamed.rahim@kcl.ac.uk

Organisational affiliation of the review

King's College, London

https://www.kcl.ac.uk/

Review team members and their organisational affiliations

Dr Noushad Rahim. King's College, London

Dr Rupert Austin. King's College, London

Dr Federico Foschi. King's College, London

Dr Shanon Patel. King's College, London

Professor Francesco Mannocci. King's College, London

Collaborators

Mr Manoharan Andiappan. King's College, London

Type and method of review

Meta-analysis, Systematic review

Anticipated or actual start date

01 April 2020

Anticipated completion date [1 change]

31 August 2021

Funding sources/sponsors

Self Funded

Conflicts of interest

Language

English

Country

England

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Ceramics; Humans; Root Canal Obturation; Tooth; Tooth Root

Date of registration in PROSPERO

26 June 2020

Date of first submission

01 April 2020

Stage of review at time of this submission [1 change]

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

26 June 2020

03 August 2021

Appendix G: PROBE 2023. Checklist of items to be included when reporting observational studies in Endodontics*

Section/ Topic	Item Number	Checklist items	Reported on page number
Title	1a	The specific area(s) of interest must be provided using words and phrases that identify the clinical problem(s) and focus of the study	115
	1b	The study design must be included in the Title, e.g., cross-sectional, cohort, case-control, case-series etc.	
Keywords	2a	Keywords indicating the specific area(s) of interest using MeSH terms or other more applicable terms must be included	
Abstract	3a	The Introduction/Background must briefly explain the rationale or justification for the study	
	3b	The aim(s)/objective(s) of the study must be provided	
	3c	The Methodology must provide (where relevant) essential information on the nature of the study design (retrospective, cross-sectional, prospective, etc.), setting, location(s), and relevant dates, including periods of recruitment, exposure, follow-up, outcome(s) assessed and statistical analysis	
	3d	The Results must describe the number of subjects that were included and analysed as well as the most significant results for all experimental and control groups. The results of statistical analysis must be reported in terms of unadjusted and confounder-adjusted outcomes (if relevant). Adverse events or side-effects must also be reported if present or confirmed as absent	
	3e	The Conclusion must interpret and summarise the primary aim/objective and main findings as well as emphasise the clinical implications	
	3f	The source(s) of funding must be provided	

Introduction	4a	The clinical problem/question, scientific background and rationale for the study must be provided, including the gap(s) or inconsistencies in the existing knowledge base	115
	4b	The primary and, if applicable, any additional/secondary aim(s) and objective(s) of the study must be provided, including any pre-specified hypotheses	
Methods *Ethics*	5a	The details (name, reference number, date) of the approval or exemption granted by an ethics committee, such as an Institutional Review Board, must be provided	127
	5b	The process used for obtaining and storing informed consent must be provided	129
Study design	5c	The key elements of the study design must be described early in the Methods section	130
Setting	5d	The details of setting(s), location(s), socioeconomic status of participants (if available) and relevant dates, including periods of recruitment, exposure, follow-up, and data collection must be provided	130
Sample size	5e	Information on how the sample size was determined *a priori* must be provided as well as the rationale for sample size calculation, preferably with reference to the published literature or a pilot study with additional detail as to why the defined sample size makes the study worthwhile	139
Participants – unmatched studies	5f	All studies should include inclusion/exclusion criteria as well as the sources and methods of participant selection. Methods of follow-up must also be provided in cohort studies and the rationale for the choice of 'cases' and 'controls' in case-control studies	128
Participants – matched studies	5g	For matched studies (e.g., cohort, case-control) the matching criteria and the numbers of participants in each group must be provided	
Variables	5h	All outcomes, exposures, predictors, potential confounders, and effect modifiers must be defined clearly	126

Data sources/ measurement	5i	Sources of data and details of the methods of assessment (measurement) for each variable of interest must be provided	135
Bias	5j	Efforts taken to identify and address potential sources of bias must be provided	136
Quantitative variables	5k	The handling of quantitative variables in the analyses must be explained. Decisions on how groupings were made and/or how category boundaries were defined for continuous variables must be described	
Statistical methods	5l	All statistical methods, including those used to control of confounding factors in the study and in the analysis of the data, must be described	138
	5m	The methods used to examine subgroups and interactions must be described, if applicable	139140
	5n	Missing data (e.g. drop-outs, data not reported) must be addressed and described	
	5o	The analytical methods that take account of the sampling strategy (if applicable) in *Cross-sectional studies* must be described	139
	5p	Sensitivity analyses, must be described when used	
Results *Participants*	6a	The number of participants in each stage of the study (i.e., eligibility, recruitment, available at follow-up and included in analyses for relevant outcome(s)) must be described	140
	6b	Reasons for non-participation (e.g., not eligible, losses/drop-outs) must be described	140
Dates	6c	Changes in baseline dates of recruitment, follow-up, and study duration reported in the Methodology must be described, if applicable	
Descriptive data	6d	The baseline demographic and clinical characteristics of study participants as well as information on exposures and potential confounders must be provided	

	6e	The number of participants with missing data must be provided for each variable. If relevant, follow-up times should be summarised clearly and accurately (e.g., average or total time)	
Outcome data	6f	Information on number of outcomes or summary measures over time must be described	
	6g	For multivariable analyses developing risk profiles or reducing the effect of confounders, the effect of all included independent variables may be reported, as well as their effects on the prediction model (if applicable)	154
Main results	6h	Unadjusted (or uncorrected or crude) estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence intervals) must be described. Which confounders were adjusted for and why they were included must also be described	154
	6i	Results in terms of relative risk should also be translated to absolute risk for a meaningful time period, if relevant	154
Additional analyses	6j	The results from any other analyses (e.g., sensitivity, subgroup analyses) must be described, if applicable, as well as adjusted analyses, distinguishing pre-specified from exploratory	164
Discussion *Key results*	7a	The main findings must be summarized with reference to the study aim(s)/objective(s)	166
Rationale	7b	The rationale for inclusion/exclusion criteria, exposure, and duration must be provided	
Clinical relevance	7c	An explanation of the clinical relevance of the primary and any additional/secondary outcome(s) must be provided	166
Strength	7d	The strength(s) of the study must be provided	166
Limitations	7e	The limitations of the study must be provided - addressing the sources of potential bias, imprecision, study design, study size and potentially important but missing confounding variables.	166

