The effect of dental loupes magnification on the amount of tooth structure removed during endodontic access cavity procedures

Thesis submitted in accordance with the University of Liverpool for the degree of Endodontic Doctorate in Dental Sciences (DDSc)

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Abstract

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By

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Introduction: Over the years, emphasis has been placed on minimally invasive endodontics, this approach calls for the least amount of preparation of dental hard tissues. The interest and use of magnifying loupes among dental practitioners and students appear to be growing and is thought to help visualise tooth preparation. The influence of the use of loupes in tooth preparation and evaluating the methods used to assess tooth tissue removal in endodontics is not fully understood and would benefit from further research.

Aims: The first aim of this research was to evaluate methods used to investigate tooth tissue removal after endodontic access cavity preparation. The second aim was to investigate the effect of dental loupes magnification on the amount of tooth structure removed during the endodontic access cavity procedure by undergraduate dental students.

Methodology:

The first part of this research project involved a review of the current literature related to the subject.

The second part was focused on investigating alternative methods of evaluating the amount of tooth tissue removal following endodontic access cavity preparation. This involved undertaking an *in-vitro* study utilising Analytical Balance, an Optical scanner, and Cone Beam Computed Tomography (CBCT) with 3D printed teeth.

The next chapter is focused on a cross over randomised study conducted at Liverpool University Dental Hospital (LUDH). Twenty undergraduate dental students, without previous experience using magnification, were recruited from LUDH and split into two even groups of 10. A PowerPoint presentation that included a video regarding the access cavity preparation and the use of magnification loupes was presented to each group before conducting the study. The research took place in a simulated clinical setting in which the first group of students prepared endodontic access cavities in three 3D-printed teeth (1 mandibular 1st molar, 1 maxillary 1st premolar, and 1 maxillary central incisor) utilising dental loupes at x3.5 magnification. The second group carried out endodontic access on three 3D-printed teeth (1 mandibular 1st molar, 1 maxillary 1st premolar, and 1 maxillary central incisor), without using dental loupes. Cone-beam Computed tomography (CBCT) and Analytical Balance were used to assess the endodontic access cavity preparations and generate data for analysis.

The final chapter discusses the clinical implications and areas for future research resulting from this project. The first study will inform future researchers on the various methods available to analyse the amount of tooth tissue removal in restorative and endodontics. The outcome of the second study could inform studies investigating the research question in other scenarios. Such as, the effect of other forms of magnification, including prismatic loupes and an operative microscope on the amount of tooth structure lost as a result of endodontic access cavity preparation. Furthermore, this can also be investigated with more experienced operators, including general practitioners, postgraduate trainees and qualified endodontic specialists.

Results: Within the limitations of this study, the first study showed that the analytical balance method was able provide an accurate measurement in sub-milligrams, while Optical scanner and CBCT were able to provide accurate volumetric data.

The second study showed that magnification (loupes) does not seem to influence the amount of tooth tissue removal during endodontic access cavity procedure by novice undergraduate students, this could be attributed to; insufficient training on the use of loupes, the use of standardised type of the loupes and students focused on the quality of the access cavity rather than the amount of tissue removed.

There was no significant difference in the size of the access cavity among the loupe group and the un-aided vision group.

Conclusion: The outcome of the study revealed that analytical balance, Optical scanner and CBCT were able to quantify the amount of tooth tissue removal after endodontic access cavity. The use of magnifying loupes does not appear to influence the amount of tooth tissue removal by novice undergraduate students during the endodontic access cavity procedure and this may be due to students requiring more training and experience before they start using the loupes. Furthermore, there is no significant difference between the loupe group and the unaided vision group in the extent of the outline form of the access cavity.

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Acknowledgement

"In the name of God, the most gracious, the most merciful"

On embarking on this doctorate programme, I believed I was well prepared for what was to come. My goals were to challenge myself, expand my knowledge and widen my horizon to new opportunities. However, I could never have foreseen the magnitude of obstacles I would encounter. Firstly, as an international student, studying such a stimulating programme in a foreign language was a steep learning curve. Also, one can easily take for granted the minutiae involved in moving to a new country and learning new customs. Undoubtedly, the greatest difficulty however was leaving my friends and family.

Therefore, I cannot express the limit of my gratitude to all those who made me feel welcome on my arrival in the UK. Firstly, to my friends, colleagues and all the staff at Liverpool University Dental Hospital. Your kindness and support was invaluable throughout my time in the UK.

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Last but certainly not least, after God, I would like to convey my highest appreciation to my family. My siblings Ahead, Alani, Haneen, Ebaa, your support throughout my training was a great motivation. In particular, my elder brother Alani, your daily encouragement and guidance will never be forgotten. Finally, my parents Falak and Ibrahim, I would not be in this position without your continuous love, sacrifice, and encouragement throughout my life. I will forever be in your debt, but I vow to spend all my efforts to repay your efforts as much as possible.

"You measure the size of the accomplishment by the obstacles you have to overcome to reach your goals"

Thesis Structure

The following is a brief overview of the subsequent chapters in this thesis, highlighting the main objectives:

- **Chapter1: Introduction:** This chapter presents the description of endodontics, traditional and modern endodontic access cavity, and magnification in endodontics
- **Chapter 2: Literature review:** This chapter includes a broad overview of scientific perspectives and evidence on endodontics.
- **Chapter 3: First study:** This chapter presents the study conducted to evaluate different methods used to investigate tooth tissue removal after endodontic access cavity preparation.
- **Chapter 4: Second study:** This chapter presents the study conducted to investigates the effect of dental loupes on the amount of tooth structure removed during endodontic access cavity procedure undertaken by undergraduate dental students.
- **Chapter 5:** clinical implications and future research: This chapter discuss the clinical implications and recommendations for future research

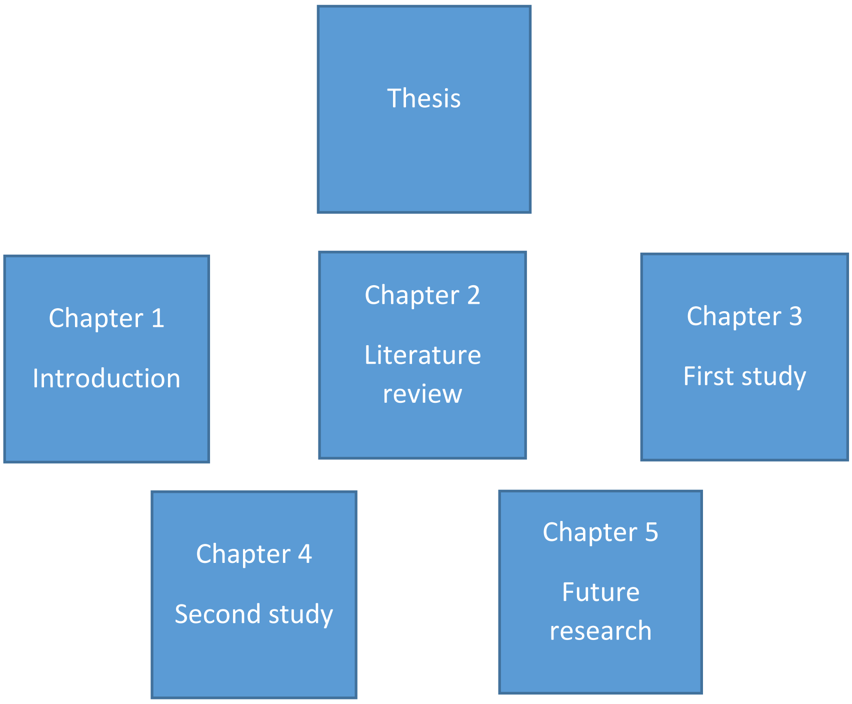

Figure 1: Showing the Thesis structure

1 Chapter 1: Introduction

Endodontic treatment consists of three equally important phases including canal preparation, microbiological control, and three-dimensional obturation (AAE, 2010).

Access cavity preparation is the first clinical step in endodontic therapy and is a key step toward the healing of pulpal and periapical infection (Moore *et al.,* 2016), (Siqueira Jr and Rôças, 2008). Access cavity preparation can be one of the most challenging and frustrating aspects of endodontic treatment, but it is the key to successful treatment (Patel and Rhodes, 2007). It should allow endodontists to remove obstructions in the pulp chamber, to locate all canal orifices and to clean the entire root canal system with minimum coronal tooth structure removed. Improper access preparation can lead to a multitude of subsequent treatment errors and ultimately case failure (Patel and Rhodes, 2007), (Christie and Thompson, 1994), (Ingle, 1985). Good access cavity design and preparation is therefore imperative for quality endodontic treatment, prevention of iatrogenic problems, and prevention of endodontic failure(Patel and Rhodes, 2007).

Root filled teeth are generally associated with shorter survival in comparison to teeth with vital pulps (Al-Nuaimi *et al*., 2017a). By far the most prevalent cause of extraction of root filled teeth is linked to their restorability (Fuss *et al.*, 1999), (Chen *et al*., 2008a).

It is clear that the residual structural integrity of the tooth is a key factor deciding prognosis as it relates to the future function of the tooth after restoration (Tang *et al*., 2010), (Nagasiri and Chitmongkolsuk, 2005). Maintaining strength and rigidity that resists structural deformation becomes the accepted objective of all restorative procedures, especially in endodontics (Gluskin *et al.*, 2014).

Different studies have shown that the preparation of endodontic access cavities decreases the strength of the teeth due to deep and extended cavity preparations that decrease the amount of dentine (Reeh *et al.*, 1989), (Steagall *et al*., 1980).

The designs of traditional endodontic cavities have remained almost unchanged for several decades (Ingle, 1985), Thus traditional endodontic cavity preparation usually results in the removal of dentine in order to explore the expected pulp chamber floor anatomy and canal openings. Additional alterations to the tooth's anatomy, such as preflaring the coronal aspect of the root canal, are usually recommended to facilitate cleaning, shaping, and filling of the root canals (Leeb, 1983). Moreover, the taper of endodontic instruments has moved from its traditional size of 0.02 to larger and even variable designs, which increases the amount of radicular dentine removed during instrumentation (Buchanan, 2000). This approach was challenged by a radical access cavity design that was proposed in recent years (Clark and Khademi, 2010a),(Clark and Khademi, 2010b). The new design of the access cavity emphasized the preservation of pericervical dentine (about four mm above and below the alveolar crest) and suggested that complete deroofing of the pulp chamber was not necessary (Neelakantan *et al*., 2018).

It is important to realise that both the remaining (residual) dentine and the modification of the origin al root canal geometry play a crucial role in the biomechanical responses of tooth structures to functional forces (Kishen, 2006). The residual dentine frequently acts as a foundation for restorative procedures following endodontic treatment (Ree and Schwartz, 2010),(Reeh *et al.*, 1989). It is therefore important to preserve the structure of coronal/radicular dentine and maintain the morphology of the root canal anatomy, in order to preserve the mechanical integrity of endodontically treated teeth (Kishen and Boveda, 2015).

New designs for endodontic access cavities, called conservative or contracted endodontic cavities, have recently been proposed to reduce the removal of the tooth structure(Clark and Khademi, 2010a). This conservative endodontic access could improve the fracture strength and long-term survival of endodontically treated teeth and preserve more tooth structure (Clark and Khademi, 2010a, Clark and Khademi, 2010b).

This design maintains the structural integrity of the peri-cervical area of the tooth (about four mm above and below the alveolar crest) has been emphasised. Maintenance of the peri-cervical dentine

(PCD), is considered to be critical to their long-term survivability and optimum function(Clark and Khademi, 2010a)

Following this, an extremely conservative approach has recently been developed, called the ultraconservative endodontic access cavity which resembles conservative access however, the chamber roof is maintained as much as possible (M, 2016). This concept aims to achieve minimally invasive endodontics as well as that of minimally invasive dentistry.

There have been several suggestions on how to classify the amount of remaining sound coronal tooth structure in root filled teeth. Some authors refer to the percentage of residual tooth structure without defining how this percentage has been measured (Aurélio *et al*., 2016) Whilst others use more generic terms such as 'substantial' or 'minimal dentine height' remaining (Creugers *et al.,* 2005), limited loss of coronal tooth structure in teeth with mesial or distal caries with cusp preservation (Mannocci *et al*., 2002). However, there is no definitive classification nor method to classify and measure the amount of remaining and removed tooth structure.

Recently, there has been an increased adoption of the use of magnification in dentistry, it has been suggested magnification improves visualization, quality, and precision of treatment, thereby improving treatment ergonomics (Das and Das, 2013). In 2012, the American Association of Endodontists (AAE), published a position statement on the use of microscopes and other magnification techniques in Endodontics, they recommend that the magnification can be utilised in; locating hidden canals that have been obstructed by calcifications, removing materials such as solid obturation materials (silver points and carrier-based materials), posts or separated instruments, assisting in access preparation to avoid unnecessary destruction of mineralized tissue, repairing biological and iatrogenic perforations, locating cracks and fractures that are neither visible to the naked eye nor palpable with an endodontic explorer and facilitating all aspects of endodontic surgery, particularly in root-end resection and placement of retrofilling material (AAE, 2012).

Broadly, in dentistry, there are two types of optical magnification systems: loupes and surgical operating microscopes. Loupes are the most common magnification system used in dentistry, they consist of two monocular microscopes, with side by side lenses, angled to focus on an object to form magnified images with stereoscopic properties that are created by the use of convergent lens systems. There is a wide range of magnification available in loupes, from × 1.5 to × 10.

Many dental practitioners use magnifying loupes routinely for clinical work, and dental undergraduates are also using them during their clinical training. Studies have suggested that loupes increased student perception of the quality of their work (Branson *et al.*, 2004), (Leknius and Geissberger, 1995) and improved ergonomics during dental procedures (Branson *et al.*, 2004), (Chang, 2002)

Other studies, however, showed only marginal and statistically insignificant improvements in student performance when magnified vision was used (Donaldson *et al*., 1998),(Rucker *et al*., 1992). While the use of magnification tools is a widely discussed topic among endodontists, the overall studies on this subject are weak and there is no clear evidence that using magnification loupes or even operating microscopes can result in a reduced amount of removal of tooth tissue during the preparation of the endodontic access cavity.

2 Chapter 2: Literature review

2.1 Introduction:

Endodontology is concerned with the study of the form, function, and health of, injuries to and diseases of the dental pulp and periradicular region as well as their prevention and treatment the principle disease being apical periodontitis caused by infection. Apical periodontitis is defined as an inflammatory disorder of periradicular tissues caused by a persistent microbial infection within the root canal system of the affected tooth (Sundqvist, 1976) (Kakehashi *et al.*, 1965). Endodontic treatment encompasses procedures that are designed to maintain the health of all or part of the dental pulp. When the dental pulp is diseased or injured, treatment is aimed at preserving normal periradicular tissues. When apical periodontitis has occurred treatment is aimed at restoring the periradicular tissues to health: this is usually carried out by root canal treatment (Endodontology, 2006).

The history of Endodontics begins in the 17th century and since then, there have been numerous advances and developments, and research has taken place.

In 1746, Pierre Fauchard described the removal of pulp tissue from the root canal. In the 18th century, Leonard Koecker cauterized exposed pulp with a heated instrument and subsequently 'protected' it with lead foil. Edwin Maynard a dentist from Washington, D.C. introduced the first root canal instrument which he created by filing a watch spring. In 1847, Edwin Truman introduced gutta-percha as a root filling material. At the end of the century, prosthetic restorations, including the Richmond or Davis crown, became increasingly popular. Since they required the use of canal posts placed in root canals in order to retain the crowns used to restore extensively damaged teeth, they created an ever-greater need for endodontic therapy. In the 19th century, Dr Meyer L. Rhein, a physician and dentist in New York, introduced a technique for determining canal length and level of obturation. At about the same time, G.V. Black suggested a measurement control to determine the length of the canal and the size of the apical foramen, so that overfilling could be prevented. These are only some of the important achievements of the pioneers of Endodontics, who made early advances, with undoubtedly surprising results, considering their means and knowledge (Menzies, 1970). More recently, the technological advances in instrumentation, optics, materials, and computer systems over the last few decades have introduced new strategies and possibilities to the dental profession. Contemporary research efforts are currently directed towards better understanding dentine behaviour and structure during ageing and function. An alternative approach is to minimize structural changes during root canal therapy, which may result in a new strategy that can be termed ‘minimally invasive endodontics. (Gluskin *et al.*, 2014)

2.2 What does endodontics involve?

Endodontics is the branch of dentistry concerned with the morphology, physiology, and pathology of the human dental pulp and periarticular tissues. Its study and practice encompass the basic and clinical sciences including the biology of the normal pulp and the etiology, diagnosis, prevention, and treatment of diseases and injuries of the pulp and associated periradicular conditions (AAE, 2012)

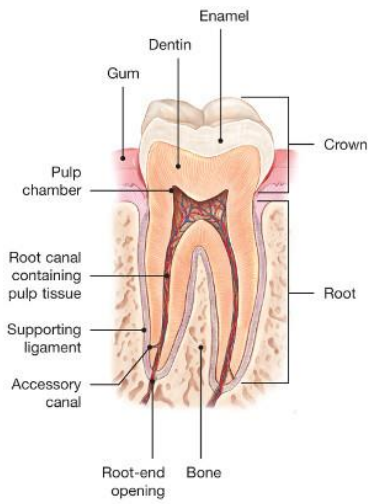

Figure 2: Root canal anatomy (AAE.2012)

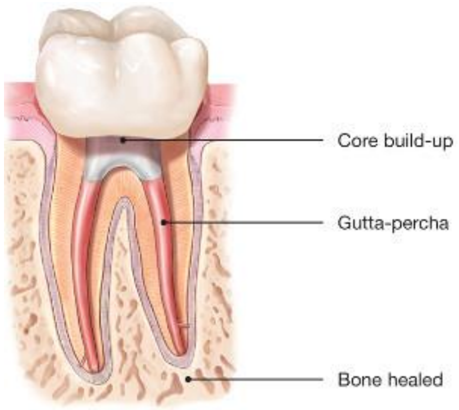

Figure 3: Root canal treatment (AAE, 2012)

Endodontic treatment includes mechanical and chemical procedures such as preparation of the access cavity and instrumentation, as well as chemicals used during the endodontic procedure, for example, irrigation solutions such as Sodium hypochlorite (NaOCl), Ethylenediaminetetraacetic acid (EDTA), and also intermediate dressing materials like Calcium hydroxide and sealers which may influence the mechanical and physical properties of dentine. (Hülsmann, 2013, Moorer and Wesselink, 1982, Stoward, 1975, Davies *et al*., 1993, Mannocci *et al.*, 2008, Sayin *et al*., 2007, Grigoratos *et al*., 2001, Sim *et al*., 2001, Marending *et al.*, 2007).

2.2.1 Access cavity configuration:

Removal of the pulp tissue starts with an analysis of the anatomy of the tooth being treated and the anatomy of the surrounding tissues. The shape of the pulp chamber is important because to some extent it determines the form of the access cavity. For maxillary and mandibular central incisors and laterals, the access cavity shape is an inverted-triangular shaped (Carrotte, 2004b), in maxillary and mandibular canines and premolars the access cavity should be oval in shape. For 1st and 2nd maxillary and mandibular posterior teeth, the shape of the access should be more trapezoidal (Foley, 1977, Abella *et al.,* 2012, Thomas *et al.*, 1993). To remove the contents of the root canal system, the coronal portion of the system, the pulp chamber and the radicular pulp should be identified, if access to the tooth is difficult treatment may be compromised (AAE, 2010). Once accessibility has been confirmed, it is necessary to visualise the position of the pulp chamber. Rotation of the tooth, angulation and any restoration relative to the roots should be evaluated (Patel and Rhodes, 2007). The location of the cementoenamel junction and furcation should also be assessed as these landmarks help to demonstrate the location of the level of the pulp floor and the position of the canal entrances. Krasner and Rankow (2004) in a study of 500 pulp chambers, determined that the cementoenamel junction was the crucial landmark for determining the position of pulp chambers and root canal orifices. They demonstrated that specific and consistent pulp chamber floor and wall anatomy exist and proposed what they termed 'laws' intended to assist clinicians in identifying root canal morphology. There are 6 'laws' described by Krasner and Rankow. These laws are:

1- Law of symmetry (1): which states that except for maxillary molars, the orifices of the canals are equidistant from a line drawn in a mesiodistal direction through the pulp chamber floor.
2- Law of symmetry (2): which states that, except for maxillary molars, the orifices of the canals lie on a line perpendicular to a line drawn in a mesiodistal direction across the centre of the floor of the pulp chamber.
3- Law is for colour change: where the colour of the pulp chamber floor is always darker than the walls.
4- Law of orifice location (1): the orifices of the root canals are always positioned at the junction of the walls and the floor.
5- Law of orifice location (2): the orifices of the root canals are located at the angles in the floor–wall junction.
6- Law of orifice location (3): the orifices of the root canals are located at the terminus of the root developmental fusion line.

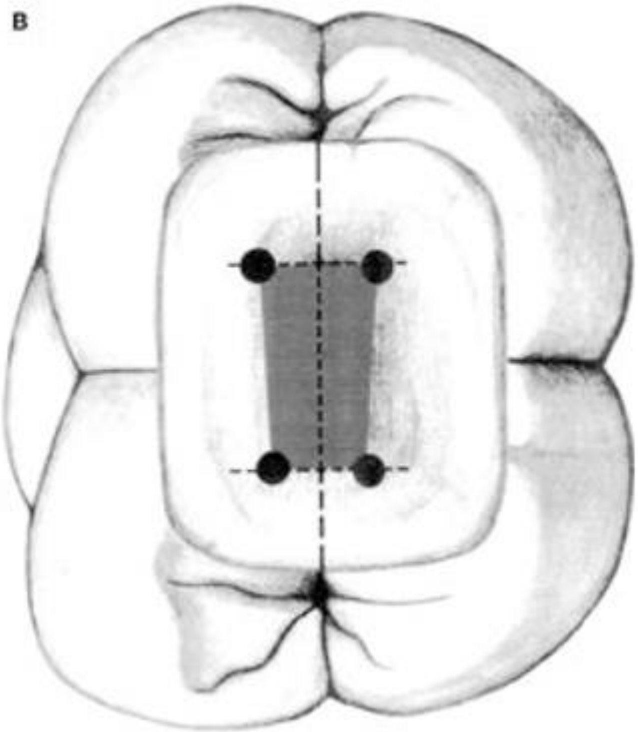

Figure 4:Laws of symmetry 1 and 2 and orifice locations 1,2 and 3 (Krasner and Rankow, 2004)

The above 'laws' were found to occur in 95% of the teeth investigated (Krasner and Rankow, 2004). The size of the access cavity is initially influenced by the anatomical position of the orifices, the number of root canal orifices in a tooth can never be known prior to the start of treatment (Patel and Rhodes, 2007). The access cavity must make the next steps easier and safer. It must, therefore, meet the following requirements: allow the removal of all the chamber contents, enable complete, direct vision of the floor of the pulp chamber and canal opening, facilitate insertion of canal instruments into the root canal opening, provide straight-line access as direct as possible to the apical one-third of the canal for preparation and canal filling instruments and provide good support for temporary restorations (Castellucci, 2004).

There are different factors that might affect access cavity configuration, for example, the angulation and any rotation of the tooth, effects of ageing and the consequences of restorative dentistry reducing the pulp chamber volume due to the deposition of secondary dentine, pulp stones, other dystrophic calcifications, caries, failing restorations, trauma and tooth wear.

2.2.2 Traditional vs. Conservative access

Many dental practitioners considered the endodontic access cavity preparation as an opening made in the tooth where the pulp can be reached. This simplification has resulted in the loss of many teeth as it's the most common cause of inadequate root canal therapy (Janik, 1984). The main purpose of access cavity preparation is to locate the root canal entrances for preparation and obturation of the root canal system. A preoperative periapical radiograph of the tooth taken with a beam-aiming device to ensure no image distortion and allow reproducibility should be studied, together with any relevant bitewing radiographs. From the radiographs, the position, depth, size and shape of the pulp chamber, number of roots, position of the pulp horns, the degree of curvature, and the presence of any lateral canals can be analysed (Patel and Rhodes, 2007). Access cavity can be initiated with high-speed burs to gain access and shape the cavity. A diamond or tungsten carbide tapered fissure bur is used for primary penetration of the roof of the pulp chamber. Tungsten carbide or tapered safe-ended diamond burs can then be used to remove the roof without damaging the floor of the pulp chamber (Carrotte, 2004b). Once the canal entrances have been located, it may be necessary to modify the shape of the access cavity to allow endodontic files to have 'straight-line' access into the coronal third of the root canal. 'Straight-line' access will minimize the probability of iatrogenic problems such as zips, elbows, and ledges, strip perforation and facilitates obturation procedures. Obviously, if the access to the apical one-third is straight for instruments used in canal preparation, this will also be the case for materials and instruments used for obturation of the root canal system. Traditionally, there was a consensus that straight line access during endodontic access cavity preparation is mandatory, (Patel and Rhodes, 2007), (Walton and Torabinejad, 2002), however, the necessity of straight line access is now being challenged. Many endodontists emphasize the importance of preserving coronal tooth structure by performing a conservative or ultraconservative endodontic access cavity preparation. (Belograd, 2016, Plotino *et al.*, 2017, Clark and Khademi, 2010a)

Although these instruments are very flexible, imperfect straight-line access may result in the files distortion and subsequent separation (fracture) due to cyclic fatigue (Patel and Rhodes, 2007). The Endo Z bur or a surgical length tapered diamond bur helps to create straight-line access to each orifice (Ruddle, 2007).

