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ORIGINAL ARTICLE

Treatment outcome of partial pulpotomy using two different calcium silicate materials in mature permanent teeth with symptoms of irreversible pulpitis: A randomized clinical trial

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Abstract

Aim: To assess the clinical and radiographic outcome of partial pulpotomy by comparing MTA Angelus and Total Fill BC, as pulpotomy agents, in mature teeth with deep caries and symptoms indicative of irreversible pulpitis.

Methodology: The study was designed as a parallel-two arm, double-blind, randomized superiority clinical trial registered at www.clinicaltrials.gov (NCT04870398). Symptomatic mature permanent teeth with deep caries fulfilling the inclusion criteria were randomly treated using either MTA Angelus or Total Fill BC. A partial pulpotomy was performed and following complete haemostasis, the capping material was placed over the remaining pulp tissue and a postoperative periapical radiograph was taken. Clinical and radiographic follow-up evaluation was performed for a median time of 2 years, whereas levels of pain intensity were evaluated preoperatively and for 7 days after intervention using Visual Analogue Scale. For the primary outcome (failure/success of treatment), the Kaplan–Meier survival curves for the capping materials were plotted and a log-rank test for equality of survivor functions was applied. A multivariable random effects Cox Regression model was also applied. For the secondary outcome (postoperatively reported pain), a multivariable mixed effects ordinal logistic regression was structured.

Results: One hundred and thirty-seven teeth in 123 patients underwent partial pulpotomy using randomly either MTA Angelus ($N=74$) or Total Fill BC ($n=63$). The percentage failure for MTA Angelus and Total Fill BC was 10.8% (8/74) and 17.5% (11/63), respectively, but the difference was not statistically significant [adjusted HR: 1.83; 95% confidence interval (CI): 0.68, 4.91; $p=.23$]. Weak evidence was found that secondary caries involvement may impose a 3.54 times greater hazard for treatment failure (adjusted HR: 3.54; 95% CI: 1.00, 12.51; $p=.05$). For each passing minute of procedural bleeding control, there was also a 57% higher hazard for treatment failure (adjusted HR: 1.57; 95% CI: 0.99, 2.48; $p=.05$). The odds for higher postoperative pain were 4.73 times greater for the Total Fill BC compared to MTA Angelus (adjusted OR: 4.73; 95% CI: 2.31, 9.66; $p<.001$).

Conclusions: Both materials exhibited similar and favourable outcome rates after partial pulpotomy in teeth with deep caries and symptoms of irreversible pulpitis. Total Fill BC was associated with a higher level of postoperative pain intensities.

KEYWORDS
deep caries, irreversible pulpitis, mature teeth, MTA Angelus, partial pulpotomy, total Fill BC

INTRODUCTION

Vital pulp therapy (VPT) of exposed pulp due to caries in mature teeth is nowadays amongst the most promising treatment options in clinical endodontology (Duncan et al., 2019; Ricucci et al., 2019). By performing VPT in vital mature teeth, a great number of root canal therapies may be prevented, thus preserving pulp vitality and consequently the health of the tissue. Preservation of pulp vitality is of great importance, due to the maintenance of the defensive mechanism of the pulp tissue and the structural integrity of the tooth (Duncan et al., 2022).

In the recent years, vital pulp treatment options have been expanded giving clinicians the opportunity to manage similar cases with a number of different treatment options, especially when no preoperative symptoms are present (complete or selective caries removal). In any case, VPT assumes accurate preoperative assessment of pulp condition irrespective of the absence or presence of symptoms. Many attempts have been made by researchers to diagnose the status of the pulp in cases of teeth with deep or extremely deep caries in the presence or absence of symptoms (Dummer et al., 1980; Mejare et al., 2012; Ricucci et al., 2014). However, despite these efforts, the accurate preoperative assessment of pulp status remains uncertain (Duncan, 2022; Duncan et al., 2019; Mejare et al., 2012; Wolters et al., 2017).

The management of deep carious lesions has been controversial during the last 10 years (Bjorndal et al., 2010; Duncan et al., 2019; Schwendicke et al., 2016). Deep caries can initiate an inflammatory and degenerative process of the pulp tissue and, if left untreated, can eventually lead to pulp necrosis and inflammation of the periapical tissues (Bjorndal et al., 2019). A previous study, using serial histologic sections, showed that when the carious lesion is deep enough, approaching the pulp, the later exhibits a localized inflammatory response in the upper layers, whereas healthy tissue can still be found in the lower layers (Ricucci et al., 2019). Based on that observation, partial amputation of the pulp is justified and feasible during clinical practice to remove any inflamed part until layers of healthy tissue are reached.

In vital teeth with signs and symptoms indicating the presence of irreversible pulpitis, there is no argument that complete caries excavation exposing the pulp and removing the irreversibly inflamed part of the tissue, if this is feasible, is the appropriate management in all cases. The final treatment choice between pulpotomy (partial or full coronal) and root canal therapy is determined upon sufficient control of bleeding and visual observation of pulp tissue under high magnification. When a partial pulpotomy is performed, bleeding should ideally be controlled within a few minutes, which probably means that the inflamed part of the pulp tissue has been efficiently removed (Duncan et al., 2019). If a blood-filled homogenous and dense tissue without further bleeding is finally obtained, then the odds of successful management and long-term pulp survival may be significantly increased. The success of this approach has been demonstrated in previous studies showing outcomes of pulpotomy in teeth with carious pulp exposure (Caliskan, 1995; Mejare & Cvek, 1993; Nosrat & Nosrat, 1998).

So far, a great number of studies have been conducted to assess the outcome of different types of VPT (Asgary & Eghbal 2013; Asgary et al., 2014, 2015, 2017, 2018; Awawdeh et al., 2018; Baranwal et al., 2022; Barrieshi-Nusair & Qudeimat, 2006; Bjorndal et al., 2010; Careddu & Duncan, 2021; Chailertvanitkul et al., 2014; Galani et al., 2017; Kang et al., 2017; Kunert et al., 2015; Kundzina et al., 2017; Linsuwanont et al., 2017; Mass & Zilberman, 2011; Qudeimat et al., 2017; Ramani et al., 2022; Taha et al., 2017, 2022; Taha & Abdelkhader, 2018a; Taha & Khazali, 2017; Tan et al., 2020; Uesrichai et al., 2019). However, only a few have evaluated the effect of partial pulpotomy on the survival of vital pulp tissue in mature teeth with signs and symptoms indicative of irreversible pulpitis (Asgary et al., 2018; Baranwal et al., 2022; Ramani et al., 2022; Taha & Khazali, 2017; Uesrichai et al., 2019). The latter five studies are randomized clinical trials (RCTs) in the field, however, limitations do exist, such as a lack of important pieces of information and compromised reporting quality, flaws in the technique or rather variable eligibility criteria for patient and teeth recruitment. For example, Taha and Khazali (2017), Asgary et al. (2018) and Baranwal et al. (2022) do not provide detailed data about the operators participating in the study (number, calibration, experience), while no magnification has been used for improved control of the pulpotomy procedure. In addition, the sample used by Asgary et al. consisted of teeth with both irreversible and reversible pulpitis. It is also noteworthy that in the study by Uesrichai et al. (2019), the sample was non-homogenous and consisted of mature and immature teeth.

To our knowledge, the present study constitutes the first RCT in which a single-experienced operator has been

involved in the treatment and performed partial pulpotomies in mature teeth with symptoms of irreversible pulpitis by observing the pulp wound surface under high magnification using an operating microscope. A bioceramic material, namely, the Total Fill BC (FKG) was tested for its ability to preserve pulp vitality and to stimulate pulp healing and compared with MTA [MTA Angelus (Angelus)]. Recently, Taha et al. (2022) examined Total Fill for its ability to maintain pulp vitality after full coronal pulpotomy.

Thus, the main purpose of the present study was to assess the clinical and radiographic outcome of partial pulpotomy in terms of success of treatment (free of clinical signs and symptoms and pathologic radiographic findings) by comparing a commercial brand of MTA [MTA Angelus (Angelus)] with a more recently introduced bioceramic material, the Total Fill BC (FKG), in mature teeth with deep caries and clinical symptoms indicative of irreversible pulpitis. The secondary aim was to evaluate the reduction of preoperative pain after partial pulpotomy and whether differences were observed between the materials tested. This is the first report of a long-term follow-up randomized clinical trial, which presents the results of a mid-term median 2-year follow-up, examining patients who have contributed a maximum of 5-year follow-up in a survival analysis.