		Both direction and magnitude of any potential bias must be discussed	
Summary and validity	7f	The discussion of the strength and limitations should be summarized in an overall assessment of the internal validity of the study	169
Interpretation	7g	A detailed interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence must be provided	
Generalisability	7h	The generalizability (external validity, applicability, real-world relevance etc.) of the study findings must be discussed	
Future directions	7i	Implication for future research and clinical practice must be described	
Conclusion(s)	8a	Explicit conclusion(s) from the study must be provided and address all the aims/objectives	169
Funding details	9a	All sources of funding and other support (such as supply of drugs, equipment etc.) as well as the role of funders must be acknowledged and described	
Conflict of interest	10a	An explicit statement on conflicts of interest must be provided, together with full affiliations of every author(s)	
Quality of images (if applicable)	11a	Details of the equipment, software and settings used to acquire the image(s) must be described in the text or legend (if applicable)	
	11b	The reason why the image(s) was acquired and the rationale for its inclusion in the manuscript must be provided in the manuscript. A justification for all images that involve ionising radiation must be included	
	11c	The circumstances (conditions) under which the image(s) were viewed and evaluated by the author(s) must be provided in the text	
	11d	The resolution, any magnification of the image(s) or modifications/enhancements (e.g., adjustments for	

		brightness, colour balance, magnification, image smoothing, staining, etc.) that were carried out must be described in the text or figure legend	
	11e	Patient(s) identifiers (names, patient numbers) must be removed for General Data Protection Regulation (GDPR) and to ensure they are anonymized or de-identified in all images	
	11f	An interpretation of the findings (meaning and implications) from the image(s) must be provided in the text	
	11g	The figure legend associated with each image must describe clearly what the subject is and what specific feature(s) is illustrated. If cases are offered to illustrate descriptions of a cohort, then the age, gender, ethnicity, and other specific attributes that are relevant to the cohort should be provided	
	11h	Markers/labels must be used to identify the key information in the image(s) and defined in the figure legend	
	11i	The figure legend of each image must include an explanation on whether it is pre-, intra- or post-treatment and follow-up and, if relevant, how images were standardised over time	

* Nagendrababu V, Duncan HF, Fouad AF, Kirkevang LL, Parashos P, Pigg M, Vaeth M, Jayaraman J, Suresh N, Arias A, Wigsten E, Dummer PMH.

PROBE 2023 guidelines for reporting observational studies in Endodontics: A consensus-based development study.

Int Endod J. 2022 Nov 23. doi: 10.1111/iej.13873.

Appendix H: Ethics Approval

HRA Acknowledgment and approval

Health Research Authority

North West - Greater Manchester Central Research Ethics Committee
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

11 December 2017

Prof Francesco Mannocci
Professor of Endodontology/ Conservative Dentistry
Floor 25, Tower Wing
Guy's Dental Hospital, London
SE1 9RT

Dear Prof Mannocci

Study title:	**Survival of root canal treated teeth restored with ceramic onlays**
REC reference:	**17/NW/0594**
Protocol number:	**IRAS 95221**
IRAS project ID:	**224248**

Thank you for your correspondence of 06 December 2017. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 December 2017

Documents received

The documents received were as follows:

Document	*Version*	*Date*

Participant consent form	1.7	10 December 2017
Participant information sheet (PIS)	1.9	10 December 2017

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]	1	
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]	1	18 July 2017
IRAS Application Form [IRAS_Form_06112017]		06 November 2017
Letter from sponsor [Email from Sponsor]	1	08 September 2017
Letter from statistician [Letter from Statistician]		
Letters of invitation to participant [Invitation Letter t]	Version 1.4	16 October 2017
Participant consent form	1.7	10 December 2017
Participant information sheet (PIS)	1.9	10 December 2017
Referee's report or other scientific critique report [Peer Review]		26 September 2017
Research protocol or project proposal [Research Protocol]	1.7	30 October 2017
Sample diary card/patient card [Reminder Letter]	1.2	09 June 2017
Summary CV for Chief Investigator (CI) [CV for Chief Investigator]	1	12 April 2017
Summary CV for student [Student CV]	1	18 September 2017
Summary CV for supervisor (student research) [Supervisor 1 CV]	1	18 September 2017
Summary CV for supervisor (student research) [Supervisor 2 CV]	1	18 September 2017

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

17/NW/0594 **Please quote this number on all correspondence**

Yours sincerely

H. Wood

Harriet Wood
REC Assistant

E-mail: nrescommittee.northwest-gmcentral@nhs.net
Copy to: *Mr. Keith Brennan*
Ms Mays Jawad, Guy's & St Thomas' Foundation NHS Trust

NHS
Health Research Authority
Skipton House
80 London Road
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Tel: 0207 104 8010
Email: hra.approval@nhs.net

Professor Francesco Mannocci
Professor of Endodontology/ Conservative Dentistry
Floor 25, Tower Wing
Guy's Dental Hospital, London
SE1 9RT

11 December 2017

Dear Professor Mannocci

Letter of HRA Approval

Study title:	**Survival of root canal treated teeth restored with ceramic onlays**
IRAS project ID:	**224248**
Protocol number:	**IRAS 95221**
REC reference:	**17/NW/0594**
Sponsor	**King's College London Dental Institute**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