The traditional endodontic cavity (TEC) designed for different tooth types have remained the same for many years with few modifications. TEC includes removal of tooth structure beyond gaining access to canal orifices to facilitate cleaning, shaping, and filling of root canals and to prevent procedural errors (Patel and Rhodes, 2007, Ingle, 1985). Removal of tooth structure, coronal to the pulp chamber, along with the chamber walls, and around canal orifices, may decrease the resistance of the tooth to fracture under functional loads (Kishen, 2006, Tang *et al.*, 2010). Fractures and possible subsequent extraction of root-filled teeth have minimised the confidence of dentists and patients in the long-term benefits of endodontic treatment (Clark and Khademi, 2010a, Tang *et al*., 2010). Consequently, the use of traditional endodontic access cavity preparation has been questioned as it may lead to endodontic failure.

Clark and Khademi in 2010 modified the endodontic cavity design to minimize tooth structure removal. Instead of completely unroofed, coronally divergent, straight-line access to canal curvatures, the conservative endodontic cavity (CEC) maintains some of the chamber roof and peri-cervical dentine. The peri-cervical dentine is located 4 mm above the crestal bone and extending 4 mm apical to the crestal bone. It acts as the “neck” of the tooth. It is important for two reasons: for ferrule and to improve fracture resistance.

Conservative endodontic access could improve the fracture strength and long-term survival of endodontically treated teeth, especially in posterior teeth (Clark and Khademi, 2010a, Clark and Khademi, 2010b). A study by Krishan *et al*. 2014 assessed the impacts of CEC on the fracture resistance of the tooth and instrumentation of canals on 3 teeth, by using extracted human intact maxillary incisors, mandibular premolars, and molars and imaging the teeth with micro-computed tomographic imaging. The proportion of the untouched canal wall (UCW) and the dentine volume removed (DVR) for each tooth type was analysed and the teeth are assigned to CEC and traditional endodontic cavity. Minimal CECs were plotted on scanned images. Canals were prepared with Wave One instruments and post-treatment micro-computed tomographic images obtained. They reported that CEC provided conservation of coronal dentine in incisors, premolars, and molars and improved resistance to fracture in molars and premolars, but it affects the efficacy of canal instrumentation in the distal canals of molars (Krishan *et al.*, 2014). In this study, the dentine volume removed, and the untouched canal wall were assessed, the endodontic access cavity has been done without any sort of magnification.

Yuan *et al*. (2016) in a study aimed to compare the biomechanics on teeth after minimally invasive (MI) preparation and straight-line (SL) preparation using finite element analysis. Six finite element analysis models of a mandibular first molar were constructed and divided into two groups (MI and SL). Two loads of 250 N, one vertically stimulating the vertical masticatory force and the other given 45° to the longitudinal axis of the tooth, were applied. Stresses in the teeth were calculated and analysed, they showed that CECs decreased the stress in the occlusal and cervical regions when this access carried out in mandibular molars (Yuan *et al.*, 2016). CECs are likely to be an advantage for patients, but they challenge operators to find all canals, debride all pulp tissue from pulp horns, and prevent procedural complications. Individually skilled dentists have met this challenge, advocating the practicality of CEC (Clark and Khademi, 2010a). Recent research on CEC in 2017 reported that CECs did not improve the fracture resistance of teeth compared with the ones prepared with TECs (Plotino *et al., 2017)*.

This CEC concept, although consistent with that of minimally invasive dentistry, is not yet well supported by research data.

Following this concept, an extremely conservative approach has recently been developed, which is termed an ultraconservative endodontic cavity(Belograd, 2016), which retains as much of the chamber roof as possible. A recent research study compared *in vitro* the fracture strength of root-filled and restored teeth with the traditional endodontic cavity (TEC), conservative endodontic cavity (CEC), or ultraconservative ‘‘endodontic cavity (NEC) access. In this study, extracted human intact maxillary and mandibular premolars and molars were selected and assigned to control (intact teeth), TEC, CEC, or NEC groups. Teeth in the TEC group were prepared following the principles of traditional endodontic cavities. Minimal CECs and NECs were plotted on cone-beam computed tomographic images. Then, the teeth were endodontically treated and restored. Specimens were then loaded to fracture in a mechanical material testing machine. They found that teeth with traditional access cavity showed lower fracture strength than the ones prepared with conventional endodontic access or ultraconservative access cavity (Plotino *et al.*, 2017). In this study, the endodontic access cavity was prepared without magnification and they assessed the fracture strength of teeth using only the mechanical material testing machine.

The results of the latter study are in agreement with reports that showed improved fracture strength of teeth because of dentine preservation achieved by decreased cavity size (Assif *et al*., 2003, AL-Omiri and AL-Wahadni, 2006). The benefits of conservative endodontic access cavity will include; increased mechanical stability and fracture resistance, increased long term survival and function, while conversely the conservative access cavity will jeopardise disinfection of pulp chamber (Neelakantan *et al*., 2018), increase the risk of missed canals (Silva *et al*., 2019), increase the untouched canal walls (Krishan *et al.*, 2014)compromised irrigant penetration, needle wedging vapour lock (Kishen and Boveda, 2015) and increase the time span of the treatment (Marchesan *et al.*, 2018).

However, clinically, ultraconservative access cavity and conservative access can mainly be performed on intact teeth that are going to be treated endodontically and is not representative of most clinical scenarios. A novel method was proposed in 2015, described as the ‘Guided Endodontics’ technique, this method allowed accurate access cavity preparation utilizing printed templates by matching CBCT data with an intra-oral scan and allow to locate all root canal in the apical third. This method still needs further investigation (Zehnder *et al.,* 2016). Maybe the aim of conservative cavity preparation should be redesigned from “removal of as little tooth structure as possible” to “removal of as little as necessary.” (Trope and Serota, 2016).

Recently, Ultrasonic instrumentation is starting to play an important role in the field of endodontics. Ultrasonic instrumentation is used to remove pulp stones, trough along grooves to uncover hidden orifices, remove obstructions and chase calcified canals. Importantly, Ultrasonic instrumentation procedures are also used to refine and finish the access preparation (Ruddle, 2007). Following the access cavity is mechanical instrumentation of the root canal system, which is considered as being one of the most key procedures in root canal treatment (Schilder, 1974, Ruddle, 2002). It aims to prepare the canal space to facilitate disinfection by irrigants and medicaments.

For many decades, the standard cutting instruments have been the reamer which is made from a square or triangular blank, machine twisted into a spiral but with fewer cutting flutes, K-type file where these instruments originally constructed from a square or triangular blank, machine twisted to form a tight spiral and Hedstrom file which is machined from a round tapered blank. A spiral groove is cut into the shank, producing a sharp blade (Carrotte, 2004b, Ruddle, 2007). These conventional 'standardized' instruments are constructed of steel. However, the evolution of nickel-titanium alloys has transformed the use of hand instruments to automated root canal preparation. Most of these instruments have different features for example radial lands which aid in keeping the instrument centred in the canal, and a non-cutting tip to guide the instrument down the canal (Carrotte, 2004c).

2.2.3 Mechanical and Chemical procedures:

Following access cavity preparation the next step is mechanical instrumentation of the root canal system, which is considered to be a key procedure in root canal treatment (Schilder, 1974, Ruddle, 2002). It aims to prepare the canal space in order to facilitate subsequent disinfection by irrigants and medicaments and also obturation. For many decades, the standard cutting instruments have been the reamer which is made from a square or triangular blank, machine twisted into a spiral but with fewer cutting flutes, K-type file where these instruments originally constructed from a square or triangular blank, machine twisted to form a tight spiral and Hedstrom file which is machined from a round tapered blank. A spiral groove is cut into the shank, producing a sharp blade (Carrotte, 2004a, Ruddle, 2007). These conventional 'standardized' instruments are constructed of steel. However, the evolution of nickel-titanium alloys has transformed the use of hand instruments to automated root canal preparation. Most of these instruments have different features for example radial lands which aid in keeping the instrument centred in the canal, and a non-cutting tip to guide the instrument down the canal (Carrotte, 2004c).

The canal preparation is one of the essential phases that eradicates infection. On the one hand, satisfactory preparation of the cervical third allows direct access of the instrument within the canal, therefore, decreasing possible complications during the biomechanical preparation, and aiding proper penetration of irrigating solutions in the apical third of the root (Zamin *et al*., 2012).

On the other hand, the mechanical action of root canal instruments can significantly reduce the strength of the root. There are contradictory reports regarding the use of manual and rotary instruments. Liu and co-workers compared the occurrence of apical cracks after preparation with hand and rotary instruments using digital images and stereomicroscopic examination and they reported that rotary instruments caused more dentinal defects than hand instruments (Liu *et al.*, 2013). Another study by Bürklein *et al*. 2012 prepared 100 mandibular incisors with rotary and reciprocating using stereomicroscope and images to evaluate cracks, reported that root canal preparation with both reciprocating and rotary instruments resulted in dentinal defects at the apical part of the canals and, reciprocating files produced significantly more incomplete dentinal cracks than full-sequence rotary systems (Bürklein *et al.*, 2013). It has been suggested that nickel-titanium instruments, due to their flexibility in curved root canals, apply less stress onto the dentine than more rigid stainless-steel files and remove dentine more circumferentially, thus preventing the creation of danger zones with insufficient remaining dentine thickness. A review in 2013 concluded that mechanical root canal preparation could produce more forces resulting in dentinal defects, and even dentine fractures, in a large number of cases, also the increased conicity of rotary nickel-titanium instruments may be a major reason for the higher occurrence of dentinal defects following rotary preparation when compared to manual preparation (Hülsmann, 2013).

Investigations have also focused on the impact of chemical factors such as irrigants and medicaments on dentine. During preparation, the root canal should always be wet, with copious irrigation used after each instrument. Sodium hypochlorite is the most effective root canal irrigant due to its exceptional bactericidal and tissue-dissolving properties, and it is considered the primary irrigation for use in endodontics (Moorer and Wesselink, 1982). The mode of action of sodium hypochlorite is based on the action of free chlorine ions on microorganisms. This mechanism includes the disintegration of long peptide chains and chlorination of the terminal protein groups of microorganisms (Stoward, 1975, Davies *et al.*, 1993). The resultant degradation of the organic constituents of dentine by sodium hypochlorite may alter the dentines mechanical properties (Mannocci *et al*., 2008). There is always debate about the recommended amount of concentration of sodium hypochlorite that should be used in endodontics. Sayin *et al*. (2007), found that sodium hypochlorite significantly reduces the microhardness of root canal dentine after only 5 min of immersion and may increase the risk of root fracture (Sayin *et al.*, 2007). Similar results have been obtained with exposure times between 15 min to 2 hours with 3% or 5% concentration (Grigoratos *et al*., 2001).

A study by Sim *et al*. 2001 reported that 5.25% sodium hypochlorite when compared with saline markedly reduced the flexural strength and elastic modulus of dentine (Sim *et al.*, 2001). In another *in vitro* study, exposure to 1% NaOCl for 1 hour did not significantly decrease the elastic modulus or flexural strength of dentine bars, but immersion in 5% and 9% solutions reduced these values by half

(Marending *et al*., 2007). Microhardness of the root dentine after irrigation with 2.5% or 6% NaOCl for different time intervals (5, 10, 20 min) decreased significantly. Both times of exposure and concentration of the irrigants showed significant effects (Slutzky-Goldberg *et al.,* 2004). Hülsmann in 2013 concluded that exposure of dentine to sodium hypochlorite affects the organic components of dentine and alters its mechanical and chemical and properties (flexural strength, elasticity). These effects are dependent on time and concentration (Hülsmann, 2013).

Another aspect that should be considered during instrumentation is the smear layer. A smear layer always forms when a metallic endodontic instrument touches a mineralized dentine wall within a root canal, it is composed of mineralized dentine as well as predentine, remnants of the pulp tissue, bacteria, and biofilm (Eick *et al.*, 1970). The smear layer should be removed as it may contain microbial cells and antigens and it may weaken the effects of disinfecting agents in dentine (Ørstavik and Haapasalo, 1990). Chelator solution such as ethylenediaminetetra aceticacid (EDTA) has been recommended for removal of smear layer (Zehnder *et al.*, 2005). It was introduced into endodontics as a chelating agent in 1957 by Birger Nygaard-Østby (Ostby, 1957). It was originally composed of the disodium salt of Ethylenediaminetetraacetic acid, distilled water, and sodium hydroxide; later a detergent was added to reduce the surface tension of the solution to, improve wetting ability onto the root canal walls and the ability to penetrate the dentine (Hülsmann *et al.*, 2003). Chelators are used in two form liquids or in the paste. EDTA only affects the inorganic part of the dentine and smear layer (hydroxyapatite) and complete removal of the smear layer can only be achieved when NaOCl has been used before the final rinse with EDTA (Qian *et al.*, 2011). A normal concentration of EDTA in endodontic treatment, usually 15–17% (Hülsmann *et al*., 2003). Erosion of dentine which is defined as a loss of tooth substance by a chemical process without bacteria (endodontists, 2015), may be a result of the dissolving action of irrigants. Severe erosion of the dentine was observed even after a short exposure (2–3 min) to 15% EDTA followed by 6% NaOCl for 2–3 min (Uzunoglu *et al.*, 2012). When dentine specimens were irrigated with 17% EDTA, 17% EGTA, 10% citric acid, or 5.25% sodium hypochlorite for different exposure times and in different sequences, the most significant erosion appeared when NaOCl(Qian *et al*., 2011) was used as the final irrigant after irrigation with chelators. Sayin *et al* (2007) reported that EDTA, when used alone or before sodium hypochlorite exposure, caused a considerable decrease in dentine microhardness, even with an immersion time of only five minutes (Sayin *et al.*, 2007). Erosion was seen in inter- and peri-tubular dentine and the tubule orifices became irregularly enlarged and showed a rough appearance. When chelators were used as the final irrigants after irrigation with sodium hypochlorite, no erosion was detected and the root canal surface presented as a smooth, non-porous intertubular surface (Hülsmann *et al*., 2003). Fracture resistance of roots was significantly decreased by chelators, 17% EDTA for 10 min and 1% NaOCl for 1 min used in combination reduced fracture resistance from 598 N (controls) to 379 N. Lower concentrations of EDTA (5%) and a shorter exposure time (1 min) resulted in less reduction (Uzunoglu *et al.*, 2012). A study by Eastman Dental Institute conducted to evaluate the effect of irrigation with 5% NaOCl alone and in conjunction with 17% EDTA on tooth surface strain, and to analyse the influence of irrigation time, root morphology and dentine thickness concluded that, irrigation with 5% with or without 17% EDTA increased tooth surface strain. The increase was significantly greater with 5% NaOCl alone than with 5% NaOCl alternated with 17% EDTA in contrast to previous findings with longer duration of irrigants exposure. Tooth length and mesio-distal root width significantly contributed to the increase in tooth surface strain (Sobhani *et al.,* 2010). An *ex vivo* study evaluates the effect of EDTA, 17% EDTAC 17% and citric acid 10% for 1, 3 and 5 min on the microhardness of root dentine, concluded that microhardness decreased with increasing time of application of chelating solutions, there were no significant differences between initial microhardness for the three groups as well as after 1 min of application of the substances. After 3 min, EDTA produced a significantly greater reduction in microhardness. However, there was no significant difference between EDTA and EDTAC after 5 min. Citric acid caused significantly less reduction in microhardness (De-Deus *et al.*, 2006).

Intracanal medications such as calcium hydroxide for a long time has been thought to increase the possibility of removing pathogens from endodontic systems. Calcium Hydroxide is the most widely used endodontic material and pulp capping agent (Yoshiba *et al*., 1994). It is also used as a short and long-term Intracanal dressing material and is present in some root canal sealers (Holland and de Souza, 1985). It remains the material of choice because of its excellent antibacterial activity and decreased cytotoxicity to the peri-radicular tissues (Rosenberg *et al.*, 2007). Cvek *et al.* 1992 have shown that the long-term use of calcium hydroxide as a root canal medicament may increase susceptibility to root fracture in traumatised anterior teeth (Cvek, 1992). Grigoratos *et al.* 2001 show a remarkable decrease in the flexural strength of dentine bars following a week-long exposure to calcium hydroxide (Grigoratos *et al*., 2001). The weakening effect of calcium hydroxide is thought to be due to its high pH, which may denature the carboxylate and phosphate groups leading to a collapse in the dentine structure (Andreasen *et al.*, 2002). A study on the effect of calcium hydroxide root filling on dentine fracture strength reported that there is 23–43.9% decrease in micro tensile fracture strength of root-filled teeth with the long-term use of calcium hydroxide (Rosenberg *et al*., 2007). According to Andreasen *et al.* 2002 the incidence of cervical root fractures following long-term calcium hydroxide treatment in the literature is around 60% (Andreasen *et al*., 2002)

2.2.4 Dentine ageing and dehydration

Studies have reported that another factor that might affect pulpless teeth is dehydration (Helfer *et al*. 1972), they showed that there was 9 per cent less moisture in the calcified tissues of pulpless teeth than in those of matching vital teeth (Helfer *et al.*, 1972). However, others contradict this view as Papa *et al.* 1994 reported that insignificant difference in the moisture content between endodontically treated teeth and teeth with vital pulp (Papa *et al*., 1994). Dentine of endodontically treated teeth shows a reduction in tubule diameter with increasing age because of deposition of minerals within the lumens (Arola *et al.*, 2009). As mineral and collagen are considered as the hard and strongest components of the tissue, respectively, an increase in brittleness and/or a reduction in fracture resistance is to be expected with ageing (Kinney *et al.*, 2001).

According to an assessment of the flexural strength of coronal dentine, there is a decrease in strength of almost 20 MPa per decade of life, and there is a 50% reduction in strength and a 75% reduction in energy needed to fracture in old compared to young dentine (Arola and Reprogel, 2005). There is also decrease in the fatigue crack growth resistance of dentine with ageing, the average rate of fatigue crack growth in old tissue is 100 times greater than that of young dentine (Arola *et al.*, 2009), so there are undesirable changes in the fracture toughness of dentine that occur with increasing age.

Proprioceptive nerve fibres are present in dental pulp and these are responsive to stimuli other than pain, such as touch and pressure (Pimenidis and Hinds, 1977). It is thought that proprioception is reduced by 30% after endodontic treatment (Randow and Glantz, 1986) with a higher pain threshold seen in non-vital teeth and therefore increased loading of non-vital teeth would be possible. However, as a mechanism to save teeth from fracture, mechano–receptors are used to subconsciously restrict the maximum biting force and consciously recognize hardness differences during chewing (VȦrlan *et al*., 2009). Endodontically treated teeth can withstand a maximum bite force compared to natural teeth, so it is able to regain a level of masticatory function like that seen in sound teeth (Woodmansey *et al.,* 2009).

2.3 The effects of endodontic treatment on teeth

Endodontic literature contains many references to the clinical perception that endodontic treatment weakens the teeth, resulting in an increased likelihood of tooth fracture. In a review article, Tang *et al*. (2010) showed that Post-endodontic tooth fractures might occur because of the loss of tooth structure and induced stresses caused by endodontic and restorative procedures such as; access cavity preparation, instrumentation and irrigation of the root canal, obturation of the instrumented root canal, post-space preparation, post selection, and coronal restoration and from inappropriate selection of tooth abutments for prostheses (Tang *et al.,* 2010). An article by Ree and Schwartz on the endo-restorative interface showed that radicular and coronal tooth structure should be preserved to the greatest possible extent during endodontic procedures, root canal preparations should attempt to preserve dentine in the coronal one-third of the root and access preparations should be made in such a way that cervical dentine is preserved to maximize the long-term restorative result and save the tooth structure (Ree and Schwartz, 2010). In a study at King's College London aimed to evaluate the outcome of secondary root canal treatment (retreatment) on posterior teeth in relation to the residual volume of coronal tooth structure, measured with an intraoral scanner, using peri-apical radiography and cone beam computed tomography (CBCT), 137 posterior teeth in 121 patients were assessed clinically and radiographically at baseline and 1 year after root canal retreatment. A clinical impression was obtained for each tooth after completion of root canal retreatment before the placement of the temporary restoration and following cast restoration placement to produce two casts. All casts were scanned using an intraoral digital scanner and the three-dimensional volume of remaining tooth structure calculated. They concluded that at 1-year follow-up, the percentage of unfavourable outcomes of root canal retreated teeth was significantly higher when less than 30% of the original tooth tissue structure was present at baseline (Al-Nuaimi *et al*., 2017a).

Criteria used for assessing success and failure of endodontic treatment are different. Outcomes were evaluated either by radiographic changes, the function of the tooth involved and/or by the presence of signs and symptoms. Another way to assess the outcome of endodontic therapy is the epidemiological approach. These methods allow the analysis of large cohorts of the patient as well as multiple treatment variables, providing dentists with more tools for clinical decision-making and assessment of tooth prognosis and referred as tooth survival (Salehrabi and Rotstein, 2004). Endodontic literature has included tooth survival as an outcome of endodontic treatment and this has been described as the continued presence and painless function of an endodontically treated tooth (Friedman and Mor, 2004). Two longitudinal studies in the United States, each with a long follow-up period, have shown retention of endodontically treated teeth in the oral cavity of between

94% and 97%, regardless of the aetiology, specific treatment technique, tooth type, or special patient characteristics. They concluded that nonsurgical endodontic treatment is a predictable procedure with an excellent long-term prognosis (Salehrabi and Rotstein, 2004, Lazarski *et al*., 2001). A research group in Taiwan investigating 1,557,547 teeth during a 5-year period after nonsurgical endodontic treatment found a retention rate in the oral cavity of more than 92.3% (Chen *et al.*, 2008b). In a recent study conducted in 2015 by a Scandinavian group 15,000 examined teeth, 420 teeth in 330 patients were randomly selected from the database and included in the study, they showed that around 81.5 % of teeth treated at a specialist clinic in endodontics survived at least for 10 years (Landys Boren *et al.*, 2015). In a systematic review conducted by Ng *et al* 2010 on tooth survival after nonsurgical root canal treatment including 14 studies published between 1993 and 2007, the pooled proportion of teeth surviving during 2–10 years ranged between 86% and 93% (Ng *et al*., 2010). *In vitro* study conducted by Reeh *et al* in 1989 compared the contributions of endodontic and restorative procedures to the loss of strength by using non-destructive occlusal loading on extracted intact maxillary second premolars, suggested that loss of tooth structure is due to restorative procedures, rather than endodontic procedures, he showed that the endodontic access cavity caused only 5% decrease in tooth stiffness, this was less than that of an occlusal cavity preparation (20%), while mesio-occlusal distal (MOD) preparation decreased stiffness by more than 60% (Reeh *et al.,* 1989). The impact of residual tooth structure and destruction under stress of endodontically treated teeth was investigated in different research. It was concluded that an endodontic access cavity with MOD preparation resulted in maximum tooth fragility. The cavity depth, isthmus width and configuration are then highly critical factors in determining the reduction in tooth stiffness and risk of fracture (Kishen, 2006, Bader *et al*., 2001). Finite element analysis (FEA) which is a numerical approach for analysing stress and deformation in the structure of any given geometry also, has been applied to look into the degree to which dentine thickness, the radius of root canal curvature, and external root morphology affect tooth fracture susceptibility. Sathorn *et al* in 2005 conducted an *in vitro* study to determine the extent to which canal size, the radius of curvature and proximal root concavity influence fracture susceptibility and pattern. A standardized cross-section of the mid-root region of a mandibular incisor was created by averaging the dimensions of 10 extracted teeth, and then the basic finite element analysis (FEA) model was created. He concluded that tooth fracture is unpredictable, and removal of dentine does not always result in increased fracture susceptibility (Sathorn *et al*., 2005).

It is possible that the mechanical properties of the pulpless tooth are different from a counterpart vital tooth but there is no absolute proof of this. The mechanical properties of human teeth are determined by their structure and composition. The structure of teeth composed of enamel, dentine, cementum and dental pulp, the first three of which constitute the hard tissue of the human tooth and are characterised by unique mechanical properties. The mechanical properties of teeth include elasticity, hardness, viscoelasticity, and fracture behaviour. Elasticity is a term used to describe the characteristic in which a material changes when an external force is applied and how it then recovers after the force is removed. Hardness is a measure of the hardness or softness of a material and also represents the ability of a solid material to resist elastic deformation, plastic deformation, and destruction, Viscoelasticity is used to characterize materials that exhibit both viscous and elastic characteristics when an external force is applied. The fracture behaviour is used to study the strength and crack growth of materials with crack-type defects (Zhang *et al*., 2014). An *in vitro* study used a universal testing machine compared biomechanical properties (punch shear strength, toughness, hardness, and load to fracture) of 23 endodontically treated teeth and their contralateral vital pairs. The results indicate that teeth do not become more brittle after endodontic treatment (Sedgley and Messer, 1992). Another study was dentine specimens obtained from 54 freshly extracted normal vital human teeth and 24 treated human pulpless teeth. These specimens were subjected to different experimental conditions (wet, air dried, desiccated, and rehydrated). Compression, indirect tensile, and impact tests were conducted to measure the mechanical properties of those specimens. They reported that the compressive and tensile strengths of dentine from pulpless teeth are not significantly different from those of normal dentine (Huang *et al.*, 1992). Fractures in endodontically treated teeth have been accepted to be due to multiple factors in origin. It could be a result of chemical factor such as endodontic irrigants and medicaments, restorative procedures, tooth structure loss, the effect of ageing, caries and anatomical position of the tooth (Kishen, 2006). An examination of 8175 patients referred to a specialist endodontic practice over a 6 year period found that the diagnosis of the cracked tooth was made in 9.7% of all teeth examined (Krell and Rivera, 2007). Another retrospective survey of 460 single-rooted and multi-rooted endodontically restored teeth that had been functioning for at least 3 years and reviewed clinically and radiographically, concluded that 3.7% had vertical root fractures (Morfis, 1990).