MATERIALS AND METHODS

This randomized clinical trial has been written according to Preferred Reporting Items for RAndomized Trials in Endodontics (PRIRATE) 2020 guidelines (Nagendrababu et al., 2020a, 2020b). The research protocol was approved by the Ethics Committee of the School of Dentistry of National and Kapodistrian University of Athens, Greece (protocol no. 459/01.03.2021). The study protocol was registered at www.clinicaltrials.gov (Registration identifier NCT04870398). No changes were made to the study protocol after the study was initiated, except for the follow-up assessment timeframe, which was further extended to five instead of the initial plan of 4 years. The present study is single-centre, parallel-group RCT. The study began in January 2017 and recruitment was completed in 2022.

Strict eligibility criteria were applied, according to which patients and relevant teeth were recruited. The criteria were as follows.

Inclusion criteria

- Patient age >10 years
- Written informed consent
- Noncontributory medical history
- Extremely deep caries extending to the pulp chamber
- Positive response to cold sensibility testing
- Presence of spontaneous pain, heightened or lingering response to thermal or electric pulp testing (EPT)
- No clinical signs of pulp necrosis such as swelling or presence of a sinus tract
- restorable and periodontally sound teeth.

Exclusion criteria

- Immature teeth
- Cariously involved teeth with no response to pulp sensibility tests
- No signs and symptoms of irreversible pulpitis
- Teeth with no evidence of bleeding after communication with the pulp chamber
- Teeth with the pulp chamber exposed to the oral environment
- Detection of periodontal pocket with a depth greater than 4 mm
- Teeth suspected for crack or incomplete crown fracture possibly responsible for pulp pathology
- No bleeding control
- Medically compromised patients.

Sample size calculation

Based on the results of prior research (Taha & Khazali, 2017) and expecting at least 80% success for the tested materials, and a difference of at least 16% in proportions between the materials, with 80% power and determining the level of statistical significance at 5%, the number of teeth in each group was determined to be 64, that is 128 in total. To account for participant loss to follow-up and potential small inequalities in treatment arms due to simple randomization and chance play, we finally enrolled 137 teeth in 123 patients.

Randomization/allocation concealment/blinding

We conducted a simple randomization procedure to allocate teeth in the study groups, using the web-based software of www.randomizer.org, with a 1:1 allocation ratio. Sequentially numbered, sealed, opaque envelopes were prepared before recruitment, with the identification number written on the outer side of the envelope before this was opened, to ensure allocation concealment. A secretary was responsible for the randomization procedure and implementation. Patients were blinded to the type of material

used for the treatment of their teeth. The operator could not be blinded during the study due to the nature of the intervention. Two experienced endodontists (more than 15 years of clinical experience) not related to the study, independently assessed the follow-up radiographs and were blinded to the capping material used in each case.

Data collection/preoperative clinical and radiographic examination

Demographic data such as age and sex and data regarding the tooth type and location were collected.

At the first appointment, the medical and dental history including the chief complaint were recorded and then clinical and radiographic examination took place. An accurate history of pain took to assess the severity of pain including the spontaneity or the lingering of pain after temperature stimulation and if there was sleep disturbance. The patients that met the inclusion criteria were informed in detail about the aims and scope of the study and those who gave their permission and signed the informed consent were enrolled with a unique identification number, following randomization.

Clinical examination initially consisted of a visual inspection of the caries lesion under an operating microscope (OPMI Pico Zeiss, Carl Zeiss Meditec AG), also evaluating the restorability of the tooth. Percussion and palpation tests were also performed as well as cold and electric pulp sensibility tests. Finally, a thorough periodontal examination took place evaluating the possibility of the existence of periodontal pockets, any attachment loss or increased mobility of the tooth. A clinical diagnosis indicating the establishment of irreversible pulpitis was set in all included cases based on the history of severe spontaneous or lingering pain to cold stimulus that was reproducible during a clinical examination.

The radiographic examination included preoperative periapical radiographs for all cases using the parallel cone technique.

Clinical intervention

All the procedures were carried out by the same experienced operator (GT, more than 15 years of clinical experience) and under an microscope using high magnification (14×, 21×). High-quality photographs were taken throughout the procedures. Profound local anaesthesia of the tooth and the surrounding tissues was achieved by using lidocaine with 1/80 000 epinephrine (Lignospan Special, Septodont). The tooth under treatment was isolated with a rubber dam and initial caries removal was performed using a sterile high-speed diamond bur. The deeper layers of caries were removed by using a series of different diameters sterile low-speed burs. After complete caries removal and pulp tissue exposure, the first cut of pulp tissue was performed using a new sterile high-speed diamond bur. After the inspection of the surgical field for residual caries, an irrigation of the cavity with NaOCl 1.5% took place for the removal of carious dentinal chips and the initial disinfection of the tissue and the cavity. For bleeding control, a moist cotton pellet with sodium hypochlorite was placed onto the pulp wound surface for 30 s. After the removal of the cotton pellet, irrigation with sterile saline took place and a sterile cotton pellet moist with sterile saline was gently placed over the pulp tissue for 2 min for final control of bleeding. If bleeding continued after the removal of the cotton pellet, a new irrigation with NaOCl 1.5% was conducted and a new sterile cotton pellet was placed over the pulp for another 1 min soaked again with sterile saline solution. In the case where bleeding continued after the removal of the new cotton pellet, a second cut of the pulp tissue was performed to reach a tissue free of inflammation and the previous procedure was repeated. If bleeding continued, the case was not considered eligible and full pulpotomy or root canal treatment was considered (at this stage the patient/tooth had not yet received the allocated intervention, no unique identification number was assigned and no envelop was used, since the treatment was not yet provided). Once haemostasis was achieved, a blood-filled homogenous tissue without dark or yellowish areas was considered essential for the placement of pulp capping material. All capping materials were prepared according to the manufacturers' instructions. After the placement of each material, a light-curing resin-modified $Ca(OH)_2$ cavity liner (Ultrablend Plus, Ultradent Products) was placed over the capping material and a temporary material (Cavit G, 3M, ESPE) was used the seal the cavity. Following this, the patient returned to the referral dentist for the permanent restoration of the tooth. A telephone communication was scheduled with the patient after each day for a week in order to get information about the clinical condition of the tooth, the pain relief and the anti-inflammatory drugs used postoperatively. In case of severe pain persisting 1 week after the intervention, the patient was scheduled for root canal treatment and the case was recorded as an immediate clinical failure and the date of failure was recorded.

Recall protocol

Follow-up clinical and radiographic examinations had been initially scheduled at 3 months after the intervention and switched to 6-month interval thereafter for the first 2 years. However, due to the pandemic difficulties, an irregular

follow-up examination took place and when symptoms appeared, a prompt appointment for examination was also scheduled. Initially, dental history was obtained, including possible pain experience or pain and discomfort during mastication as well as documentation of the functionality of the tooth. The teeth were also clinically examined for signs and symptoms such as pain or discomfort during percussion, swelling or sinus tract, presence of periodontal pocket and absence of positive response to cold testing. Radiographic examination included the assessment of periapical status, the formation of calcified dentinal bridge beneath the capping material as well as the possible presence of internal resorption or root canal obliteration. Finally, the quality of coronal restoration was assessed clinically and radiographically. Two calibrated and experienced endodontists with more than 12 years of clinical experience evaluated radiographically all the cases. Any minor disagreements between the evaluators were resolved through discussion until a consensus was reached.

Outcome measures

The primary outcome of the study was the survival of amputated pulp after its capping with either of the two tested materials. This was defined clinically in the absence of pathologic signs and symptoms such as spontaneous or lingering pain, tenderness to percussion and swelling as well as the response to cold sensibility test. Radiographically, assessment of the periapical tissues was conducted. If periapical tissues were normal preoperatively, then they were expected to be normal in postintervention follow-up. If a periapical radiolucency was present preoperatively, then a complete healing of periapical tissues was expected. Under the above conditions, the cases were considered successful. If a case presented severe spontaneous or lingering pain, tenderness or pain to percussion, swelling or sinus tract with the persistence of periapical lesion or the emergence of a new one, then it was considered as a failure.