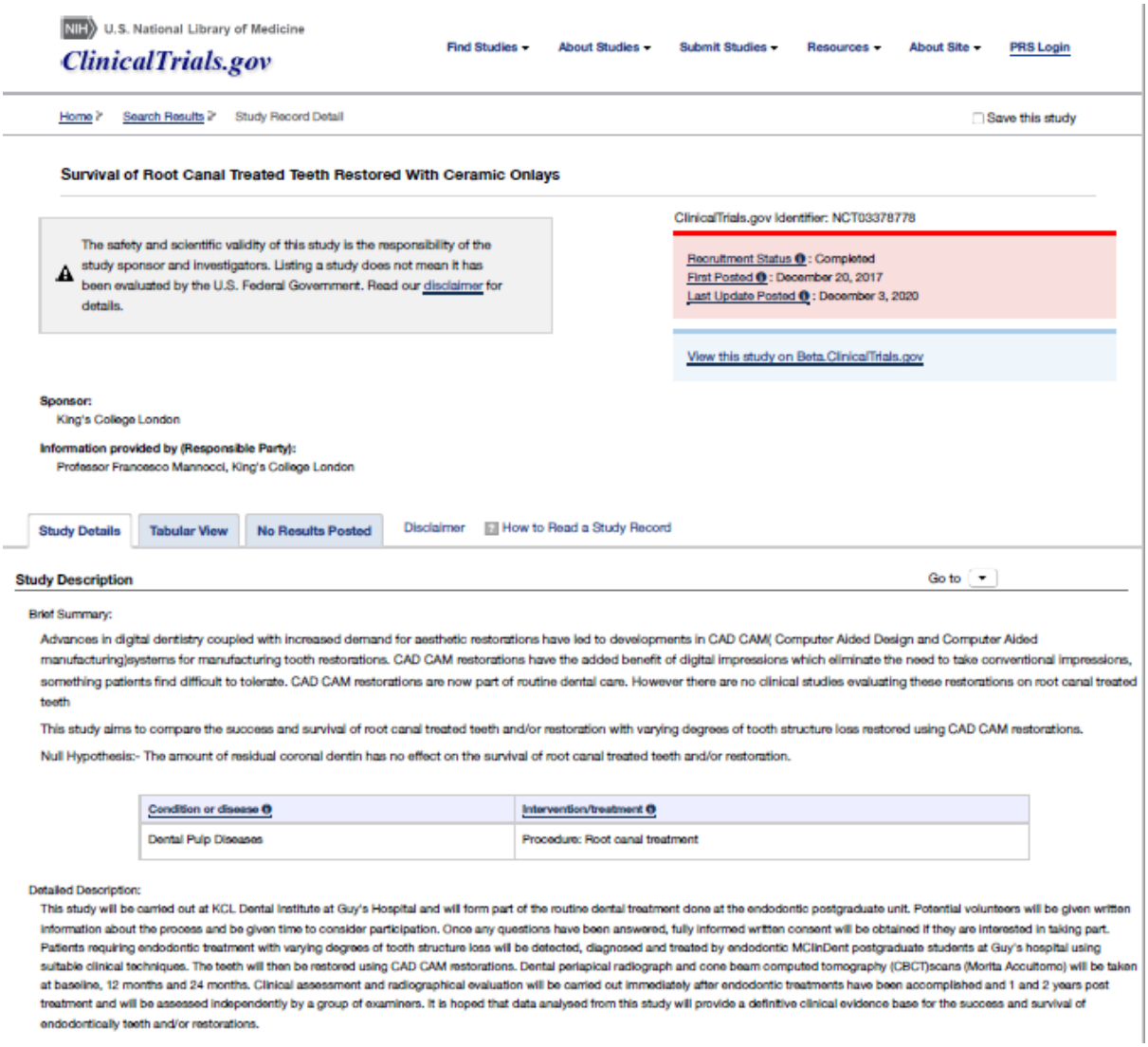
The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Appendix I: Registration with ClinicalTrials.gov



U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site | PRS Login

Home > Search Results > Study Record Detail

Save this study

Survival of Root Canal Treated Teeth Restored With Ceramic Onlays

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03378778

Recruitment Status : Completed
First Posted : December 20, 2017
Last Update Posted : December 3, 2020

View this study on Beta.ClinicalTrials.gov

Sponsor:
King's College London

Information provided by (Responsible Party):
Professor Francesco Mannocci, King's College London

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:

Advances in digital dentistry coupled with increased demand for aesthetic restorations have led to developments in CAD CAM(Computer Aided Design and Computer Aided manufacturing)systems for manufacturing tooth restorations. CAD CAM restorations have the added benefit of digital impressions which eliminate the need to take conventional impressions, something patients find difficult to tolerate. CAD CAM restorations are now part of routine dental care. However there are no clinical studies evaluating these restorations on root canal treated teeth

This study aims to compare the success and survival of root canal treated teeth and/or restoration with varying degrees of tooth structure loss restored using CAD CAM restorations.

Null Hypothesis:- The amount of residual coronal dentin has no effect on the survival of root canal treated teeth and/or restoration.

Condition or disease	Intervention/treatment
Dental Pulp Diseases	Procedure: Root canal treatment

Detailed Description:

This study will be carried out at KCL Dental Institute at Guy's Hospital and will form part of the routine dental treatment done at the endodontic postgraduate unit. Potential volunteers will be given written information about the process and be given time to consider participation. Once any questions have been answered, fully informed written consent will be obtained if they are interested in taking part. Patients requiring endodontic treatment with varying degrees of tooth structure loss will be detected, diagnosed and treated by endodontic MClinDent postgraduate students at Guy's hospital using suitable clinical techniques. The teeth will then be restored using CAD CAM restorations. Dental periapical radiograph and cone beam computed tomography (CBCT)scans (Morita Accuitomo) will be taken at baseline, 12 months and 24 months. Clinical assessment and radiographical evaluation will be carried out immediately after endodontic treatments have been accomplished and 1 and 2 years post treatment and will be assessed independently by a group of examiners. It is hoped that data analysed from this study will provide a definitive clinical evidence base for the success and survival of endodontically teeth and/or restorations.