Different research reported that the preparation of endodontic access cavities reduces the strength of the teeth, because of deep and extended cavity preparations which minimize the amount of dentine (Reeh *et al*., 1989, Steagall *et al.*, 1980). The remaining structural integrity of the tooth is a key factor that determines success as it relates to the future function of the tooth after restoration (Tang *et al.*, 2010). The importance of conserving the bulk of dentine was revealed in maintaining the structural integrity and in the prognosis of endodontically restored teeth (Ree and Schwartz, 2010), as the fracture resistance and stress distribution of endodontically treated teeth is directly affected by the quantity of residual coronal dentine (Reeh *et al.*, 1989). Increased tooth resistance to fracture can be accomplished by a larger amount of residual hard dental tissue(Sorensen and Engelman, 1990), and by preserving and maintaining cervical tissue to create the ferrule effect (Al-Wahadni and Gutteridge, 2002), which is a 360-metal collar of the crown surrounding the parallel walls of the dentine extending coronally to the shoulder of the preparation. To maintain the restored endodontically treated tooth, a minimal 1.5mm ferrule is considered to be required in anterior teeth (Sorensen and Engelman, 1990).

2.4 Methods of assessing tooth tissue removal:

There are several techniques that have been used to measure the amount of tooth structure removed by tooth preparation, including a physical cross-sectional method widely used by many researchers. However, this was a destructive technique which was criticised as the researcher is required to produce sectioned teeth or thin sections of teeth leading to loss of experimental samples. (Swain and Xue, 2009). Murphy *et al*. (2009) attempted to assess both the thickness to height ratio and volume of remaining coronal tooth structure using a laser profilometer scanner and apply a tooth restorability index (TRI). The authors in this study blocked undercuts of dentine walls with a siloxane impression material to overcome the inability of a laser profilometer to scan these undercuts (Murphy *et al.*, 2009). This measurement method is therefore inaccurate as it was not able to scan the dentine undercuts and its ability to predict endodontic outcome has not been proven in clinical trials.

Recently, other methods have been used in order to assess the amount of tooth tissue removal by tooth preparation such as: analytical balance, optical scanners and micro computed tomography. (Edelhoff and Sorensen, 2002), (Al-Nuaimi *et al*., 2017a), (Hussain *et al.*, 2007), (Neelakantan *et al*., 2018), (Moore *et al.*, 2016). To the best of our knowledge no study used CBCT to evaluate the amount of tooth tissue removal during endodontic access cavity.

2.4.1 Analytical balance (Gravimetric)

One of the methods for measurement of removed tooth structure is weighing the teeth before and after endodontic access cavity. An analytical balance (often called a "laboratory balance") is a class of balance designed to measure small mass in the sub-milligram range. There is not enough data in the restorative literature about the principle of operation of an analytical balance. What follows here is a brief explanation about the analytical balance. The measuring pan of an analytical balance (0.1 mg or better) is inside a transparent enclosure with doors so that dust does not collect and so any air currents in the room do not affect the balance's operation. The balance will not give a stable reading if the sliding doors are open because of air currents. A vibration-free, flat and horizontal surface is required for proper operation of such balances, usually a free-standing table with a marble surface plate. It is simple and easy method. Electronic laboratory balances work on the principle of magnetic force restoration. In this system, the force exerted by the object being weighed is lifted by an electromagnet. A detector measures the current required to oppose the downward motion of the weight in the magnetic field. (Morse and Baer, 2015). An *In vitro* study at Eastman Dental Hospital aimed to measure and compare the mass of tissue structure removed from incisor and canine teeth following successive preparations used the digital analytical balance to measure the baseline mass for each tooth in grams, In this study twenty-two intact, disease- and restoration-free teeth were collected from consenting patients undergoing dental extractions at Eastman Dental Hospital. The teeth were stored in 4% formaldehyde saline and successively prepared for an access opening (AC), endodontic instrumentation (EI), porcelain laminate veneer (PV), metal-ceramic (MC) crown, and post-and-core (PC) preparations. The baseline mass for each tooth was measured and recorded in grams, at baseline, and after each preparation, on a digital analytical balance. They concluded that mean percentage of removed tooth tissue increased successively from EI, AC, PC, and PV preparation, with the greatest change from the previous procedure occurring for MC crown preparation (Hussain *et al.*, 2007). In this study, the digital analytical balance was the only method used to measure the amount of tooth tissue removed. Another study was conducted by a German group to quantify and compare the amount of tooth structure removed when various innovative and conventional tooth preparations designs were completed. In this study, the amount of coronal tooth structure removed was measured with gravimetric analysis. Tooth preparations for porcelain laminate veneers and resin-bonded prostheses required approximately one-quarter to one-half the amount of tooth reduction of conventional complete-coverage crowns. (Edelhoff and Sorensen, 2002).

2.4.2 Optical scanner

Computer-aided design (CAD)/computeraided manufacturing (CAM) is a field of dentistry and prosthodontics using CAD/CAM to improve the design and creation of dental restorations, especially dental prostheses, including crowns, veneers, inlays and onlays, fixed bridges, dental implant restorations, dentures (removable or fixed), and orthodontic appliances.

The CAD/CAM systems are classified into laboratory systems and chairside systems. In this study, a laboratory system was used. CAD/CAM can be further classified into open and closed systems (Tapie *et al.*, 2015). The laboratory CAD systems must always be an open system because after acquiring the data and designing the restoration, the data has to be stored in an STL file (STereoLithography or Standard Tessellation Language). (Zimmermanna *et al.*, 2015). All CAD/CAM systems consist of three components: A digitalisation tool/scanner that transforms geometry into digital data that can be processed by the computer, software that processes data and, depending on the application, produces a data set for the product to be fabricated and a production technology (a computerized milling device), that transforms the data set into the desired product. The first two parts of the system play roles in the CAD phase, while the third is responsible for the CAM phase (Beuer *et al.*, 2008a).

Basically, there are two different scanning possibilities: optical scanners and mechanical scanners. There are various types of optical scanners available, which may be used as Intraoral scanning which means they work in a dental office, while the extraoral methods are mainly related to laboratory work which can scan a die or cast in the laboratory. Al-Nuaimi *et al* (2017) used an intraoral digital scanner to measure the mass of tooth tissue removal in his study which aimed to evaluate the outcome of secondary root canal treatment (retreatment) on posterior teeth in relation to the residual volume of coronal tooth structure. After re-root canal treatment had been completed, an impression was taken before and after crown placement. The impressions were poured, and all casts were digitalised to generate 3D sets. All these data sets were imported into a software for superimposition. Once the superimposition was performed the differences in the volume of remaining coronal tooth structure between these two data sets were computed to obtain the percentage of remaining coronal tooth structure and they concluded that at 1-year follow-up, the percentage of unfavourable outcomes of root canal retreated teeth was significantly higher when less than 30% of the original tooth tissue structure was present at baseline (Al-Nuaimi *et al.*, 2017a). Optical scanners are usually used extensively in prosthodontic research

2.4.3 CBCT

Cone Beam Computed Tomography (CBCT) is a diagnostic imaging modality that provides high-quality, accurate three-dimensional (3D) representations of the osseous elements of the maxillofacial skeleton(Scarfe *et al*., 2009). CBCT scanners are based on volumetric tomography, using a 2D extended digital array providing an area detector. This is combined with a 3D x-ray beam. The CBCT hardware consists of an X-ray source and detector, or sensor, mounted on a rotating gantry. During imaging, a cone-shaped X-ray beam is emitted from the X-ray source and is directed through the area of interest in the patient's maxillofacial skeleton. Having passed through the area of interest, the beam is projected on to the X-ray detector, as both it and the X-ray source rotate synchronously 180°-360° around the patient's head, in a single sweep. The scan time typically ranges from 10-40 second, depending on the equipment and exposure parameters employed. During the exposure sequence, hundreds of basis images (projection images) of the area of interest are acquired (Durack and Patel, 2012). The projection images are then reconstructed, using sophisticated software, to produce a cylindrical or spherical volume of data, called the field of view (FOV).

Each projection image is comprised of up to and in excess of 216,124 (512 x 512) pixels. The reconstructed, three-dimensional data set will comprise 5123 three dimensional pixels, or voxels (Patel, 2009). Reconstructed CBCT images can be displayed in a variety of ways. A commonly used option is for the images of the area of interest to be displayed, simultaneously, in the three orthogonal planes (axial, sagittal and coronal), affording the clinician a truly three-dimensional view of the area of interest.

The use of CBCT technology in clinical practice provides a number of potential advantages; as image accuracy, rapid scan time, reduced image artefact (Scarfe *et al.*, 2006)and the production of three-dimensional images allow for a comprehensive appreciation of the anatomy. As well as this, slices of the volumetric data can be chosen by the clinician and anatomical noise can be easily eliminated (Scarfe and Farman, 2008). On the other hand, there are some disadvantages of CBCT, a significant issue that can affect the image quality and diagnostic accuracy of CBCT images is the scatter and beam hardening artefacts caused by high-density adjacent structures, such as enamel, and radiopaque materials such as metal posts, restorations and root filling materials (Mora *et al*., 2007). These artefacts can reduce the diagnostic yield of the images (Lofthag-Hansen *et al*., 2007). CBCT has several applications in the field of endodontics, it can be used for detection of periapical periodontitis, assessment of potential surgical sites, assessment, and management of dental trauma, assessment of canal morphology and anatomy, diagnosis, assessment and management of root resorption and assessment of the outcome of endodontic treatment (Patel, 2009)

2.5 Magnification

Dentistry is becoming increasingly dependent on new techniques to give patients the high standard of care they expect. Dentists performing endodontic treatment should develop new skills including working with new materials, increased magnification and lighting for better vision of the pulp space. The concept of minimally invasive endodontics has developed as a result of our increased desire to conserve tooth structure such as dentine and preserve its' mechanical properties together with the increasing use and the evolution of new endodontic instrumentation. One way of enhancing the performance of a clinician is to improve visualisation by facilitating eyesight, which is considered very important in dentistry. However, fewer than 10% of dentists try to improve visualisation through the use of magnification, even though dentistry is a visually demanding job (Forgie *et al.*, 1999). In 1978, Dr Apotheker and Dr Jako introduced the concept of magnification, in the form of an operating microscope, into dentistry. They concluded that the improvements in visual acuity, made possible using the operating microscope, would be beneficial to the discipline of endodontics (Apotheker and Jako, 1981). In the late 1980s, endodontist Dr. Gary Carr concluded that the magnification and illumination made possible with the microscope could be beneficial to endodontists and started promoting the usage of the dental operating microscope (DOM) as an important component of the armamentarium used in the improvement of outcomes of endodontic apical surgeries (Das and Das, 2013). There are four magnification systems used in dentistry: simple magnifying glasses in spectacle frames, hinged magnifiers that can be attached to either spectacle frames or worn attached to a headband, multiple lens systems commonly called loupes or surgical telescopes and the operating microscope (Forgie *et al*., 1999). There are five basic benefits derived from using DOM in endodontics; including; increased visualization, enhanced ergonomics, precision of treatment, ease of proper digital documentation and effective communication ability through integrated video (van As, 2007).

On the other hand, there are some disadvantages of magnification, especially in the initial phase, the most important one is the need for training. Friedman *et al.* 1998 concluded that the learning curve of the operating microscope could be lengthy and difficult (Friedman *et al.,* 1999). Other disadvantages include the relatively high cost of the equipment and instruments (Moura Jr, 2009). There are some clinical procedures in which the use of magnification is of little benefit, for example, denture work, orthodontics, and shade matching. Working with magnification has become a widely accepted practice in non-surgical and surgical endodontics. Besides increasing the accuracy of the endodontic procedure, these devices are suggested to improve diagnosis because of better visualization of the treatment field. For example, they allow determination of the presence of isthmuses, accessory canals or micro-fractures of the root, which are otherwise difficult to recognize and treat (Del Fabbro *et al.,* 2015). The use of well-focused illumination and magnification devices was recommended as a standard of care in endodontic therapy (Hargreaves and Berman, 2015, Kim and Kratchman, 2006). Different factors should be considered before choosing magnification, for example, a working distance which is the distance, at which the optics of a loupe are sharply focused. To be able to work effectively and comfortably for long periods of time it is important that the patient's mouth is positioned at a distance which the dentist finds acceptable (Forgie *et al.,* 2001). This working distance is between 28 cm for dental students to 36 cm for clinicians over 45 years. Another factor is the field of view, which is defined as the area that can be seen under magnification. As the level of magnification increases, the area that can be seen decreased. Magnification levels of x3 to x4 and less will provide an acceptable field of view to allow easy orientation, with the main problem encountered is the insertion of instruments into the field of view. This problem can be eliminated by close four-handed dentistry or by looking over the top of the magnification devices during entry of the instrument. Also, depth of view which is the range over which the image remains sharply focused as with field of view, the depth of field (focus) decreases as the power of magnification increases. This means that in some high-magnification systems even a small head movement will lead to losing focus (Burton and Bridgman, 1991).

Optical magnification has expanded the horizons of endodontics. The improvement of visual acuity through optical magnification is becoming a part of modern dental practice. The most important benefits when using an operating microscope are an excellent visualization of the operating field, greater illumination, and magnification, less iatrogenic occurrences, relaxed upright ergonomics.

Different research on Operating microscopes OM has been conducted last few years. Park *et al*. 2014 conducted a study to examine the effect of the access size and straight-line path of access on third-year dental students' ability to locate a second mesiobuccal (MB2) canal in maxillary first and second molars. One hundred and six third-year dental students at one Faculty of Dentistry performed simulated root canal treatment with the aid of 2x magnification loupes on extracted teeth. A postgraduate endodontic student subsequently made a reasonable search for an untreated MB2 canal with the aid of a dental operating microscope. The mesiobuccal roots were then sectioned horizontally for determination of the canal configuration. The dental students were able to treat an MB2 canal in 15.8 per cent of the teeth, but this was not associated with satisfactory access criteria. The postgraduate endodontic student identified an MB2 canal in 54.7 per cent of the remaining tooth samples excluding those where the MB2 canal was found by the dental students, this represented 94.3 per cent of those teeth confirmed by horizontal sectioning of the root to have an MB2 canal. It was concluded that a predoctoral endodontic curriculum in a dental school might need to consider multiple approaches to facilitate students' ability to search for and treat difficult root canal anatomy thoroughly (Park *et al.*, 2014). Another study on the benefits of operating microscopes aimed to determine whether using the OM would improve students' performance in endodontic access cavity preparation and canal identification. In this research, thirty-six dental students prepared access cavities and located canals in extracted maxillary molars, before and after training, they then divided the students into three groups. The standard group received a lecture and practice in preparation of access cavities. The microscope group received identical instruction using the OM. The control group received lectures only. All groups received equal content and instruction time (2 hr 20 min). Endodontic teaching staff graded preparations according to a globally validated, multidimensional 5-point rating scale. They subdivided the access cavity preparation into 3 dimensions: outline form, cavity walls, and cavity floor. Each dimension was graded on a 5-point scale from 1 (poor quality) to 5 (excellent quality). The microscope group improved significantly in their access cavity preparations and also significantly outperformed both the standard and control groups in the accuracy of identifying canals. They concluded that use of the OM significantly improved student's ability to find canals and positively impacted the quality of access cavity preparation (Rampado *et al.,* 2004)..

Rubinstein R and Kim S in 1999 demonstrated one-year healing rates of endodontic surgery performed under the surgical operating microscope in conjunction the with the microsurgical technique was 96.8 per cent (Rubinstein and Kim, 1999).

Another magnification system is loupes or surgical telescopic, which is a multiple lens system involving a compound lens system either in line, using the Galilean concept or via a system of prisms (Forgie, 2001). Many dental practitioners use magnifying loupes instead of OM for their clinical work, and dental undergraduates are increasingly wearing them during their training (Forgie *et al.*, 1999). Pace SL *et al*. 2005 described two forms of loupes, the flip-up loupe which is mounted on a bracket and attached to the frame of the eyeglasses, the attachment may be either a single hinge or a vertical attachment hinge, and these can be flipped up when it is not in use. The other one is through-the-lens (TTL) loupes, which are less bulky and more aesthetically pleasing. TTL loupes are also called fixed telescopes (Pace and II, 2005). Prism loupes are the most advanced type of loupe magnification available today. They are low-power telescopes that use refractive prisms. Prism loupes give better magnification, larger fields of view, wider depths of field, and longer working distances than other types of loupes (Arora, 2016). The advantage of both systems is that working distance can be controlled, the optical quality of the lenses tends to be higher, and magnification levels can be greater, generally up to x6 magnification.

A survey to determine the extent of the use of loupes among dental trainers and trainees in Scotland in order to quantify the level of the use of magnification in general dental practice in Scotland and second, to determine the current and potential areas of clinical use of magnification by general dental practitioners. A questionnaire was sent to all general dental practitioners in Scotland. The questionnaire asked the practitioners about their experience of magnification and their opinions on possible areas for clinical use. The survey lead them to the conclusion that the need for loupes in dental practices is justified not only to improve the quality of work but also to enhance the ergonomics of dental trainers and trainees (Forgie *et al.*, 1999). In a later publication by the same author into restoration removal both with and without the aid of magnification, two clinicians with no previous experience in the use of magnification and 2 clinicians with experience of magnifying loupes took part in a cavity preparation study. The two novice's clinician were removed 12 class 1 composite restorations from natural teeth on models, using unaided vision or 2.6 magnification. They concluded that there was a significant change in cavity size during removal of class I composite fillings, with both unaided vision and 2.6 magnifying loupes, the range in cavity size change was large for both approaches, however, the use of 2.6 magnification resulted in a decrease in cavity size compared with unaided vision (Forgie *et al.,* 2001). After preparation the cavities were photographed and their outline was digitized from the prints into a drawing and analysis package, and the area of each cavity was measured. (Forgie *et al*., 2001)

Whitehead and Wilson in 1992, conducted an *in vitro* experimental study to investigate the influence of the use of x 3 magnification loupe aids on decision-making behaviour. In this study one hundred extracted premolar and molar teeth selected for the investigation. Fifty of the teeth selected contained moderate to large dental amalgam restorations placed prior to extraction. The remaining 50 teeth were unrestored but displayed staining of the fissure systems. Four teachers of restorative dentistry were required to examine the teeth and reach one of the following decisions in each case; operative intervention with restoration of the intact tooth and replacement of the existing restoration (restore) , the second decision is that the tooth surface and restoration is acceptable (leave) or thirdly, that no operative intervention is required at this recall but special attention to be paid to this surface at subsequent recall visits (defer). They reported that restorative decision-making behaviour was modified when magnification was used, with an increase in the number of restorations planned for replacement and an increase in the number of teeth surfaces planned for restoration (Whitehead and Wilson, 1992).

Conversely, Donaldson and co-workers conducted a study to determine if magnification had a positive effect on student amalgam preparation on paediatric clinics. Fifty-two third-year students were randomly assigned to experimental (magnification) or control (no magnification) groups. Members of the experimental group used magnification in their daily work in the paediatric dentistry clinic, they concluded that there was no significant difference when undergraduates wore magnifying loupes for a trial period in the clinic of paediatric dentistry (Donaldson *et al.*, 1998). Although the use of magnification devices is a widely discussed issue amongst endodontists, the overall studies regarding this topic are poor, and there is no clear evidence that the use of magnification loupes or even operating microscope would lead to a reduced amount of tooth tissue removal during endodontic access cavity preparation.

2.6 Training

Dental education was previously structured in such a way that students largely learned what the instructor chose to teach them. This traditional approach was mainly disciplined-based. Nowadays, the current trend is towards competency-based education, which provides a sequence of defined learning outcomes to students so that upon graduation they may be considered as qualified beginners in dental practice (Yip and Smales, 2000). Generally, many researchers identify five stages in the development of the dental student. The novice is the most primitive of learners, heavily dependent on the teacher for structuring tasks and the methods used to perform them. In dental education, students in their first two years are novices. From the midpoint to very nearly the end of formal dental education, students are considered as beginners. Beginners are slightly more accurate and faster than novices (Chambers and Eng Jr, 1994). Competence is the third stage of professional growth and is marked by independence, supported by basic internalized standards and an acceptable repertoire of skills and knowledge. This is when students are ready for graduation. The next level of growth is called proficiency, and this includes a further reorganisation of what is known and what can be accomplished and an active experimentation with matching one’s interests and skill set to alternative environments. The final stage is called mastery or expertise, it is only reached after years of dental practice has permitted the dentist to go beyond the technical aspects of the profession and integrate his or her efforts around patient care (Chambers, 1998). Competence in dental practice combine appropriate supporting knowledge and professional attitudes, and they are performed reliably in natural settings without assistance (Chi, 2014). Most of the research did not include the area of training students or dentists and the level of competency before conducting an experiment. A study by Rampad *et al.* 2004 on the benefit of the operating microscope for access cavity preparation by novice's undergraduate students, they divide the student into 3 groups, the standard group received a lecture and practice in preparation of access cavities, the microscope group received identical instruction using the OM and he control group received lectures only. All groups received equal content and instruction time around 2 hrs 29 minutes, a standardized 20-minute slide presentation on tooth anatomy and access cavity preparation followed by OM training consisting of a 10-minute slide presentation and 35-minute hands-on instruction, then further instruction consisting of 2 exercises, discriminative learning instruction and operative skills development, but there is no clear data on the level of competency of dental student (Rampado *et al*., 2004). Another study by Park *et al*. 2014 investigated the identification of second mesiobuccal canal by students using loupes without control, where third-year dental students performed root canal treatment on maxillary molar teeth. The outcome of this study suggests that a predoctoral endodontic curriculum in a dental school may need to consider a multifaceted approach to facilitate students' ability to thoroughly search for and treat challenging root canal anatomy. In this study, the preclinical session was given to the student to perform access cavity without mention of how many sessions and level of training (Park *et al*., 2014)

2.7 Conclusion

In conclusion, endodontics is widely practised in dentistry and is important for retaining teeth damaged through trauma and disease. It involves the use of fine motor and visual skills in an attempt to minimise the potentially adverse effects of iatrogenic damage and weakening of teeth through over-preparation. Over the years there has been a move towards greater conservation of tooth tissue during tooth preparation and this trend is also relevant to endodontic practise.

3 Chapter 3: Methods of studying tooth tissue removal

3.1 Introduction:

As described previously, endodontic treatment involves drilling into teeth in order to access the root canal system. The main purpose of access cavity preparation is to locate the root canal entrances for preparation and obturation of the root canal system. Removal of tooth structure, coronal to the pulp chamber, along with the chamber walls, and around canal orifices, may decrease the resistance of the tooth to fracture under functional loads (Kishen, 2006, Tang *et al.*, 2010). Fractures and possible subsequent extraction of root-filled teeth have minimized the confidence of dentists and patients in the long-term benefits of endodontic treatment (Clark and Khademi, 2010a, Tang *et al*., 2010).

Root filled teeth are generally associated with a shorter survival compared with teeth with vital pulps.

The longevity of root canal treated teeth is significantly affected by the reduction in the amount of remaining coronal tooth structure(Al-Nuaimi *et al.*, 2017b). This is due to a combination of dental caries, restorations, endodontic treatment and fractures. By far the most prevalent cause for extraction of root filled teeth is related to their perceived restorability. Whilst recommendations based on expert opinion have been suggested, there is little objective evidence on a threshold level or minimum quantifiable amount of remaining coronal tooth structure to affect the survival of teeth. Establishing a reliable method to quantify the amount of remaining coronal hard tooth structure may assist in predicting the survival of endodontically treated teeth and aid in treatment planning.(Caplan and Weintraub, 1997, Al-Nuaimi *et al.*, 2017b). This chapter describes how the extent of this tooth preparation was evaluated in this study

3.2 Aim:

To evaluate methods used to investigate tooth tissue removal after endodontic access cavity preparation.

3.2.1 Analytical balance (Gravimetric):

A trial was carried out using the analytical balance (Sartorius TE 124S) (Figure 5) in the Liverpool University Dental Hospital research wing. The aim of the study was to investigate if the amount of tooth tissue removal in endodontic access cavity preparation can be quantified using an analytical balance. The initial step commenced by investigating if all the plastic teeth were the same weight before an endodontic access cavity, in order to ascertain standardisation.

