EVALUATING POSTOPERATIVE PAIN, COST-EFFECTIVENESS, AND PATIENT ACCEPTABILITY OF FULL PULPOTOMY COMPARED TO ROOT CANAL TREATMENT IN TEETH WITH SYMPTOMATIC IRREVERSIBLE PULPITIS: A PRELIMINARY CLINICAL STUDY

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FACULTY OF DENTISTRY
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RESEARCH REPORT SUBMITTED IN FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF ORAL SCIENCE (RESTORATIVE DENTISTRY)

FACULTY OF DENTISTRY
UNIVERSITI MALAYA
KUALA LUMPUR

2024

UNIVERSITI MALAYA

ORIGINAL LITERARY WORK DECLARATION

Name of Candidate: Foo Kent Room

Registration/Matric No: 22062269

Name of Degree: Masters of Oral Science

Title of Research Report ("this Work"): Evaluating Postoperative Pain, Cost-Effectiveness, And Patient Acceptability of Full Pulpotomy compared to Root Canal Treatment in Teeth with Symptomatic Irreversible Pulpitis: A Preliminary Clinical Study

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EVALUATING POSTOPERATIVE PAIN, COST-EFFECTIVENESS, AND PATIENT ACCEPTABILITY OF FULL PULPOTOMY COMPARED TO ROOT CANAL TREATMENT IN TEETH WITH SYMPTOMATIC IRREVERSIBLE PULPITIS: A PRELIMINARY CLINICAL STUDY

ABSTRACT

Introduction: Full pulpotomy is suggested to be an alternative treatment option for root canal treatment (RCT) of permanent mature teeth with irreversible pulpitis. **Aims:** This study aimed to compare postoperative pain, cost-effectiveness and acceptability of the full pulpotomy procedure with conventional RCT in patients attending the dental clinics of the Faculty of Dentistry, Universiti Malaya diagnosed with symptomatic irreversible pulpitis (IRP) in the posterior permanent teeth with mature roots. **Methodology**: Twenty-eight patients were included in this study and equally randomised into two groups, full pulpotomy (n=14) and RCT (n=14). The first group underwent full pulpotomy procedure and filled using Biodentine (Septodont, Saint Maur des Fosses, France), while the second group underwent conventional RCT procedures. Patients were given questionnaires to assess acceptability and cost effectiveness of the treatment on the day after first visit. Preoperative and postoperative pain scores on days 1, 3 and 7 were recorded using the universal pain assessment tool. Two sets of pain score data were collected (after the first visit and after treatment was completed). Data were collected and statistically analysed through the Mann-Whitney U test. **Results:** At day 1, pulpotomy recorded a significantly lower pain score postoperatively after the first visit when compared to RCT (p=0.022). The postoperative pain score on day 3 and day 7 after first visit was not significantly different between these two groups. Regarding the pain score after completing treatment, the difference in postoperative pain score for these two groups was not significant for day 1, day 3 and day 7. Both full pulpotomy and RCT achieved high satisfaction in terms of cost effectiveness, with full pulpotomy recording higher satisfaction in terms of treating dental pain with a significant difference (p=0.022). Patients who underwent both

treatment modalities reported similar, high levels of acceptability in this clinical trial (P>0.05). **Conclusion:** Given the study limitations, full pulpotomy may be a good substitute for RCT for treatment in cases of symptomatic IRP in permanent mature teeth in terms of postoperative pain, cost effectiveness and patient acceptability.

Keywords: full pulpotomy, root canal treatment, postoperative pain, cost effectiveness, acceptability.

ABSTRAK

Pengenalan: Pulpotomi penuh dicadangkan sebagai pilihan rawatan alternatif untuk rawatan saluran akar (RCT) dalam rawatan gigi kekal dengan pulpitis tidak boleh pulih. **Matlamat:** Objektif kajian ini adalah untuk membandingkan kesakitan selepas rawatan, keberkesanan kos dan kebolehterimaan pulpotomi penuh dengan rawatan saluran akar (RCT) dalam gigi belakang kekal dengan akar matang yang didiagnosis dengan pulpitis tidak dapat dipulihkan. **Metodologi:** Dua puluh lapan pesakit telah dimasukkan ke dalam kajian ini dan dibahagikan secara rawak kepada dua kumpulan, pulpotomi penuh (n=14) dan RCT (n=14). Kumpulan pertama menjalani pulpotomi penuh menggunakan Biodentin (Septodont, Saint Maur des Fosses, Perancis), manakala kumpulan kedua menjalani RCT. Pesakit diberi soal selidik untuk menilai kebolehterimaan dan keberkesanan kos rawatan pada hari selepas lawatan pertama. Skor kesakitan direkodkan menggunakan alat penilaian kesakitan umum sebelum dan selepas operasi pada hari ke-1, ke-3 dan ke-7. Dua set data skor kesakitan dikumpulkan (selepas lawatan pertama dan selepas rawatan selesai). Data dikumpul dan dianalisis secara statistik melalui ujian Mann-Whitney U. **Keputusan:** Pada hari ke-1, pulpotomy penuh mencatatkan skor kesakitan selepas operasi yang lebih rendah secara signifikan selepas lawatan pertama berbanding dengan RCT (p=0.022). Skor kesakitan selepas operasi pada hari ke-3 dan ke-7 selepas lawatan pertama tidak berbeza secara signifikan antara kedua-dua kumpulan ini. Berkenaan dengan skor kesakitan selepas rawatan selesai, perbezaan skor kesakitan selepas operasi untuk kedua-dua kumpulan ini tidak signifikan untuk hari ke-1, ke-3 dan ke-7. Kedua-dua pulpotomi penuh dan RCT mencapai tahap kepuasan yang tinggi dari segi keberkesanan kos, dengan pulpotomi penuh mencatatkan kepuasan yang lebih tinggi dalam merawat kesakitan gigi dengan perbezaan yang signifikan (p=0.022). Pesakit yang menjalani kedua-dua kaedah rawatan melaporkan tahap kebolehterimaan yang serupa dan tinggi dalam percubaan klinikal ini (P>0.05). **Kesimpulan:** Memandangkan keterbatasan

kajian, pulpotomi penuh mungkin merupakan pengganti RCT yang baik untuk rawatan dalam kes pulpitis tidak dapat dipulihkan simptomatik dalam gigi matang kekal tanpa periodontitis apikal dari segi kesakitan selepas pembedahan, keberkesanan kos dan penerimaan pesakit.

Kata kunci: pulpotomi penuh, terapi saluran akar, kesakitan selepas rawatan, keberkesanan kos, kebolehterimaan.

ACKNOWLEDGEMENTS

My sincere appreciation and admiration go out to my supervisors, Associate Professor Dr. Hany Mohamed Aly Ahmed, Dr. Nora Sakina Mohd Noor, and Dr. Noor Hayati Azami. I will never be able to repay everyone for their kindness and hard work throughout this research journey.

A special thank you to all my dental surgery assistants who supported me in my clinical procedure and the dental officers at the Primary Care Clinic who assisted me in patient recruitment. I would like to convey my gratitude to my new dental officers, Dr. Lee Yung Fook and Dr. Loh Jing Sheng, as they have helped me a lot during the early stages of patient recruitment and the pilot study of this research.

Without the support of my wife and two small children, I could never complete this work. I apologize for not being able to spend more time with each of you during this time.

My fellow classmates' unwavering support and motivation consistently propel me closer to the finish line, even in the face of numerous setbacks and difficult obstacles. You all deserve everything wonderful in the world.

I will always be grateful to more people that I should have acknowledged but was unable to do so due to space constraints.

From the bottom of my heart, thank you so much.

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LIST OF SYMBOLS AND ABBREVIATIONS

AAE	:	American Association of Endodontists
AAP	:	Acute Apical Periodontitis
CSC	:	Calcium Silicate Cements
DPC	:	Direct Pulp Capping
EPT	:	Electric Pulp Tester
ESE	:	European Society of Endodontology
GIC	:	Glass Ionomer Cement
IPC	:	Indirect Pulp Capping
IRP	:	Irreversible Pulpitis
MTA	:	Mineral Trioxide Aggregate
CEM	:	Calcium Enriched Mixture
RCT	:	Root Canal Treatment
NaOCl	:	Sodium Hypochlorite
TGF	:	Transforming Growth Factor
VPT	:	Vital Pulp Therapy

CHAPTER ONE: INTRODUCTION

1.1 Study background

According to definitions given by American Association of Endodontists (AAE 2020), symptomatic irreversible pulpitis (IRP) is a clinical diagnosis that the vital, inflamed pulp is unable to heal based on both subjective as well as objective findings with symptoms such as sharp pain against thermal stimulus, spontaneous, lingering and radiating pain. Older research supporting the notion that conservative treatment of this inflamed pulp would typically result in pulp necrosis rather than healing led to the introduction of the term "irreversible". Currently, root canal treatment (RCT) is the conventional treatment for most cases with IRP (AAE 2020). Although the success rate for RCT is high and can reach up to 98%, it has certain drawbacks as RCT is technique sensitive due to the complexity of the root canal system and iatrogenic errors which can arise during RCT such as ledges, over-instrumentations and root perforations (Asgary et al., 2022, Ahmed et al. 2023).

According to recent research, the coronal pulp tissue of teeth that have historically been diagnosed with IRP frequently only exhibits partial inflammation, in which the radicular pulp tissue has no inflammation (Ricucci et al., 2014). With the development of minimal invasive endodontic, vital pulp treatment (VPT) techniques such as partial and full pulpotomy have been suggested for the management of IRP (Wolter et al., 2017). Pulpotomy is a minimally invasive dental procedure whereby the coronal part of a vital pulp is removed to keep the underlying radicular pulp vital (AAE, 2020).

Full pulpotomy is considered to be definitive treatment for carious pulp exposures in deciduous teeth, immature permanent teeth, and traumatized pulp exposures (Galani et al., 2017). In the past, pulpotomy is often performed to alleviate severe dental pain caused by pulp inflammation or infection in permanent teeth, which is followed by conventional

RCT. It provides rapid pain relief, offering patients immediate comfort (Hasselgren et al., 1989).

In order to find out whether temporary pain relief could be obtained through pulpotomy of a vital pulp, McDougal et al. (2004) identified 73 patients with IRP to receive pulpotomy with one of the two intermediate restorative materials: Caulk IRM (Dentsply Caulk, Milford, Del.) or an IRM base with glass ionomer core (Fuji IX GP, GC America, Alsip, Ill.). The patients were then monitored for a full year to evaluate radiographic changes, restoration integrity, and pain. They concluded that pulpotomy using either restorative material provided a reliable six-month pain-free interim treatment (McDougal et al., 2004).