Appendix J: Informed Consent Training

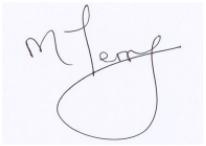
Certificate of Attendance

Mohamed Rahim

Informed Consent for Research: In Depth

Comprising 6.5 hours of participatory professional development and learning
KCL : 06 November 2017

WFC
Confidence from Clarity



Mark Terry – Senior Consultant

Appendix K: Invitation Letter

Guy's and St Thomas' NHS
NHS Foundation Trust

Noushad Rahim
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KING'S College LONDON

Guy's Hospital
Great Maze Pond
London SE1 9RT

INVITATION LETTER

Title: The success and survival of teeth and restoration following root canal treatment with varying degrees of tooth structure loss restored with CAD CAM restorations.

REC Ref No: 17/NW/0594

Dear Sir / Madam,

We would like to invite you to take part in our research study.

In brief, this research study aims to assess the survival and success of root canal treatment and the ceramic restoration. The root canal treatment and the restoration would be done as routine treatment. Additional requirement for this study are the follow up visits at 12 months and 24 months after completion of the treatment where the tooth would be assessed clinically and radiographically (CBCT scan) to see if the treatment has been successful. A detailed description follows in the Participant Information Sheet. A member of the team is available to go through the participant information sheet at the assessment appointment. If you have any questions about this project please contact Dr Noushad Rahim.

Yours sincerely,

Noushad Rahim

Abbreviations:

CAD CAM: Computer Aided Design- Computer Aided Manufacturing

CBCT: Cone Beam Computed Tomography

Appendix L: Participant Information Sheet

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

Guy's Hospital
Great Maze Pond
London SE1 9RT

PARTICIPANT INFORMATION SHEET

Study title "SURVIVAL OF ROOT CANAL TREATED TEETH AND RESTORATION RESTORED USING CERAMIC ONLAYS"

REC Ref Number: 17/NW/0594

Dear Sir/Madam,
When you attend your assessment appointment, you may be approached to take part in a research study. Please take as long as you require to read the following information with regard to your potential participation. Thank you in advance.

What is the purpose of the study?
Our study is an approved Clinical PhD Research study.

The aim of this study is to assess the success and survival of both root canal treated teeth and the restoration. The tooth that requires root canal treatment will be treated and then restored with a crown / partial crown using computer aided design and computer aided manufacturing technology. The tooth and the restoration is then followed up for treatment success using Cone Beam CT and clinical assessment.

Dental radiographs (X-rays) are usually taken immediately after completion of treatment and on a periodic basis (review appointments), usually after 1 and 2 years after treatment has been completed to assess how successful treatment has been. The amount of information gained from conventional dental radiographs is limited as the images produced are only 2 dimensional (like a photograph). The Cone Beam CT is a 3-dimensional scan which is the latest technology for imaging teeth. It allows us to assess your tooth in 3-dimensions and therefore generates potentially more precise information about your tooth including the degree of healing. This specialised Cone Beam Computed Tomography scan gives us a better understanding of the anatomy of your tooth and detect signs of healing earlier than conventional radiographs. Review appointments will also be arranged 1 and 2 years after the completion of your root canal treatment.

Cone Beam CT scans will be taken before treatment, 12 months and 24 months after the completion of your root canal treatment and crown. The additional radiation dose from this scan is minimal and equates to about 2.43% of annual background radiation, which is equivalent to taking a flight from London to New York. The final restoration placed on your tooth will also be assessed clinically, for any defects, at the review appointments and corrected if there are any defects.

This study is being carried out as the researcher's partial fulfilment of the requirements for the degree of Doctor of Philosophy (PhD).

What will I have to do?
Patients who agree to take part in this study will be required to attend 2 additional visits (Visit 4 and 5) to Guy's Hospital for follow-up of the root canal treated tooth during a 24-month period as shown in the flow chart. A CBCT scan will be made at baseline, 12 and 24 month follow up and compared with the pre-operative CBCT scan to assess the success of treatment. You will be sent a reminder at 12 and 24 months by letter, email or SMS to

attend the follow- up. The follow up examination will be to check if the restoration has fractured/ chipped, stained, come off or the tooth has fractured.

Why have I been invited?

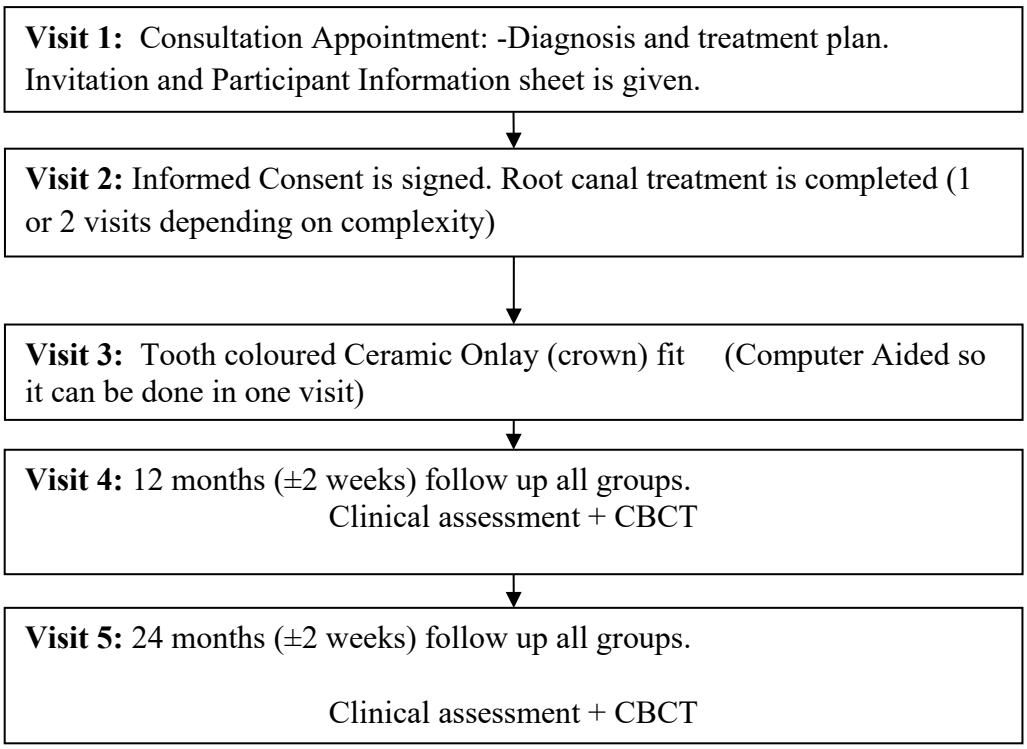
We are inviting you to take part in this study because you have a tooth that requires an endodontic treatment (root canal treatment) followed by a crown/ onlay restoration. This makes you suitable for this study. We hope to recruit 120 volunteers.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do not take part in the study, you will not be required to give a reason. This will not affect the standard of treatment you receive in any way.