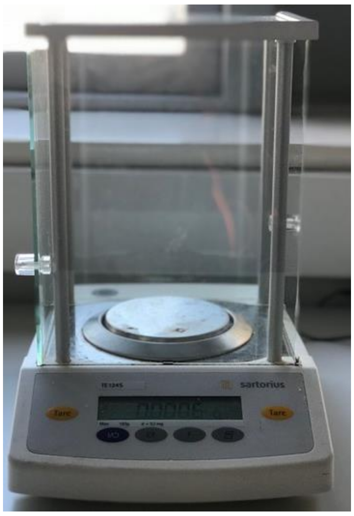

Figure 5: Analytical Balance

The standardisation made the assessment easier to apply and guaranteed a high degree of reproducibility of the experimental design, which makes the results of such studies valid (Lim and Webber, 1985). The second step was to test if the water from high-speed handpieces affected the gravimetric evaluation of plastic teeth after endodontic access cavity as solids have a certain affinity for water and may absorb moisture from the handpiece or even laboratory air.

The analytical balance was turned on by pressing the power button in the control bar and left for several seconds until the screen showed 0.0000, the chamber door was opened and the tooth was placed in the centre of the pan and then the chamber was closed. The reading on the display screen was recorded as soon as the value had remained stable for a few seconds. 10 plastic teeth (2 maxillary central incisors, 2 maxillary premolars, 2 mandibular molars and 2 maxillary molars) were weighed individually before an endodontic access cavity for 3 consecutive times per each tooth to ensure reproducibility and repeatability of the measurements.

An endodontic access cavity was prepared in each tooth in the dental laboratory using a high-speed handpiece, size 2 round bur for anterior and premolar teeth, size 4 round bur for molar teeth and endo Z bur which is lateral cutting edges are used to flare, flatten, and refine the internal axial walls. (Ruddle, 2007)

The teeth were weighed again after an endodontic access cavity was prepared, for 3 consecutive times per tooth using the same method, then the teeth were immersed in water for 24 hrs to test if the teeth were absorbing water or not and then weighed again using the same method. After 72hrs the same plastic teeth were weighed after dehydration in an incubator at 60 °C.

All the results were recorded. The method was able to detect the amount of tooth tissue removal in sub-milligram by calculating the difference in weight of the teeth before and after endodontic access cavity. This method allows for the quantification of the weight of tooth tissue removed by tooth preparation however, there is no data regarding the shape of the access cavity.

3.2.2 Optical scanner:

The aim of using this device was to investigate if the plastic teeth can be scanned before and after endodontic access cavity in order to obtain a high-quality image showing the required information relating to tooth preparation.

The basis of this type of scanner is the collection of three-dimensional structures in a so-called 'triangulation procedure'. Here, the source of light (for example laser) and the receptor unit are in a definite angle in their relationship to one another. Through this angle, the computer can calculate a three-dimensional data set from the image on the receptor unit. Either white light projections or a laser beam can serve as a source of illumination (Beuer *et al.*, 2008b).

Figure 6: Optical Scanner

DS30 optical scanner was used (Figure 6) to scan the plastic teeth before access cavity preparation. 3 plastic teeth (upper central incisor, upper premolar and lower molar) were mounted on the scanner. The scanner was able to clearly display a 3-dimensional image of the teeth before cavity preparation. The same teeth were scanned again following cavity preparation, but the scanner was able to scan only the first 2-3mm of the access cavity from the occlusal aspect and the rest of the access cavity was not shown in the image. To solve this problem of not showing the access cavity completely, a decision was made to take an impression of the access cavity and scan the impression instead of attempting to scan the endodontic access cavity.

Different materials were tried in order to gain a replica of the access cavity. Firstly, light body impression material (3M Espe, Express Tm 2 Light Body Standard) was used. The problem with light body material is that once it is set inside the cavity it will tear during removal from the access cavity, even with the application of a separating medium. Medium body impression material (PROVIL NOVO: MEDIUM REGULAR SET) (Figure 7), was the second material of choice, the problem with this material was its inability to flow inside the cavity and record the details of the access cavity.

Figure 7: PROVIL NONO: MEDIUM REGULAR SET

The third material tried was an addition- Vulcanizing Duplication silicone (Z-DUPE) (Henry Schein) (Figure 8). This material flowed inside the access cavity and was easily removed without distortion with the use of smoothex (Whip mix) (Figure 9), a separating medium used inside the cavity before application of the silicone.

Figure 8: Vulcanizing Duplication Silicone

Figure 9: Separating Medium (Whip mix)

After the access cavity has been prepared the smoothex were sprayed inside the access cavity and left for one minute, and the excess was removed using a dental probe. The injection of the material into the access cavity required a modification of the normal plastic syringe. This was done by removing the normal tip of the plastic syringe and replacing it with a large tip from the etching gel system (Figure 10). The duplication silicone was mixed in a plastic cup using a spatula and the impression material was loaded into the plastic syringe and slowly injected into the cavity ensuring that the tip remained buried in the material to reduce air blows.

Figure 10: Modified Plastic Syringe

To be able to standardize the amount of the silicone injected inside the cavity, a ‘Memosil cap’ had been constructed on the occlusal surface of each tooth prior to cavity preparation. However, a drawback of the Memosil was its’ tendency to tear after a couple of trials. In order to solve this problem ‘composite caps’ (Spectrum) (Figure 11), were constructed on each tooth (mandibular molar, upper first premolar and upper central incisor).

Figure 11: Positioning Device with Composite Cap

These caps were applied directly after the injection of the silicone inside the cavity. The impression material takes around 5-6 minutes for the complete set. Once the material showed a complete set, the cap was removed from the tooth (Any excess was removed with the cap as well), then the impression material was removed slowly from the access cavity, the replica of impression showed in (Figure 12).

Figure 12: Impression replicas

The next step was to scan the replica by using the DS30 optical scanner. A paper clip was used to attach the tip of the impression and the impression was placed on the scanner. The results were a 3D replica of the access cavity. Materialise software package (Materialise N.V., Leuven, Belgium) was used to superimpose the 3D replica image over the 3D tooth image. The difference in volume was calculated and the results gave the amount of tooth tissue removal.

3.2.3 Cone beam computed tomography:

Cone beam computed tomography scan times are typically 10 to 40 seconds long, depending on the scanner used and the exposure parameters selected. The X-ray beam is pulsed; therefore, the actual exposure time is a fraction of this (2–5 s), resulting in up to 580 individual 'mini-exposures' or ‘projection images’ during the course of the scan. Sophisticated software then processes the collected data into a format that closely resembles that produced by medical CT scanners. Each mini-exposure or projection image generates a pixel matrix consisting of 262 144 (512 · 512) pixels. The resulting dataset from CBCT consists of up to 580 individual matrices, which are then reconstructed using powerful personal computers into three-dimensional data sets, consisting of over 100 million voxels (5123). To increase resolution, the number of pixels per matrix (projection image) may be increased from 5122 to 1024. The resulting reconstructed three-dimensional volume of data will then consist of 10243 voxels. Slices may be displayed in a number of different ways. One option is for the images to be displayed in the three orthogonal planes axial, sagittal and coronal simultaneously, allowing the clinician to gain a truly three-dimensional view area of interest.

3D Accuitomo XYZ view tomograph from (J. MORITA MFG.CORP) (Figure 13), were used for this study at the radiology department at Liverpool University Dental Hospital. The first challenge was to scan the plastic teeth on the CBCT. One plastic tooth was scanned on the device on (60 KV and 7 MA). The result of the scan was transferred to the Mimic software package (Materialise N.V., Leuven, Belgium) to evaluate the scanned image. This software program can provide image segmentation, quantitative analysis, and three-dimensional model reconstruction.
The image quality was good, with high clarity. Therefore, it was decided to use CBCT as a method to assess the amount of tooth tissue removal after endodontic access cavity preparation. In order to scan multiple teeth at one time, a positioning device was fabricated to allow 6 teeth to be scanned.

Figure 13: CBCT

The positioning device was created as follows:

A separating medium (Sodium Alginate solution) (Figure14), was applied on a flask and a pink wax mould (Figure 15), inserted inside the flask, Plaster of Paris was mixed and added to the flask (Figure 16) making sure that plaster of Paris was not present on the edge of the flask in order to allow accurate closure of the flask.

Figure 14: Separating Medium

Water and a damp sponge can be used to remove voids and smooth the plaster of Paris around the pink wax mould. A separating medium (Sodium alginate) should be applied to the Plaster of Paris and allowed dry to prevent the two halves of the flask bonding to each other. The plaster of Paris was mixed as described above and added to the other half of the flask.

Figure 15: Pink Wax Mould

Figure 16: Plaster of Paris inside the flask

After finishing this process, the flasks are closed against each other (Figure17) (so that the metal edges of the flasks are in contact with each other) and left for 45 minutes until set. The flask was then placed in the boil out system for 8 minutes to allow the pink wax to soften and melt (if left longer the way become liquid).

Figure 17: Flask locked against each other

Following this, the flask was removed, opened and the mould was ready to be processed (Figure18). All the remaining wax was boiled away.

Figure 18: Mould

A separating medium (sodium alginate) applied inside the mould and then the acrylic resin was mixed and packed into the flask (Figure19), the flasks then inserted into the press to ensure metal to metal contact and this will allow the excess to be removed).

Figure 19: Separating Medium inside the mould

Clamp the flask (Figure 20) and process the acrylic. The acrylic moulds were retrieved following the curing of the acrylic inside the flask, deflask the acrylic and trimming.

Carding wax was inserted at the bottom of each space in the acrylic mould to temporarily hold the plastic teeth in the exact position required with the crowns of the teeth that are clearly visible above the mould (Figure21). Following this, the teeth were removed, and a separating medium (Vaseline) applied around the roots of the teeth (to allow ease of insertion and removal of the teeth from the positioning device).

Figure 20: Clamped Flaks

Figure 21: Insertion of Carding Wax

The teeth were again inserted inside the positioning device and a cold cure acrylic resin was mixed in a liquid state and poured inside the positioning device using a metal spatula. The positioning device was then immersed in hydrpflask for 5 minutes for the complete set. The positioning device was ready for use (Figure 22) so that the teeth were able to be inserted and removed as needed (Figure 23).

Figure 22: Positioning device

Figure 23: Positioning device with teeth

Scanning was done for 6 teeth in the positioning device without access cavity (2 maxillary central incisors, 2 maxillary 1st premolar, and 2 mandibular 1st molars), at once and the quality of the image was deemed to be acceptable. Endodontic access cavities were prepared using a high-speed handpiece, round bur size 2 for anterior teeth and size 4 for premolar and molar and an endo z bur. The teeth were scanned again using CBCT (60 KV and 7 MA). (The images were exported in DICOM format and then imported into Materialise Mimics (Materialise N.V., Leuven, Belgium).

The images were filtered using a pre-set gray value to minimise noise. The area of interest was selected manually for all the images and a segmentation process was carried out. The segmentation process was done manually by a single operator to ensure standardisation. The volume segmented was used to calculate and generate a 3D rendered image by the software. The volume of each 3D image was extracted from the software. The difference in the volume of the teeth between pre and post access cavity preparation was calculated.

3.3 Image analysis:

Image analysis is the next step after acquiring the images from both CBCT and optical scanner.

Analysis of images is conducted for different purposes such as visualisation, measuring, quantitative or qualitative analysis, three-dimensional assessment, and design. (Stock, 2008).

It is important to use software capable of analysing and reconstructing the images with accuracy. Materialise software package (Materialise N.V., Leuven, Belgium), was chosen, due to its accuracy.

The two main software's used from the package are Mimic (Materialise N.V., Leuven, Belgium) for its image segmentation, and three-dimensional model reconstruction and 3Matic (Materialise N.V., Leuven, Belgium) for its three-dimensional model's superimposition and comparison analysis. The accuracy of the software were verified and showed highly accurate results in comparison with histological sections and live measurements of different aspects. The investigation of the package was done through multiple independent studies not influenced by the software company (Moerenhout *et al*., Gelaude *et al.*, 2008, Jamali *et al.*, 2007).

3.4 Discussion:

Remaining tooth structure is a key factor that determines prognosis as it relates to the future function of the tooth after restoration (Tang *et al*., 2010). There is little evidence on the impact of remaining coronal tooth structure on the survival of teeth that have undergone root canal retreatment. It appears that, among technical elements of root canal therapy, access preparation and post preparation are the most relevant in rendering the tooth more susceptible to significant destabilisation (Lang *et al*., 2006). Establishing methods to assess the amount of tooth tissue removal during endodontic access cavity procedure may help to predict the survival of endodontically treated teeth and their prognosis.

This pilot study investigated different methods used to assess the amount of tooth tissue removal after the endodontic access cavity.

The use of an analytical balance provided an accurate measurement in sub-milligrams regarding the weight of tooth tissue removal before and after endodontic access cavity. This measurement represented the amount of tooth tissue removal by weight only but was not able to provide any data regarding the shape and quality of the access cavity and the strategic importance of the remaining tooth structure. Also, natural teeth may not be suitable for this type of analysis because of the presence of the pulp chamber, intertubular dentine, and dentinal tubules, which may influence the gravimetric measurements. (Edelhoff and Sorensen, 2002), (Hussain *et al.*, 2007)

Also, the results from this pilot study showed that plastic teeth replicas absorb water, and the teeth should be placed in the incubator for 72hrs for complete dehydration before they are weighed.

The extra-oral optical scanner was the second method used to analyse tooth tissue removal. This method provided volumetric data about the amount of tooth tissue removal. To the best of our knowledge, no other study has evaluated the extra-oral optical scanner to assess the amount of tooth tissue removal.

Al-Nuaimi *et al* in 2017, assessed residual Coronal Tooth Structure following endodontic cavity preparation using intra-oral digital scanner and Micro-CT. Non-invasive access cavities were cut in 34 human extracted molar teeth. All teeth were scanned with an intra-oral digital scanner and micro-CT. They concluded that the volumetric accuracy of the intra-oral scanner is adequate to be used to create accurate virtual models that reproduce the residual coronal tooth structure. They also concluded that scanning the intra-coronal aspect of the endodontically accessed tooth, for reliable assessment of the loss of tooth structure during endodontic treatment, can be used to make inferences about the prognosis of the endodontic and restorative treatment, leading to improvement in treatment planning process. In this study, an intra-oral optical scanner was used for analysis, however in our study, an extra-oral optical scanner was used. The problem encountered with this method was that the scanner was only able to scan a clear image of the tooth before the endodontic access cavity preparation. Once the access has been made the scanner was only able to scan the first 2-3 mm into the prepared cavity. As a result of this finding a negative replica of the prepared cavity was made using an impression material (an addition- Vulcanizing Duplication silicone (Z-DUPE) (Henry Schein) (Figure 8). This material was stable and easily injected and removed from the endodontic access cavity.

The third method used for analysis was the CBCT. The use of CBCT technology produces a three-dimensional image of the tooth before and after endodontic access cavity (Figure 24,25)

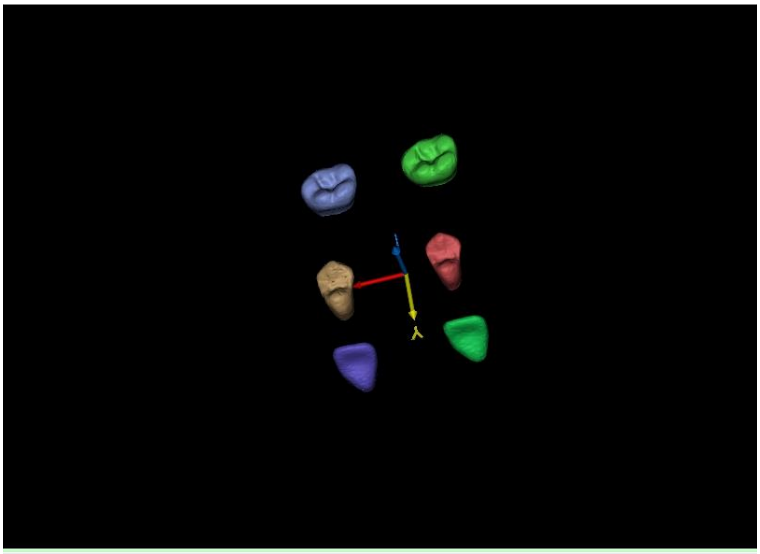

Figure 24: 3D image of the teeth before endodontic access cavity

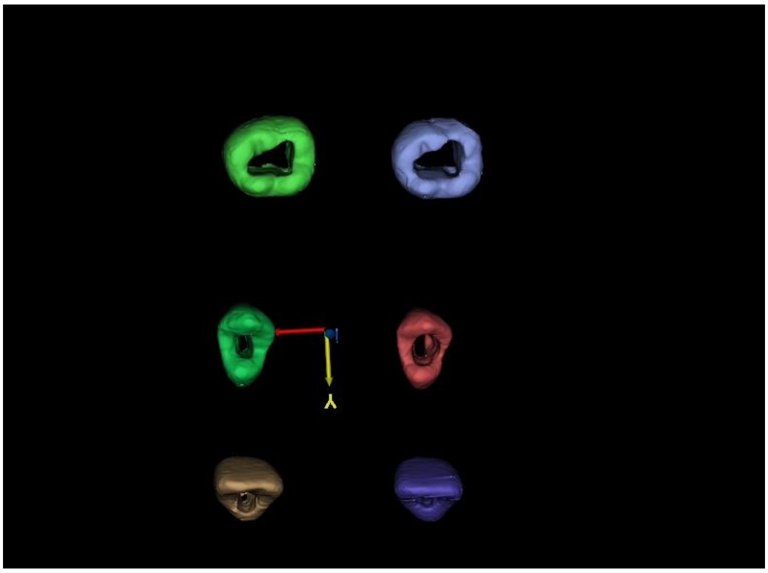

Figure 25:3D image of the teeth after endodontic access cavity

Using the Materialise software package (Materialise N.V., Leuven, Belgium, the teeth were scanned using CBCT. The images were exported in DICOM format and then imported into Materialise Mimics. The images were filtered using a pre-set gray value to minimise noise. The access cavity area was selected manually for all the images and a segmentation process was carried out. The segmentation process was done manually by the investigator to ensure standardisation. The volume segmented was used to calculate and generate a 3D rendered image by the software. The volume of each 3D image was extracted from the software and then the difference in volume of the teeth between pre and post access cavity preparation was calculated.

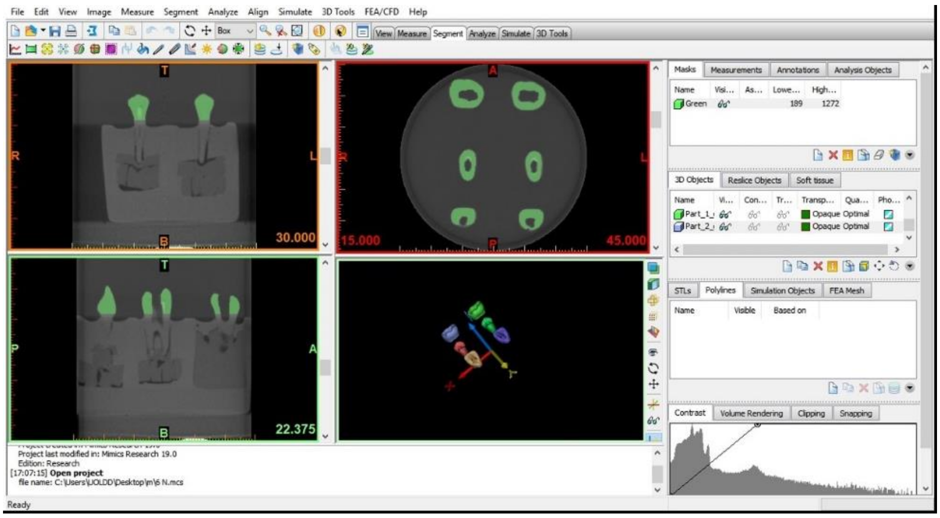

Figure 26: Showing the segmentation process

The Analytical balance results provide an accurate measurement in sub-milligrams regarding the weight of tooth tissue removal before and after endodontic access cavity. It is simple and straightforward method, however, there is no data can be provided regarding the shape and quality of the access cavity. The method can only be used with 3D printed teeth as it is possible to standardise the plastic teeth, while it is difficult to standardise the natural teeth.

The optical scanner method results can provide volumetric data regarding the amount of tooth tissue removal. The scanner was able to provide 3D image for the tooth before the endodontic access cavity, and once the access cavity prepared, the scanner could not scan more than 2-3mm intra-coronally. Taking a negative replica for the access cavity and scan it, was difficult, as we need to standardise the amount of the silicone injected inside the cavity. It is also taking a long time to perform.

The results from CBCT method provide volumetric data as well. It produces a three-dimensional image of the tooth before and after endodontic access cavity, and with the utilisation of Mimic software the difference in volume between pre and post access cavity preparation can be measured. This method can provide data regarding the volume, size and shape of the access cavity. The image of the scan is very accurate, and the slices of the volumetric data can be chosen by the researcher.

4 Chapter 4: The effect of using dental loupes during endodontic access cavity procedure by undergraduate dental students

4.1 Introduction:

It is clear that the remaining structural integrity of the tooth is a key factor that determines prognosis, as it relates to the future function of the tooth after restoration. (Tang *et al*., 2010, Nagasiri and Chitmongkolsuk, 2005). Maintaining strength and stiffness that resists structural deformation becomes the recognised goal of all restorative procedures, being especially applicable in endodontics (Gluskin *et al*., 2014). Compromised structural or mechanical integrity of teeth results in different types of tooth fractures, which are known to be one of the most common causes for tooth extraction (Kishen and Boveda, 2015). The endodontic access cavity is considered the first step in root canal treatment. Traditionally, the design of endodontic access cavities have remained unaltered for the past several decades (Ingle, 1985). The conventional endodontic access cavity preparation commonly involved removal of dentin in order to explore the expected pulp chamber floor anatomy and canal openings and preflaring the coronal aspect to facilitate cleaning, shaping and obturation. Recently, new designs for endodontic access cavities called conservative or ultraconservative access cavity has been introduced (Belograd, 2016, Clark and Khademi, 2010a). The concept of this access cavity is to maintain the mechanical stability of the tooth by minimizing tooth structural removal as well as preserving more dentine and this could improve the fracture strength of endodontically treated teeth and subsequently the long-term survival and function of endodontically treated teeth.(Bóveda and Kishen, 2015, Asundi and Kishen, 2001).

In 2012, the American Association of Endodontics (AAE) stated that endodontics could benefit from the use of a DOM in achieving proper conservative access (AAE, 2012).however, To the best of our knowledge, no study has yet evaluated the amount of tooth tissue removed during endodontic access procedure with and without magnification. .

4.2 Aim:

The aim of this study was to investigate the effect of dental loupes on the amount of tooth structure removed during endodontic access cavity procedures undertaken by undergraduate dental students and to investigate the correlation between CBCT and Analytical balance.

4.3 Methods and materials:

4.3.1 Study design:

A crossover randomised study was conducted at Liverpool University Dental Hospital (LUDH). Ethical approval was obtained from the research ethics committee at the University of Liverpool (Reference number: 2647). An email was sent to 3rd-year undergraduate dental students at Liverpool University Dental Hospital to recruit them for the study. The students had already completed a preclinical course in basic endodontics as a component of the third year undergraduate BDS curriculum. This was undertaken on anterior and premolar teeth. The students had no previous experience with using magnification. The recruitment email included an information sheet, risk assessment form and consent form. The information sheet detailed the following participant inclusion criteria; the ability to use the supplied loupes and students should have no previous experience with using any form of dental magnification. Whereas the exclusion criteria included students with corrective glasses and students who have used magnification before.

Twenty undergraduate students were recruited based on the design of previous studies (Bowers *et al*., 2010), (Rampado *et al*., 2004). One hundred and eighty 3D designed teeth (DRSK RCT Model), were used in the study; 60 maxillary central incisors, 60 maxillary first premolars and 60 mandibular first molar teeth (Figure 26).

Figure 27: 3D designed teeth

The 3D designed teeth were used in the study to ensure standardisation. The standardisation made the assessment easier to apply and ensure a high degree of reproducibility of the experimental design, which makes the results of such studies valid (Lim and Webber, 1985). The twenty students were split into 2 groups, group (A) of 10 students and group (B) of 10 students. A PowerPoint presentation made by the investigator was given to each group before conducting the study. The presentation detailed the ideal access cavity features, technique for access cavity preparation and a detailed video regarding the access cavity preparation for maxillary central incisor, maxillary first premolar and mandibular first molar teeth and the use of magnification loupes. As well as the PowerPoint presentation, twenty-minute hands-on instruction on how to use the loupes was provided. The following set of instruments were provided for each student: a front surface mirror, DG16 endodontic probe, long shank small excavator, 3x5 magnifying loupes, Size 2 diamond round bur to be utilised for premolars and anterior teeth, whereas, a size 4 round bur was used for molar teeth, as well as a Muller bur (size 120.140), Endo Z bur, Endodontic syringe, and high and low speed handpiece.

The students performed the experiment in a clinical simulation suite. All teeth were set up on the right side of the phantom head. The participant groups were arranged according to a randomly assigned seating plan. The right-side group started access cavity preparations with loupes while the left side groups started without loupes.