With the advancement of biocompatible calcium silicate based-materials, full pulpotomy has been considered as the alternative treatment option for symptomatic IRP other than just interim treatment (Wolter et al., 2017). Literature provides evidence that by stimulating repair at the dentine-pulp complex, the calcium-based cement, with its capacity to offer a biocompatible alternative to dentine, can maintain pulp vitality and facilitate pulp healing (Bachoo et al., 2013).

When compared to conventional RCT, full pulpotomy typically requires less time, making it a convenient option for patients (Zafar et al., 2020). Besides, it is less technique sensitive especially for teeth with complex root canal anatomy such as teeth with curved canals, C-shaped canals and others (Zafar et al., 2020, Ahmed et al., 2023). In terms of treatment cost, one study found that full pulpotomy is more cost effective when compared to RCT (Asgary et al., 2022).

Conventional RCT currently is the main treatment option for patients with IRP attending the dental clinics at the Faculty of Dentistry, Universiti Malaya. Therefore, this clinical study aimed to compare the postoperative pain, cost-effectiveness and patients'

acceptability of the full pulpotomy with conventional RCT in permanent posterior mature teeth with symptomatic IRP.

1.2 Statement of the problem

For the majority of cases of IRP, RCT is currently the recommended treatment option (AAE, 2020). However, the clinical results of RCT are influenced by the complex anatomical variations of the root canals as it may cause incidences such as missed canals and other iatrogenic complications such as root perforation (Ahmed et al., 2023). Studies have documented the incidence of missed canals in teeth treated with RCT of up to 48%, especially on the maxillary molar (Witherspoon et al., 2013). One systematic review showed the incidence of perforations varied from 0.6% to 17.6% and the most frequent causes of perforations were tooth type, tooth morphology and the practitioner's experience (Sarao et al., 2021). Therefore, full pulpotomy has been suggested as one of the treatment options for symptomatic IRP which is minimally invasive and can preserve the tooth vitality when compared to conventional RCT. When choosing a course of treatment, one of the primary concerns for patients with symptomatic IRP is postoperative pain. Research findings have shown a marked difference in terms of pain relief reported in cases comparing full pulpotomy to RCT with the full pulpotomy group reporting lower scores than RCT (Galani et al., 2017). Currently, there are lack of prospective randomised clinical trials to provide the evidence needed to support full pulpotomy and increase patient acceptability in Malaysia.

1.3 Justification of the study

A high success rate for full pulpotomy in patients with symptomatic IRP has been shown in single arm intervention study with follow-up period of up to 1 year (Taha et al., 2018). ESE and the AAE position statements have addressed the need for more randomised clinical trials with longer follow-up to compare the treatment outcome between pulpotomy and RCT before making pulpotomy as the treatment of choice (ESE 2019,

AAE 2021). A few clinical studies have compared the postoperative pain between these two treatment options for IRP and the results demonstrated that the full pulpotomy postoperative pain scores were statistically significantly lower compared to RCT (Galani et al., 2017; Taha et al., 2023). However, more evidence is needed to increase the acceptability of pulpotomy as an alternative treatment option in permanent teeth with IRP compared to RCT in Malaysia. Thus, this randomised clinical trial aims to provide evidence for postoperative pain, cost effectiveness and acceptability of full pulpotomy compared to RCT undertaken on patients attending the dental clinics, Faculty of Dentistry, Universiti Malaya.

1.4 Research objectives

1.4.1 General objective

To compare postoperative pain, cost-effectiveness and acceptability of the full pulpotomy with conventional root canal treatment in permanent posterior teeth with mature roots diagnosed with symptomatic irreversible pulpitis.

1.4.2 Specific objectives

1. To compare the postoperative pain of full pulpotomy with conventional root canal treatment in mature permanent posterior teeth with symptomatic irreversible pulpitis.
2. To examine the cost-effectiveness of patients towards full pulpotomy and conventional root canal treatment in mature permanent posterior teeth with symptomatic irreversible pulpitis.
3. To assess the acceptability of patients to both full pulpotomy and root canal treatment procedures in mature permanent posterior teeth with symptomatic irreversible pulpitis.

1.5 Research questions

1. Is there a significant difference in terms of postoperative pain of full pulpotomy when compared to conventional RCT in mature permanent posterior teeth with symptomatic IRP?
2. Is full pulpotomy cost-effective when compared to conventional RCT in mature permanent posterior teeth with symptomatic IRP?
3. Is there a significant difference in terms of acceptability of patients to both full pulpotomy and RCT procedure in mature permanent teeth with symptomatic IRP?

1.6 Research hypothesis

1. There is no significant difference in the postoperative pain of full pulpotomy compared to conventional RCT in mature permanent posterior teeth with symptomatic IRP.
2. There is no significant difference in terms of cost-effectiveness when comparing full pulpotomy to conventional RCT in mature permanent posterior teeth with symptomatic IRP.
3. There is no significant difference in the acceptability of patients to both full pulpotomy and RCT procedure in mature permanent posterior teeth with symptomatic IRP.

CHAPTER TWO: LITERATURE REVIEW

2.1 Pulp inflammation

Dental pulp creates an inflammatory response to eliminate pathogens and promote healing (Zanini et al., 2017). Inflammation of the pulp can be caused by various factors and can lead to varying degrees of pain and discomfort. Literature operates under the assumption that pulp exposure resulting from caries serves as a dependable indication of irreversible inflammation, primarily due to understanding the pulp's response to the progression of caries lesions. Dentine destruction by caries leads to a heightened and intensified inflammatory reaction as it approaches the pulp (Reeves et al., 1966). Nonetheless, inflammation typically does not progress to an irreversible state until the caries lesion nears exposure or directly exposes the pulp. Upon direct interaction between pulp tissue and bacteria within the caries biofilm, a significant inflammatory response, necrosis, and infection almost always ensue. These pathological processes initiate at specific tissue compartments and gradually advance towards the apex (Langeland, 1987). Diagnosis of pulpitis usually is confirmed by patient history, clinical examination, radiographic findings and clinical testing (pulp sensitivity test). Pulpitis can be categorised into two main types: reversible pulpitis and IRP (AAE 2020) (Table 2.1).

Histologically, Dummer et al. (1980) concluded that it might be impossible to precisely classify the pulp condition of all painful teeth or to distinguish clearly between pulps that can be saved or not because they could not find a clear correlation between signs or symptoms and pulp histologic conditions. Nonetheless, a histological investigation by Ricucci et al. (2014) illustrated a notable correlation between well-defined criteria for histological and clinical classification of pulp status, particularly evident in instances of reversible pulpitis or absence of disease, whereas in terms of IRP cases, a few teeth would still be treated needlessly even though the diagnosis of IRP was matched histologically in a high number of cases. A significant proportion, specifically 84.4%, of instances that

were clinically identified as exhibiting IRP demonstrated the presence of inflammation and infection localized within a restricted area adjacent to the carious exposure. Moreover, in 16% of these instances, the pulp displayed either mild inflammation or maintained a histological appearance consistent with normality (Ricucci et al., 2014). This observation suggests the potential for the pulp to be preserved through conservative interventions that involve the removal of the irritative stimulus and the infected tissue through the procedure of pulpotomy.

2.1.1 Reversible pulpitis

By definition, reversible pulpitis is a clinical diagnosis that suggests that, upon removal of the irritant, the pulp inflammation should subside and the pulp is able to heal (AAE, 2020). Common causes include caries and extensive restoration. Patients may experience discomfort or sensitivity when a stimulus such as cold and sweet is applied but the symptom will disappear shortly after removal of the stimulus (AAE, 2020). The pain experience is usually not spontaneous and does not disturb sleep. In the periapical area of the suspected tooth, there are no significant radiographic changes. The management of reversible pulpitis is to remove the aetiological factor such as caries, followed by restoration (AAE, 2020).

2.1.2 Irreversible pulpitis

On the other hand, IRP is a clinical diagnosis showing the vital inflamed pulp is not capable of healing based on subjective and objective findings (AAE, 2020). The symptoms of IRP may include spontaneous pain, sharp pain against hot and cold stimuli, lingering pain after removal of stimulus, referred pain and pain upon postural changes (AAE, 2020). Sometimes, the pain may disturb the patient's sleep. Deep caries, large restorations, or fractures involving pulp are examples of common causes of IRP. Teeth with IRP usually do not show pain or discomfort to percussion and no significant radiographic changes on the periapical region as the pulpal inflammation has not yet

involved the periapical tissue (AAE, 2020). Abbott and Yu (2007) proposed a classification of the clinical status of the pulp and divided IRP into 2 stages, which are acute IRP and chronic IRP. The patient may experience a sudden onset of acute IRP, which could wake them up at night. The pain is spontaneous and ranges in intensity from moderate to extremely severe. On the other hand, similar symptoms to those of acute IRP will be present in chronic IRP, but they will be far less severe. Patients may report moderate pain that is more intermittent than continuous and that can be managed with standard analgesics.

Table 2.1: Comparison between reversible and irreversible pulpitis (AAE, 2020)

	Reversible Pulpitis	**Symptomatic Irreversible Pulpitis**
Spontaneous pain	Absent	Present
Pain to thermal stimuli	Possible	Present
Pain lingers to thermal stimuli	Absent	Present
Sleep disturbance	Absent	Possible

2.1.3 New trends for pulp classification

For pulp diseases, numerous categorisation schemes have been proposed. However, since there is little correlation between them, the majority are based on histopathological findings rather than clinical findings, which causes confusion. The majority of classifications combine histology and clinical terminology, leading to inaccurate diagnoses and language. As a result, creating a treatment plan in clinical practice becomes even more difficult and unclear (Abbott and Yu, 2007).

With a better understanding of pulp morphology, the question about the healing capability of pulp tissue in mature permanent tooth with IRP has gained prominence. According to histological investigations done by Ricucci et al. (2014), inflammation is often present in a small portion of the pulp at the exposure site in case of IRP, and the pulp around the roots which is not affected by caries would frequently have normal histological

architecture. As a result, a novel classification system for pulp inflammation has just been introduced (Wolters et al. 2017), with the goal of connecting diagnosis to certain minimally invasive treatments. Under this classification, pulp diseases are divided into initial pulpitis, mild pulpitis, moderate pulpitis and severe pulpitis (Table 2.2). The recommended treatment for initial and mild pulpitis is indirect pulp capping (IPC), while moderate and severe pulpitis cases are recommended to be treated with full pulpotomy (Wolter et al., 2017).