What will happen to me if I take part?

If you decide to take part in this research your dental care will proceed as normal. The following flow chart will help you understand what will happen:



What is the drug or procedure that is being tested?

We are not testing any new procedure or drug under development. We are trying to compare the success rate and survival rate of teeth and restoration with varying degrees of tooth structure loss following endodontic treatment procedure. Cone beam computed tomography has been proved by previous research studies to detect the presence of bony disease around the tooth roots earlier than conventional X-rays. This can help improve our diagnosis and treatment plan for future patients. The computer-generated crown is a precise and accepted treatment procedure.

What are the side effects of taking part?

There are no side effects of taking part in this study other than those expected from routine dental care.

What are the possible disadvantages and risks of taking part?

Every exposure to ionising radiation (x-rays) carries a risk. However, due to the low doses of radiation from dental x-rays including CBCT, this risk is negligible. Periapical x-rays are normally taken for routine dental treatment and the effective dose from this conventional x-ray is equal to 0.19% of annual background radiation. This is the same as cosmic radiation exposure on board an aircraft for a 3-hour flight. The dose from the CBCT scan is equal to 2.43% annual background radiation and is about the same as the cosmic radiation on board a high-altitude aircraft over a 7-hour long flight, e.g., from London to New York.

What are the possible benefits of taking part?
There is no direct benefit from the study. The participants will benefit by having the tooth restored using CAD CAM tooth-coloured ceramic restorations. These are computer generated and can be placed at the same visit eliminating an extra visit to have these fitted otherwise. Traditionally done crowns are prepared and then an impression (mould) is made which is sent to a lab and can take around 2 weeks before it is ready to be fitted. The computer-generated crowns can be made and fitted at the same appointment and does not require taking a mould which patients with gagging sensation find uncomfortable. The Cone Beam Computed Tomography scans could allow us to accurately and objectively assess how successful your treatment has been. And the information we get from this study may influence future treatment planning decisions. The benefit of attending the recall, would be to know, if the treatment is successful or if any further treatment is required. Repairs to the restoration or treatment to rectify any problems detected, can be done at the recall. There will not be any reimbursement of travel expenses.

What if something goes wrong?
If you have a concern about any aspects of this study, you should speak to the researchers who will do their best to answer your questions. Please contact the Chief Investigator Prof. Francesco Mannocci (email: francesco.mannocci@kcl.ac.uk, telephone: 02071881573).
If you have a complaint, you should talk to your research doctor who will do their best to answer your questions. If you remain unhappy, you may be able to make a formal complaint through the NHS complaints procedure. Details can be obtained through the Guy's and St Thomas' Patient Advisory Liaison Service (PALS) on 0207 1888188, address: PALS, KIC, Ground floor, north wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH.
This trial is co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation Trust. The sponsors will at all times maintain adequate insurance in relation to the study independently. Kings College London, through its own professional indemnity (Clinical Trials) and no fault compensation and the Trust having a duty of care to patients via NHS indemnity cover, in respect of any claims arising as a result of clinical negligence by its employees, brought by or on behalf of a study patient.

Will my taking part in this study be kept confidential?
Each patient will be given a unique identification number, which will be used throughout the study. All information that is collected about you during the course of the research will be kept strictly confidential and accessed only by authorised people. The personal data and research data will be stored separately at the office of the Chief Investigator Prof Francesco Mannocci. The data will be stored for 4 years after the conclusion of the study, in line with data regulations. The personal data may be accessed for monitoring and/or auditing of the trial.

What will happen to the results of the research study?
Results of this research will be published in appropriate dental and scientific journals. No personal information or other information that could be identified as relating to you will be published. You will be informed of the results of the study by email, SMS or post if you wish to know.

Who is organising and funding the research?
King's College London.

Who has reviewed the study?
This study has been reviewed by the Greater Manchester Central Research Ethics Committee.

Summary
You are invited to participate in this study because you have a tooth that needs endodontic treatment procedure. After completion of endodontic treatment, the tooth will be restored with a ceramic onlay. During the follow-up visits at 12 months and 24 months post treatment, your tooth and restoration will be examined, and Cone Beam Computed Tomography scans will be taken and evaluated.
Thank you for taking the time to read this invitation to take part in this study. If you have any questions about this project, please contact Noushad Rahim.

Contact for Further Information
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Biomaterials research group
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Sponsor: Guy's and St Thomas' NHS Foundation Trust.

Title: Survival of root canal treated teeth restored with ceramic onlays.

IRAS number 224248, Clinical Trial REC No 17/NW/0594

Supplementary Patient Information Sheet on the use of data

Guy's and St Thomas' NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Guy's and St Thomas' NHS Foundation Trust will keep identifiable information about you for 4 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information:

https://www.guysandstthomas.nhs.uk/research/patients/about.aspx

Principal Investigator: M Noushad Rahim
mohamed.rahim@kcl.ac.uk

Guy's and St Thomas' NHS Foundation Trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Guy's and St Thomas' NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in Guy's and St Thomas' NHS Foundation Trust who will have access to information that identifies you will be people who need to contact you to for clinical reasons or appointment purposes or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Guy's and St Thomas' NHS Foundation Trust will keep identifiable information about you from this study for 4 years after the study has finished.