Figure 28: Operative skills suite

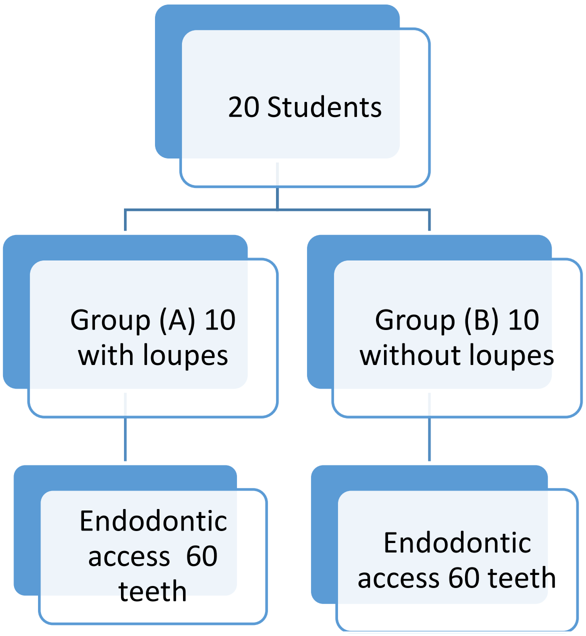

Figure 28: shows study design, number of participants

The first group carried out endodontic access preparations on three 3D printed teeth, starting with one maxillary central incisor, followed by one maxillary first premolar and finally one mandibular first molar. They utilised dental loupes with x3.5 magnification, 420 mm focal distance and a LED light attached (Figure 29). It was ensured that the loupes were used for the full procedure.

The second group carried out endodontic access cavities on three 3D printed teeth, again starting with one maxillary central incisor, followed by one maxillary first premolar and finally one mandibular first molar. This was completed without the aid of dental loupes.

Both groups then crossed over, using the same protocol as the other group, with the total time taken to conduct the study being 2 hours and 45 minutes.

Figure 29: 3.5 x 420 Loupe with LED light

The data was analysed using two methods, Analytical Balance and CBCT. Analytical Balance involves comparing the weight of the teeth following preparation and calculating the weight of lost material by measuring compared to the standardised initial pre-access weight of each tooth. Furthermore, each of the intact three tooth types were fixed in a positioning device and an initial CBCT scan was taken. Following, the experiment i.e. access cavity preparations, each participants' six teeth (three for each group) was fixed together in a positioning device and a post-preparation CBCT scan was taken. These scans were uploaded to Mimics software and compared with the initial tooth scans for evaluation of volumetric change. Further details on the complete protocol for these two methods can be found in Chapters 3.2.2 and 3.2.4 respectively.

4.4. Results:

The data from the study was collected and entered into a Microsoft Excel sheet 2013. The SSPS was used for statistical analysis. Univariate Analysis of Variance (ANOVA) was utilised to analyse the data to assess if there is a difference in the amount of tooth tissue removal with magnification compared to no magnifications, the effect of tooth type (central, premolar or molar), the order of using magnification and the operator on tooth tissue removal. A Persons correlation will be used to assess if there is a correlation between the CBCT and Analytical Balance.

CBCT/Volume

Univariate analysis				
Variables	**DF (Hypothesis)**	**DF (Error)**	**F**	**S**
Loupes	1	96	.003	.958
Order	1	96	.085	.771
Teeth	2	96	135.222	.000
Students	19	96	4.716	.000

Table 1: showing the variables that had a significant effect on the CBCT/Volume

Univariate Analysis of Variance was used with CBCT to analyse the effect of loupes, order, teeth, and students on the amount of tooth tissue removal. The table showed that teeth and students had a statistically significant effect ($p \leq 0.05$). This indicates that teeth and students affected the amount of tooth tissue removal during endodontic access cavity.

CBCT/Volume Mean and SD

CBCT		Number of teeth	Number of students	Mean volume	SD
Loupes	**Incisors**	**40**	**20**	**31.334**	**18.67032**
	Premolars	**40**		**63.329**	**19.78736**
	Molars	**39**		**109.7915**	**35.01603**
No Loupes	**Incisors**	**40**	**20**	**21.658**	**16.4419**
	Premolars	**40**		**65.8525**	**28.51392**
	Molars	**39**		**117.6345**	**48.91469**

Table 2: Showing the mean, SD with the CBCT/Volume

Analytical Balance

Variables	DF (Hypothesis)	DF (Error)	F	S
Loupes	1	96	1.866	.175
Order	1	96	1.746	.190
Teeth	2	96	236.130	.000
Students	19	96	2.058	.012

Table 3: showing the variables the had a significant effect on the analytical balance/Weight

Univariate Analysis of Variance was used with Analytical balance to analyse the effect of loupes, order, teeth, and students on the amount of tooth tissue removal. The table showed that teeth and students had a statistically significant effect (p≤0.05). This indicates that teeth and students affect the amount of tooth tissue removal during endodontic access cavity.

Analytical Balance Mean/SD

Analytical Balance		Number of teeth	Number of students	Mean	SD
Loupes	Incisors	40	20	0.0419	1201
	Premolars	40		0.058	0.02367
	Molars	39		0.1364	0.03442
No Loupes	Incisors	40	20	0.0373	0.01011
	Premolars	40		0.0549	0.01932
	Molars	39		0.1287	0.02494

Table 4: Showing the Analytical Balance Mean and SD

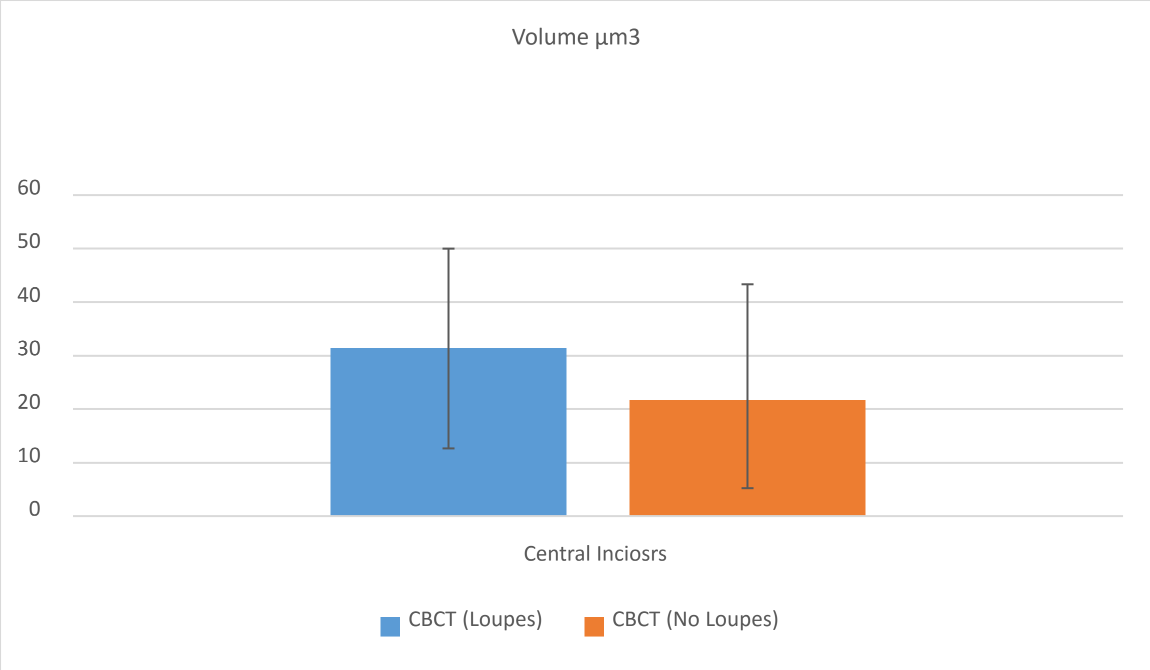

Figure 29: Illustrating the difference between the volume of access cavity in central incisors with loupes and without loupes

Figure 30 shows a graph representing the means and standard deviation of the difference in volume during endodontic access cavity in maxillary central incisors with and without loupes using CBCT for analysis. There is no significant difference.

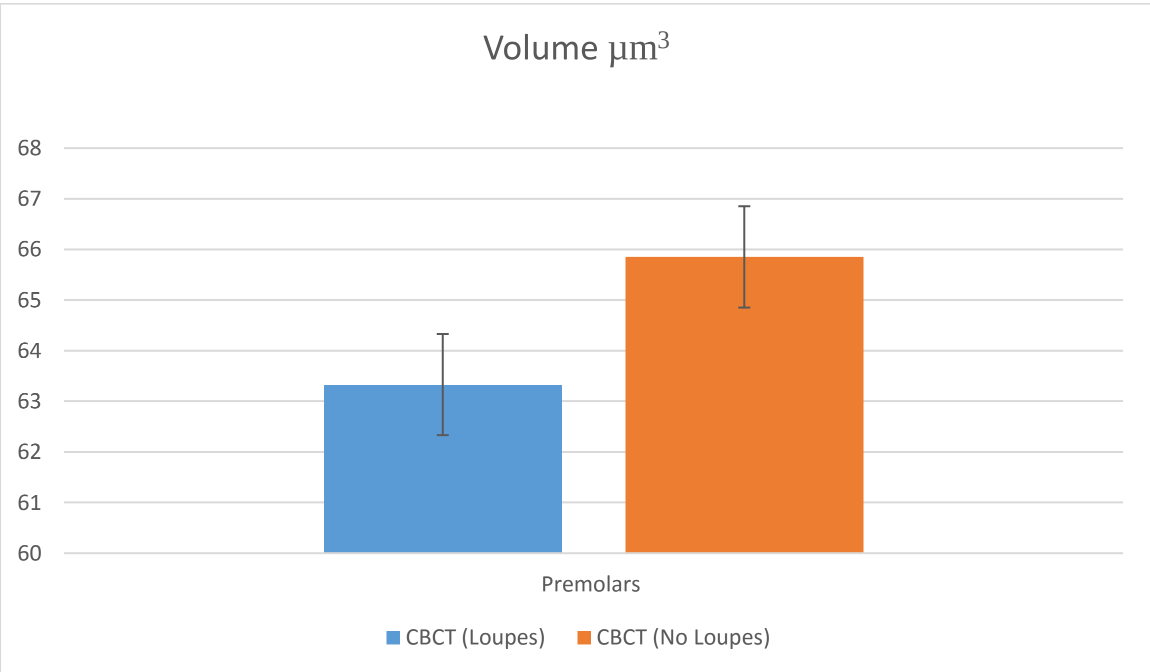

Figure 30: Illustrating the difference between the volume of access cavity in premolars with and without loupes using CBCT

Figure 30 shows a graph representing the means and standard deviation of the difference in volume during endodontic access cavity in maxillary 1st premolars with and without loupes using CBCT for analysis. There is no significant difference.

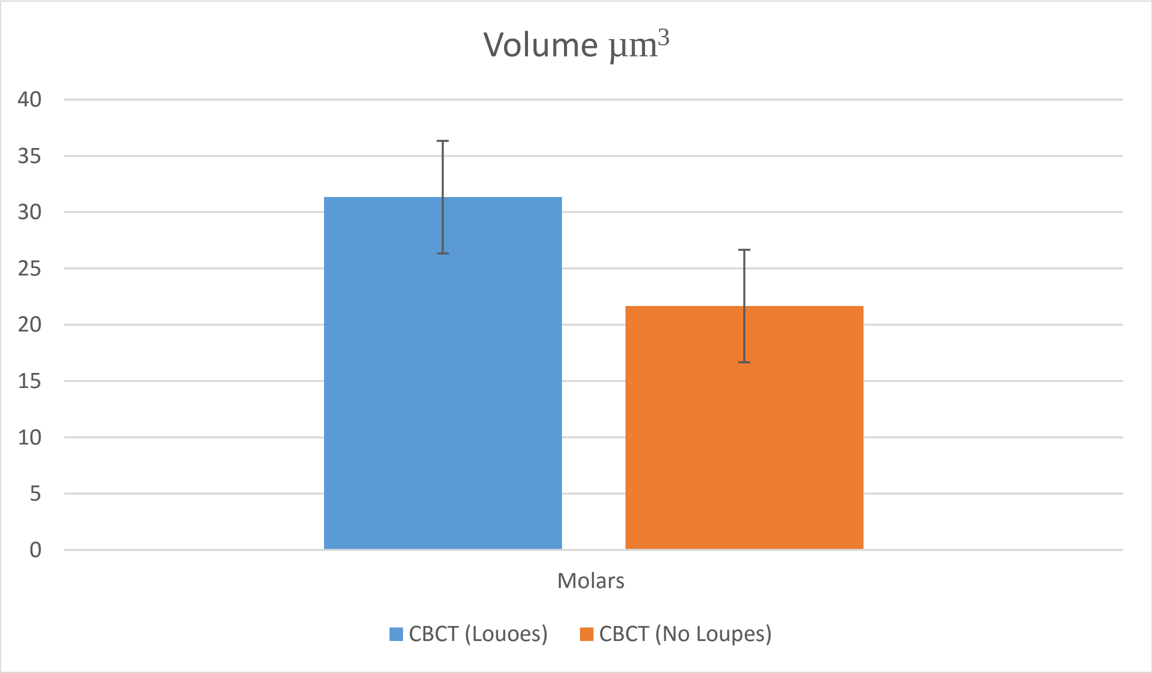

Figure 31: Illustrating the difference between the volume of access cavity in molars using CBCT with and without loupes

Figure 31 shows a graph representing the means and standard deviation of the difference in volume during endodontic access cavity in mandibular 1st molars with and without loupes using CBCT for analysis. There is no significant difference.

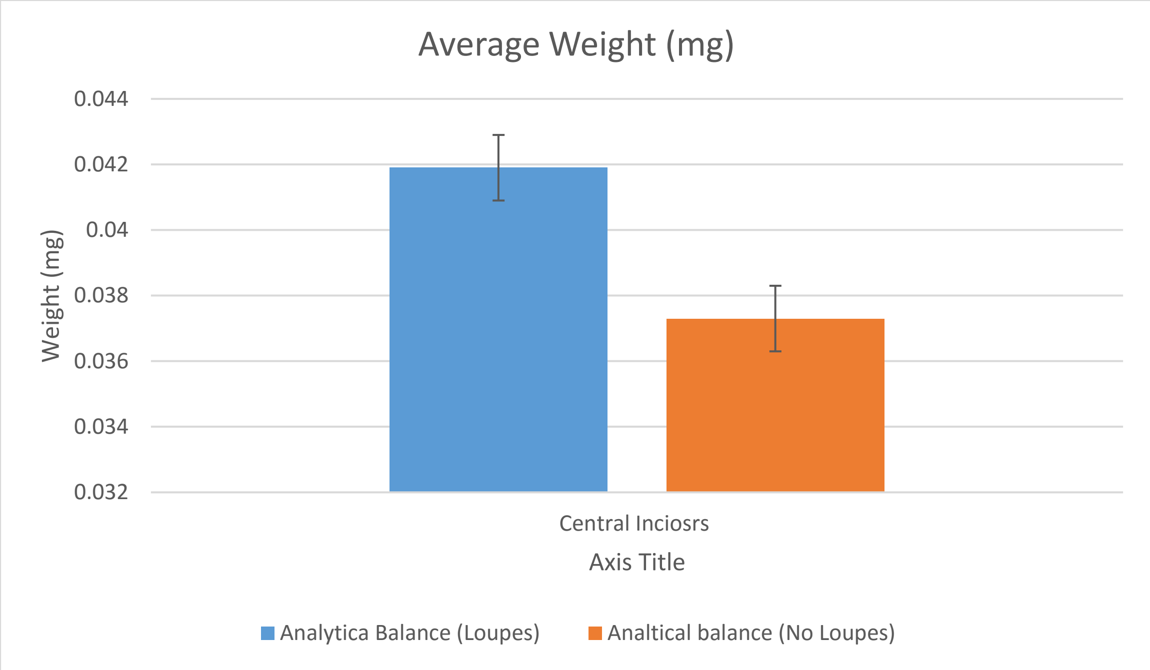

Figure 32: Showing the difference between the weight of access cavity in central incisors with loupes and without loupes using Analytical Balance

Figure 32 shows a graph representing the means and standard deviation of the difference in weight during endodontic access cavity in maxillary central incisors with and without loupes using Analytical Balance for analysis. There is no significant difference.

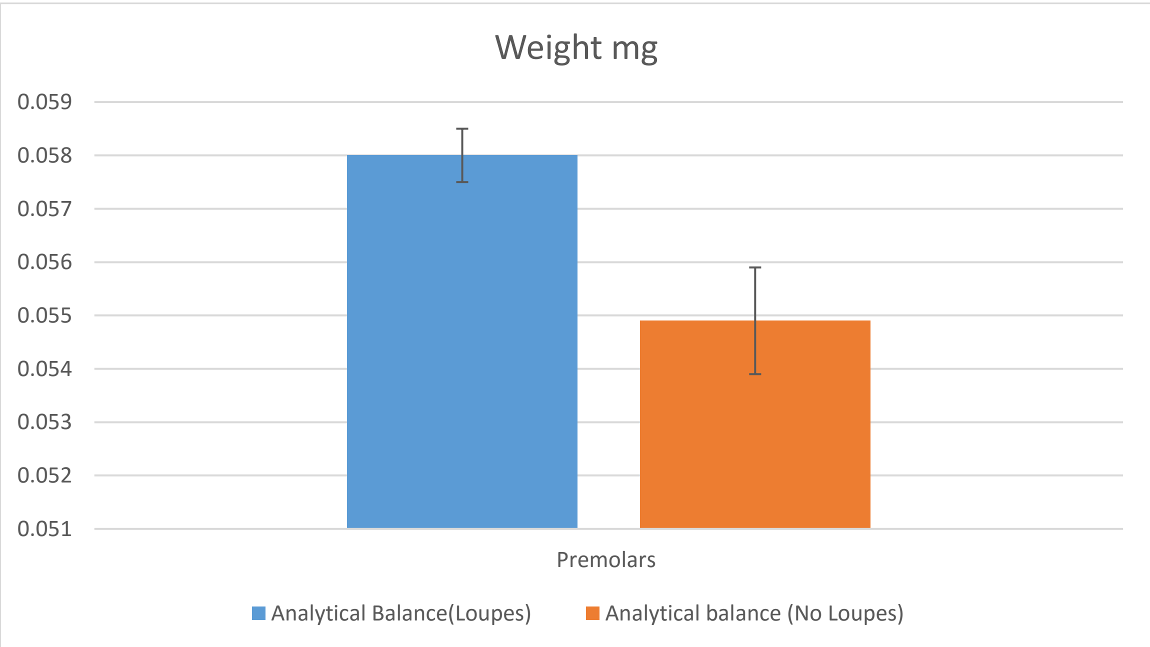

Figure 33: Showing the difference between the volume of access cavity in premolars with loupes and without loupes using Analytical Balance

Figure 33 shows a graph representing the means and standard deviation of the difference in weight during endodontic access cavity in maxillary 1st premolars with and without loupes using Analytical Balance for analysis. There is no significant difference.

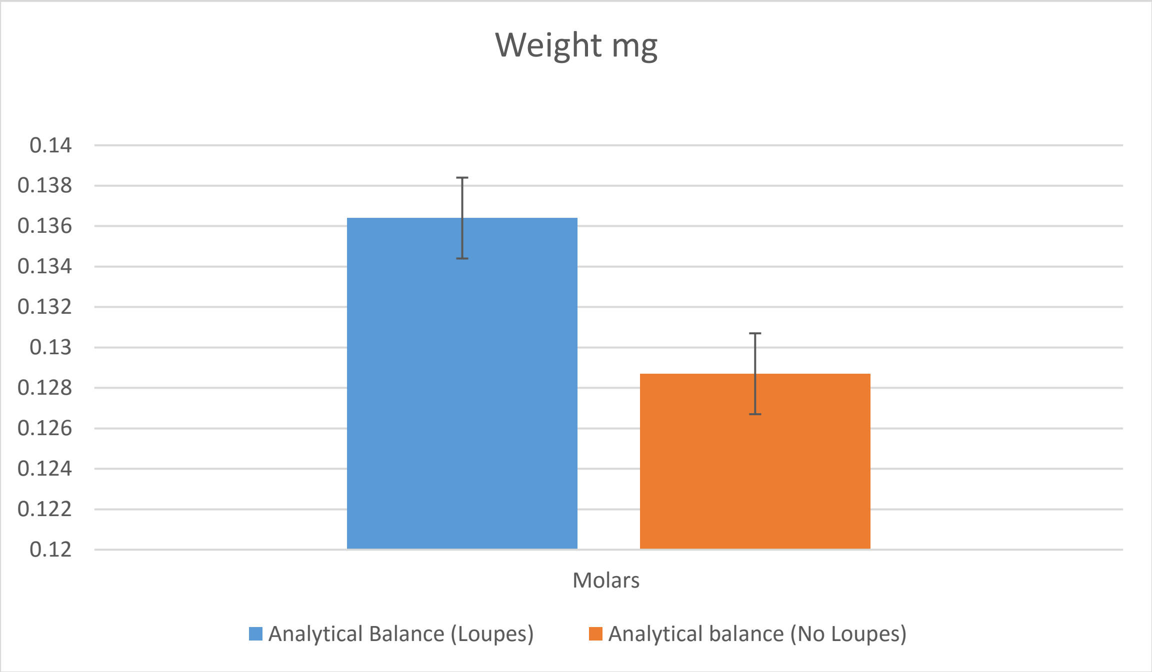

Figure 34: Showing the difference between the weight of access cavity in molars with loupes and without loupes using Analytical Balance

Figure 34 shows a graph representing the means and standard deviation of the difference in weight during endodontic access cavity in mandibular 1st molars with and without loupes using Analytical balance for analysis. There is no significant difference.

Magnification	Tooth Type	Perforation
Loupe	Anterior	0
	Premolar	0
	Molar	1
No loupe	Anterior	0
	Premolar	0
	Molar	1

Table 5: Showing the number of complication/Perforation

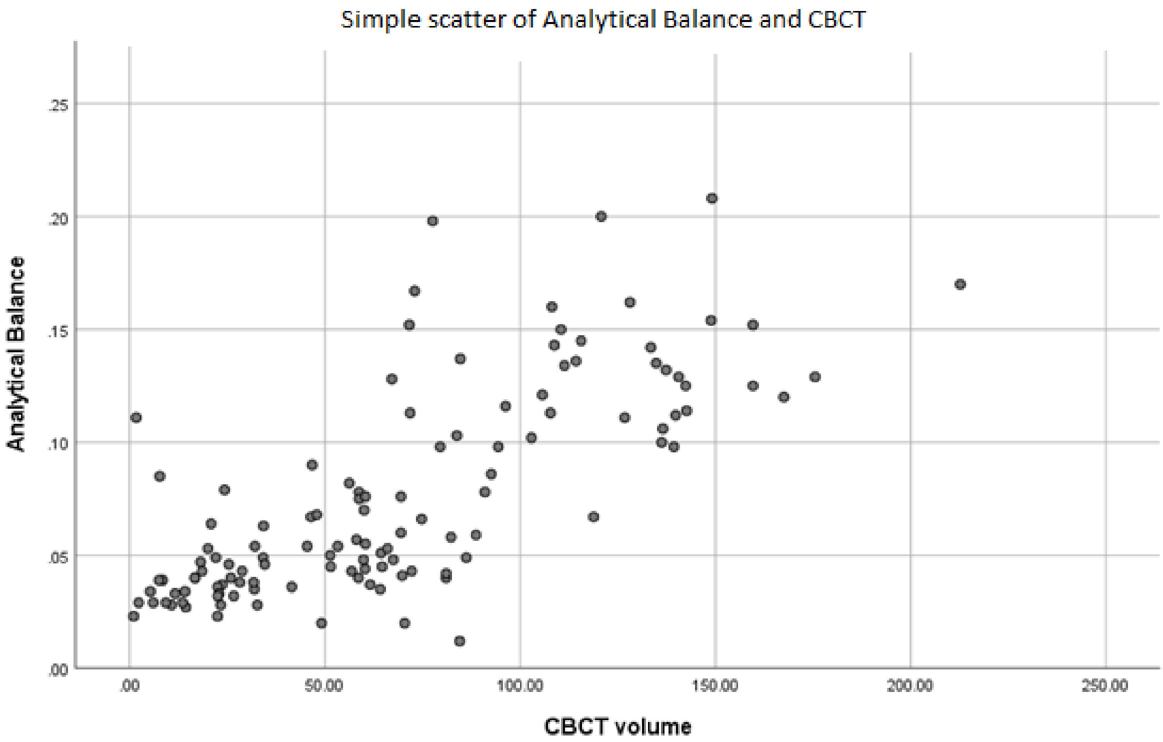

Figure 35: The Pearson's correlation

The Pearson's correlation coefficient is 0.750.

Figure 36 shows a simple scatter plot representing Analytical balance and CBCT. There is a significant correlation between the analytical balance and the CBCT. The Pearson's correlation is 0.750 in this study. The Pearson's correlation has a value between +1 and -1. A value of +1 is total positive linear correlation, 0 is no linear correlation and -1 is total negative linear correlation.