The secondary outcome measure was immediate postoperative pain. The assessment took place in the recall examination of each patient 1 week postoperatively. Patients were asked if they experienced or not pain postoperatively, they were asked to rate pain [according to the Visual Analogue Scale (VAS) scale], and also about the duration and the characteristics of the pain and any anti-inflammatory drugs needed for pain control.

Statistical analysis

Continuous data were checked for normality of residual distribution through the Shapiro–Wilk tests and visually through q–q plots. Descriptive statistics with cross-tabulations were also performed. Baseline characteristics of the sample were tabulated and frequency distributions were presented for all preoperatively examined variables (sex, age, type of tooth, caries location, type of caries, pain symptoms, pain reporting as per VAS scale, objective findings, sensibility to cold and EPT, presence of lesion, widening of ligament space and pain duration), as well as for variables examined during the procedure of pulp capping or postoperatively (timing for bleeding control in minutes, pain reporting through VAS, pain duration and use of analgesic/anti-inflammatory drugs), separately by capping material (MTA Angelus or Total Fill BC), or jointly. In addition, descriptive characteristics of the sample at the end of the assessment period (for the time each unit of analysis contributed to the data) were presented for the following variables: integrity of periapical tissues, dentinal bridge formation, pulp chamber or canal obliteration, sensibility to cold and EPT, quality of restoration, crown discoluoration and tooth functionality.

For the primary outcome (failure/success of treatment), the Kaplan–Meier survival curves for the capping materials were plotted and a log-rank test for equality of survivor functions was applied. As more than one teeth contributed to the sample analysed, we used a multilevel approach to account for clustering. The random effects parameter was the patient unit, which represents cluster variability. A multivariable random effects Cox Regression model, using the date of entry to the study as the timeline, was built to map the effect of intervention (MTA Angelus vs. Total Fill BC) on the outcome. A number of predefined variables were also tested (age of patients, caries location, type of caries, objective findings, time of bleeding control). Any tooth reaching the 5-year follow-up without presenting the outcome (i.e., failure), was considered censored and did not contribute further (end-of-study censoring). The proportional hazards assumption was checked through the Nelson Aalen plot for log cumulative hazard by type of capping material.

For the secondary outcome (postoperatively reported pain according to the VAS scale), a multivariable mixed effects ordinal logistic regression was structured, to examine the effect of intervention (MTA Angelus vs. Total Fill) on pain. Additional pre-defined variables comprised age, preoperative pain, objective findings and time of bleeding control.

A two-sided p-value of .05 was used to determine statistical significance for all analyses, along with 95% confidence intervals (CIs). All the analyses were performed using STATA version 15.1 software (Stata Corporation), following an intention-to-treat approach.

RESULTS

A total of 123 patients were recruited and followed after randomization, 74 (60.2%) females and 49 (39.8%) males, with a median overall age of 36 years (interquartile range, IQR: 21). The total number of teeth included and randomized were 137, 74 (54.0%) subject to MTA Angelus treatment and 63 (46.0%) received Total Fill BC (Figure 1). The overall number of failures of the treatment procedures jointly was 19, 8 (42.1%) in the

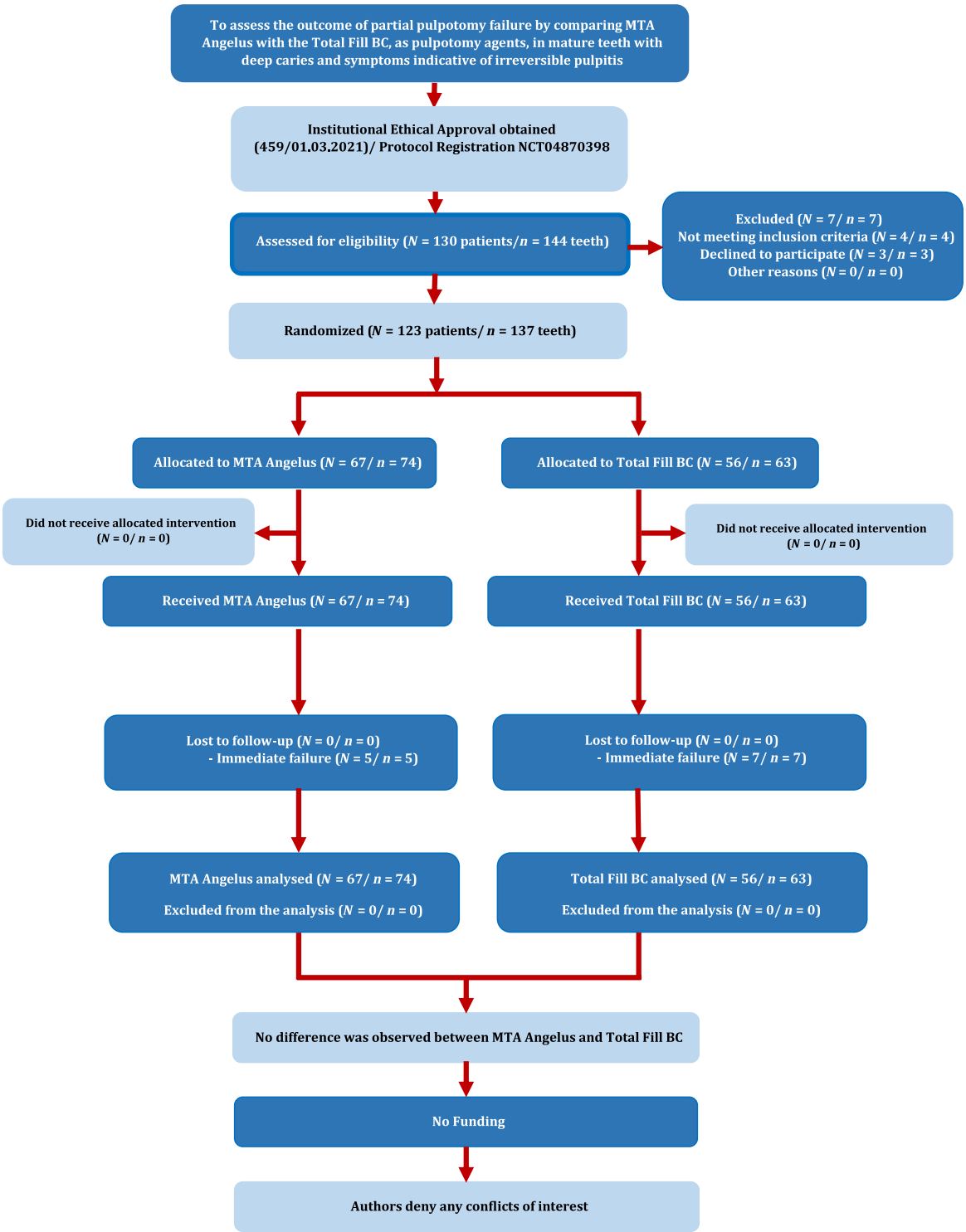

FIGURE 1 PRIRATE 2020 Flowchart of patient/teeth recruitment, randomization and postrandomization follow-up.