Appendix M: Informed Consent Form

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

Study Number:
Patient Identification Number for this trial:

CONSENT FORM FOR RESEARCH STUDY

Title of Project: "Success and survival of root canal treated tooth restored using ceramic onlays**"**

Name of Researcher: Noushad Rahim

Please initial in the boxes to confirm

- I confirm that I have read and understood the information sheet dated **10-12-2017** (version **1.9)** for the above study. ☐
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
- I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from Guy's Hospital, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
- I agree to take part in the above research study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person Taking Consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix N: Reminder Letter

Guy's and St Thomas' NHS
NHS Foundation Trust

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London SE1 9RT

<LETTERDATE>>

<<PATIENTNAME>>

<<ADDRESS>>

Dear <<GREETNAME>>,

We would like to remind you that your follow up appointment for the root canal treatment and restoration is now due.

If you would like to contact us on 020xxxxxxx, we will be happy to arrange an appointment time to suit you.

In brief, this appointment is part of a research study to see if the root canal treatment and the crown has been successful. A clinical examination and a CBCT scan will be performed at this appointment to assess the outcome of treatment. This appointment is a recall to follow up on the root canal treatment and restoration you had about 12 months ago.

Yours sincerely,

Dr Noushad Rahim

Appendix O: Imaging Protocol

Guy's and St Thomas' NHS
NHS Foundation Trust

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IMAGING PROTOCOL

The patients who consent to take part in the study will receive routine endodontic treatment which will involve a preoperative radiograph, a master cone radiograph and a post op radiograph. A CBCT scan may also be prescribed if indicated.

The additional radiation exposure that the patients will be exposed to for taking part in this study will be during the review scans (Small FOV CBCT) at 12 months and 24 months post op.

Stage	Procedure	Type of Dose	Radiation
First Stage	Consultation and Consent	Routine Treatment Dosage	Periapical radiograph and 1 small fov CBCT
Second Stage	Treatment	Routine Treatment Dosage	Periapical radiographs
Third Stage	Recall	Study Dose	1 small field CBCT at 12 months and 1 at 24 months

Patient Selection Criteria

Consenting patients above 18 years and in good general health.
Needs Root canal treatment.

Exclusion Criteria

Pregnant, breast feeding.
Patients under 18 years.
Patients above 64 years.
Patients unable to give consent.
Not involving patients from prisons.
Not involving patients who cannot read, write or understand English.

Exposure Factors

Exposure Factors	Kv	mAs	DAP
Small FOV CBCT	90	4 (posterior teeth)	4.52 mGy
Periapical Radiograph	70	1.4	34 mGy.cm²

Anatomical Region to be radiographed: Maxillary or mandibular molar.

Number of scans/ Images per procedure: 3 Periapical Radiograph, 1 CBCT scan. 2 additional CBCT scans during recall at 12 months and 24 months

Study Time Line: 2 years follow up with a recall assessment at 12 months and 24 months

Abbreviations

CBCT: Cone Bean Computed Tomography

FOV: Field of View

Kv: Kilovolt

mAs: Milliampere second

DAP: Dose-Area Product

mGy: milligray

Appendix P: Modified USPHS criteria for clinical evaluation of dental restorations.

Category	Rating and characteristics A: Alpha, B: Bravo, C: Charlie, D: Delta	Baseline	One-year follow-up
Anatomical form	A: Restoration's contour is continuous with existing anatomical form and margins B: Restoration is slightly over-contoured or under-contoured C: Marginal overhang or tooth structure (dentine or enamel) is exposed D: Restoration is missing, traumatic occlusion or restoration causes pain in the tooth or adjacent tissue		
Secondary caries	A: No visible caries C: Caries contiguous with the margin of the restoration		
Retention	A: Present B: Partial loss C: Absent		
Marginal adaptation	A: Excellent continuity at resin–enamel interface; no ledge formation, no discolouration B: Slight discolouration at resin–enamel interface; ledge at the interface C: Moderate discolouration at resin–enamel interface measuring 1mm or greater D: Recurrent decay at the margin		
Polishability	A: Smooth and highly shiny, similar to enamel B: Smooth and satin, highly reflective C: Rough and shiny, satin, somewhat reflective D: Rough and dull or satin, not reflective		
Surface staining	A: Absent C: Present		
Sensitivity	Pre-operative sensitivity (yes/no) Post-operative sensitivity (yes/no)		
Soft tissue health	A: Excellent response, no inflammation B: Slight inflammation of gingival tissue C: Moderate to severe gingival inflammation		
Proximal contact points	A: Present C: Absent		

Appendix Q: Grading for FDI and USPHS Criteria

Patient Identification number: Date: BASELINE

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

FDI criteria /USPHS criteria for assessment of restorations

The FDI criteria with their various categories and their grading (in italic: the revisions of 2010), and the correspondence with the USPHS criteria, with their various criteria and their grading (in italic: the modified USPHS)

FDI CRITERIA *(modified in 2010)*				CORRESPONDANT USPHS CRITERIA	
CATEGORIES	**SUB-CATEGORIES**	**FIVE STEPS GRADING**	**TWO STEPS GRADING**	**CATEGORIES** *(modified)*	**GRADING**
a) Aesthetic properties	1. Surface luster	1. **Clinically excellent/very good**2. **Clinically good** (after correction very good) 3. **Clinically sufficient/satisfactory** (minor shortcomings with no adverse effects but not adjustable without damage to the tooth) 4. **Clinically unsatisfactory** (repair for prophylactic reasons) 5. **Satisfactory poor** (replacement necessary)	Acceptable (1,2,3) Non acceptable (4,5)	*Surface texture*	**Alpha** (clinically ideal) **Bravo** (showing minor deviations from the ideal, nevertheless acceptable) (except for retention and secondary caries) **Charlie** (should be replaced to avoid future damage) **Delta** (requiring immediate replacement)
	2. Staining *a. Surface* *b. Margin*			Cavo-surface marginal discoloration	
	3. Colour *match* and translucency			Color match	
	4. *Esthetic anatomical form*			Anatomic contour	
	5. Fracture of material and retention			*Fracture, retention*	
b) Functional properties	6. Marginal adaptation			Marginal integrity	
	7. Wear			*Occlusion*	
	8. Proximal anatomical form (contact point/food impact)			-	
	9. Radiographic examination (when applicable)			-	
	10. Patient's view			-	
	11. Postoperative (hyper-sensitivity) and tooth vitality			*Postoperative sensitivity*	
c) Biological properties	12. Recurrence of caries, erosion, abfraction			Secondary caries	
	13. Tooth integrity (enamel cracks)			-	
	14. Periodontal response (always compared to a reference tooth)			-	
	15. Adjacent mucosa			-	
	16. Oral and general health			-	