Table 2.2: New clinical pulp diagnosis terminology by Wolters et al. (2017)

Suggestion for new clinical pulp diagnosis terminology by Wolters et al.	
Initial pulpitis	Increased but no prolonged response to the cold stimulus, no spontaneous pain and not sensitive to percussion.
Mild pulpitis	Increased and prolonged response to cold, warmth and sweet stimuli up to 20 s before subsides, may be sensitive to percussion. The histological situation that best fits these data would suggest that the crown pulp is the only area with limited local inflammation.
Moderate pulpitis	Clear symptoms, strong, increased and prolonged reaction to cold stimulus, which can last for minutes, may be sensitive to percussion test with spontaneous dull pain that prescription drugs can largely alleviate. The histological situation that best fits these data would suggest that the coronal pulp is the only area with extensive local inflammation.
Severe pulpitis	Severe spontaneous pain and clear pain reaction to thermal (cold and warm) stimuli, often, sharp to dull throbbing pain, disturbed patient sleep due to worsening of pain upon lying down. Tooth is very sensitive to percussion and palpation. The histological situation that best fits these data would suggest that extensive local inflammation in the coronal pulp that possibly extends into the radicular pulp

2.2 RCT

Currently, RCT is the recommended treatment for teeth displaying symptoms and indicators of IRP. It is a multi-step dental procedure which usually requires few dental visits to complete the treatment. The procedure starts with access cavity, identify root canal, chemo-mechanical instrumentation, obturation and placement of definitive filling (Tomson et al., 2014).

2.2.1 Rational of conventional RCT

Dentine and the pulp are related as part of the dentine-pulp complex, and the pulp is a connective tissue that is highly innervated and vascular. Pulp conditions in teeth with IRP are believed to be unlikely to return to normal simply by eliminating the irritants (Abbott and Yu, 2007). Therefore, RCT is indicated to remove the entire pulp tissue including the coronal and radicular pulp tissue followed by filling to save the tooth from being extracted (ESE, 2006).

2.2.2 Outcomes of RCT

The success rate of RCT is generally quite high. With modern techniques and materials, the success rate has significantly improved over the years. In the RCT case with vital pulp, studies showed that the success rate ranges from 82.8 to 98%. (Kojima et al., 2004; Asgary et al., 2022). It is noteworthy that these studies and the success rates that are cited frequently evaluate efficacy rather than effectiveness because they are conducted in specialised centres or universities, whereas an RCT would be conducted in a general practice setting with more demanding circumstances. Efficacy demonstrates whether an intervention can work under ideal conditions while effectiveness assesses how well it works in real-world contexts, providing valuable insights into its practical utility and impact (Singal et al., 2014).

Studies using epidemiological and cross-sectional methods have shown a lower treatment success rate ranging from 34 to 76%, which may be the result of incomplete or poor quality RCT (Asgary et al., 2022). Besides, dentine tissue loss occurs frequently in teeth undergoing RCT and this leads to the weakening of mechanical integrity of RCT treated tooth (Kishen 2006). The literature lists numerous potential complications that can arise during RCT, including root perforations during access cavity preparation and tooth discolouration, instrumentation, loss of working length, canal transportation, separated

root canal files, missed root canals, issues during root canal filling, and post endodontic restorations (Sarao et al., 2021; Witherspoon et al., 2013: Ahmed et al., 2023).

2.2.3 Factors affecting success and failure of RCT

Several studies investigated the success rates of RCT across different populations, methodologies, and follow-up periods. While success rates vary, a systematic review by Ng et al. (2007) reported an overall success rate of RCT from between 1996 and 2002 varied from 60% to 100% depending on loose criteria or from 31% to 96% according to strict criteria. The radiographic success criteria used in the study above have been categoried as "strict" (complete resolution of the peri-apical lesion at recall) or "loose" (reduction in the peri-apical lesion's size at recall). Another systematic review done by the same authors showed that the results of RCT were found to be significantly improved by factors such as: absence of periapical radiolucency prior to RCT; satisfactory coronal restoration and good obturation quality without voids, extending to 2 mm within the radiographic apex (Ng et al., 2008). Majority of the factors above require a good understanding of pulp morphology and the results of RCT are affected by the complex anatomy of the root canals. Due to changes in endodontic materials and treatment techniques, Burns et al. (2022) have done a meta-analyses to summarise the success rate of RCT between 2003 and 2020 using the same categories used by Ng et al. (2007). The result showed that the weighted pooled success rates were estimated to be 92.6% under "loose criteria" and 82.0% under "strict" criteria. Improvements are evident over time in the reported success rates of RCT with the advancement of endodontic techniques, instruments and materials.

Research has also shown that premolar and anterior teeth have greater success rates with RCT than molar teeth (Laukkanen et al., 2019). However, the presence of a variety of dental anomalies in the roots and canals contribute additional difficulties for the operator during RCT.

2.3 Vital pulp therapy (VPT)

VPT are procedures to preserve the vitality of the dental pulp following injury caused by trauma, cavities, or restorative procedures (AAE, 2021). For many years, the goal of VPT was to enable root formation (apexogenesis) in immature adult teeth by preserving the radicular pulp. The scope of VPT has expanded in the modern era; in addition to pulpectomy and RCT for mature teeth, practitioners may now consider treating teeth that were previously believed to have irreversibly inflamed pulps by VPT. Along the years, partial or complete pulpotomy and indirect or direct pulp capping (DPC) have been included in VPT procedures (AAE 2021).

2.3.1 Direct pulp capping (DPC) and indirect pulp capping (IPC)

IPC is defined as application of a biomaterial onto a thin dentine barrier in a one-stage carious-tissue removal procedure, usually to hard dentine (ESE, 2019). Over a 12-month period, study showed that the clinical success rates for IPC with Glass Ionomer Cement (GIC) and Biodentine were up to 83.3% (Hashem et al., 2015).

On the other hand, DPC is the process of applying a biomaterial directly to the exposed pulp after maintaining an aseptic working field and before the permanent restoration is put in place immediately (ESE 2019). Compared to IPC, DPC is performed when the pulp is directly exposed, while IPC is done when there is a risk of pulp exposure, but it has not occurred yet. Both procedures aim to preserve pulp vitality and avoid the need for RCT by promoting dentine repair and sealing off the pulp from bacterial invasion. Study done by Dammaschke et al. (2010) showed that the survival rate of DPC done using calcium hydroxide were 76.3% after 13.3 years. The success rate of DPC treatment was significantly correlated with the patient's age, the type of pulp capping material used, and the size of the pulp exposure site (Cho et al., 2013).

2.3.2 Partial pulpotomy

The procedure of partial pulpotomy entails the removal of a portion of the coronal pulp tissue after exposure followed by the direct application of a biomaterial onto the remaining pulp tissue before the final restoration (ESE, 2019). In cases where carious exposures necessitate the physical removal of biofilm and superficially inflamed pulp tissue, which may harbour microorganisms, a degree of pulp tissue elimination may be advantageous. Studies have shown that during a two-year timeframe, partial pulpotomy procedure using Mineral Trioxide Aggregate (MTA) resulted in positive treatment outcomes in the dentition of young patients diagnosed with reversible pulpitis, but produced unfavourable results in cases where the pulp exposure areas were larger than 5 mm (Chailertvanitkul et al., 2014).

2.3.3 Full pulpotomy

In a full pulpotomy, the coronal pulp is entirely removed at the level of root canal orifice, and before a permanent restoration is positioned, a biomaterial is applied directly onto the pulp tissue at the root canal orifice (ESE, 2019). VPT currently is the recommended treatment for immature teeth with pulp inflammation (AAPD, 2023). Preserving radicular pulp tissues, which may aid in the completion of apexogenesis in immature permanent teeth, is the main goal of pulpotomy for immature tooth (Sadaf, 2020). Full pulpotomy is recommended for immature permanent teeth with cariously exposed pulps (AAPD, 2023).

In terms of mature permanent teeth, after the notion of minimally invasive endodontics was proposed and further mentioned in positional statement of AAE 2021 and ESE 2019, researchers have suggested that full pulpotomy is a viable alternative to RCT in treating symptomatic IRP in permanent mature but more long term follow up studies are needed before making full pulpotomy as treatment of choice (Asgary et al., 2022; Duncan et al., 2023).

2.3.4 Rational of full pulpotomy in permanent mature tooth

Previously, it was believed that there was little connection between the histological condition of the pulp in permanent teeth and the clinical signs and symptoms (Selzer et al., 1963). Nevertheless, this was recently questioned, and a histological study revealed a strong correlation between the clinical manifestations of pulpitis and the histopathological condition of an affected dental pulp. The radicular pulp remained viable in cases of IRP, but the coronal pulp was primarily exhibiting morphological changes indicative of inflammation or necrosis (Ricucci et al., 2014). This implies that radicular pulp may be preserved during a pulpotomy procedure, thereby avoiding the requirement for RCT. This minimal invasive endodontic approach can preserve the tooth structure and vitality (Wolter et al., 2017).

2.3.5 Protocol for full pulpotomy procedure for mature permanent molar tooth

Regarding the protocol for VPT, the recent AAE (2021) Position Statement on VPT have some recommendations regarding pulp management, placement of biomaterials and restoration as follows:

1. Sodium hypochlorite (NaOCl) as irrigation solutions.
2. Contemporary materials such as calcium silicate cements (CSC).
3. Immediate placement of permanent restorative materials.

Controlling pulp bleeding and cleaning the coronal pulp are key factors in the success of VPT. Compared to other irrigation solutions, NaOCl is more suitable for pulpotomy procedure due to its antimicrobial properties which can disinfect the dentine pulp interface, removing the biofilm, blood clot and fibrin. Besides, NaOCl is good hemostatic agent in pulpotomy procedure without compromising the pulp integrity (Hafez et al, 2002). When compared to other pulpotomy agent such as formocresol, histopathological study has shown that the incidence of severe inflammation and pulp necrosis post pulpotomy are lower in NaOCl group when compared to formocresol.

(Haghgoo et al., 2012). In terms of success rates, the literature reports that pulpotomy using NaOCl are comparable to those with formocresol and ferric sulfate (Vostatek et al., 2011).

The use of CSC such as MTA and Biodentine in VPT procedures has gained more popularity (Parirokh et al., 2018). Direct application of Biodentine to the pulp resulted in the induction of an early stage of reparative dentine synthesis (Laurent et al., 2011). Immediate permanent restoration after VPT can prevent microleakage and reduce postoperative sensitivity of the patient (AAE, 2021).