MTA Angelus group and 11 (57.8%) in the Total Fill BC group. The percentage failure for MTA Angelus and Total Fill BC was 10.8% (8/74) and 17.5% (11/63), respectively. Twelve out of 19 teeth presented an immediate failure, within a week after treatment. Most teeth included were molars (109/137; 79.6%), with a proximal caries location (97/137; 70.8%). The type of caries the included teeth presented was almost evenly distributed to primary (65/137; 47.4%) and secondary (72/137; 52.6%). Most patients reported spontaneous pain for the teeth included (97/137; 70.8%), while the remaining patients (40/137; 29.2%) reported lingering pain to a cold stimulus. Pain to cold (122/137; 89.1%) was the main finding during clinical examination while in some cases this was also followed by pain to percussion (15/137; 10.9%). The most prevalent patterns of pain prior to treatment, according to the 10 scale VAS assessment were values 7 (64/137; 46.7%) and 8 (44/137; 32.1%). In most of the included teeth, there was no periapical lesion identified upon radiographic examination (128/137; 93.4%), while in more than half, widening of the ligament space was detected (81/137; 59.1%). There was a median of 2 days (IQR: 1) duration of pain prior to the visit, while the procedural time for bleeding control averaged 4.25 min (standard deviation, SD: 1.25). Postoperatively, most patients reported pain intensity at level 3 according to VAS (55/137; 40.1%), pain duration for a median of 2 days (IQR: 2) and also use of analgesic/anti-inflammatory drugs (103/137; 75.2%; Table 1). Patients and respective teeth were followed for a median of 2 years (IQR: 1.6–2.4), with a maximum observation period of 5.0 years and a minimum time of case contribution to the trial—with the exclusion of the 12 immediate failure cases—0.3 years. By treatment group, the median follow-up time was 2.1 years (IQR: 1.8–2.8) for the MTA Angelus group and 1.9 years (IQR: 1.6–2.3) for the Total Fill BC group. End-of-study censoring was documented solely in one case which reached the 5-year follow-up free of outcome (failure). The overall time at risk for the sample was 275.3 years, breaking down to 167.6 years for the MTA Angelus group and 107.7 years for the Total Fill BC, with a total incidence (failure) rate of 0.07. All the failures were distributed within the first 6 months for the MTA Angelus group, whereas extended to more than 1.5 years post-treatment for the Total Fill BC group (Figure 2).

At the end of the assessment period, considering the last day of assessment of each tooth, after excluding the 12 cases that presented immediate failure and could not be prospectively assessed for over a week, most teeth examined demonstrated normal periapical tissues (115/125; 92%), signs of dentinal bridge formation (102/125; 81.6%), as well as no signs of pulp canal

TABLE 1 Demographic characteristics of the sample (tooth is unit of analysis, unless otherwise stated), by capping material [$n = 137$ teeth, in $N = 123$ patients].

	Capping material		Total
	MTA *n* (%)	Total fill BC *n* (%)	*n* 100%
Sex[a]			
Female	39 (52.7)	35 (47.3)	74
Male	28 (57.1)	21 (42.9)	49
Total	67 (54.5)	56 (45.5)	123
Age[a] in median [interquartile range, IQR]	34 [24]	38 [19.5]	36 [21]
Tooth type			
Anterior	1 (20.0)	4 (80.0)	5
Premolar	9 (39.1)	14 (60.9)	23
Molar	64 (58.7)	45 (41.3)	109
Primary outcome			
Success	66 (55.9)	52 (44.1)	118
Failure	8 (42.1)	11 (57.8)	19
Total	74 (54.0)	63 (46.0)	137
Preoperative signs and symptoms [categorical data]			
Caries location			
Occlusal	22 (55.0)	18 (45.0)	40
Proximal	52 (53.6)	45 (46.4)	97
Type of caries			
Primary	34 (52.3)	31 (47.7)	65
Secondary	40 (55.6)	32 (44.4)	72
Pain symptoms			
Spontaneous	56 (57.7)	41 (42.3)	97
Lingering	18 (45.0)	22 (55.0)	40
Reporting of pain (VAS scale 1–10)			
4	2 (100.0)	0 (0.0)	2
5	1 (100.0)	0 (0.0)	1
6	18 (75.0)	6 (25.0)	24
7	31 (48.4)	33 (51.6)	64
8	20 (45.5)	24 (54.5)	44
9	2 (100.0)	0 (0.0)	2
Objective findings			
Pain to cold	63 (51.6)	59 (48.4)	122
Pain to cold plus percussion	11 (73.3)	4 (26.7)	15
Preoperative sensibility (cold)			
Yes++	21 (51.2)	20 (48.8)	41
Yes+++	53 (55.2)	43 (44.8)	96
Preoperative sensibility (EPT)			
Yes++	27 (39.7)	41 (60.3)	68
Yes+++	47 (68.1)	22 (31.9)	69
Widening of ligament space			
No	27 (48.2)	29 (51.8)	56
Yes	47 (58.0)	34 (42.0)	81

TABLE 1 (Continued)

	Capping material		Total
	MTA *n* (%)	Total fill BC *n* (%)	*n* 100%
Periapical lesion			
No	66 (51.6)	62 (48.4)	128
Yes	8 (88.9)	1 (11.1)	9
Preoperative or during procedure Signs and Symptoms [Continuous data] Mean (standard deviation, SD) or Median [interquartile range, IQR]			
Pain duration (in days)	Median 2 [IQR: 1]	Median 2 [IQR: 1]	Median 2 [IQR: 1]
Time for bleeding control during procedure (in minutes)	Mean 4.16 (SD: 1.34)	Mean 4.36 (SD: 1.15)	Mean 4.25 (SD: 1.25)
Postoperative symptoms [categorical data]			
Reporting of pain (VAS scale 1–10)			
0	19 (79.2)	5 (20.8)	24
1	17 (56.7)	13 (43.3)	30
2	31 (56.4)	24 (43.6)	55
3	5 (27.8)	13 (72.2)	18
4	2 (22.2)	7 (77.8)	9
5	0 (0.0)	1 (100.0)	1
Analgesic/Anti-inflammatory drug use			
0	23 (67.7)	11 (32.3)	34
1	51 (49.5)	52 (50.5)	103
Postoperative signs and symptoms [continuous data] Median [interquartile range, IQR]			
Pain duration (in days)	Median 1 [IQR: 3]	Median 2 [IQR: 1]	Median 2 [IQR: 2]

[a]Patient is the unit of analysis ($N = 123$).

obliteration (102/125; 81.6%). Response to EPT was negative in 66 out of 125 teeth (52.8%) and showed mild positive reaction in 56/125 (44.8%). Quality of permanent restoration was adequate in almost all teeth (123/125; 98.4%), while crown discolouration was detected in 16 teeth (16/125; 12.8%), all of which had a successful treatment outcome. Tooth functionality was normal in all cases that presented a successful treatment outcome (118/125; 94.4%; Table 2).

Figure 3 shows the survival probabilities by capping material, based on the Kaplan–Meier estimates. No significant differences were observed between the materials (log-rank test: $p = .27$). Likewise, the multivariable Cox regression model did not reveal evidence of a difference in hazard for tooth failure between the groups (MTA Angelus vs. Total Fill BC, adjusted HR: 1.83; 95% CI: 0.68, 4.91; $p = .23$). We further found scarce evidence that secondary caries under an already existing restoration may impose 3.54 times greater hazard for treatment failure (adjusted HR: 3.54; 95% CI: 1.00, 12.51; $p = .05$). There was also weak evidence that with each passing minute of procedural bleeding control, there was 57% higher hazard for treatment failure (adjusted HR: 1.57; 95% CI: 0.99, 2.48; $p = .05$; Table 3).

With regard to postoperatively reported pain by the patients, the odds for higher pain values in VAS scale compared to lower were 4.73 times greater for the Total Fill BC compared with the MTA Angelus (adjusted OR: 4.73; 95% CI: 2.31, 9.66; $p < .001$). Similarly, for a minute increase in procedural time for bleeding control, the odds of higher pain values on the VAS scale compared to lower were 3.05 times higher (adjusted OR: 3.05; 95% CI: 2.14, 4.35; $p < .001$). There was no significant effect identified for age, preoperatively reported pain and objective findings ($p > .05$ in all instances; Table 4). Representative images of the cases are illustrated in Figures 4–11.

DISCUSSION

The present study was conducted with the aim to evaluate the clinical and radiographic outcome of partial pulpotomy by comparing a recently introduced bioceramic material (Total Fill BC) with a commonly used MTA brand as is the case for MTA Angelus. To our knowledge, it is the first trial on partial pulpotomy which was conducted solely in mature teeth with symptoms of irreversible pulpitis. As already reported, previous similar studies included either both mature and immature teeth or teeth both with reversible and irreversible pulpitis (Asgary et al., 2018; Uesrichai et al., 2019).