4.5 Discussion:

The results from this study showed that there is no significant difference in the size of the access cavity between the loupe group and the un-aided vision group. This may be due to a lack of experience among the students. They may prefer to focus on the quality of the cavity of endodontic access rather than the amount of removal of tooth tissue. With enhanced illumination and magnification, the students could focus on removing more tooth structure, gaining straight line access and focus on minute details of the cavity. However, the quality of the access cavity was not assessed in this study.

The study was designed in a cross over randomised format. A crossover design enables comparisons between and within groups in the same environment, and participants can indicate preferences for one method versus another. (Mills *et al.,* 2009).

The 3D printed teeth were used to ensure standardisation. The standardisation made evaluation easier to apply and ensured a high degree of reproducibility of the experimental design which validated the results of such studies (Lim and Webber, 1985). However, they could also influence the amount of tooth tissue removal, this is may be due to difference in the hardness between 3D printed teeth and dentine in natural teeth (Al-Sudani and Basudan, 2017).

Central incisors, maxillary 1st premolars, and mandibular 1st molars were chosen to cover the morphology feature of permanent teeth. Maxillary Central incisors are often involved in root canal treatment especially following trauma, and it is the most commonly affected tooth in either permanent or primary dentition because of their exposed position in the dental arch (Rocho and Cardoso, 2002), (Altun *et al.*, 2009). Upper 1st premolars have two roots in the majority of cases according to a recent CBCT study (de Lima *et al*., 2019). The mandibular first molar is considered to be the most common tooth involved in the endodontic procedure because it is the earliest permanent tooth to erupt and are most prone to suffer from caries (Vertucci *et al.,* 2006).

Another finding is that the use of magnification (loupes) does not seem to influence the amount of tooth tissue removal. This study used one level of magnification (3.5x) and this may not have been optimal. The decision to use dental loupes with 3.5x magnification (and 42cm focal distance) in this study was based on evidence that 3.5x magnification has been found to perform well for other clinical tasks (Forgie *et al.*, 1999), (Burton and Bridgman, 1991). Participants in the magnification arm were forced to use a standard working distance of 42cm based on the focal distance of the dental loupes. However, participants in the non-magnification arm were not standardised to a fixed working distance. Therefore, participants in the non-magnification arm could theoretically have been working at various working distances. The working distance for this group could have been standardised by adjusting the height of the phantom head to a fixed distance from the operator's eyes. However, it should be noted that all dental practitioners naturally operate at different working distances in accordance with variable body dimensions (i.e. height, arm length and irrespective of the need for prescription glasses). Therefore, it would be impractical to standardise the working distance for all participants, primarily due to ergonomics, posture and comfort. It would be more appropriate to have personalised loupes for each participant in accordance with their favoured working distance. Although this would be unfeasible due to the associated increase in expenditure and logistical requirements.

A portable LED Headlight was provided to all students with intensity between 15000-30000 Lux for the improvement of the visual acuity and this level of intensity is considered to be safe whilst minimizing glare (Gultz and Kaim, 1997), (James and Gilmour, 2010). Furthermore, this level of magnification is easily accepted by inexperienced users whilst still giving a noticeable level of magnification for the clinician (Forgie *et al.,* 2001). However, the loupes required a period of adaptation (James and Gilmour, 2010), which could affect the results of this study. Another finding of the study is the presence of correlation between the results of analytical balance and the results of the CBCT. Analytical balance is a simple and easy method used to analyse the amount of tooth tissue removal, while the CBCT is able provide more information about the shape, amount of tooth tissue removal and the quality of the access cavity. There is no study investigating the correlation between the different methods to assess the amount of tooth tissue removal. Both methods are non-destructive and allow the samples to be analysed several times.

Several studies have looked at the role of magnification in enhancing clinical performance, vision, fine motor skills, locating extra canals and access cavity preparation with operating microscopes (Perrin *et al*., 2014),(Donaldson *et al.*, 1998), (Bowers *et al.,* 2010), (Rampado *et al.*, 2004), (Park *et al.,* 2014). To best of our knowledge, there is no study investigating the effect of loupes on the amount of tooth tissue removal during endodontic access cavity procedure.

Many dental schools now require their students to use magnifying loupes during preclinical and clinical education. This study introduced undergraduate dental students to dental magnification (loupes) in a short-focused course and assessed the benefit of the loupes in preserving tooth tissue during endodontic access cavity.

The result showed that there is no significant difference in the size of the access cavity with and without loupes and this, contradicted with another study aimed to quantify any cavity size change following removal of tooth-coloured restorations *in vitro* using unaided vision and 2.6x magnification without mentioning the loupes type. The results from Forgie *et al* 2001 study showed that there was a significant change in cavity size during removal of a class I composite restoration with both unaided vision and 2.6x magnification (Forgie *et al.,* 2001). However, the study by Forgie *et al* was carried out by four clinicians and utilised 48 teeth without training on how to use magnification.

The findings also contradicted with a study conducted by Rampado *et al* in 2004. Rampado aimed to determine whether using the OM would improve students' performance in endodontic access cavity preparation and canal identification by undergraduate students. The study concluded that the use of the OM significantly improved student's ability to find canals and positively impacted the quality of access cavity preparation. The Rampado study was conducted using only maxillary molars and an operating microscope, and the microscope group students went through longer training before the study. As well as this, it is possible that operating microscope magnification provides broader visibility in comparison to loupes magnification, and this could explain the difference in the results.

On completion of this experiment, both groups were collectively asked for verbal feedback on their experience using magnification. Five students out of twenty students reported that using loupes was 'difficult'. This may be due to the standardised type of loupes used in the study however, it also could be as a result of an insufficient training period on the use of loupes The students were given a presentation about the access and the loupes and also a 20 minutes hands-on instruction about the loupes, despite this training, it is difficult to provide the specific training time required for students to adapt to a new technology (Graber *et al.,* 1998). This could be explained by competency-based education, which provides a sequence of defined learning experiences to dental students from novices to expertise. However, the quality of the dental work carried out by students is dependent on experience, training, and manual dexterity(Giuliani *et al.,* 2007), (Gansky *et al.,* 2004)

In this study, the students were at the first stage of their competency-based education. Nevertheless, a surprising result of this study is that the students were performing the access cavity in mandibular 1st molar teeth for their first time and, only 2 students made a perforation, one of them while he was using the loupes and the other without loupes. In the author's opinion, performing endodontic access cavity in a mandibular 1st molar for the first time successfully and without perforation could be due to the detailed video given to the students before conducting the study, the step by step presentation on how to perform access cavity and it could be also attributed to their level of competency.

The author of this study tried to determine if the use of magnifying loupes is associated with benefits for the patients and dentists regarding a more conservative endodontic access cavity which could minimise tooth structure removal, improving the outcome of root canal treatment and minimizing tooth fracture after root canal treatment.

The need for further research is necessary in order to investigate the effect of an operating microscope with higher magnification in the amount of tooth tissue removal, a comparison between students using the OM and students using dental loupes would be of interest. In addition, if a trained dentist, endodontist performed the study using loupes or operating microscope, would the results be in favour of the dentists, endodontists. Furthermore, if the students were given a period of adaption and used the loupes for a long time would that make a difference. In addition, a comparison between students using the OM and students using dental loupes would be of interest.

4.6 Conclusion:

Within the limitations of this study, there is insufficient evidence to suggest dental loupes, at 3.5x magnification, influences the size of the endodontic access cavity preparation by novice undergraduate students. This could be attributed to insufficient experience with using loupes, as well as limited clinical experience and the use of loupes with a standardised working distance. However, there was a significant association with the effect of tooth type, with molar teeth having a significantly increased amount of tooth tissue removal. There was also a significant variation in results amongst operators.

5 Chapter 5: Clinical implication and future research:

5.1 Clinical implications:

The outcome of the pilot study showed that analytical balance, optical scanner, and CBCT can all be used to calculate the amount of tooth tissue removal during endodontic access cavity procedure. In addition, there is a correlation between the analytical balance and CBCT. This will inform any future researchers on other methods to analyse the amount of tooth tissue removal in restorative and endodontics.

The outcome of the second study revealed that the use of loupes does not appear to influence the amount of tooth tissue removal by novice undergraduate students during the endodontic access cavity procedure. This is may be because students need more training period and experience before using the loupes. Furthermore, there is no significant difference between the loupe group and the unaided vision group in the size of the access cavity.

5.2 Future research:

Investigate the effect of an operating microscope with higher magnification in the amount of tooth tissue removal in the hands of novice's students. This will help to inform and to apply modifications to the preclinical training protocol for dental students.

A study can be conducted by a trained dentist/ endodontist using loupes or an operating microscope. This will help in comparing the level of experience between the clinician.

The same study can be conducted using prismatic loupes which provide the highest optical quality available today.

Further investigation should be conducted regarding the loupes as a continuation phase to this study and based on the findings:

The 1st phase will investigate the effect of more dedicated training time on the loupes with more experienced students.

The 2nd phase will analyse the quality of endodontic access cavity. The quality of the access cavity can be evaluated according to a set of criteria.

The 3rd phase is to compare between students using the OM and students using dental loupes during endodontic access cavity procedure. This will help to inform the dental school on the best approach to training undergraduate students.

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7 Appendices:

7.1: Appendix 1: Abstract accepted for publication in international endodntic journal

Does the use of magnification loupes affect tooth tissue removal during endodontic access procedures?

M.AL Agha, PW Smith, E Mowad, FD Jarad.

School of Dentistry, University of Liverpool

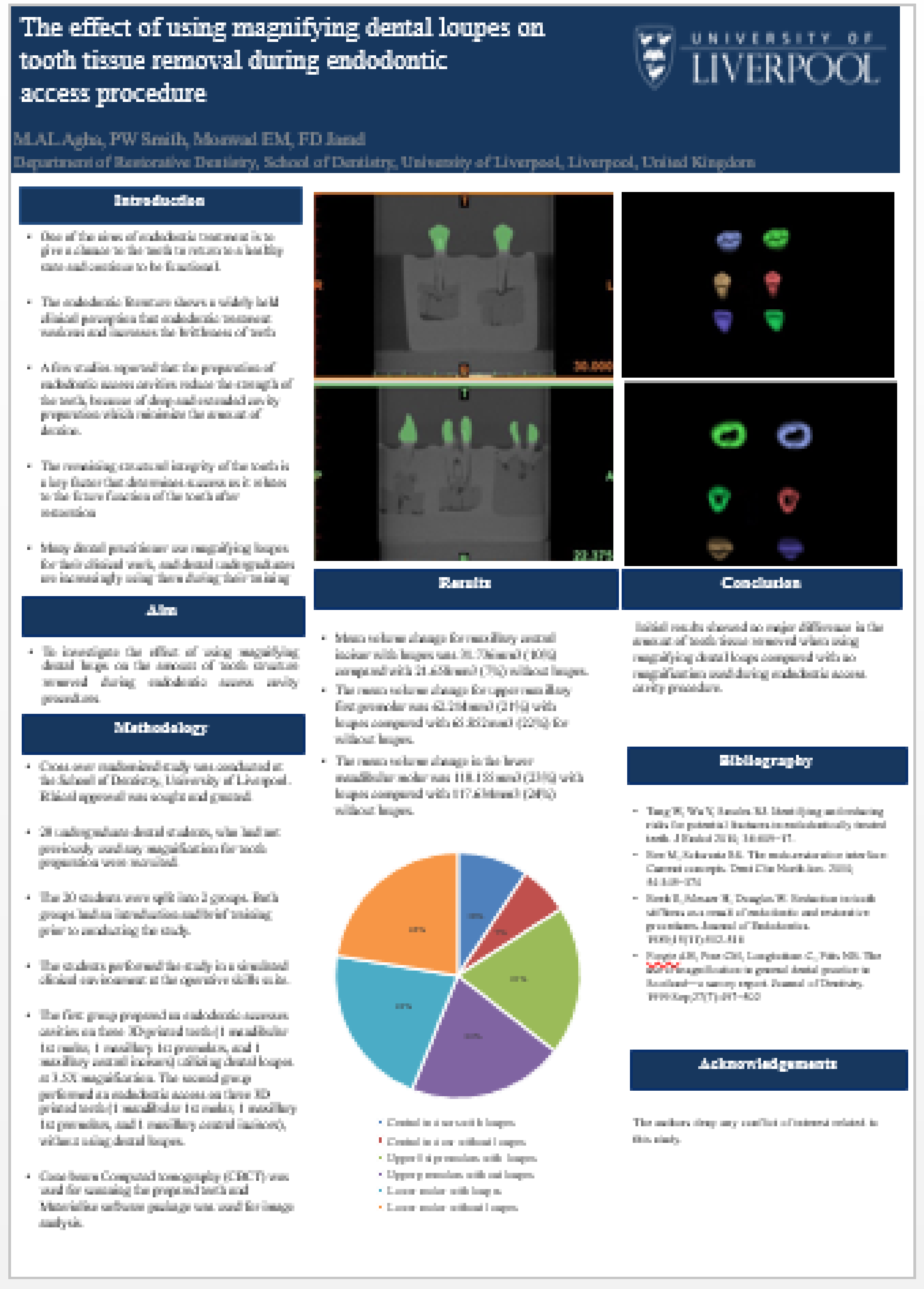
Aim: To investigate the effect of dental loupes magnification on the amount of tooth structure removed during endodontic access cavity procedure

Methodology: Cross over randomized study design conducted at Liverpool University Dental Hospital (LUDH). Ethical approval sought and twenty undergraduate dental students, who had not previously used any magnification were recruited from Liverpool University Dental Hospital (LUDH) and were split into two groups with 10 students each. A power point presentation including a video regarding the access cavity preparation and the use of magnification loupes given to each group before conducting the study. The students performed the study on simulated clinical condition, all teeth were set up on the lower right quadrant of the phantom head at operative skill room. The first group carried out an endodontic accesses on three 3D printed teeth (1 mandibular 1st molar, 1 maxillary 1st premolars, and 1 maxillary central incisors) utilizing dental loupes at x3.5 magnification. The second group carried out an endodontic accesses on three 3D printed teeth (1 mandibular 1st molar, 1 maxillary 1st premolars, and 1 maxillary central incisors), without using dental loupes. Cone beam Computed tomography (CBCT) was used for analysing the data.

Results: Mean volume change for maxillary central incisor with loupes was: 31.736 (10%) and without loupes 21.658 (7%). The mean volume change for upper maxillary first premolar was 62.214 (21%) with loupes and 65.852 (22%) without loupes. The mean volume change in the lower mandibular molar was 110.155 (23%) with loupes and 117.634 (24%) without loupes.

Conclusion: Initial results showed that no difference in the amount of tooth tissue removal with and without loupes during endodontic access cavity procedure.

7.2 Appendix 2: Poster presented in the biennial congress of the European society of endodontics, Vienna 2019:



7.3 Appendix 3: Recruitment email

Version 1
2-2-2018

UNIVERSITY OF LIVERPOOL

Dear Colleague:

We are seeking 20 male or female volunteers to take part in laboratory research that investigates if the use of loupes (magnification) will affect the amount of tooth tissue removal during an endodontic access cavity. Volunteers are required to prepare endodontic access cavities in 6 different plastic teeth (2 mandibular 1st molar, 2 maxillary 1st premolars, and 2 maxillary central incisor) in the right side of the phantom head. The 20 volunteers will be divided into 2 groups of equal number. The first group of 10 volunteers will prepare the teeth with magnification loupes, the second group of 10 dentists will also endodontically access the 6 plastic teeth without loupe. The two groups will then cross over after. The study will be conducted over 2 days on July 2018, and it will take 2 hours each day.

In order to take part, you must fulfil the following criteria:

- *Fifth year dental students.*
- *Not wearing corrective glasses*
- *Never used magnification before.*

All participants will be given the opportunity to use 3.5 magnification loupes. Please see the attached informed consent for more information.

Thank you for reading this.

Dr Phil Smith Supervisor Chief Investigator

Professor Fadi Jarad Principal Investigator

Mustafa Alagha Lead student investigator

7.4 Appendix 4: Participant information sheet

Version:3

29-05-2018

Participant information sheet

1-Research title:

Does the use of magnification affect tooth tissue removal during endodontic access procedures performed on plastic teeth replicas?

2-Dear colleague:

You are being invited to participate in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives and GP if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

Thank you for reading this.

3-Purpose of the study:

Increasing numbers of patients are having root canal treatment (endodontics) as an alternative to tooth extraction. Root canal treatment involves cleaning and shaping inside the roots of teeth (root canal system). An essential part of root canal treatment is gaining access to the root canal system which requires making a cavity in the tooth through which the root canals can be reached. This cavity is an access cavity and the configuration of this has an impact not only on the ability to reach the root canal but can weakening of the tooth. The latter is an unwanted consequence of endodontic treatment and the need for conservation of tooth tissue whilst drilling access cavities has become recognised.

The aim of this investigation is to evaluate whether the use of magnifying loupes by fifth year dental students influences the extent and quality of endodontic access cavities prepared in plastic tooth replicas.

The objectives of the study:

1st objective: Assess amount of tooth tissue removal during endodontic procedures

2nd objective: Assess the configuration of endodontic access cavity

3rd objective: See whether tooth type affects access preparation under magnification.

4th objective: Investigate the effect of operator experience on tooth tissue preservation

4-Why have I been chosen to take part?

We have chosen fifth year dental students as the study requires novice users of magnification loupes to evaluate the amount and pattern of tooth structure removal for endodontic access cavities. We aim to enrol 20 fifth year dental students from Liverpool Dental School.

5-Do I have to take part?

The participation is voluntary and you are free to withdraw at anytime, without explanation, and without incurring a disadvantage

6- What will happen if I take part?

The initial proposal involves a sample size of twenty fifth year dental students who have not previously used loupes (magnification), recruited from Liverpool University Dental Hospital (LUDH) and will be divided into two groups. The first group of 10 dentists will utilize loupes at x3.5 magnification, to prepare endodontic access cavities in plastic teeth (simulated) positioned in a simulated patient (2 mandibular 1st molar, 2 maxillary 1st premolars, and 2 maxillary central incisor) on the right side of the phantom head. While the second group of 10 dentists will also prepare endodontic access in plastic teeth (2 mandibular 1st molar, 2 maxillary 1st premolars, and 2 maxillary central incisor) without the use of loupes.

The two groups will then cross over. The first group of 10 dentists will then endodontically access 6 plastic teeth (2 mandibular molars, 2 maxillary 1st premolars, and 2 maxillary central Incisors) without the use of loupes on the right side of the phantom head, while the second group will endodontically access 6 plastic teeth (2 Molars, 2 Premolars, and 2 Incisors) with loupes on the right side of the phantom head.

The student investigator is Mustafa Alagha, Dr Phil Smith is the Chief Investigator and primary supervisor. Professor Fadi Jarad is the Principal Investigator and secondary supervisor. The data produced from the research will be securely stored on the M drive which is password protected on a university computer within a locked room. Any paper data will be securely locked in a cabinet and any identifiable codes will be destroyed. Source data will be stored for 5 years from the date of completion of the research. Data is fully anonymised, and will not contain names, age, date of birth, email addresses or personal home address. Any anonymised and coded datasets will also be stored for 5 years from the time of the submission of the dissertation resulting from the study. The data will be accessed only by the researcher (Mustafa Alagha), by the primary supervisor (Dr Phil Smith) and secondary supervisor (Professor Jarad).

7- Expenses and / or payments:

Not applicable

8-Are there any risks in taking part?

Risks and hazards are those likely to be encountered when preparing cavities in teeth. You will be required to wear the usual personal protective equipment comprising: plastic apron, protective eyewear, facemask and gloves. You will carry out the operative procedures in the operative skills suite in the Dental School following the same health and safety procedures that you have used throughout your dental degree during the numerous dental skills courses you have completed to date. There is a very small risk of sharps injury from the burs used in dental handpieces so please ensure that burs are removed from handpieces when they are not being used to prepare the teeth. When you attend the OSS suite there will be a brief verbal presentation relating to the health and safety procedures that you need to adopt during the study.

9- Are there any benefits in taking part?

The opportunity to use loupe magnification in plastic replica tooth preparation.

10- What if I am unhappy or if there is a problem?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting [Dr Phil Smith, Telephone:01517065206] and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Ethics and Integrity Office at ethics@liv.ac.uk. When contacting the Research Ethics and Integrity Office, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make."

11- Will my participation be kept confidential?

As it is likely that more than one participant will be making preparations in teeth at the same time it will not be possible to guarantee that your participation will be confidential. However, the data produced from the research will be anonymised and securely stored on the M drive which is password protected on a university computer within a locked room. Any paper data will be securely locked in a cabinet and any identifiable codes will be destroyed. Source data will be stored for 5 years from the date of completion of the research. Any anonymised and coded datasets will also be stored for 5 years from the time of the submission of dissertation. After 5 years I will ask Liverpool IT to destroy the online data from the server. The data will be accessed only by the researcher (Mustafa

Alagha), the primary supervisor (Dr Phil Smith) and secondary supervisor (Prof Fadi Jarad). In University of Liverpool software, (the study data) will be secured confidentially within the university platform and no breach of confidentially with no personal details shared from the study. Data is fully anonymised, no information on name, age, date of birth, email addresses or personal home address will be used.

12- What will happen to the results of the study?

Findings will be disseminated at a conference presentation and published in peer review journal. Individual participants will not be identifiable from the results.

13-What will happen if I want to stop taking part?

You can withdraw at any time, without explanation. Results up to the period of withdrawal may be used, if you are happy for this to be done, if you are not happy to do so, the results will destroyed and no further use is made of them.

14- Who can I contact if I have further questions?

Chief Investigator: Dr Phil Smith BDS, MDS, PhD, FDS, DRD, MRD, FDS (Rest Dent), RCS (Edin), FHEA

University of Liverpool, School of Dentistry

Contact number: 01517065206

Email: pwsmith@liverpool.ac.uk

Contact details of investigatory team

Chief Investigator:

Dr Phil Smith

Contact number: 0151 7065206

Email: p.w.smith@liverpool.ac.uk

UNIVERSITY OF LIVERPOOL

Version:3

29-05-2018

Principal Investigator:

Professor Fadi Jarad

Contact number: 0151 706

Email: F.Jarad@liverpool.ac.uk

Lead student investigator:

Mustafa Alagha

Email: mustafa@liverpool.ac.uk

7.5 Appendix 5: Consent form

Version number: 2

Date: 05/06/2018

UNIVERSITY OF LIVERPOOL

Participant consent form

Title of the research project: Does the use of loupes affect tooth tissue removal during endodontic access procedures?

Researcher(s): Mustafa Alagha

Please initial box

1. I confirm that I have read and have understood the information sheet dated [29/05/2018] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected. In addition, should I not wish to answer any particular question or questions, I am free to decline. ☐
3. I understand that, under the General Data protection regulation (GDPR) 2016. I can at any time ask for access to the information I provide, and I can also request the destruction of that information if I wish up until the point of anonymization. ☐
4. I understand that other authorised researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form. ☐
5. I agree to take part in the above study. ☐
6. I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any publications. ☐
7. I understand that I must not take part if I'm student with corrective glasses or student who have used magnification before. ☐
8. I understand and agree that once I submit my data it will become anonymised (within 24 hours), and I will therefore no longer be able to withdraw my data. ☐
9. I understand that the fully anonymised data will be held securely at the University of Liverpool until it is finally destroyed after 5 years. ☐

Version number: 2

Date: 05/06/2018

Participant name	Date	Signature
Name of person taking consent	Date	Signature
Researcher	Date	Signature
Mustafa Alagha	2-2-2018	Mustafa Alagha

Chief Investigator
Dr Phil Smith
LUDH, L3 5PS,
[07397241708]
pwsmith@liverpool.ac.uk

Student Investigator
Mustafa Alagha
LUDH, L3 5PS, Pembroke, Pl
m.al-agha@liverpool.ac.uk

7.6 Appendix 6: Risk Assessment sheet

VERISON 2
22-4-2018

UNIVERSITY OF LIVERPOOL

RISK ASSESSMENT FORM

School/Department: School of dentistry	**Building:** Liverpool University dental hospital
Task: A study to assess amount of tooth tissue removal using magnification (loupes) on plastic teeth replicas	
Persons who can be adversely affected by the activity: Dentists, Researcher	

Section 1: Is there potential for one or more of the issues below to lead to injury/ill health (tick relevant boxes)

People and animals/Behaviour hazards

Allergies		Too few people		Horseplay		Repetitive action		Farm animals	
Disabilities		Too many people		Violence/aggression		Standing for long periods		Small animals	
Poor training		Non-employees		Stress		Fatigue		Physical size, strength, shape	
Poor supervision		Illness/disease		Pregnancy/expectant mothers		Awkward body postures		Potential for human error	√
Lack of experience		Lack of insurance		Static body postures		Lack of or poor communication		Taking short cuts	
Children		Rushing		Lack of mental ability		Language difficulties		Vulnerable adult group	

What controls measures are in place or need to be introduced to address the issues identified?

Identified hazards	CURRENT CONTROLS	RISK SCORE	ADDITIONAL CONTROLS REQUIRED (To include responsibilities and timescales)	RESIDUAL RISK SCORE
Potential for human error when preparing plastic teeth	Participants are recently qualified dentists familiar with the equipment, surroundings and procedures	2	None identified	2

VERISON 2
22-4-2018

What controls measures are in place or need to be introduced to address the issues identified?