2.3.5 Factors affecting outcome of pulpotomy procedure

The success rate of full pulpotomy in permanent teeth is influenced by several factors, including the choice of materials and patient-specific factors. These elements collectively determine the prognosis and long-term outcomes of the procedure. Nonetheless, there currently exists a lack of consensus regarding the diagnostic and prognostic indicators that ascertain the effectiveness of pulpotomy in managing IRP case (McHugh et al., 2023). Research indicated that the efficacy of pulpotomy treatment outcomes was significantly associated with the age of the patient as the dental pulp in younger individuals exhibits a higher cellular density and demonstrates an enhanced capacity for healing and regeneration subsequent to the excision of the inflamed pulp tissue (Anta et al., 2022). The efficacy of VPT has markedly escalated with the incorporation of biocompatible substances, including CSCs. Studies have shown that VPT have high success rate when using MTA and other CSCs such as Biodentine due to their good sealing properties and biocompatibility (AAE, 2021). Calcium hydroxide is no longer advocated as a pulp capping agent owing to the emergence of tunnel defects within the hard tissue barrier. Such defects present a conceivable avenue for microleakage, and the resultant deeper coagulative necrosis and inflammation observed culminate in suboptimal clinical outcomes (McHugh et al., 2023). A shortened time interval following the

placement of a definitive restoration after VPT serves as a crucial predictor for positive clinical outcomes (AAE, 2021).

2.3.6 Outcomes of full pulpotomy procedures

In a systematic review, Aguilar et al., (2011) compared the success rate of outcome of different VPT techniques, which is DPC, full pulpotomy, and partial pulpotomy. The results showed that partial and full pulpotomy have higher success rate up to 99.40% compared to DPC for a review period of more than three years. The authors assumed that the higher success rate of pulpotomy was due to more complete removal of the inflamed pulp tissue.

With proper case selection and treatment protocol, research showed that even in teeth with indications and symptoms of IRP, full pulpotomy success rates after one year vary was very high in terms of clinical and radiography findings (Taha et al., 2018). Another systematic review done by Cushley et al., (2019) showed that full pulpotomy have 93.97% and 88.39% success rate in clinical and radiographic finding respectively for 36 months follow-ups. A more recent randomised controlled trial showed that the two years success rate for two group of full pulpotomy using two different types of calcium disilicate cement exhibited equivalent result when compared to RCT (Asgary et al., 2022). In terms of histologically, research have showed that there was formation of dentinal bridge with no inflammation of the pulp two month after the full pulpotomy done (Eghbal et al., 2009).

2.4 Postoperative pain

Postoperative pain is one of the main concerns for patients with IRP when deciding the treatment plan. For the current conventional treatment, which is RCT, a systematic review showed that root canal-related pain was highly prevalent prior to treatment, but it

decreased gradually after one day and significantly to almost non-existent levels after seven days (Pak et al., 2011).

A number of studies compared the postoperative pain in pulpotomy with RCT postoperative pain, but the findings are not consistent. Over the course of the 7-day study period, a randomised clinical trial has showed that there are no differences in the reduction of pain intensity were observed between the partial pulpectomy group, the total pulpectomy group, or the pulpotomy group; however, the total pulpectomy group demonstrated a higher level of pain relief in comparison to the pulpotomy group (Eren et al., 2018). A comparison of the effects of the various emergency treatment procedures performed on the molar teeth revealed that the most common procedure for postoperative pain was partial pulpectomy (13%), followed by pulpotomy (8%) and complete pulpectomy (6%) (Oguntebi et al., 1992). Although these two studies showed pulpectomy is better in terms of controlling postoperative pain, there are limitations for the result as both of the studies did not use calcium silicate cement for the pulpotomy procedure which is recommended in AAE positional statement in 2019.

Galani et al. (2017) have done a clinical trial to compare the postoperative pain between full pulpotomy and conventional RCT. MTA was placed during the pulpotomy procedure and the results showed that full pulpotomy group experienced more symptomatic relief, as evidenced by the mean postoperative pain scores for that group being statistically significantly lower. Another clinical trial showed that full pulpotomy using endodontic CEM had the better pain-relieving effects than conventional RCT in IRP cases (Asgary et al., 2010). Both studies showed that pulpotomy group performed better than RCT in terms of postoperative pain when calcium silicates are used during the pulpotomy procedure.

Table 2.3: Summary of multiple postoperative pain result of pulpotomy and RCT from different studies

Authors	Year	Sample size	Tooth involved	Pulpotomy agent used	Outcome
Oguntebi et al.	1992	956	Permanent mature molars with IRP	Zinc Oxide Eugenol	The percentage of individuals who experienced postoperative pain following partial pulpectomy displayed the highest figure, followed by pulpotomy, and complete pulpectomy.
Asgary et al.	2010	407	Vital permanent molar tooth with symptomatic IRP	CEM	Compared to patients in the pulpotomy group, those in the RCT group reported significantly more pain.
Galani et al.	2017	54	permanent mandibular first and second molars with pulp exposure due to caries	MTA	There was a significant difference ($P<0.05$) in the incidence and reduction of pain between the RCT and full pulpotomy groups. The full pulpotomy group reported lower scores.
Eren et al.	2018	66	Permanent mature molars with symptomatic IRP with or without acute apical periodontitis	Zinc Oxide Eugenol	In comparison to the pulpotomy group, the total pulpectomy group experienced greater pain intensity reductions.
Eghbal et al.	2020	550	Vital molar teeth with history of IRP	MTA, CEM	There were no remarkable variances noted among the three study groups with respect to postoperative pain. (RCT, Pulpotomy with MTA, Pulpotomy with CEM).
Taha et al.	2023	60	Permanent molar teeth with IRP	Biodentine	On the first day following pulpotomy, the levels of pain exhibited a significant decrease in comparison to those experienced after RCT.

2.5 Cost effectiveness and acceptability

There is a need to compare the cost effectiveness and acceptability of full pulpotomy and RCT as treatment option for IRP in permanent posterior tooth. In terms of treatment cost, full pulpotomy is considered more cost effective by a few authors when compared to RCT (Asgary et al, 2022; Duncan et al., 2023; Taha et al., 2023). Furthermore, full pulpotomy typically requires less time than more extensive endodontic treatments, making it a convenient option for patients. In terms of indirect cost, pulpotomy would be less expensive because it required less equipment, travel expenses, specialized facilities, and radiography (Yazdani et al., 2014). In terms of acceptability, according to a recent study done by Taha et al. to compare patients' satisfaction after RCT and pulpotomy, the results showed that both pulpotomy and RCT patients expressed a high level of overall satisfaction with their treatment. But in terms of the amount of time required, the pain during the procedure, the pleasantness, and the cost, there was a marked higher satisfaction in pulpotomy group (Taha et al., 2023).

CHAPTER THREE: METHODOLOGY

3.1 Study design

The present randomised clinical trial has received approval from the Medical Ethics Committee, Faculty of Dentistry, Universiti Malaya [DF RD2309/0068 (L)]. It is registered with clinicaltrials.gov (https://clinicaltrials.gov with ID NCT06002698).

3.1.1 Protocol design

Prospective randomised control clinical trials of parallel groups.

3.1.2 Eligibility criteria

The included clinical trials adopted the following criteria:

- *Inclusion criteria*:
    1. Patients with a minimum age of 12 years old.
    2. Mature posterior permanent tooth with restorations or deep caries that are causing symptomatic IRP.
    3. Spontaneous lingering pain (moderate to severe).
    4. Tooth is responsive to sensibility testing which is cold test and Electric Pulp Tester (EPT) on multiple sites.
    5. The tooth can be isolated adequately during treatment and restorable.
- *Exclusion criteria:*
    1. Teeth with active periodontal disease (pocket depth >5mm).
    2. Teeth with apical periodontitis and present of periapical radiolucency.
    3. Teeth indicated for elective RCT for restorative purposes.
    4. Complex medical history that may affect the healing ability.
    5. Teeth with trauma history or present of clinically significant crack line.

6. Any evidence of purulence or uncontrolled bleeding from the coronal chamber that cannot be controlled with a cotton pellet with 2.625% NaOCl for 10 minutes.
7. Patients who are pregnant or breast-feeding.

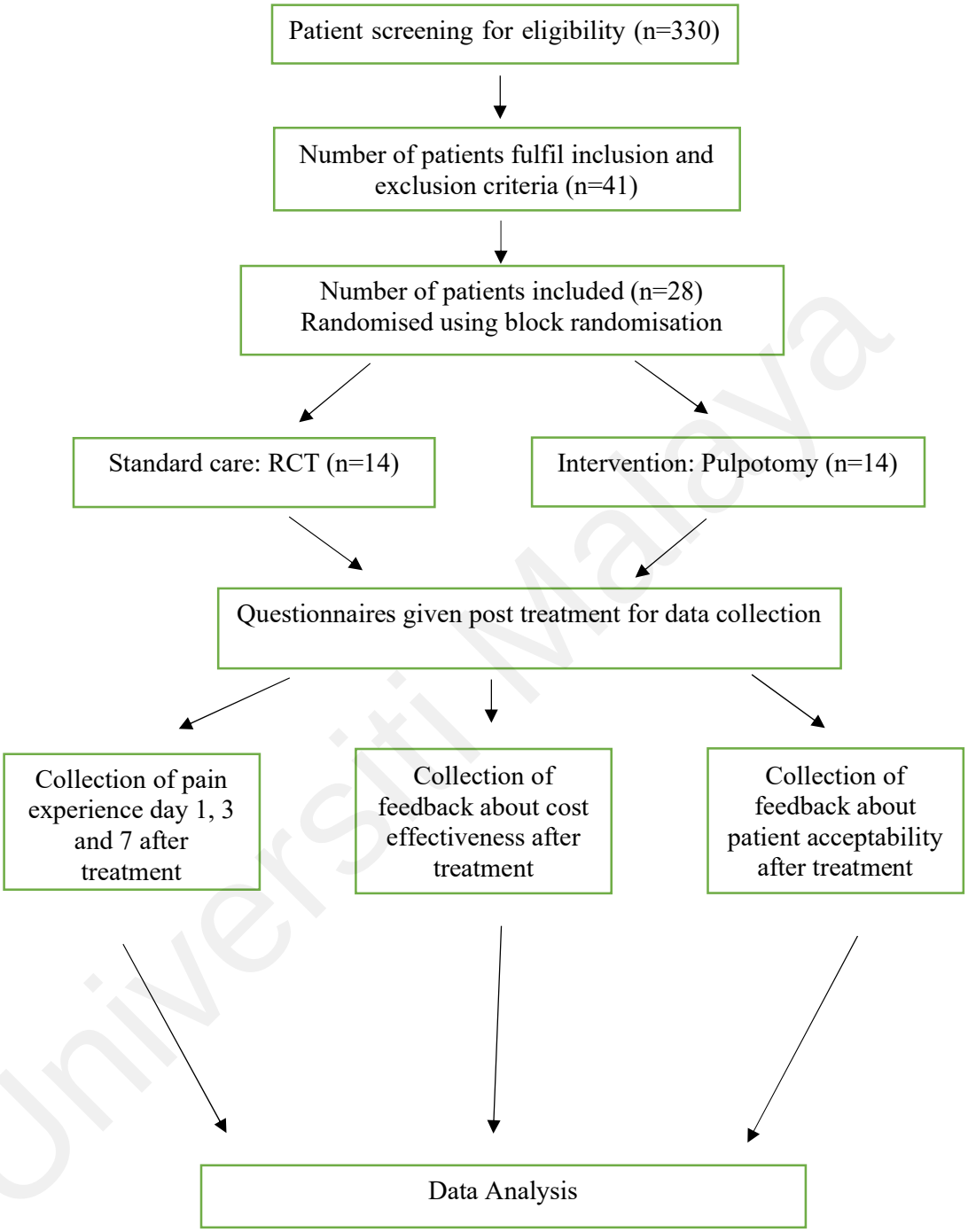
3.2 Sample size

The data from a pilot study involving six patients were used to calculate the sample size (Kunselman, 2024). Two groups of patients were randomly assigned (n=3). The pilot study followed the same protocol as the main study. A total of 22 patients were determined to be sufficient for two groups based on the results of the pilot study (effective size 1.3, power = 80%, significance level = 0.05). Recruitment period started from August 2023 until May 2024. All patients who attended the Primary Care Clinic at the Faculty of Dentistry, Universiti Malaya with symptom of IRP were screened. Out of the 330 patients screened, 41 met the inclusion and exclusion criteria, and 28 patients were ultimately enrolled in this randomised controlled trial.