Two calcium silicate materials were examined for their ability to perform when placed over an amputated pulp with preoperative symptoms of irreversible pulpitis. The Total Fill material is basically used for the first time under the present settings for partial pulpotomy; so far, only one study investigating the outcome of full pulpotomy has assessed the ability of the material to maintain the vitality of radicular pulp (Taha et al., 2022). As far as MTA Angelus is concerned, the rationale for its selection was based on its wide utilization and its reference standards. Secondly, it has been reported to cause a variable degree of crown discolouration and from a clinical point of view, any additional assessment in this respect could have been of interest. Under the settings of the present trial, the material was placed within the appropriate thickness and thoroughly cleaned from the axial walls. As such, the findings of the present study showed that only 13 teeth from the MTA Angelus group exhibited a slight degree of crown discolouration, as it was revealed during the clinical follow-up examinations. Speculations may thus exist on the impact of the way of its placement and the cleaning process of the material from the axial internal surfaces of the teeth.

The overall percentage success rate of partial pulpotomy was 86.1%. Both capping materials exhibited high

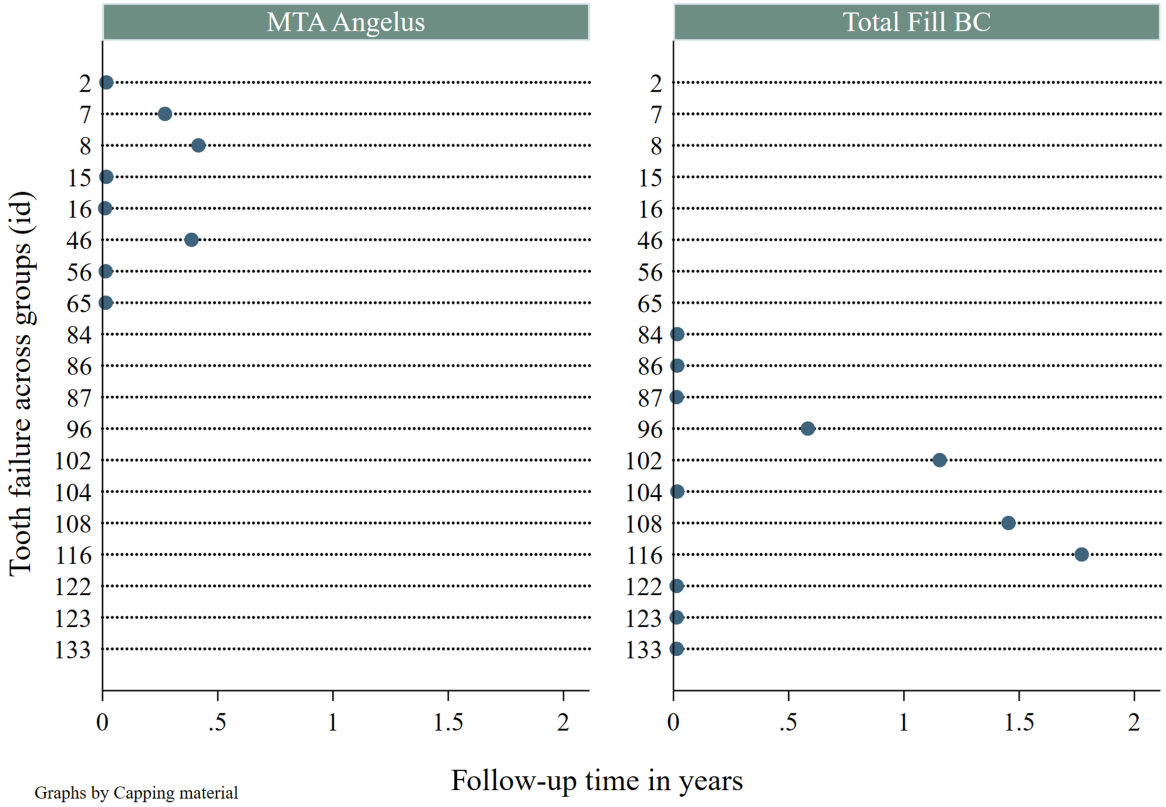

FIGURE 2 Dot-plot indicating failure experience across time, by capping material.

and comparable successful outcomes, 89.2% for MTA Angelus and 82.5% for Total Fill BC with no significant differences between them. These results are in accordance with previous findings for ProRoot MTA by Taha and Khazali (2017) and Biodentine by Jassal et al. (2023) who described successful outcomes in 85% and 88% in similar cases, respectively. However, such percentages are higher compared to those mentioned by Careddu and Duncan (2021) and Baranwal et al. (2022) who reported a successful outcome in the percentage range of 78% to 80% for Biodentine in cases of irreversible pulpitis. Regarding Total Fill BC, a recent trial on full pulpotomy reported a 91.9% success, which is higher compared to the finding of the present study (Taha et al., 2022). No other treatment effect comparison may be made on partial pulpotomy performed with Total Fill so far, since there is no previous evidence in the field.

Regarding the secondary outcome of the study which was the presence and the intensity of postoperative pain, a significant difference was observed in favour of MTA Angelus compared to Total Fill BC. More specifically, we identified 4.73 times greater odds for higher postoperative pain values in the Total Fill group compared to MTA Angelus. This finding is reported for the first time in studies of VPT. In cases of irreversible pulpitis, an immediate decrease in pain levels or the complete elimination of preoperative pain is of great importance for the patients, since preoperative pain is normally of high intensity. It is worth noting that most of the patients in the present study mentioned a significant reduction of pain postoperatively with a median value of level 3 on the VAS scale. In this respect, we have strong evidence to support that partial pulpotomy significantly reduced the levels of preoperative pain in cases with symptoms of irreversible pulpitis treated with MTA Angelus.

Another interesting finding was the impact of the time of bleeding control on the primary and secondary outcomes of pulpotomy. First, weak evidence was identified that with each passing minute of procedural bleeding control, there was an increased hazard of treatment failure. Despite weak evidence for this finding, this is the first time, a clinical trial reports timing of bleeding control and cross-linking with a negative expected outcome of partial pulpotomy. In the present study, the overall mean time for bleeding control was 4.25 min overall, with a more prolonged duration for the Total Fill group. One might consider this as indicative of a more advanced stage of irreversible pulpitis, a fact that might possibly justify the arithmetically higher number of failures for Total Fill recorded. The impact on postoperative pain was more pronounced if bleeding control was prolonged. Further studies are needed in this respect to provide evidence of confirmatory findings.

Increased level of pulp irritation due to secondary caries under a permanent restoration appeared as a weak

TABLE 2 Descriptive characteristics (signs and symptoms) of the sample (tooth is unit of analysis) at the end of the assessment period (final evaluation).

	Capping material	Total	
	MTA *n* (%)	Total fill BC *n* (%)	*n* 100%
Periapical tissues			
Not normal	5 (50.0)	5 (50.0)	10
Normal	64 (55.7)	51 (44.3)	115
Dentinal bridge formation			
No	11 (47.8)	12 (52.2)	23
Yes	58 (56.9)	44 (43.1)	102
Pulpal obliteration			
No	55 (53.9)	47 (46.1)	102
Partially	14 (60.9)	9 (39.1)	23
Sensibility (cold)			
No	48 (53.3)	42 (46.7)	90
Yes+	19 (61.3)	12 (38.7)	31
Yes+++	2 (50.0)	2 (50.0)	4
Sensibility (EPT)			
No	37 (56.1)	29 (43.9)	66
Yes+	30 (53.6)	26 (46.4)	56
Yes+++	2 (66.7)	1 (33.3)	3
Quality of restoration			
Inadequate	2 (100.0)	0 (0.0)	2
Adequate	67 (54.5)	56 (45.5)	123
Crown discolouration			
No	56 (51.4)	53 (48.6)	109
Yes	13 (81.3)	3 (18.7)	16
Tooth functionality			
Not normal-pain	3 (42.9)	4 (57.1)	7
Normal	66 (55.9)	52 (44.1)	118
Total	69 (55.2)	56 (44.8)	125

Note: Teeth that presented immediate failure (procedure failed within a week), were not included ($n = 125$).

indicator for increased hazard for treatment failure. The presence and extent of secondary caries should be assessed with caution and management of vital mature teeth with symptoms of irreversible pulpitis might represent a scenario where the clinical decision to undertake vital pulp treatment might be considered complicated in the absence of other evidence. In any case, clinical observation of the inflammatory pulp tissue is of paramount importance.