Identified hazards	CURRENT CONTROLS	RISK SCORE	ADDITIONAL CONTROLS REQUIRED (To include responsibilities and timescales)	RESIDUAL RISK SCORE
Sharps injury from dental burs	Participants will be using familiar instruments for preparing plastic teeth in a familiar environment wearing usual PPE	2		

Section 2: Common Workplace hazards. Is there potential for one or more of the issues below to lead to injury/ill health (tick relevant boxes)

Fall from height		Poor lighting		Portable tools		Fire hazards		Chemicals		Asbestos	
Falling objects		Poor heating or ventilation		Powered/moving machinery		Vehicles		Biological agents		Explosives	
Slips, trips, falls		Poor space design		Lifting equipment		Radiation sources		Waste materials		Genetic modification work	
Manual handling		Poor welfare facilities		Pressure vessels		Lasers		Nanotechnology		Magnetic devices	
Display screen equipment		Electrical equipment		Noise or vibration		Confined spaces		Gases		Extraction systems	
Temperature extremes		Sharps	√	Drones		Cryogenics		Legionella		Robotics	
Home working		Poor signage		Overseas work		Overnight experiments		Unusual events		Community visits	
Late/lone working		Lack of/poor selection of PPE		Night work		Long hours		Weather extremes		Diving	

VERISON 2
22-4-2018

Section 3: Additional hazards: are there further hazards NOT IDENTIFIED ABOVE that need to be considered and what controls are in place or needed? (list below)

Additional hazards	CURRENT CONTROLS	RISK SCORE	ADDITIONAL CONTROLS REQUIRED (To include responsibilities and timescales)	RESIDUAL RISK SCORE
N/A				

What controls measures are in place or need to be introduced to address the issues identified?

Identified hazards	CURRENT CONTROLS	RISK SCORE	ADDITIONAL CONTROLS REQUIRED (To include responsibilities and timescales)	RESIDUAL RISK SCORE
Sharps injury from dental burs	**Participants will be using familiar instruments for preparing plastic teeth in a familiar environment wearing usual PPE**	**2**		

Section 4: Emergency arrangements (List any additional controls that are required to deal with the potential emergency situation)

Emergency situation	Additional control required
N/A	

Risk assessor (signature)………………………………………………Date………… Authorised by (signature)……………………………………………Date…………

VERISON 2
22-4-2018

COMPLETING THE RISK ASSESSMENT FORM

- School/Department – note down the School and/or Department where the task is being carried out
- Building – note the specific building(s) where the task is being carried out
- Task – specific clearly the task being carried out
- People would could be adversely affected – think of all the people who could be affected by what you are doing
- Hazards – tick all the relevant hazards in sections 1 and 2. If ticked you will need to log what controls are already in place to protect people from the hazard and what extra controls are required (if any) in the relevant control boxes. As part of the control measures you will need to make a decision of the level of risk based on the tables below. NB – it is likely that other hazards may exist that are not captured in sections 1 and 2. Section 3 should be used to capture any additional hazards and controls not listed in Sections 1 and 2.
- Emergency procedures – list the basic procedures that need to be taken if a critical incident occurs
- Signature – the people completing and approving the assessment must sign the relevant boxes at the end of the document

Likelihood	
1	Very unlikely
2	Unlikely
3	Fairly likely
4	Likely
5	Very likely

Consequence	
1	Insignificant – no injury
2	Minor – minor injuries needing first aid
3	Moderate – up to seven days absence
4	Major – more than seven days absence; major injury
5	Catastrophic – death; multiple serious injury

Consequences					
5	5	10	15	20	25
4	4	8	12	16	20
3	3	6	9	12	15
2	2	4	6	8	10
1	1	2	3	4	5
	1	2	3	4	5
	Likelihood				

- Additional control required - list any additional control required that will reduce the risk rating score. Ensure responsibilities for tasks and timescales are added
- Residual risk score – re-calculate the risk score after the introduction of the additional controls. Compare residual risk score with table below. Take further action if necessary.

ACTION TO BE TAKEN	
1-4 Acceptable	No further action but ensure controls are maintained
5-9 Adequate	Look to improve at next review.
10-16 Tolerable	Look to improve within specified timescale
17-25 Unacceptable	Stop activity and make immediate improvements

7.7 Appendix 7: General Data Protection Regulation

Version:1

05-06-2018

UNIVERSITY OF LIVERPOOL

General Data Protection Regulation (GDPR)

As a University we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

The University of Liverpool takes great care to abide by our legal and moral obligations when handling your personal and healthcare data. Due to changes introduced in the EU General Data Protection Regulation (GDPR), we are writing to provide you with information on the lawful basis on which we are processing your data. The lawful basis for the processing of your personal data for the research study which you have participated in is a task in the public interest.

The data you have provided for the study (Does the use of magnification affect tooth tissue removal during endodontic access procedures performed on plastic teeth replicas?) will be stored for 5 years. You are free to withdraw your consent for your data to be collected, processed, or stored at any time. However, if the data has already been anonymised it will not be possible to withdraw your data.

We will not share your data unless you have provided explicit consent for us to do so.
The data controller for this study Dr Phil Smith, and can be contacted on 07397241708, pwsmith@liverpool.ac.uk and the University Data Protection Officer, Mrs Victoria Heath, can be contacted on 0151 794 2148.

The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113

7.8 Appendix 8: Ethical approval application:

Research Ethics Application Form - 2647

Section 1: Project details

Note to applicant: The following help and support is available to assist you in completing your application:

- **User guides:** Applicant User Guide | Student Applicant User Guide
- Select the (i) icon next to a question for question-specific help
- Select **Help** from the top of the page for a list of contacts and frequently asked questions
- **Training:** It is a mandatory condition that all Principal Investigators and Supervisors have completed the Epigeum research ethics training module before submitting an application for research ethics approval
- **Email support** at the bottom of each section: Ethics System Support for technical issues using the system | Research ethics query for general queries relating to research ethics

Section 1: Project details - Project titles

1.1 Project title (full title)

Does the use of magnification affect tooth tissue removal during endodontic access procedures performed on plastic teeth replicas?

1.2 Project lay title

Does the use of magnification conserve tooth tissue during endodontic access procedures performed on plastic teeth replicas ?

Section 1: Project details - Application type

1.3 Please answer the following question:

- ( ) I am a member of staff
- (•) I am a postgraduate student
- ( ) I am an undergraduate student

Note to applicant: Research ethics applications for postgraduate and undergraduate projects must be shared with your Supervisor. Your Supervisor is responsible for providing guidance on the application and signing off once completed.

Please use the **Share** button on the left side panel to share the form, ensuring that you grant full access to your Supervisor.

1.4 Have you used the 'Share' function button on the left hand side to share the form with your Supervisor?

- (•) Yes
- ( ) No

1.5 Please indicate the type of the research project:

- ○ This is an undergraduate student project
- ● This is a taught postgraduate student project (for example: MA, MRes, MSc, MBA, LLM student projects)
- ○ This is a postgraduate research student project (for example: PhD student projects)
- ○ This is a staff project
- ○ This is a staff application to cover a collection of student projects

Note to applicant: It is a requirement that all university research and teaching staff complete the mandatory training module in research ethics, which can be accessed following these instructions. You will not be able to submit an application for approval unless the Supervisor (Principal Investigator) has completed the training.

Section 1: Project details - Lead Investigator

Note to applicant: Staff on honorary contracts do not automatically fall within the University's Insurance Policy. If your project involves staff on honorary contracts, please contact the University's Risk and Insurance Manager, John Stone, to arrange the appropriate insurance provisions.

1.6 Lead Student Investigator

Use the 'Search User' function above to select a Lead Student Investigator

Title	First Name	Surname
Mr	Mustafa	Al Agha

Email: mustafaa@liverpool.ac.uk

Course/degree full title: DDSc Endodontics

1.7 Supervisor (Principal Investigator)

Use the 'Search User' function above to select a Supervisor

Title	First Name	Surname
Dr	Phil	Smith

Department: School of Dentistry

Telephone: 0151 706 5206

Email: pwsmith@liverpool.ac.uk

Section 1: Project details - School / Institute

1.9 Please select the Principal Investigator's / Supervisor's School or Institute: (for Veterinary research projects select Institute of Veterinary Science)

Institute of Clinical Sciences

Section 1: Project details - Co-Investigators

1.10 Are there any University of Liverpool Co-Investigators involved in the study?

- (selected) Yes
- No

1.11

Use the "Search User" function above to select a University of Liverpool Co-Investigator

Title	First Name	Surname
Dr	Fadi	Jarad

Department: School of Dentistry

Telephone: 0151 706 5219

Email: fjarad@liverpool.ac.uk

Section 1: Project details - Student Investigators

1.14 Are there any other Student Investigators involved in the study?

- Yes
- (selected) No

Section 1: Project details - Other staff

1.16 Are there any other staff not named above who will be involved in the study?

- Yes
- (selected) No

Section 1: Project details - Project dates

1.18 Proposed start date:

25/06/2018

1.19 Proposed end date:

01/09/2019

Section 1: Project details - Project funding

1.20 Has the study received external funding or a Knowledge Exchange voucher?

- ( ) Yes
- (x) No

Section 1: Project details - Determining whether research ethics approval is required

1.22 Please select whether your research involves:

- [x] Human participants (including owners of animals)
- [ ] Human tissue (including all samples of human material, e.g. bodily fluids)
- [ ] Personal data

Note to applicant: If you are unsure whether the data you will be processing is classified as 'personal data', please use the Information Commissioner's Office guidance on "What is personal data"

- [ ] None of the above

Thank you for completing Section 1: Project information

Please use the **Next** button on the left side panel to progress to the next section of the form.

Email support:

Ethics system support | Research ethics query

Section 2: Review routes - NHS Research Ethics Committee review

Note to applicant: For certain types of research projects, it is a statutory requirement that approval is obtained from a NHS Research Ethics Committee (for example, studies involving: NHS patients; adults who lack the capacity to consent; health research on prisoners; social care projects funded by the Department of Health etc.)

Please use the HRA decision tool to determine whether your study requires approval from a NHS Research Ethics Committee.

Section 2: Review routes - Animal Welfare and Ethical Review Body

Note to applicant: Studies involving animal experiments in the UK are regulated by the Home Office, and require approval from an Animal Welfare and Ethical Review Body.

Section 2: Review routes - other research ethics committees

Note to applicant: If your research involves any of the following categories, it will be outside of the remit of a University ethics committee and will require review by another committee.

2.1 Does your study involve any of the following?

- [ ] Research undertaken by students studying on one of the University's online degree programmes run in partnership with Laureate
- [ ] Research that is led by Liverpool School of Tropical Medicine staff or students
- [ ] Research activities which require review by a NHS Research Ethics Committee

Note to applicant: Please use the HRA Decision Tool if you are unsure whether your research requires review by a NHS Research Ethics Committee.

- [ ] Procedures that are carried out on any living vertebrate, other than man, and any living cephalopod which are NOT considered recognised veterinary clinical practice, recognised agricultural practice or animal husbandry practice or covered precisely by an Animal Test Certificate under Veterinary Medicines Regulations
- [x] None of the above

Section 2: Review routes - Previous ethical review

Note to applicant: If your research has already received approval from another research ethics committee, a University of Liverpool research ethics committee will assess the review provided by the other research ethics committee.
If a University of Liverpool committee rejects the review provided by the other research ethics committee, you will be asked to make an application in full to a University of Liverpool research ethics committee.

2.2 Has the study already received ethical approval from another research ethics committee?

- ( ) Yes
- (•) No
- ( ) Yes - however, a review by a University of Liverpool research ethics committee is also required

Section 2: Review routes - Research conducted outside the UK

2.14 Are you undertaking research in a site outside the United Kingdom? (this does not include internet studies based in the UK)

Note to applicant: The University's policy on Research Conducted Outside the UK requires that - wherever possible - approval is be obtained from a local research ethics committee before an application is made to a University of Liverpool research ethics committee.

- ☐ Yes - there is no relevant local research ethics committee in the region
- ☐ Yes - there is a relevant local ethics committee, however no approval has been obtained
- ☐ I have obtained permission from the Chair to apply for University ethical approval prior to obtaining local approval
- ☒ No

Thank you for completing Section 2: Other research ethics committees

Please use the **Next** button on the left side panel to progress to the next section of the form.

Email support

Ethics system support | Research ethics query

Section 3: Description of the research - Procedures

3.1 Does the application request approval for any of the following:

Note to applicant: Guidance on each of the following application procedures is available on the research ethics webpages.

- ○ The Interchange programme as a whole (School of Sociology, Sociology, and Criminology)
- ○ An individual project undertaken as part of the Interchange programme (School of Sociology, Sociology, and Criminology)
- ○ A collection of projects - undergraduate or taught postgraduate - which fall within a taught module
- ○ A research programme which involves a series of studies using the same methodology
- ◉ None of the above

Section 3: Description of the research - Methods

3.5 Please select which of the following methods/procedures will be used in the study:

- [ ] Archival research (primary source data held in public or private archives)
- [ ] Autoethnography
- [ ] Human stem cell research using totipotent or pluripotent stem cells (where research ethics approval is not required by a National Health Service research ethics committee)
- [ ] Human tissue (including all samples of human material, e.g. bodily fluids)
- [ ] Interviews (including focus groups)
- [ ] Invasive experiments on human participants (including magnetic resonance imaging studies)
- [ ] Observations
- [x] Non-invasive experiments on human participants
- [ ] Questionnaires (including surveys)
- [ ] Secondary analysis of data (including audits)
- [ ] Other

Relating only to veterinary research projects

- [ ] Clinical observations and non-invasive procedures on animals
- [ ] Procedures that are carried out as part of recognised veterinary practice, recognised agricultural practice or animal husbandry practice or covered precisely by an Animal Test Certificate under Veterinary Medicines Regulations
- [ ] Secondary analysis of veterinary clinical, agricultural, or animal husbandry records
- [ ] Use of tissues previously collected from animals

Section 3: Description of the research - Aims

Note to applicant The research aims must be described using language that can be understood by a **lay reader**. Please note that <u>your application will be returned</u> if the description of the research aims and design is not written in language that can be understood by a non-expert reader.

3.6 Please describe the research aims:

To help Committee members understand the proposal, please write a minimum of 200 words

Increasing numbers of patients are having root canal treatment (endodontics) as an alternative to tooth extraction. Root canal treatment involves cleaning and shaping inside the roots of teeth (root canal system). An essential part of root canal treatment is gaining access to the root canal system which requires making a cavity in the tooth through which the root canals can be reached. This cavity is an access cavity and the configuration of this has an impact not only on the ability to reach the root canal but can also lead to weakening of the tooth. The latter is an unwanted consequence of endodontic treatment and the need for conservation of tooth tissue whilst drilling access cavities has become recognised. The aim of this investigation is to evaluate whether the use of magnifying loupes by recently graduated dentists influences the extent and quality of endodontic access cavities prepared in plastic tooth replicas.

Section 3: Description of the research - Design

Note to applicant The research design must be described using language that can be understood by a **lay reader**. Please note that <u>your application will be returned</u> if the description of the research aims and design is not written in language that can be understood by a non-expert reader.

3.7 Please describe the research design:

To help Committee members understand the proposal, please write a minimum of 200 words

The initial proposal involves a sample size of twenty newly graduated dentists who have not previously used magnification (loupes), they will be recruited from Liverpool University Dental Hospital (LUDH) and will be divided into two groups. The first group of 10 dentists will utilize loupes at x3.5 magnification, to prepare endodontic access cavities in plastic teeth replicas (DRSK Co) (Maxillary centrals catalogue number 2111-101 RWH, maxillary first premolars , catalogue number 2422-101-RWH, mandibular first molar, catalogue number, 3623-101-RWH), positioned in a simulated patient (2 mandibular 1st molar, 2 maxillary 1st premolars, and 2 maxillary central incisor) on the right side of the phantom head. While the second group of 10 dentists will also prepare endodontic access in plastic teeth replicas (2 mandibular 1st molar, 2 maxillary 1st premolars, and 2 maxillary central incisor) without the use of magnification (loupes)

The two groups will then cross over. The first group of 10 dentists will then endodontically access 6 plastic teeth replicas (2 mandibular molars, 2 maxillary 1st premolars, and 2 maxillary central incisors) without the use of magnification (loupes) on the right side of the phantom head, while the second group will endodontically access 6 plastic teeth replicas (2 Molars, 2 Premolars, and 2 Incisors) with magnification (loupes) on the right side of the phantom head. Dentists will be invited by University email to volunteer in this study.

Section 3: Description of the research - Protocol/Study Plan

3.8 Would you like to submit a protocol or study plan?

- [x] Yes
- [ ] No

3.9 Please upload a study proposal / protocol:

Type	Document Name	File Name	Version Date	Version	Size
Study Proposal/Protocol	Protocol N	Protocol N.docx	25/04/2018	2	52.9 KB

To add multiple documents, use the **Upload Document** button after adding the previous document

Thank you for completing section 3: Description of the research

Please use the **Next** button on the left side panel to progress to the next section of the form.

Email support

Ethics system support | Research ethics query

Section 9: Non-invasive experiments

9.7 Please provide details of the participant group:

20 newly graduated dentists from Liverpool University Dental Hospital

9: Non-invasive experiments - Recruitment and consent

9.8 Please state the total number of research participants to be recruited

20

9.9 Please describe how the sample size was calculated:

The number of the participants are estimated number based on previous studies.

9.10 Please describe how potential participants will be identified:

Newly graduated dentists from University of Liverpool Dental School with less than 12 months post qualification experience who have never used magnification (loupes) before

9.11 Please list the inclusion criteria for the study:

-Dentists with less than 12-month post qualification experience.
-Dentist able to use supplied magnification (loupes)
-Dentists who have never used magnification before.

9.12 Please list the exclusion criteria for the study:

-Dentists with corrective glasses
-Dentists who have used magnification before.
-Dentists with more than 12-month experience.

9.13 Please provide a justification for your exclusion criteria

- The magnification (loupes) available for use in this study have through clear lens magnification and are not compatible with corrective spectacles and therefore cannot be used in this study
-Dentist who have used magnification before and have experience more than 12 months are expected to have increased skills in access cavity preparation and this is likely to influence the results as a major objectives of the study is to investigate if the use of magnification (loupes) for the first time will affect the extent of tooth tissue removal by novice users of the magnification (loupes)

9.16 Please describe how you will obtain informed consent from participants:

An informed consent form will be attached to an email to potential study participants and we will ask the participants to sign it before volunteering in the study.

9.17 Please describe how long you will allow potential participants to decide whether or not to take part:

In early of April 2018 an email will be sent which will include the informed consent and information sheet and they will have a month to decide if they want to participate or not

9.18 Please upload a copy of the participant information sheet:

Note to applicant: The participant information sheet must follow this template, unless there is a requirement to tailor the form to ensure that the content is more accessible to the research population (for example: child-friendly information sheets).

Type	Document Name	File Name	Version Date	Version	Size
Participant Information Sheet	Version 3 information sheet	Version 3 information sheet.docx	29/05/2018	3	45.3 KB

To add multiple documents, use the **Upload Document** button after adding the previous document

9.19 Please upload a copy of the participant consent form:

Note to applicant: The participant consent form must follow this template, unless there is a requirement to tailor the form to ensure that the content is more accessible to the research population (for example: child-friendly information sheets).

Type	Document Name	File Name	Version Date	Version	Size
Participant Consent Form	Version 2 consent form	Version 2 consent form.docx	05/06/2018	2	54.5 KB
Participant Consent Form	New GDPR	New GDPR.docx	05/06/2018	1	40.1 KB

To add multiple documents, use the **Upload Document** button after adding the previous document

9.24 Will advertisements, email, or other types of invitation be used to recruit participants to the study?

- (x) Yes
- ( ) No

9.25 Please upload a copy of the advertisement:

Type	Document Name	File Name	Version Date	Version	Size
Advertisement	Email	Email.docx	02/02/2018	1	40.4 KB

To add multiple documents, use the **Upload Document** button after adding the previous document

9: Non-invasive experiments - Ethical considerations

9.26 What are the risks to the participants?

Risks and hazards are those likely to be encountered when preparing cavities in teeth. The participants will be wearing usual personal protective equipment comprising: protective plastic aprons, protective eyewear, facemasks and gloves. the study will take place in the Operative Skills Suite (OSS) in the Dental School that participants will have used throughout their dental studies for clinical simulations such as the operative techniques being employed in this study. A yellow sharps bin will also be provided for safe storage and disposal of all categories of sharp waste. Participants will receive a brief verbal presentation on Health and safety protocols for OSS that they need to implement when attending to take part in the study.

9.27 What are the risks to the researchers?

No risk for the researcher apart from normal risk during presence in the operative skills laboratory. The researcher will be wearing usual personal protective equipment: protective apron, facemask, protective eye wear and gloves.

9.28 Will research participants receive any reimbursements for taking part in this research?

- ( ) Yes
- (x) No

9.30 Please describe the arrangements are in place for monitoring and auditing the conduct of the research:

Any adverse events will be recorded in the OSS logbook and study file and reported as University policy. Any incidents related to data protection will be recorded on a study file and discussed with co-investigators and deal with it as per University policy

9.31 Please upload a copy of the relevant risk assessment which covers the research activity:

Type	Document Name	File Name	Version Date	Version	Size
Risk Assessment	Risk assessment form V,2	Risk assessment form V,2.docx	22/04/2018	2	51.3 KB

To add multiple documents, use the **Upload Document** button after adding the previous document

Please confirm:

- [x] I have read and understood the University's policy on reporting adverse events

Thank you for completing Section 9: Non-invasive experiments.

Please use the **Next** button on the left side panel to progress to the next section of the form.

Email support

Ethics system support | Research ethics query

Section 23: Data Management

Note to applicant: Advice, tools, and support are provided to help researchers manage data collected during research projects can be found on the University's Research Data Management website.

Please select the types of data that will be used in the project, and answer associated questions. Click **Add Another** to add additional data types:

23.1 Data Types

Other

Please describe how the data will be collected:

The plastic teeth will be collected and stored in plastic container and will be assessed anonymously using different methods including weighing and optical scanning. Following analysis of tooth preparations a Microsoft word document will be written to describe and discuss the results.

Please describe how the data will be stored:

The data produced from the research will be securely stored on the M drive which is password protected on a university computer within a locked room. Any paper data will be securely locked in a cabinet and any identifiable codes will be destroyed. No personal identifiable data will be stored.

Please describe how long the data will be stored for and how this was decided:

Source data will be stored for 5 years from the date of completion of the research. Any anonymised and coded datasets will also be stored for 5 years from the time of the submission of dissertation.

Please describe the plans to ensure the data can be made available for re-use (e.g. open data, safeguarded data, or controlled data):

There is no plans to make the data available for reuse. This will be made clear on the consent form

Please describe the plans for the destruction of the data:

After 5 years the files will be deleted from the M drive and any paper will be disposed in confidential waste

Please explain who will have access to the data:

The data will be accessed only by the researcher (Mustafa Alagha), The primary named supervisor (Dr Phil Smith) and the secondary named supervisor (Professor Fadi Jarad)

23: Data Management - Control

I understand that the Principal Investigator/Supervisor should act as the primary custodian for the data generated by the study

- [x] I agree

23: Data Management - Confidentiality

23.2 Please describe the arrangements in place to ensure the duty of confidentiality towards participants is respected:

The study data will be secured confidentially within the university M drive and no breach of confidentially with no personal details recorded in the study.
Teeth prepared by the dentists will be anonymesied when collected and no feedback will be given.
The cosent from will be stored in a folder in a lockable secured cupboard in the supervisor room

23.3 Are there any factors which may compromise the duty of confidentiality towards participants?

- [ ] Yes
- [x] No

23: Data Management - Anonymity

23.5 Will participant responses be anonymised?

- [x] Yes
- [ ] No

23.6 Please describe the level of anonymisation in place:

Data is fully anonymised, no information on name, teeth prepared, age, date of birth, email addresses or personal home address will be recorded

23: Data Management - Consent

23.9 Please describe the arrangements for informing participants of how the data will be used, processed, shared, and destroyed.

In the information sheet that will be send to the participants there will be an information that will outline how the data will be used for example the data will be destroyed after 5 years from the study, the participants prepared teeth will be anonymised.

23: Data Management - Dissemination

23.10 Please describe how the findings of the research will be disseminated (e.g. peer reviewed journal, conference presentation, dissertation thesis etc.):

Findings will be disseminated at a conference presentation and published in peer review journal

23.11 Please describe any ethical issues that arise from this dissemination

No ethical issue is anticipated from the dissemination

23: Data Management - Feedback

23.12 Will feedback of the findings be given to participants at the participants' request?

- [ ] Yes
- [x] No

Thank you for completing Section 23: Data Management

Please use the **Next** button on the left side panel to progress to the next section of the form.

Email support

Ethics system support | Research ethics query

Section 24: Other Governance Permissions

24.1 Will the research involve Sensitive IT Usage?

Note to applicant: If you are unsure what constitutes 'Sensitive IT usage' please see the help text, or contact the University's Information Security Officer, Mr David Hill, for confirmation.