3.3 Randomisation

After the clinical diagnosis of IRP has been confirmed and informed consent has been obtained, 28 participants were randomly allocated to full pulpotomy group (n=14), and RCT group (n=14). The participant was served as the randomisation unit. A block randomisation method in concealed envelopes were used to complete the randomisation process. To create the randomisation sequence, blocks of 4 and 8 were utilized.

3.4 Flow chart of the study



3.5 Clinical procedure

3.5.1 Assessment

Prior to commencing the procedure, it is imperative to conduct an assessment on the patient to confirm whether the tooth exhibits characteristics indicative of symptomatic IRP, such as sharp and lingering pain triggered by thermal stimulus, typically occurring 30 seconds or more after the stimulus is removed, along with the presence of spontaneous pain. A cotton wool isolation technique was employed, followed by drying, before subjecting the tooth to a cold test at -50ºC using Endofrost (Coltene, Switzerland) and EPT (Digitest II Parkwell Edgewell, USA) on multiple cusps of the tooth. Detailed clinical examination was done to ensure the tooth was free from deep periodontal pocket, mobility and significant crack line. 2D periapical radiograph (using Soredex Minray machine set at 6 mA, 70kV with 0.25 ms exposure time and Durr Dental photostimulable phosphor image plate) was done to visualise the extent of caries lesion/restoration and the periapical region as part of the diagnostic process. Essential information to document includes details on prior analgesic medication, response to percussion and palpation examinations, tooth mobility, and duration of pulpal bleeding.

3.5.2 Full pulpotomy

Local anaesthesia of 2% mepivacaine with 1:100,000 epinephrine injection solution (Scandonest, Septodont, SaintcMaur des Fossés, France) was administered followed by rubber dam tooth isolation. Before beginning caries excavation, the cavity was cleaned by wiping it with a 2.625% NaOCl solution using a cotton wool pellet. To ensure optimal access to the coronal pulp, all residual caries was non-selectively excavated, and any unsupported enamel was removed. Using a high-speed handpiece with water coolant, the roof of the pulp chamber was removed using a non-end cutting tapered diamond bur. No attempt to control the haemorrhage was made until the entire coronal pulp had been amputated. The coronal pulp was excised down to the extent of the root canal orifice using

a high-speed bur with water irrigation visualised under magnification at the range of 8.5x-13.6x using surgical microscope (Zeiss OPMI pico, Carl Zeiss, Göttingen, Germany). The pulp stumps were cleanly excised, with no tissue tags extending across the floor of the pulp chamber. The pulp chamber was irrigated with a 2.625% NaOCl solution. Gentle pressure on the pulp wound with a 2.625% NaOCl soaked cotton pellet was carried out up to 10 minutes until a blood clot forms (haemostasis). The wound was checked for haemostasis every 2 minutes and time required to achieve haemostasis was recorded.

Biodentine (Septodont Ltd., Saint Maur des Fausse´s, France) was mixed according to the manufacturer's instructions and the pulp chamber was filled with a Biodentine. Composite resin was placed as definitive restoration and a minimum of 3 mm Biodentine cap thickness was retained under the definitive restoration. A postoperative periapical radiograph (using a parallel cone technique) was taken.

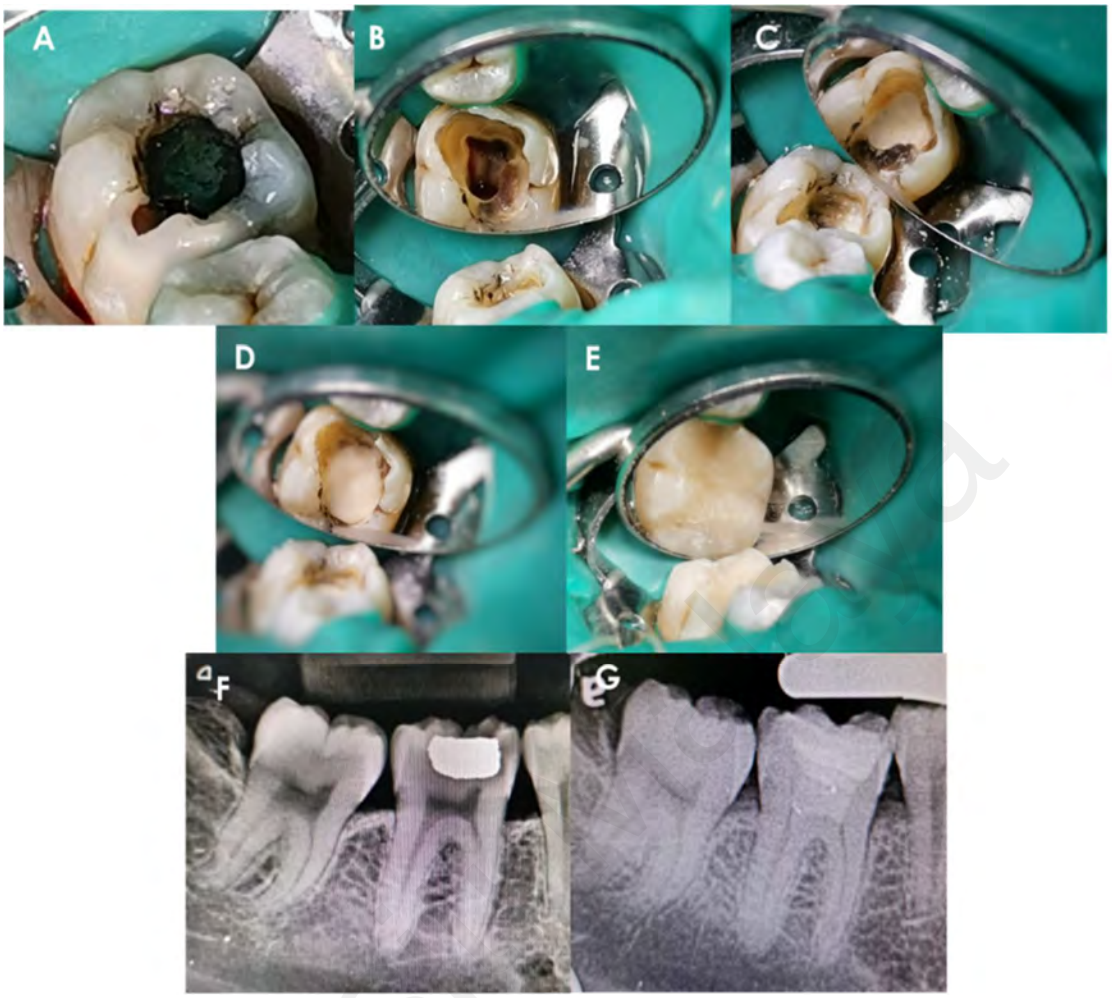


Figure 3.1: Pulpotomy group (molar). Case 1. Clinical photographs: (A) Preoperative, (B) Coronal pulpotomy with hemorrhage control, (C) Biodentine application, (D) GIC lining, (E) Composite restoration; Radiographs: (F) Preoperative, (G) Postoperative.

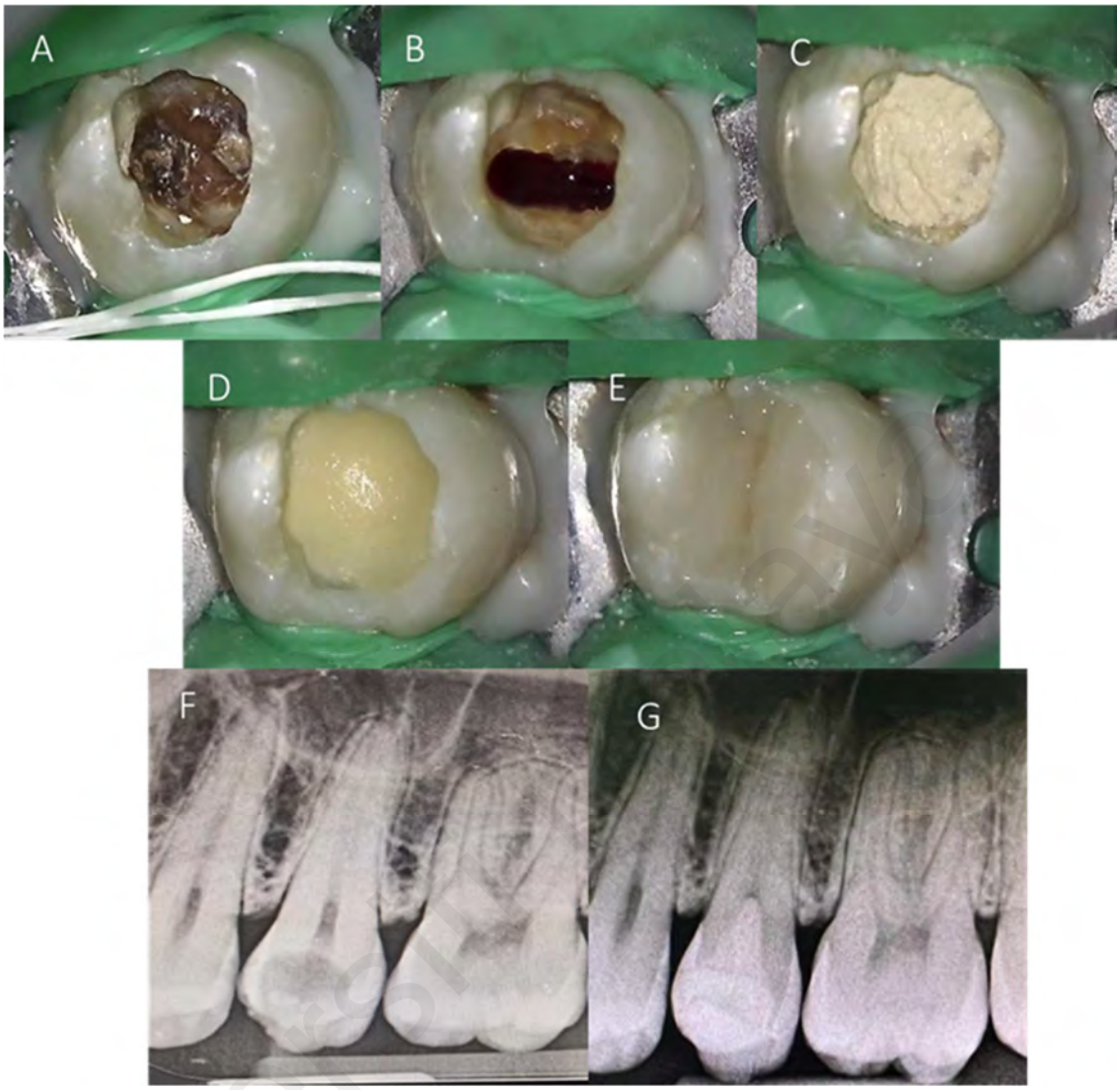


Figure 3.2: Pulpotomy group (Premolar). Case 2. Clinical photographs: (A) Preoperative, (B) Coronal pulpotomy with hemorrhage control, (C) Biodentine application, (D) GIC lining, (E) Composite restoration; Radiographs (F) Preoperative, (G) Postoperative.