A major effort was made in the present study to provide a long-term follow-up examination for both materials tested. For this reason, a median follow-up period of 2 years was recorded overall. Two years follow-up has been suggested as an adequate timeframe for pulpotomy using MTA (Simon et al., 2013), and failures tended to occur within this timeframe. Indeed, in the present study, all failures took place within the first 2 years, irrespective of individual variability in lengthier follow-up times. Of the 12 immediate failures, five occurred in the MTA Angelus group, whereas the remaining seven were recorded in the Total Fill BC group. However, it should be noted that all MTA Angelus failures occurred within the first 6 months, while failures for the Total Fill BC group extended to more than after 1.5 years. This is certainly an interesting finding if one considers that most of the failures described regarding VPT are anticipated to occur within the first months following the treatment procedure. Late failures are considered less acceptable compared to early failures and may be associated with two critical factors. First, with the inability of the capping material to maintain a stable and robust environment for the pulp vitality and health in the long-term; and second, with the quality of the permanent restoration and its ability to prevent bacterial reinfection (Tan et al., 2020). The type of coronal permanent restoration has been shown to be a potential predictor for late failure. In a relevant pulpotomy study, 77.8% of the restorations in the failure group were classified to be unsatisfactory (Demarco et al., 2005). In addition, in a recent study by Tan et al. (2020), teeth that underwent pulpotomy and were restored with glass ionomer cement were associated with a greater risk of a need for further intervention (Tan et al., 2020). However, it should be noted that of a total of 61 included teeth, only three were permanently restored with glass ionomer cement, and one of those was lost to follow-up after the first recall examination (Tan et al., 2020). Nevertheless, when the quality of permanent restoration is sufficient, then, the clinical efficiency of the capping material remains to be checked. In the present study, no association could be documented between the quality of the permanent restoration and the outcome of partial pulpotomy as the quality of coronal restorations was judged clinically and radiographically as adequate in almost all cases. Out of the nine cases in which the restorations were considered inadequate, only two failed, while the remaining were deemed successful after the replacement of the defective restorations following the first recall examination.

Age had been traditionally considered to play an important role in the outcome of VPT. This is because most of the vital pulp studies generally included young patients (Barrieshi-Nusair & Qudeimat, 2006; Mejare & Cvek, 1993; Qudeimat et al., 2007). In the present study, the median overall age of the patients included was 36 years. The results did not reveal any significant association between the patient's age and the outcome of partial pulpotomy.

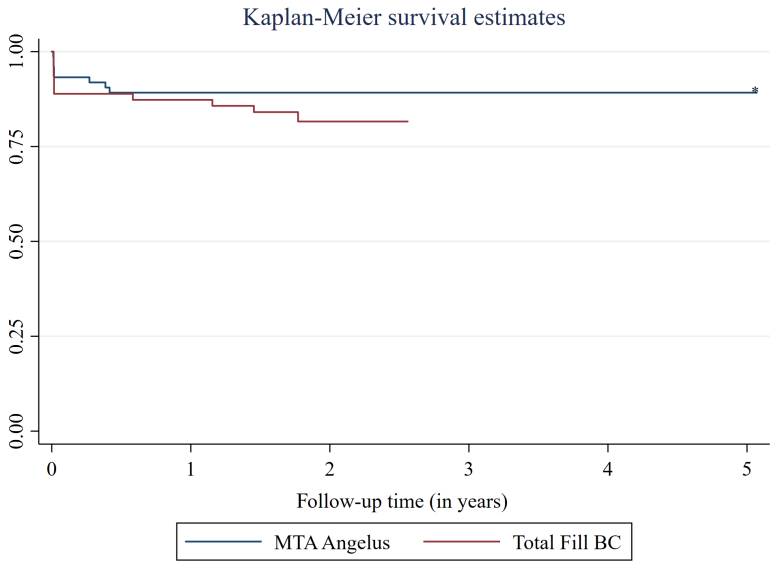

FIGURE 3 Cumulative the survival probabilities by capping material, based on the Kaplan–Meier estimates.

TABLE 3 Multivariable random effects Cox regression model for the effect of capping material, age, caries location, type of caries, objective findings and procedural time of bleeding control, on treatment outcome (failure vs. success), with respective Hazard Ratios (HRs) and 95% Confidence Intervals (CIs).

	HR	95% CI	*p*-value
Capping material			
MTA angelus	Reference		
Total fill BC	1.83	0.68, 4.91	.23
Age			
Per unit	1.03	0.99, 1.08	.15
Caries location			
Occlusal	Reference		
Proximal	2.58	0.96, 6.93	.06
Type of caries			
Primary	Reference		
Secondary	3.54	1.00, 12.51	.05
Objective findings			
Pain to cold	Reference		
Pain to cold + percussion	2.40	0.71, 8.11	.16
Time of bleeding control			
Per unit	1.57	0.99, 2.48	.05

TABLE 4 Multivariable mixed effects ordinal logistic regression for the effect of capping material, age, preoperative reported pain, objective findings and procedural time of bleeding control, on postoperative patient reported pain (VAS scale), with respective Odds Ratios (OR) and 95% Confidence Intervals (CIs).

	OR	95% CI	*p*-value
Capping material			
MTA angelus	Reference		
Total fill BC	4.73	2.31, 9.66	<.001
Age			
Per unit	1.00	0.98, 1.03	.85
Pre-operative pain (VAS)			
Per unit	1.27	0.82, 1.97	.28
Objective findings			
Pain to cold	Reference		
Pain to cold + percussion	2.68	0.85, 8.41	.09
Time of bleeding control			
Per unit	3.05	2.14, 4.35	<.001

This agrees both with the results of a similar randomized clinical trial which concluded that age was not a prognostic factor related to the success rate of partial pulpotomy (Kang et al., 2017), and of a recent systematic review including patients aged between 6 and 52 years (Elmsmari et al., 2019).

In a similar way to age, preoperative pain did not appear as a significant predictor, one that might potentially impact in the outcome of partial pulpotomy. In all cases of the present study, a spontaneous or lingering pain to cold stimulus was present at the time of the first appointment. These two types of pain have been generally described as the two major clinical signs of irreversible pulpitis (Bergenholtz & Spangberg, 2004). The intensity of the pain was recorded during the study, but this appears not to influence the results of partial pulpotomy. We could suggest this is a reasonable finding since severe preoperative pain does not necessarily demonstrate that pulp may not be capable of surviving and eventually healing (Ricucci et al., 2014, 2019; Taha et al., 2017). Several studies that examined histologically teeth with symptoms of irreversible pulpitis have shown that in some cases, inflammation

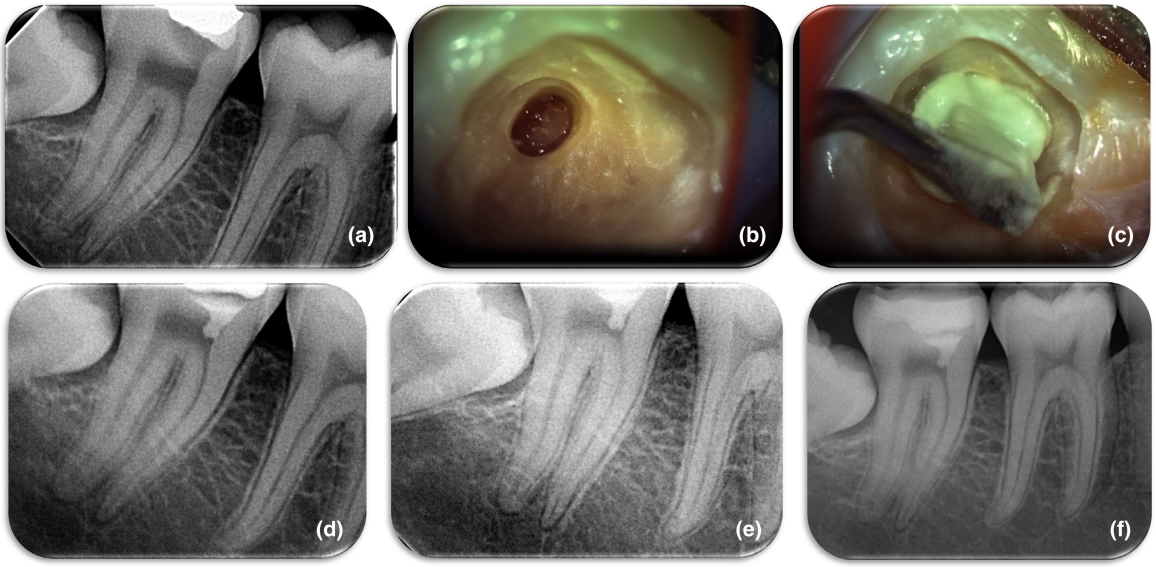

FIGURE 4 (a) Initial radiograph of a mature second mandibular molar of a 17-year-old patient. Note the extremely deep caries under the permanent restoration and the widening of periodontal ligament space, (b) complete caries removal and first communication with the pulp chamber. Note the pulp stone inside the mass of the tissue, the stone has to be removed, (c) placement of MTA Angelus as pulp capping material, (d) postoperative radiograph of the case, (e) 6-month recall radiograph, (f) 24-month recall radiograph, note that the widening of periodontal ligament space has been resolved.