Appendix R: FDI Criteria

	1. Surface lustre	**2. Surface Staining**	**3. Colour match and translucency**	**4. Esthetic anatomic form**	**5. Fracture of material and retention**
1. Clinically excellent/very good	1.1 Luster comparable to enamel.	2.1 No surface staining	3.1 Good colour match. No difference in shade and translucency	4.1 Form is ideal	5.1 No fractures/cracks.
2. Clinically good (after polishing probably very good)	1.2 Slightly dull, not noticeable from speaking distance	2.2 Minor Staining, easily removable	3.2 Minor deviations in shade and translucency	4.2 Form is slightly deviated from ideal	5.2 Small hairline crack.
3. Clinically sufficient/ satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/t damage to the tooth.)	1.3 Dull surface but acceptable if covered with film of saliva	2.3 moderate surface staining, also present on other teeth; not esthetically unacceptable.	3.3 Clear deviations but acceptable 3.3.1 More opaque; 3.3.2 More translucent; 3.3.3 darker; 3.3.4 brighter	4.3 Form deviates from ideal but is esthetically acceptable	5.3 Two or more larger hairline cracks and/or material chip fractures affecting the marginal integrity or approximal contact.
4. Clinically unsatisfactory (but reparable)	1.4 Rough surface, cannot be masked by saliva film, simple polishing is not sufficient	2.4 Surface staining present on the restoration and is unacceptable; major intervention	3.4 localised deviation that can be corrected3.4.1 Too opaque.	4.4 Form is affected and unacceptable esthetically. Intervention is necessary.	5.4.1 Material chip fractures which damage the marginal quality or approximal contacts. 5.4.2 Bulk fractures with partial loss (less than half of the restoration).

		necessary for improvement			
5. Clinically poor (replacement necessary)	1.5 Quite rough, unacceptable plaque retentive surface	2.5 Severe staining or subsurface staining (generalized or localised) not accessible for intervention	3.5 Unacceptable replacement necessary	4.5 Form is unsatisfactory or lost. Replacement is needed	5.5 (Partial or complete) loss of restoration or multiple fractures.

B. Functional properties	**6. Marginal adaptation**	**7. Occlusal contour and wear a. qualitatively b. quantitatively**	**8. Approximal anatomical form a. contact point b. contour**	**9. Radiographic examination (when applicable)**	**10. Patient's view**	**11. Postoperative (hyper)sensitivity And tooth vitality**
1.Clinically excellent/very good	6.1 Harmonious outline, no gaps, no white or discoloured lines.	7a.1 Physiological wear equivalent to the enamel. 7b.1 Wear corresponding to 80-120% of enamel.	8a.1 Normal contact point (floss or 25 µm metal blade can pass). 8b.1 Normal contour.	9.1 No pathology, harmonious transition between restoration and tooth.	10.1 Entirely satisfied with aesthetics and function.	11.1 No hypersensitivity, normal vitality.
2. Clinically good (after polishing probably very good)	6.2.1 Marginal gap (<150µm), white lines. 6.2.2 Small marginal fracture removable by polishing. 6.2.3 Slight ditching, slight step/flashes, minor irregularities.	7a.2 Normal wear is only slightly different from that of enamel. 7b.2 50-80% or 120-150% wear compared to that of corresponding enamel.	8a.2 Contact point slightly too strong but has no disadvantage (floss or 25 µm metal blade can only pass with pressure). 8b.2 Slightly deficient contour.	9.2.1 Acceptable material excess present 9.2.2 Positive/negative step present at margin <150 µm.	10.2 Satisfied 10.2.1 Aesthetics. 10.2.2 Function, e.g. Minor roughness.	11.2 Minor hypersensitivity for a period, normal vitality.
3. Clinically sufficient/ satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/t damage to the tooth.)	6.3.1 Gap <250 µm not removable. 6.3.2 Several small marginal fractures 6.3.3 Major irregularities, ditching or flash, steps.	7a.3 Different wear rate than enamel but within the biological variation. 7b.3 <50% or 150-300% of corresponding enamel.	8a.3 Somewhat weak contact, no indication of damage to tooth, gingiva, or periodontal structures; 50 µm metal blade can pass. 8b.3 Visibly deficient contour.	9.3.1 Marginal gap <250 µm. 9.3.2 Negative steps visible <250 µm. 9.3.3 Poor radiopacity of filling material. No adverse effects were noticed.	10.3 Minor criticism but no adverse clinical effects. 10.3.1 aesthetic shortcomings. 10.3.2 Some lack of chewing comfort. 10.3.3 Unpleasant treatment procedure.	11.3.1 Moderate hypersensitivity. 11.3.2 Delayed/ mild sensitivity; no subjective complaints, no treatment needed.
4.Clinically unsatisfactory (but reparable)	6.4.1 Gap>250 µm or dentine/base exposed. 6.4.2 Severe ditching or marginal fractures.	7a.4 Wear considerably exceeds normal enamel wear or occlusal contact points are lost. 7b.4 Restoration >300% of enamel wear or antagonist >300%.	8a.4 Too weak and possible damage due to food impaction; 100 µm metal blade can pass. 8b.4 Inadequate contour. Repair possible.	9.4.1 Marginal gap >250 µm. 9.4.2 Material excess accessible but not removable. 9.4.3 Negative steps >250 µm and reparable.	10.4 Desire for improvement. 10.4.1 Aesthetics. 10.4.2 Function, e.g., Tongue irritation. Reshaping of anatomic form or	11.4.1 Intense hypersensitivity. 11.4.2 Delayed with minor subjective symptoms. 11.4.3 No clinical detectable sensitivity. Intervention is necessary, but not replacement.