3.5.3 RCT

In the RCT group, the procedure was completed with a minimum of two visits. Injection of local anaesthesia of 2% mepivacaine with 1:100,000 epinephrine injection solution (Scandonest, Septodont, SaintcMaur des Fossés, France) was done followed by rubber dam tooth isolation. Access cavity was done and inflamed pulp tissue was removed. Canal

orifices were identified and enlarged. The working length was determined using an apex locator (Root ZX II, J.Morita, Japan) and confirmed with periapical radiograph. Irrigation protocol was done using 5.25% NaOCl. Cleaning and shaping of the canals were done according to ProTaper Next (Dentsply Tulsa, Dental Specialties, Tulsa, OK, USA) or ProTaper Universal Hand Files (Dentsply Tulsa, Dental Specialties, Tulsa, OK, USA) system in the sequence to apical size 2-3 larger than initial binding file. Non-setting calcium hydroxide paste UltraCal (Ultradent, South Jordan, USA) was placed as intracanal medicament in between visit. Root canal filling was done using gutta percha and root canal sealer AH Plus sealer (Dentsply Detrey, Konstanz, Germany) with cold lateral or warm vertical compaction technique. Composite resin was applied as definitive restoration to ensure coronal seal. Good quality postoperative radiograph was taken using parallel cone technique.

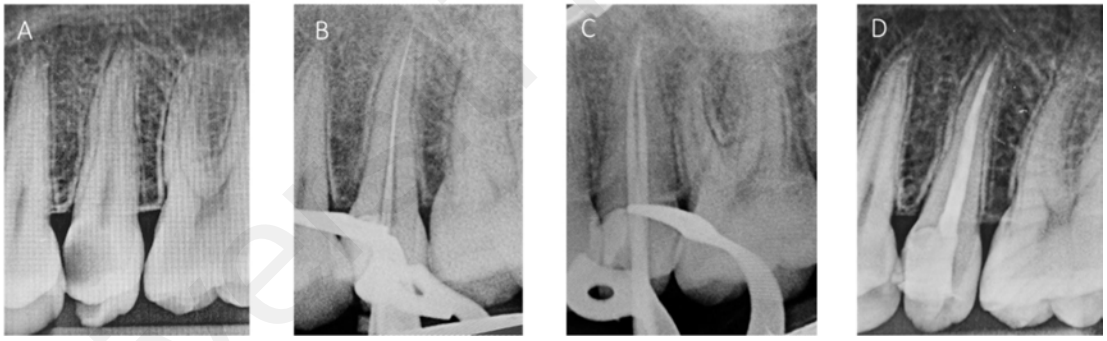


Figure 3.3: RCT group (Premolar). Case 3. (A) Preoperative PA 15, (B) PA 15 for corrected working length, (C) PA 15 for master cone, (D) Post RCT PA 15.

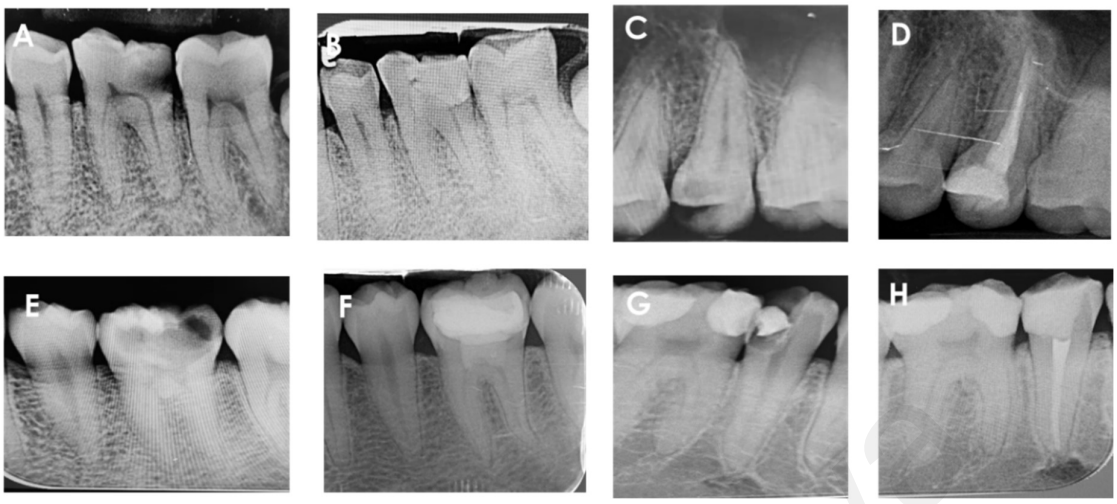


Figure 3.4: Preoperative and postoperative radiographs respectively for pulpotomy and RCT groups: (A, B) Case 4; (C, D) Case 5; (E, F) Case 6; (G, H) Case 7.

Follow up assessment on:

1. Acceptability and cost effectiveness of the treatment and on the day after the treatment.
2. Short term outcome of pain on days 1, 3 and 7 after the treatment.
3. Patients who were not suitable for this clinical trial for example false positive pulp sensibility test or uncontrolled blessing during pulpotomy procedure were referred to undergraduate or postgraduate students to continue for RCT.
4. Patients who experienced worsening pain after full pulpotomy procedure were being offered alternative treatment (RCT or extraction). The same was being applied to RCT arm; patient was offered alternative treatment including retreatment or extraction. Tooth with fracture line detected during the procedure was being treated by either prosthodontic treatment or extraction.

Questionnaire was used to compare the cost effectiveness of both treatments from perspective of patients using scale as follows:

Table 3.1: Level of satisfaction with score

Level of satisfaction	Score
Very Satisfied	5
Satisfied	4
Neutral	3
Dissatisfied	2
Very Dissatisfied	1

Regarding patients' acceptability toward both treatment groups, patients were given a questionnaire to assess whether they were willing to recommend the treatment to others experiencing similar pain using scale as below:

Table 3.2: Level of acceptability with score

Level of acceptability	Score
Very Likely	5
Likely	4
Neutral	3
Unlikely	2
Very Unlikely	1

3.6 Statistical analysis

Data were analysed using IBM SPSS Statistics version 29.0 software (IBM Corporation, Armonk, NY, USA). Data were described using means and standard deviations. The data showed non-normal distribution according to the Shapiro-Wilk test of normality. Thus, it was examined using non-parametric tests. Mann-Whitney U test was used to compare demographic data (age, gender and type of tooth), preoperative and postoperative pain score and data regarding cost effectiveness and acceptability. $P<0.05$ was considered statistically significant.

CHAPTER FOUR: RESULTS

There was a statistically significant difference (P<0.05) in the type of tooth between the two groups. There are more molar teeth in the pulpotomy group, whereas there are more premolars in the RCT group. Gender and age differences between the groups were not statistically significant (P>0.05) (Table 4.1).

Table 4.1: Demographics of the patients participating in the study

	Gender		Mean Age	Tooth Type	
Group	**Male**	**Female**	**Mean ± SD**	**Premolar**	**Molar**
Pulpotomy (n=14)	6	8	37.2 ± 11.1	4	10
RCT (n=14)	4	10	33.4 ±10.8	10	4
Total (n=28)	10	18	35.3 ± 10.9	14	14

The Universal Pain Assessment Tool was used to measure the pain score. The mean preoperative pain scores for the pulpotomy (7.79±1.12) and RCT (7.64±1.15) groups were comparable, and the difference was not statistically significant (P>0.05). For comparison of pain score after first visit, pain score at day 1 showed statistically significant difference between the two groups (P<0.05) with pulpotomy (1.36±1.95) reported a lower pain score when compared to RCT (3.21±2.01). The mean pain scores for both groups subsequently decreased over the next few days. The pulpotomy group reported less pain at day 3 and day 7 compared to the RCT group. The pain score on both days was not statistically significant (P>0.05). Most of the patients from both groups experienced no pain at day 7 (Table 4.2).

Table 4.2: Comparison of preoperative and postoperative mean pain score after first visit

	Treatment Group	N	Mean± SD	p value
Preoperative pain score	RCT	14	7.64±1.15	0.755
	Pulpotomy	14	7.79±1.12	
Day 1 postoperative pain score (First Visit)	RCT	14	3.21±2.01	0.022
	Pulpotomy	14	1.36±1.95	
Day 3 postoperative pain score (First Visit)	RCT	14	2.00±1.71	0.302
	Pulpotomy	14	1.43±1.99	
Day 7 postoperative pain score (First Visit)	RCT	14	0.71±0.99	0.674
	Pulpotomy	14	0.57±0.94	

When comparing the pain score after completed treatment, the RCT group showed a lower pain score at days 3 and 7 and pulpotomy showed lower pain score at day 1 but the difference was not statistically significant (Table 4.3). Figure 4.1 showed the comparison of preoperative and postoperative pain scores in pulpotomy and RCT groups over the periods of 7 days for two set of data, which were after first visit and completed treatment.