was confined to the small area of the coronal pulp close to the carious lesion and does not extend more than 2 mm from the site of carious exposure (Ricucci et al., 2019; Seltzer et al., 1963). It has also been reported that small areas of tissue necrosis may be detected at the exposure site, however vital and healthy tissue may be detected beneath the inflamed area (Ricucci et al., 2019). The above histological observations have been confirmed by the findings of vital therapy studies which have been conducted including in their sample teeth with signs of irreversible pulpitis, presenting satisfactory outcome rates (Asgary & Eghbal, 2013; Eghbal et al., 2009; Kumar et al., 2016; Qudeimat et al., 2017; Taha & Abdelkhader, 2018a; Taha & Khazali, 2017; Uesrichai et al., 2019).

An interesting controversy in pulpotomy studies has been the pulpal wound lavage. So far, saline solution, sodium hypochlorite and chlorhexidine have been used to disinfect the pulp wound and to control bleeding (Ballal et al., 2020; Bjorndal et al., 2010). However, the possible impact of the irrigant used during the procedure has not yet been clearly clarified. A recent systematic review investigating the pulp wound lavage in VPT studies after carious exposures concluded that 14 out of the 27 included studies used sodium hypochlorite, whereas 10 used only saline or water (Munir et al., 2020). In addition, one trial compared pulp wound lavage with 2.5% sodium hypochlorite to saline while another compared 5% glutaraldehyde to water, both in immature molar pulpotomies (Munir et al., 2020). The authors identified that sodium hypochlorite is used mainly in more recent publications. A randomized trial on partial pulpotomy of 80 immature molars compared two different pulp lavage methods using 2.5% sodium hypochlorite or 0.9% sterile saline and found no significant differences in the outcome of partial pulpotomy after 24 months of follow-up examination (Ozgur et al., 2017). However, it should be noted that in the group of 2.5% sodium hypochlorite plus MTA, the success rate was 94.4%, whereas the respective proportion in the group of 0.9% sterile saline plus MTA was 100% (Ozgur et al., 2017). On the other hand, a significant difference in the outcome of direct pulp capping was observed between the two mentioned lavage methods in the study of Ballal et al. (2022). After 12 months of follow-up examination, the authors reported 55% survival rate in the group of physiologic saline solution and 89% in the group of 2.5% of sodium hypochlorite, thus concluding that sodium hypochlorite lavage considerably improved the survival time of caries exposed and directly capped pulps (Ballal et al., 2022). In the present study, a combined method was used for pulp would lavage. Irrigation with 1.5% of sodium hypochlorite was initially used for the removal of carious dentin chips. For bleeding control, a moist cotton pellet with sodium hypochlorite was placed onto the pulp wound surface for 30 s followed by an irrigation with sterile saline solution. Then, a new cotton pellet soaked with sterile saline was used for the final control of bleeding. The rationale of the procedure followed in the present clinical trial was framed under the notion of avoiding leaving residual sodium hypochlorite on the pulp surface. Any further breakdown of the sample to assign teeth to different types of lavage

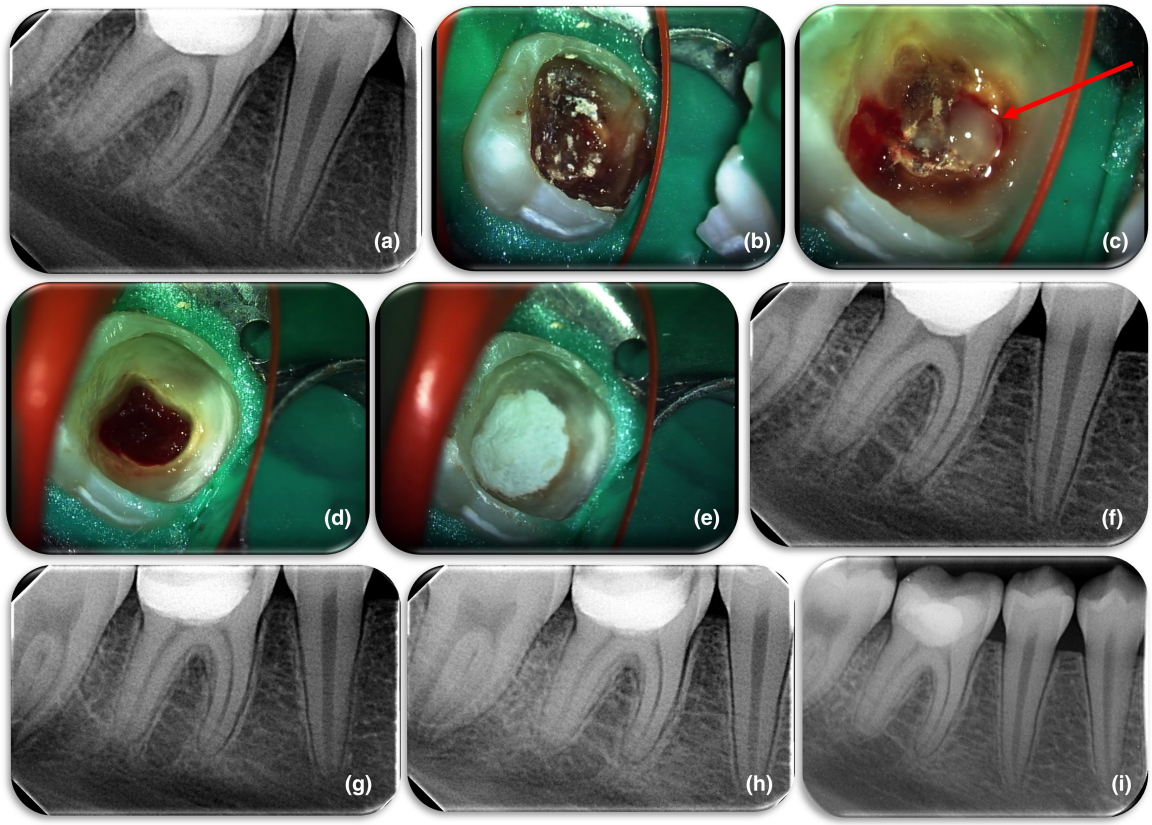

FIGURE 5 (a) Initial radiograph of a mature first mandibular molar of a 16-year-old patient with periapical lesion in both roots, (b) initial clinical figure of the tooth and caries after appropriate isolation, (c) pus drainage after communication with pulp chamber during caries removal, (d) complete caries removal and adequate control of bleeding after pulpotomy, (e) appropriate placement of MTA Angelus over the remaining coronal pulp tissue, (f) postoperative radiograph. (g) 6-month recall radiograph. Note the inadequate margins of the permanent coronal restoration (h). 12-month recall radiograph. The inadequate restoration has not been replaced (i). 30-month recall radiograph, no lesions are present and complete periapical healing has occurred, fortunately, a new sufficient restoration is in place.

methods was out of the scope of the present study and would cause unnecessary subgrouping, leading to loss of power of the study to detect any interarm differences attributed to the interventions *per se*.