- [ ] Yes
- [x] No

24: Other Governance Permissions - Health and Safety

24.2 Is the research activity covered by a Health and Safety risk assessment?

- [x] Yes
- [ ] No

24: Other Governance Permissions - Sponsorship

24.3 Does your research:

- [ ] Involve patients and users of the NHS including use of their data, tissue or other bodily material
- [ ] Involve relatives or carers of NHS patients
- [ ] Use NHS premises or resources
- [ ] Involve a Clinical Trial of an Investigational Medicinal Product (CTIMP)

Note to applicant: It is a criminal offence to conduct any CTIMP without a sponsor.

- [x] None of the above

24: Other Governance Permissions - Identifiable personal health information

24.4 Will this project hold fully identifiable personal health information about individuals?

- ( ) Yes
- (x) No

Thank you for completing Section 24: Other governance permissions

Please use the **Next** button on the left side panel to progress to the next section of the form.

Email support

Ethics system support | Research ethics query

Section 25: Declaration and Submission

25.1 Are there any additional ethical issues you would like to discuss that are not mentioned elsewhere in the form?

- ( ) Yes
- (x) No

25: Declaration and Submission - Training

Note to applicant: It is a requirement that all university research and teaching staff complete the mandatory training module in research ethics, which can be accessed following these instructions. You will not be able to submit an application for approval unless the Principal Investigator has completed the training.

25.3 Please provide details of your most recent training in research ethics

Dr Phil Smith completed University of Liverpool Ethics training June 3rd 2016
Mustafa Alagha completed Introduction to Good Clinical Practice (Secondary Care)
September 25, 2016

25: Declaration and Submission - Research tools

25.7 Are there any additional research tools or attachments that you would like to upload?

- ( ) Yes
- (x) No

25: Declaration and Submission - Feedback

25.9 Would you like to leave feedback on the online system?

- ( ) Yes
- (x) No

25: Declaration and Submission - Declarations

25.11 Are there any declarations of interest to disclose?

Note to applicant: All University staff and students are required to recognise and disclose activities that might give rise to conflicts of interest or the perception of conflicts and to ensure that such conflicts are seen to be properly managed or avoided.

Further information can be found in the University of Liverpool Statement of Policy and Procedure on Disclosure of Interest.

- ( ) Yes
- (x) No

25: Declaration and Submission - Sign Off

Note to applicant: You must agree to the following:

The information in this form is accurate to the best of my knowledge and belief. I understand that the information and conditions contained in this application apply to all co-applicants and other investigators - and that it is my responsibility to ensure they abide by them. I undertake to adhere to the terms of the application and any conditions set by the Committee.

- [x] I agree

I understand that I am responsible for notifying the Committee of any changes to the terms of the ethical approval through the amendment procedure. I understand that I am responsible for monitoring the research at all times. I understand that I am responsible for immediately stopping the research and alerting the Committee of any serious adverse events within 24 hours of the occurrence.

- [x] I agree

I have read and understand the University's Policy on Research Ethics. I have read and understand the Concordat to Support Research Integrity. I undertake to abide by the ethical principles laid down by relevant professional societies.

- [x] I agree

25.1 [illegible]?

- [x] Yes

Note to applicant: To get your application signed off by your supervisor, select **Request Signature** below.

Please note that this will lock the form while your supervisor assesses the content of the application. Once the form is signed off by your supervisor, it will be automatically submitted for review, therefore no further changes can be made.

If sign off has been requested and you need to unlock the form to make further changes, select the **Unlock** button from the left side panel. This will mean you will invalidate the sign off process and you will need to request sign off again, so please do not request sign off until the form is fully complete.

Please select Request Signature to request sign off from your Supervisor

Signed: This form was signed by Dr Phil Smith (pwsmith@liverpool.ac.uk) on 07/06/2018 8:08 AM

This is the end of the application form.

After your signature request has been authorised by your supervisor, you will receive an email to confirm the form has been submitted.

Email support

Ethics system support | Research ethics query

7.9 Appendix 9: Ethical approval letter

UNIVERSITY OF LIVERPOOL

Health and Life Sciences Research Ethics Committee (Human participants, tissues and databases)

8 June 2018

Dear Dr Smith

I am pleased to inform you that your application for research ethics approval has been approved. Application details and conditions of approval can be found below. Appendix A contains a list of documents approved by the Committee.

Application Details

Reference:	2947
Project Title:	Does the use of magnification conserve tooth tissue during endodontic access procedures performed on plastic teeth replicas ?
Principal Investigator/Supervisor:	Dr Phil Smith
Co-Investigator(s):	Mr Mustafa Al Agha, Dr Fadi Jarad
Lead Student Investigator:	-
Department:	School of Dentistry
Approval Date:	08/06/2018
Approval Expiry Date:	Five years from the approval date listed above

The application was **APPROVED** subject to the following conditions:

Conditions of approval

- All serious adverse events must be reported via the Research Integrity and Ethics Team (ethics@liverpool.ac.uk) within 24 hours of their occurrence.
- If you wish to extend the duration of the study beyond the research ethics approval expiry date listed above, a new application should be submitted.
- If you wish to make an amendment to the research, please create and submit an amendment form using the research ethics system.
- If the named Principal Investigator or Supervisor leaves the employment of the University during the course of this approval, the approval will lapse. Therefore it will be necessary to create and submit an amendment form using the research ethics system.
- It is the responsibility of the Principal Investigator/Supervisor to inform all the investigators of the terms of the approval.

Kind regards,

Health and Life Sciences Research Ethics Committee (Human participants, tissues and databases)

ethics@liverpool.ac.uk

0151 795 4358

Appendix - Approved Documents

Page 1 of 2

(Relevant only to amendments involving changes to the study documentation)

The final document set reviewed and approved by the committee is listed below:

Document Type	File Name	Date	Version
Advertisement	Email	02/02/2018	1
Risk Assessment	Risk assessment form V.2	22/04/2018	2
Study Proposal/Protocol	Protocol N	23/04/2018	2
Participant Information Sheet	Version 3 information sheet	29/05/2018	3
Participant Consent Form	Version 2 consent form	05/06/2018	2
Participant Consent Form	New GDPR	05/06/2018	1

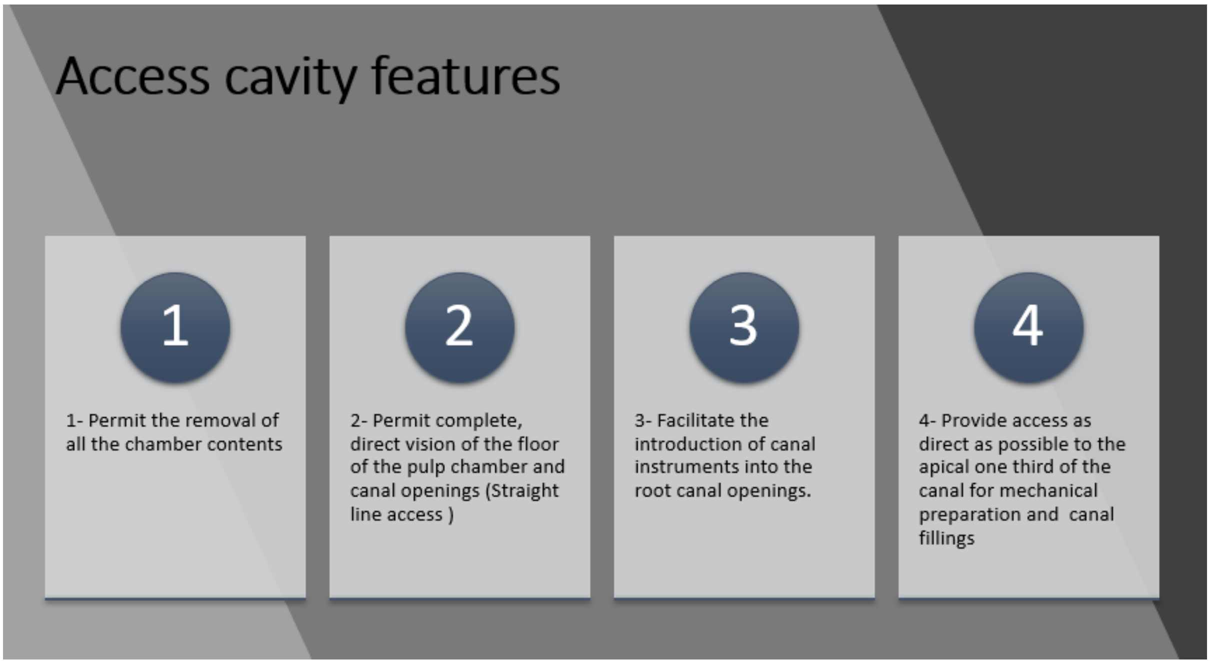
7.10 Appendix 10: Presentation given to students

Endodontic access cavity

Mustafa Alagha

Background

- The main purpose of access cavity preparation is to locate the root canal entrances for cleaning, shaping, and filling of root canals and to prevent procedural errors (Patel and Rhodes 2007, Ingle 1985).
- Endodontic access cavities involve removal of tooth structure to gain access to canal orifices.



Health and safety

You will be required to wear the usual personal protective equipment comprising: plastic apron, protective eyewear, facemask and gloves.

Yellow sharp bins provided for disposal of the sharps

Instructions

Group A:

- Endodontic access cavity for 6 teeth (2 mandibular 1st molar, 2 maxillary 1st premolars, and 2 maxillary central incisor) with loupes

Group B:

- Endodontic access cavity for 6 teeth (2 mandibular 1st molar, 2 maxillary 1st premolars, and 2 maxillary central incisor) without loupes

The groups will then cross over

Instructions

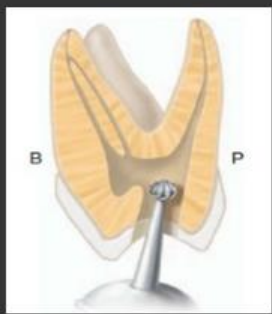
- Flip Up Loupes 3.5 magnification and Working distance 420mm


LED headlight

Technique for access cavity

1- Penetration phase:

This phase is performed using a round diamond bur with high-speed handpiece, The objective of this phase is to “penetrate” the pulp chamber by breaking through the roof with the bur



Technique for access cavity

2- Enlargement phase:

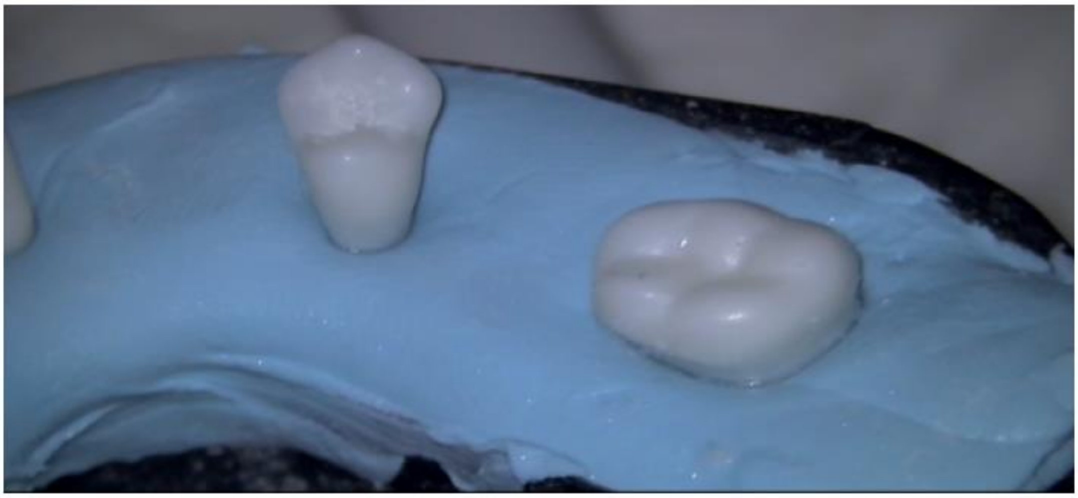
- This phase is performed with a round bur with a low-speed handpiece. Overhanging dentine left behind in the preceding phase are removed. During this phase, the definitive form of the access cavity begins to emerge

Technique for access cavity

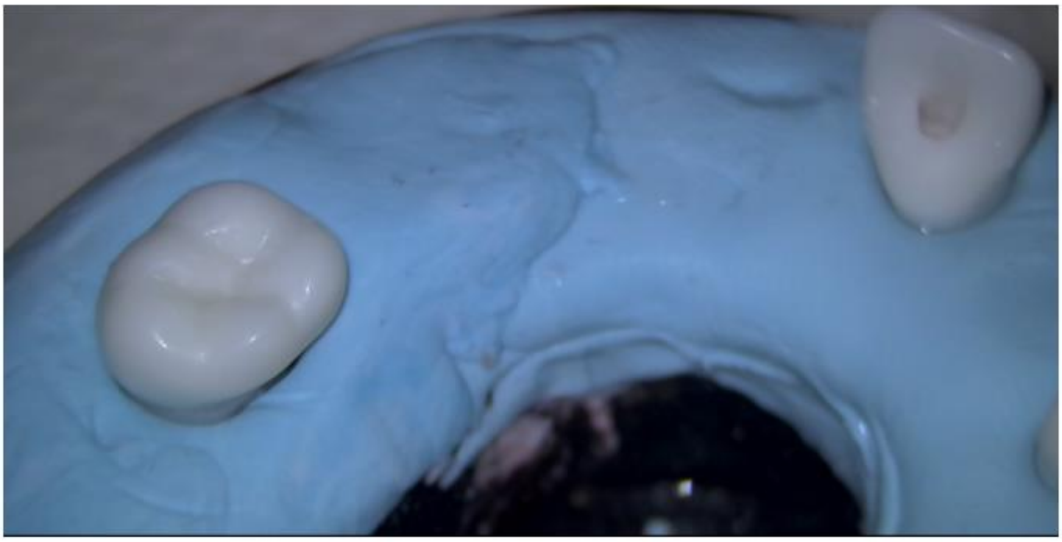
- 3- Finishing and flaring phase:
- This phase requires a non-end-cutting diamond bur. It is used to finish off the work performed during the preceding two phases and to smooth the walls of the access cavity and locate the canals

Central incisor

Upper 1st Premolar Access Cavity



Lower 1st Molar Access Cavity



7.11 Appendix 11: SSPS Output

```
DATASET ACTIVATE DataSet0.
UNIANOVA cbctvol BY loupes order tooth student
  /RANDOM=student
  /METHOD=SSTYPE(3)
  /INTERCEPT=INCLUDE
  /CRITERIA=ALPHA(.05)
  /DESIGN=loupes order tooth student.
```

Univariate Analysis of Variance

Notes

Output Created		11-APR-2019 09:46:16
Comments		
Input	Data	C:\Users\gburnsid\Downloads\nn1 restructured.sav
	Active Dataset	DataSet0
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	120
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics are based on all cases with valid data for all variables in the model.
Syntax		UNIANOVA cbctvol BY loupes order tooth student /RANDOM=student /METHOD=SSTYPE(3) /INTERCEPT=INCLUDE /CRITERIA=ALPHA(.05) /DESIGN=loupes order tooth student.
Resources	Processor Time	00:00:00.02
	Elapsed Time	00:00:00.03

```
[DataSet0] C:\Users\gburnsid\Downloads\nn1 restructured.sav
```

Page 1

Between-Subjects Factors

		Value Label	N
loupes	0	No loupes	60
	1	Loupes	60
order	1		60
	2		60
tooth	1	Incisor	40
	2	Premolar	40
	3	Molar	40
student	1		6
	2		6
	3		6
	4		6
	5		6
	6		6
	7		6
	8		6
	9		6
	10		6
	11		6
	12		6
	13		6
	14		6
	15		6
	16		6
	17		6
	18		6
	19		6
	20		6

Tests of Between-Subjects Effects

Dependent Variable: cbctvol

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	559239.168	1	559239.168	209.672	.000
	Error	50676.882	19	2667.204[a]		
loupes	Hypothesis	1.589	1	1.589	.003	.958
	Error	54291.619	96	565.538[b]		
order	Hypothesis	48.095	1	48.095	.085	.771
	Error	54291.619	96	565.538[b]		
tooth	Hypothesis	152946.807	2	76473.403	135.222	.000
	Error	54291.619	96	565.538[b]		
student	Hypothesis	50676.882	19	2667.204	4.716	.000
	Error	54291.619	96	565.538[b]		

a. MS(student)

b. MS(Error)

Expected Mean Squares[a,b]

Source	Variance Component		
	Var(student)	Var(Error)	Quadratic Term
Intercept	6.000	1.000	Intercept, loupes, order, tooth
loupes	.000	1.000	loupes
order	.000	1.000	order
tooth	.000	1.000	tooth
student	6.000	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

```
UNIANOVA cbctsurf BY loupes order tooth student
  /RANDOM=student
  /METHOD=SSTYPE(3)
  /INTERCEPT=INCLUDE
```

Page 3

```
/CRITERIA=ALPHA(.05)
/DESIGN=loupes order tooth student.
```

Univariate Analysis of Variance

Notes

Output Created		11-APR-2019 09:46:23
Comments		
Input	Data	C:\Users\gburnaid\Downloads\nn1 restructured.sav
	Active Dataset	DataSet0
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	120
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics are based on all cases with valid data for all variables in the model.
Syntax		UNIANOVA cbctaurf BY loupes order tooth student /RANDOM=student /METHOD=SSTYPE(3) /INTERCEPT=INCLUDE /CRITERIA=ALPHA(.05) /DESIGN=loupes order tooth student.
Resources	Processor Time	00:00:00.03
	Elapsed Time	00:00:00.02

Page 4

Between-Subjects Factors

		Value Label	N
loupes	0	No loupes	60
	1	Loupes	60
order	1		60
	2		60
tooth	1	Incisor	40
	2	Premolar	40
	3	Molar	40
student	1		6
	2		6
	3		6
	4		6
	5		6
	6		6
	7		6
	8		6
	9		6
	10		6
	11		6
	12		6
	13		6
	14		6
	15		6
	16		6
	17		6
	18		6
	19		6
	20		6

Tests of Between-Subjects Effects

Dependent Variable: cbctsurf

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	259115.791	1	259115.791	195.823	.000
	Error	25141.081	19	1323.215[a]		
loupes	Hypothesis	246.046	1	246.046	1.216	.273
	Error	19417.054	96	202.261[b]		
order	Hypothesis	182.114	1	182.114	.900	.345
	Error	19417.054	96	202.261[b]		
tooth	Hypothesis	8408.013	2	4204.007	20.785	.000
	Error	19417.054	96	202.261[b]		
student	Hypothesis	25141.081	19	1323.215	6.542	.000
	Error	19417.054	96	202.261[b]		

a. MS(student)

b. MS(Error)

Expected Mean Squares[a,b]

	Variance Component		
Source	Var(student)	Var(Error)	Quadratic Term
Intercept	6.000	1.000	Intercept, loupes, order, tooth
loupes	.000	1.000	loupes
order	.000	1.000	order
tooth	.000	1.000	tooth
student	6.000	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

```
UNIANOVA ab BY loupes order tooth student
  /RANDOM=student
  /METHOD=SSTYPE(3)
  /INTERCEPT=INCLUDE
```

```
/CRITERIA=ALPHA(.05)
/DESIGN=loupes order tooth student.
```

Univariate Analysis of Variance

Notes

Output Created		11-APR-2019 09:46:29
Comments		
Input	Data	C:\Users\gburnaid\Downloads\nn1 restructured.sav
	Active Dataset	DataSet0
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	120
Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics are based on all cases with valid data for all variables in the model.
Syntax		UNIANOVA ab BY loupes order tooth student /RANDOM=student /METHOD=SSTYPE(3) /INTERCEPT=INCLUDE /CRITERIA=ALPHA(.05) /DESIGN=loupes order tooth student.
Resources	Processor Time	00:00:00.03
	Elapsed Time	00:00:00.03

Between-Subjects Factors

		Value Label	N
loupes	0	No loupes	60
	1	Loupes	60
order	1		60
	2		60
tooth	1	Incisor	40
	2	Premolar	40
	3	Molar	40
student	1		6
	2		6
	3		6
	4		6
	5		6
	6		6
	7		6
	8		6
	9		6
	10		6
	11		6
	12		6
	13		6
	14		6
	15		6
	16		6
	17		6
	18		6
	19		6
	20		6

Tests of Between-Subjects Effects

Dependent Variable: ab

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	.698	1	.698	814.430	.000
	Error	.016	19	.001[a]		
loupes	Hypothesis	.001	1	.001	1.866	.175
	Error	.040	96	.000[b]		
order	Hypothesis	.001	1	.001	1.746	.190
	Error	.040	96	.000[b]		
tooth	Hypothesis	.196	2	.098	236.130	.000
	Error	.040	96	.000[b]		
student	Hypothesis	.016	19	.001	2.058	.012
	Error	.040	96	.000[b]		

a. MS(student)

b. MS(Error)

Expected Mean Squares[a,b]

	Variance Component		
Source	Var(student)	Var(Error)	Quadratic Term
Intercept	6.000	1.000	Intercept, loupes, order, tooth
loupes	.000	1.000	loupes
order	.000	1.000	order
tooth	.000	1.000	tooth
student	6.000	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

```
DATASET ACTIVATE DataSet1.
MEANS TABLES=cbct_inc_vol cbct_inc_surf cbct_pre_vol cbct_pre_surf cbct_mol
_vol cbct_mol_surf
    ab_inc ab_pre ab_mol BY loupes
```

```
 /CELLS=MEAN COUNT STDDEV.
```

Means

Notes

Output Created		11-APR-2019 09:49:31
Comments		
Input	Data	C:\Users\gburnsid\Downloads\nn1.sav
	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	loupes
Syntax		MEANS TABLES=cbct_inc_vol cbct_inc_surf cbct_pre_vol cbct_pre_surf cbct_mol_vol cbct_mol_surf ab_inc ab_pre ab_mol BY loupes /CELLS=MEAN COUNT STDDEV.
Resources	Processor Time	00:00:00.02
	Elapsed Time	00:00:00.01

```
[DataSet1] C:\Users\gburnsid\Downloads\nn1.sav
```

Warnings

Split variable loupes has been specified as a grouping variable following BY keyword in the variable list. If Total category is needed for this variable it should be specified as a grouping variable and not a split variable. Otherwise, it must be removed from the variable list.
Execution of this command stops.

```
 SPLIT FILE OFF.
MEANS TABLES=cbct_inc_vol cbct_inc_surf cbct_pre_vol cbct_pre_surf cbct_mol
_vol cbct_mol_surf
    ab_inc ab_pre ab_mol BY loupes
  /CELLS=MEAN COUNT STDDEV.
```

Means

Notes

Output Created		11-APR-2019 09:49:41
Comments		
Input	Data	C: \Users\gburnsid\Download s\nn1.sav
	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	40
Missing Value Handling	Definition of Missing	For each dependent variable in a table, user-defined missing values for the dependent and all grouping variables are treated as missing.
	Cases Used	Cases used for each table have no missing values in any independent variable, and not all dependent variables have missing values.
Syntax		MEANS TABLES=cbct_inc_vol cbct_inc_surf cbct_pre_vol cbct_pre_surf cbct_mol_vol cbct_mol_surf ab_inc ab_pre ab_mol BY loupes /CELLS=MEAN COUNT STDDEV.
Resources	Processor Time	00:00:00.00
	Elapsed Time	00:00:00.02

Case Processing Summary

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
cbct_inc_vol * loupes	40	100.0%	0	0.0%	40	100.0%
cbct_inc_surf * loupes	40	100.0%	0	0.0%	40	100.0%
cbct_pre_vol * loupes	40	100.0%	0	0.0%	40	100.0%
cbct_pre_surf * loupes	40	100.0%	0	0.0%	40	100.0%
cbct_mol_vol * loupes	40	100.0%	0	0.0%	40	100.0%
cbct_mol_surf * loupes	40	100.0%	0	0.0%	40	100.0%
ab_inc * loupes	40	100.0%	0	0.0%	40	100.0%
ab_pre * loupes	40	100.0%	0	0.0%	40	100.0%
ab_mol * loupes	40	100.0%	0	0.0%	40	100.0%

Report

loupes		cbct_inc_vol	cbct_inc_surf	cbct_pre_vol	cbct_pre_surf
No loupes	Mean	21.6580	-42.1365	65.8525	-43.3960
	N	20	20	20	20
	Std. Deviation	16.44190	12.06570	28.51392	19.62911
Loupes	Mean	31.3340	-30.8450	63.3290	-48.4840
	N	20	20	20	20
	Std. Deviation	18.67032	9.80512	19.78736	14.40906
Total	Mean	26.4960	-36.4908	64.5908	-45.9400
	N	40	40	40	40
	Std. Deviation	18.04245	12.26595	24.25863	17.19005

Report

loupes		cbct_mol_vol	cbct_mol_surf	ab_inc	ab_pre	ab_mol
No loupes	Mean	117.6345	-58.1680	.0373	.0549	.1287
	N	20	20	20	20	20
	Std. Deviation	48.91469	25.23008	.01011	.01932	.02494
Loupes	Mean	109.7915	-55.7800	.0419	.0580	.1364
	N	20	20	20	20	20
	Std. Deviation	35.01603	28.50908	.01201	.02367	.03442
Total	Mean	113.7130	-56.9740	.0396	.0564	.1325
	N	40	40	40	40	40
	Std. Deviation	42.17538	26.59969	.01120	.02138	.02992