Table 4.3: Comparison of preoperative and postoperative mean pain score after completed treatment

	Treatment Group	N	Mean± SD	p value
Preoperative pain score	RCT	14	7.64±1.15	0.755
	Pulpotomy	14	7.79±1.12	
Day 1 postoperative pain score (Completed treatment)	RCT	14	1.86±2.03	0.300
	Pulpotomy	14	1.36±1.94	
Day 3 postoperative pain score (Completed treatment)	RCT	14	0.50±0.65	0.473
	Pulpotomy	14	1.43±1.99	
Day 7 postoperative pain score (Completed treatment)	RCT	14	0.07±0.27	0.063
	Pulpotomy	14	0.57±0.94	

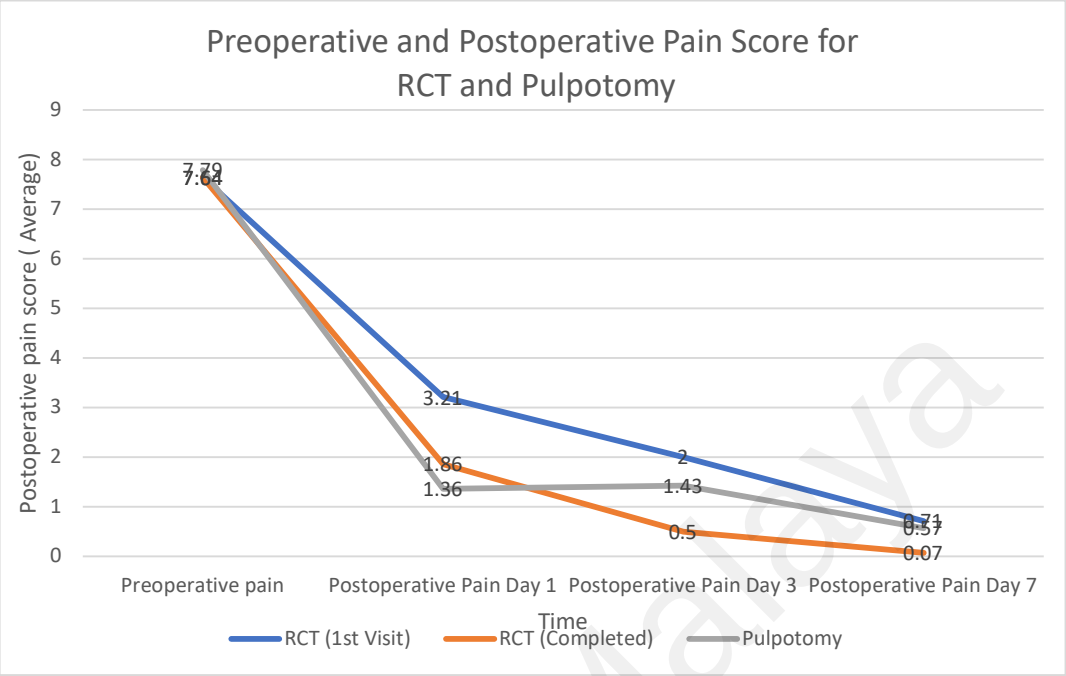


Figure 4.1: Preoperative and postoperative pain scores in pulpotomy and RCT groups over the periods of 7 days (after first visit and completed treatment).

Result showed that patients had high satisfaction towards the cost effectiveness of pulpotomy and RCT with pulpotomy recorded higher score in terms of treating dental pain, time taken to complete the procedure and cost of the treatment but only the difference in treating dental pain was statistically significant (P<0.05) (Table 4.4).

Table 4.4: Comparison of mean score of cost effectiveness from patients' perspective

	Treatment Group	N	Mean± SD	p-value
Treating dental pain	RCT	14	4.21± 0.58	0.022
	Pulpotomy	14	4.71±0.47	
Time taken to complete procedure	RCT	14	3.93±0.73	0.114
	Pulpotomy	14	4.36±0.63	
Cost of treatment	RCT	14	4.07±0.62	0.122
	Pulpotomy	14	4.43±0.51	

The results showed that patients from pulpotomy group were more likely to recommend their treatment to others when compared to RCT group. The difference between two group was not statistically significant (P>0.05) (Table 4.5).

Table 4.5: Comparison of mean score of acceptability from patients' perspective

	Treatment Group	N	Mean± SD	p-value
Recommend to others with similar pain	RCT	14	4.00±0.78	0.122
	Pulpotomy	14	4.43±0.51	

CHAPTER FIVE: DISCUSSION

Recent clinical and histological evidence raises doubts regarding the long-standing notion that RCT is the exclusive treatment option for mature permanent teeth diagnosed with IRP. Procedures such as full pulpotomy for VPT are not just easier to perform but also cost-effective in comparison to conventional RCT. Full pulpotomy for IRP in permanent teeth has shown promising outcomes compared to RCT. Research has revealed the effectiveness of full pulpotomy in permanent teeth with IRP, showcasing a clinical success rate of 93.97% and a radiographic success rate of 88.39% after a 3-year follow-up period (Cushley et al., 2019). Systematic reviews showed comparable long-term success rates between pulpotomy and RCT, but in the same time emphasising the need for more high-quality randomized clinical trials to establish definitive conclusions (Afrashtehfar et al., 2023). These findings suggest that full pulpotomy can be a successful alternative to RCT for IRP in permanent teeth, providing a viable treatment option with favourable outcomes.

Including only patients aged 12 years and above in these clinical trials for permanent molars and premolars was due to clinical and developmental reasons. By age 12, most permanent molars and premolars have fully erupted and completed root development or are nearing completion. Younger patients might still have developing roots, which could influence the pulpal response and healing process after pulpotomy (Nolla, 1952).

The first hypothesis of the study was partially accepted in terms of postoperative pain. There was a significant difference for day 1 postoperative pain after the first visit, with full pulpotomy showing the better result, while there was no significant difference for postoperative pain at days 3 and 7 between full pulpotomy and RCT after the first visit. There was no significant difference in postoperative pain on day 1, day 3, and day 7 for these two groups after completed treatment. The second hypothesis was partially accepted

as there was a significant difference in one of the factors of cost effectiveness which was treating dental pain. The third hypotheses were accepted as there was no significant difference in terms of acceptability of patients in both treatment groups.

5.1 Postoperative pain

Postoperative pain is a critical factor influencing patient preference and clinical decision-making. Research consistently indicates that patients experience less immediate postoperative pain following full pulpotomy compared to RCT (Table 2.3). The reduced immediate pain associated with full pulpotomy can be attributed to the less invasive nature of the procedure. However, the RCT data used for postoperative pain comparison in the studies above are majority single visit RCT. Multiple research papers have investigated the incidence of postoperative pain in single-visit versus multiple-visit RCT. Studies have shown conflicting results regarding the frequency of postoperative pain between the two approaches. While one study found no significant difference in postoperative pain incidence regardless of the number of visits (Singh et al., 2012), another study reported higher postoperative pain and tenderness in single-visit RCT initially, with similar outcomes in the long term compared to multiple visits (Dhyani., 2022) Traditionally, multiple-visit RCT has been more common due to the belief that it allows better infection control through the use of intracanal medicaments between visits. Surveys of dental practitioners provide insights into the prevalence of single-visit and multiple-visit RCT. A survey conducted by Savani et al. (2014) in the United States reported that a significant number of endodontists and general dentists still preferred multiple-visit RCT.

Thus, the present study provided data about the preoperative and postoperative pain scores of multiple visits of RCT and single visits of full pulpotomy. Two sets of postoperative pain data were provided for the RCT group; one was postoperative pain data collected during the first visit after pulp extirpation was done, while another set of

postoperative pain data was collected during the last visit after obturation was done. In the current randomised controlled trial, the average baseline preoperative pain scores exhibited similarity, with no statistically significant difference observed among the groups ($P>0.05$). The mean postoperative day 1 pain score showed a statistically significant lower ($P<0.05$) in the pulpotomy group when compared to the RCT first visit, suggesting a higher level of symptomatic relief in this group. The results presented align with the study conducted by other studies that practiced single-visit RCT, which also observed a greater reduction in pain following pulpotomy compared to RCT during postoperative day 1 (Asgary et al., 2013; Galani et al., 2017; Taha et al., 2023). Consequently, it can be inferred that pulpotomy may serve as a viable option for providing urgent pain relief when compared to both single-visit and multiple-visit RCT.

When the coronal pulp is inflamed or infected, it often causes significant pain due to the pressure and release of inflammatory mediators. By removing this portion of the pulp during full pulpotomy, the source of inflammation and infection is eliminated, thereby reducing pain (Rosenbury et al., 2002). On the other hand, potential origin of postoperative pain following the first visit of RCT is the contamination and irritation of periapical tissues, which is typically caused by the endodontic instrumentation (Genet et al., 1987). The mean postoperative pain score for both groups continued to decrease to mild pain on day 3 and eventually no pain on day 7 with no statistically significant different ($P>0.05$). In fact, when we compared the results of postoperative pain of single visit full pulpotomy with multiple visit RCT after completed treatment, multiple visit RCT showed lower pain scores on day 3 and day 7 and the pain score of pulpotomy was lower on day 1 but the difference was not significant ($P>0.05$) among these two groups. From this, it can be seen that pulpotomy is a feasible alternative to multiple-visit RCT as well in terms of postoperative pain.

5.2 Cost effectiveness and acceptability

In order to compare the cost-effectiveness of both treatment options from a patient perspective, patients were assessed using a questionnaire regarding satisfaction in terms of treating dental pain, the time taken for the treatment and also the cost of the treatment. In terms of treating dental pain, results from the questionnaire showed that patients in the pulpotomy group experienced higher satisfaction compared to those undergoing RCT and the difference was statistically significant ($P<0.05$). As RCT also aims for complete removal of pulp tissue, it involves a more extensive process of cleaning the entire root canal system. This can sometimes lead to prolonged discomfort during the healing period.

In terms of time taken for the treatment, full pulpotomy achieved marginally higher patient satisfaction when compared to RCT, according to the data from questionnaires. Pulpotomy is generally a quicker procedure and can be completed in a single visit, which is advantageous for both the dentist and the patient whereas RCT usually requires multiple visits to complete the cleaning, shaping, and filling of the root canals. Each visit can be time-consuming, contributing to a longer overall treatment time. When comparing both treatment modalities in terms of treatment cost, results from the questionnaire showed that patients were more satisfied with a full pulpotomy although the difference was not significant ($P>0.05$). Full pulpotomy procedure requires fewer materials, less chair time, and typically involved fewer visits. RCT is generally more costly due to the extensive nature of the procedure and the use of specialized equipment, especially in molars. The potential for multiple appointments for RCT can increase indirect costs for patients, including time off work and transportation costs. The results regarding the cost effectiveness are in accordance with findings by Taha et al (2023), who demonstrated that patients were more satisfied with pulpotomy than RCT on permanent molar in terms of the time taken for the treatment, cost, pleasantness, and intraoperative pain.