	6.4.3 Larger irregularities or steps (repair necessary).				refurbishing is possible.	
5. Clinically poor (replacement necessary)	6.5.1 Restoration (complete or partial) is loose but in situ. 6.5.2 Generalised major gaps or irregularities.	7a.5 Wear is excessive. 7b.5 Restoration or antagonist >500% of corresponding enamel	8a.5 Too weak and/or clear damage due to food impaction and/or pain/ gingivitis. 8b.4 Insufficient contour requires replacement.	9.5.1 Secondary caries, large gaps, large overhangs. 9.5.2 Apical pathology. 9.5.3 Fracture/loss of restoration or tooth.	10.5 Completely dissatisfied and/or adverse effects, incl. pain.	11.5 Intense, acute pulpitis or nonvital tooth. Endodontic treatment is necessary, and restoration must be replaced.

C. Biological properties	12. Recurrence of caries (CAR), erosion, abstraction	13. Tooth integrity (enamel cracks, tooth fractures)	14. Periodontal response (always compared to a reference tooth)	15. Adjacent mucosa	16. Oral general health
1.Clinically excellent/very good	12.1 No secondary or primary caries.	13.1 Complete integrity.	14.1 No plaque, no inflammation, no pockets.	15.1 Healthy mucosa adjacent to restoration.	16.1 No oral or general symptoms
2. Clinically good (after polishing probably very good)	12.2 Small and localised. 1. Demineralisation 2. Erosion or 3. Abfraction	13.2.1 Small marginal enamel fracture (<150 µm). 13.2.2 Hairline crack in enamel (<150 µm).	14.2 Little plaque, no inflammation (gingivitis), no pocket development. 14.2.1 Without overhangs, gaps, or inadequate anatomic form 14.2.2 With overhangs gaps or inadequate anatomic form.	15.2 Healthy after minor removal of mechanical irritations (plaque, calculus, sharp edges, etc.)	16.2 Minor transient symptoms of short duration; local or generalised.
3.Clinically sufficient/satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/t damage to the tooth.)	12.3 Larger areas of 1. Demineralisation 2. Erosion or 3. Abfraction/ dentine not exposed. Only preventive measures are necessary.	13.3.1 Marginal enamel defect <250 µm. 13.3.2 Crack <250 µm. 13.3.3 Enamel chipping 13.3.4 Multiple cracks.	14.3 Difference up to one grade in the severity of papilla bleeding index (PBI) compared to baseline and compared to control tooth. 14.3.1 Without overhangs, gaps, or inadequate anatomic form 14.3.2 With overhangs, gaps, or inadequate anatomic form.	15.3 Alteration of mucosa but no suspicion of a causal relationship with a restorative material.	16.3 Transient symptoms, local and/or general.
4. Clinically unsatisfactory (but reparable)	12.4.1 Caries cavitation and suspected undermining caries. 12.4.2 Erosion in dentine. 12.4.3 Abrasion/abstraction in dentine. Localised and accessible can be repaired.	13.4.1 Major marginal enamel defects; gap >250 µm or dentine or base exposed. 13.4.2 Large cracks >250 µm, probe penetrates. 13.4.3 Large enamel chipping or wall fracture.	14.4 Difference of more than one grade PBI in comparison to control tooth or increase in pocket depth>1 mm requiring intervention. 14.4.1 Without overhangs, gaps, or inadequate anatomic form 14.4.2 With overhangs gaps or inadequate anatomic form	15.4 Suspected mild lichenoid or toxic reaction.	16.4 Persisting local or general symptoms of oral contact stomatitis or lichen planus or allergic reactions. Intervention is necessary but no replacement.
5. Clinically poor (replacement necessary)	12.5 Deep caries or exposed dentine that is not accessible to repair the restoration.	13.5 Cusp or tooth fracture.	14.5 Severe/ acute gingivitis or periodontitis. 14.5.1 Without overhangs, gaps, or inadequate anatomic form	15.5 Suspected severe allergic, lichenoid, or toxic reaction.	16.5 Acute/ severe local and/or general symptoms.

			14.5.2 With overhangs gaps or inadequate anatomic form		

Appendix S: Glossary and definition of commonly used terms

Restoration: a broad term applied to any material or prosthesis that restores or replaces lost tooth structure, teeth, or oral tissues

Inlay: a fixed intracoronal restoration; a dental restoration made outside of a tooth to correspond to the form of the prepared cavity, which is then luted into the tooth

Onlay: a partial-coverage restoration that restores one or more cusps and adjoining occlusal surfaces or the entire occlusal surface and is retained by mechanical or adhesive means; comp, Partial-Coverage Crown

Crown: an artificial replacement that restores missing tooth structure by surrounding part or all of the remaining structure with a material such as cast metal alloy, metal-ceramics, ceramics, resin, or a combination of materials

Margin: the outer edge of a crown, inlay, onlay, or other restoration

Finish Line: a boundary surface of a tooth preparation is termed the finish line or finish curve.

Partial-coverage restoration Synonyms: - Onlay, Partial-Coverage Crown, Partial-Coverage Retainer, Three-Quarter Crown

Post: a post usually made of metal or fiber-reinforced composite resin that is fitted into a prepared root canal of a natural tooth; yttria-stabilized zirconia is also used as a post material; when combined with a core, it provides retention and resistance for an artificial crown; it is also used as a platform for retentive attachment systems and for a non-retentive overdenture post-coping

Post-and-coping: a post with an incorporated coping; the coping encompasses the tooth root and functions as an abutment for an overdenture, fixed partial denture, or fixed complete denture.

Post-and-core: a post with incorporated core; it provides retention and resistance for an artificial crown; it is also used as a platform for retentive attachment systems and non-retentive overdenture abutments.

Luting agent: any material used to attach or cement indirect restorations to prepared teeth.

ETT: Endodontically treated tooth. A tooth that has had non-surgical root canal treatment.

Post endodontic restoration: Definitive restoration provided to an endodontically treated tooth.

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