Patients who underwent both treatment modalities reported high levels of acceptability in this clinical trial. Results showed that patients from the full pulpotomy group are slightly more likely to recommend their treatments to others who experience similar pain ($P>0.05$).

5.3 Operator experience with pulpotomy techniques

The operator in this study was a first-year postgraduate student who had limited experience in VPT procedures. Consequently, general dentists might be able to reproduce the results of this study in their clinical practices. The process of a full pulpotomy is considered uncomplicated as it only involves the removal of coronal pulp, but adequate knowledge about tooth anatomy is needed to ensure the complete removal of coronal pulp tissue. A thorough understanding of the tooth anatomy, particularly in the context of a high-attached pulp horn tooth, is essential for the successful execution of a full pulpotomy (Ahmed et al., 2024). The higher positioning of the pulp horn can complicate the removal process, necessitating a more meticulous approach to prevent removing unnecessary dentine around the pulp chamber. The importance of achieving straight-line access in full pulpotomy of permanent posterior tooth was to ensure more thorough debridement of the coronal pulp chamber (Patel and Rhodes, 2007). Complete removal of infected pulp tissue reduces the likelihood of reinfection. For the full pulpotomy in tooth without pulpal floor such as premolars, there are lack of anatomical landmark to indicate the level for sufficient coronal pulp tissue removal. In this study, removal of pulp tissue for premolars which lack of pulpal floor were done until cementoenamel junction of the tooth

5.4 Case selection of pulpotomy

Case selection and correct diagnosis are fundamental to the success of a full pulpotomy. The ESE position statement in 2019 suggested that when there is partial IRP in the coronal pulp, a full pulpotomy may be effective when performed aseptically under a rubber dam. In this study, patients with the chief complaint of symptomatic pulpitis were screened for

suitability to be recruited. Following a thorough examination of the relevant teeth, pulp sensibility tests and caries depth as determined by radiography, there were only 41 patients out of 330 screened patients who fulfilled all the inclusion and exclusion criteria, which represent around 12% of the screening rate. This is one of the limitations of full pulpotomy as the case selection criteria for pulpotomy procedures are usually strict. Among the 41 patients who fulfilled all the criteria, 28 patients were included in this study. The main reason of exclusion (n=10) at this stage was due to patient factor such as prefer for extraction, failed to come for appointment for more than 3 times and prefer to continue treatment at private clinic. There were 3 cases in which the teeth were responded to an EPT and cold test but found to be necrotic pulp without bleeding upon assessment of the cavity. Studies showed that a pulp sensibility test can produce false positives in cases of partial necrosis or when the pulp is undergoing degeneration but still contains some viable nerve fibres (Jafarzadeh et al., 2010). In addition to providing additional diagnostic information about the degree of pulp inflammation, direct visualization of the pulp tissue under magnification during and after haemostasis can also help identify potential necrotic tissues that need to be removed before the pulpotomy medication is applied. The state of the pulp is difficult to evaluate, yet it is essential to the success or failure of pulp therapy. There is no solid instrument to assist in assessing how far into the pulp the infection has spread. According to Matsuo et al., (1996), the success rate was correlated with the extent of bleeding upon pulpal exposure. One explanation could be that the extent of bleeding from the exposure site indicates how inflamed the pulp is. The risk of IRP and the extent of bleeding upon exposure would both be increased by more severe pulp inflammation (Matsuo et al., 1996). Aguilar et al. (2011) proposed that it is possible for the pulpal inflammation to spread to the radicular pulp or that the inflamed pulp has not been entirely removed if the bleeding does not stop within 10 minutes. Therefore, it is suggested to alter the course of treatment, such as by switching from a full

pulpotomy to a pulpectomy, if there is uncontrolled bleeding from the pulp for more than 10 minutes.

5.5 The use of sodium hypochlorite (NaOCl) in pulpotomy and RCT

NaOCl is commonly used in VPT and same goes for this clinical trial as well for its antimicrobial properties and excellent ability to control bleeding. The concentration of NaOCl employed in the present investigation for full pulpotomy was 2.625%, achieved through the dilution of an equivalent volume of the full-strength 5.25% NaOCl solution. Besides being a good haemostatic agent, it has been observed that NaOCl has the potential to be utilised in a safe manner when coming into direct contact with pulp tissue at a range of concentrations, spanning from more diluted solutions to those with full bottle strength, while ensuring that the integrity of the pulp is not compromised (AAE, 2021; Demir et al., 2007; Tang et al., 2000).

A number of studies assessed the impact of different NaOCl concentrations on different treatment-related aspects; however, the findings of these investigations have been inconclusive (Hand et al., 1978; Moorer et al., 1982; Spångberg et al.,1973). Higher concentrations of NaOCl are more toxic than lower concentrations while also having a better tissue dissolving ability (Hand et al., 1978; Spångberg et al.,1973). Hafez et al (2002) showed that that around 3% NaOCl solution is biocompatible as a haemostatic agent and dental pulps treated with this particular concentration did not exhibit any signs of pulpal necrosis after either 7 or 27 days. Moreover, the utilisation of NaOCl during pulpotomy also aids in the decontamination process and chemical removal of debris and clot, alongside the establishment of a dentine-pulp interface devoid of organic biofilm prior to adhesive capping (AAE, 2021).

5.6 Biodentine

In terms of materials used in this study, Biodentine is a CSC based material that is increasingly used in pulpotomy due to its favourable biological and mechanical

properties. Laurent et al. (2012) showed the promising biological properties of Biodentine and significantly increased TGF-B1 secretion from pulp cells in her study. Transforming Growth Factor (TGF) is a growth factor whose role in angiogenesis, recruitment of progenitor cells, cell differentiation, and mineralization has been highlighted in research (Laurent et al., 2012). When compared to other CSC materials such as MTA, Biodentine shows improved physical characteristics such as a shorter setting time (12 minutes), higher viscosity, easier application, and less discolouration (Mustafa et al., 2020). The improved handling properties enabled single visit pulpotomy in this study with placement of definitive composite restoration in the first visit after full pulpotomy. One of the most important parts of endodontic procedures is the definitive restoration. For a tooth receiving VPT, the restorative treatment plan should include immediate permanent restoration. A high success rate was observed in teeth that underwent VPT with CSC serving as the main sealing material and the teeth were promptly restored with a permanent restoration (AAE, 2021). Successful outcomes are strongly predicted by the quality of the restoration and the shortest length of time following VPT for permanent restoration (Galani et al., 2017). The prevention of microleakage, preservation of the biomaterial layer, decrease in postoperative sensitivity and thermal conductivity, and creation of a foundation for cuspal coverage restoration are among the benefits of immediate restoration that have been indicated (AAE, 2021).

The need to place at least 3 mm of Biodentine for a full pulpotomy is supported by several factors highlighted in the literature (AAE, 2021). One of the primary reasons for using at least 3 mm of Biodentine is to ensure a proper seal against bacterial infiltration. Biodentine has excellent sealing properties, but adequate thickness is essential to maintain this seal and prevent microleakage, which can lead to treatment failure. Literature indicates that a minimum thickness of 3 mm is necessary to create an effective barrier that promotes healing and prevents bacterial penetration (Wang et al., 2023). However,

the limitations of Biodentine include its expensive cost and the significant amount of excess material wasted in each capsule.

5.7 Limitation of this study

The main limitation of this study is the small sample size (n=28) due to the strict inclusion and exclusion criteria of this study. This was evident since only 12% among all the patients with the symptoms of IRP were included during the patient recruitment period. The purpose of the criteria is to make sure the samples are homogenous among these two groups to minimise the impact of confounding factors that could influence the outcome. However, a small sample size may make the results more susceptible to variability and increase the risk of Type II errors (Wolf et al.,2013).

The second limitation arises from the inability to obtain extensive data regarding the cost-effectiveness and patient acceptance of these treatment methods over an extended period, given the short time frame of the study. The existing data is derived from patients after their first visit, however, a longitudinal analysis may be required to capture patients' enduring perspectives, which could be influenced by clinical outcomes.

5.8 Impact of this study

In Malaysia, RCT is the recommended treatment for IRP with a success rate of approximately 85%, according to a retrospective study by a local university (Mustafa et al., 2018). However, for IRP cases involving complex root canal anatomy, such as narrow pulp chamber and curved canals, advanced equipment such as dental microscopes and ultrasonic tips are necessary for quality treatment. Unfortunately, not all general practice settings can afford these advanced tools due to their high cost. While referring difficult RCT cases to an endodontist is always an option, certain regions, especially rural areas are facing the issue of lack endodontist services. Consequently, full pulpotomy might be a viable option for treating IRP in posterior teeth for general practitioners with limited endodontic equipment as well as for teeth with limited accessibility and complex anatomy

such as second and third molars. The data from this study on patient postoperative pain, cost-effectiveness, and acceptability of pulpotomy versus RCT could provide valuable clinical evidence for general practitioners when selecting a suitable treatment option for IRP.

Recently, a prospective meta-analysis has been proposed to synthesise evidence, offering benefits such as streamlined adaptive design and reduced research inefficiency and bias (El Karim et al., 2023). Data from this study will contribute to a multicentre prospective meta-analysis to address gaps in current knowledge and meet the need for well-designed, sufficiently powered randomised trials (El Karim et al., 2023). This is necessary to generate the data required to change current clinical practices on IRP, as emphasized by the AAE and ESE positional statements (ESE, 2019; AAE, 2021).

CHAPTER SIX: CONCLUSIONS

6.1 Conclusions

Given the limitation of the study, it can be concluded that:

1. Except for day 1, there is no significant difference in the postoperative pain of full pulpotomy compared to conventional RCT in mature permanent posterior teeth with symptomatic IRP.
2. There is no significant difference in terms of cost-effectiveness when compared full pulpotomy to conventional RCT in mature permanent posterior teeth with symptomatic IRP except from the aspect of treating dental pain with full pulpotomy recorded higher satisfaction.
3. There is no significant difference in the acceptability of patients to both full pulpotomy and RCT procedure in mature permanent posterior teeth with symptomatic IRP.

6.2 Clinical recommendations

Full pulpotomy can be a good alternative approach for RCT for treatment in cases of symptomatic IRP in permanent mature teeth without apical periodontitis in terms of postoperative pain, cost effectiveness and patient acceptability.

6.3 Direction for future studies

The main limitation of this study was the small sample size (n=28) due to time constraints and the inability to compare the long-term treatment outcome as our trial in this phase was graded as a short-term study. Thus, the teeth treated in this study are designated for a longer term evaluation to collect further data regarding the cost effectiveness of the treatment and patient acceptability. More clinical outcomes such as survival rate of the tooth radiographically among these two treatment modalities are planned to be covered,

and the existing clinical study is ongoing for larger sample size with more parameters to be evaluated at intervals of six months and one year.

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