Although one might speculate that a single-operator approach governing the clinical procedure might induce a potentially limited generalizability, we consider the methodology of our study in this respect also a unique strength for the following reasoning: all the cases were managed by a single experienced operator and under the use of high magnification and this is indicative of a high level of standardization of the procedure. A wide range of variability regarding the number and the experience of involved operators has been documented in VPT studies. Some of them have included several dentists (Asgary et al., 2018; Bjorndal et al., 2010; Kang et al., 2017; Kundzina et al., 2017), while others recruited postgraduate students for performing the vital pulp treatment procedure (Linsuwanont et al., 2017; Taha et al., 2022; Taha & Abdelkhader, 2018a, 2018b; Taha & Khazali, 2017). So far, six studies have been carried out by a single operator (Careddu & Duncan, 2021; Galani et al., 2017; Keswani et al., 2014; Nosrat et al., 2013; Qudeimat et al., 2017; Ramani et al., 2022). As previously discussed, this element gives an additional advantage to the findings of such studies, since the procedure is more calibrated and quite similar for all treated teeth. In addition, in most of the pulpotomy studies, it is not clear whether a magnification device was used for the visual inspection of the remaining pulp tissue. High magnification is critical during all stages of the pulpotomy procedure. Careful and universal removal of caries from the axial walls of the tooth and the bottom of the cavity, removal of residual caries from the site of exposure, careful first cut of the inflamed pulp tissue and visual inspection of the wound surface for the presence of white or extremely red areas of the tissue are some of the most substantial tasks that should ideally be performed by an experienced clinician under high magnification.

Dentinal bridge formation after the pulpotomy procedure is considered to be a significant indicator of a favourable outcome of partial pulpotomy (Duncan et al., 2022; Leye Benoist et al., 2012; Nosrat & Nosrat, 1998). This is

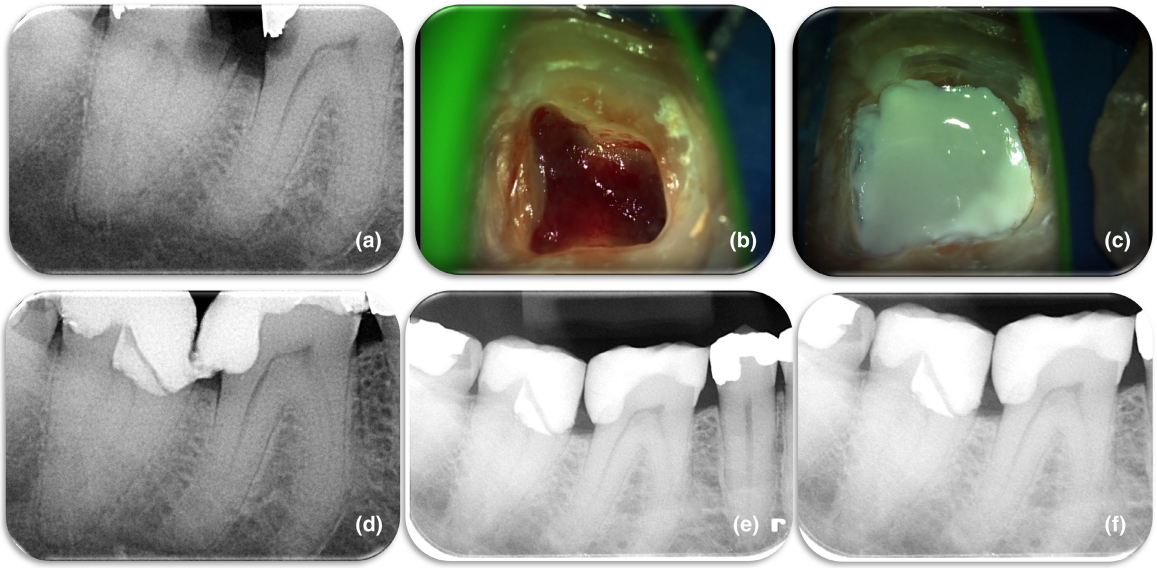

FIGURE 6 (a) Initial radiograph of a mature second mandibular molar of a 54-year-old patient with extremely deep caries and symptoms of lingering pain to cold stimulus. Deep caries is also present at the distal surface of the first molar (b). Control of bleeding, the tissue is ready for capping, (c) Placement of Total Fill BC over the coronal pulp tissue, (d) Postoperative radiograph of the case. Caries in first molar has been removed (e) 6-month recall radiograph, sufficient restorations have been placed in both teeth (f) 36-month recall radiograph, the patient is symptom free, and the teeth are fully functional.

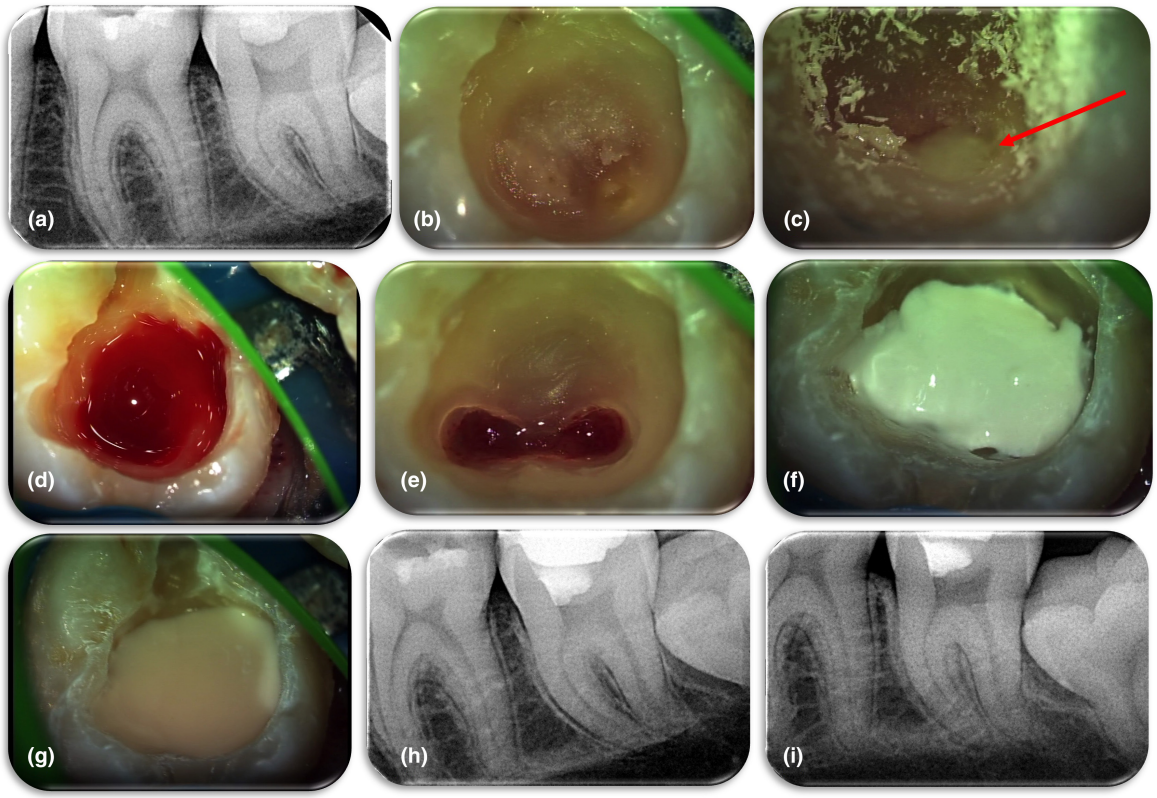

FIGURE 7 (a) Initial radiograph of a mature second mandibular molar of a 22-year-old patient with symptoms of spontaneous pain and sleep disturbance, (b) clinical figure of the tooth after partial caries removal (extremely deep caries under the permanent restoration), (c) Pus drainage after communication with pulp chamber during caries removal, (d) complete caries removal and sufficient control of bleeding, (e) placement of Total Fill BC over the coronal pulp tissue, (f) Postoperative radiograph of the case, (g) 36-month recall radiograph of the case, the patient is symptom-free, and the tooth is functional and responds normally to EPT.

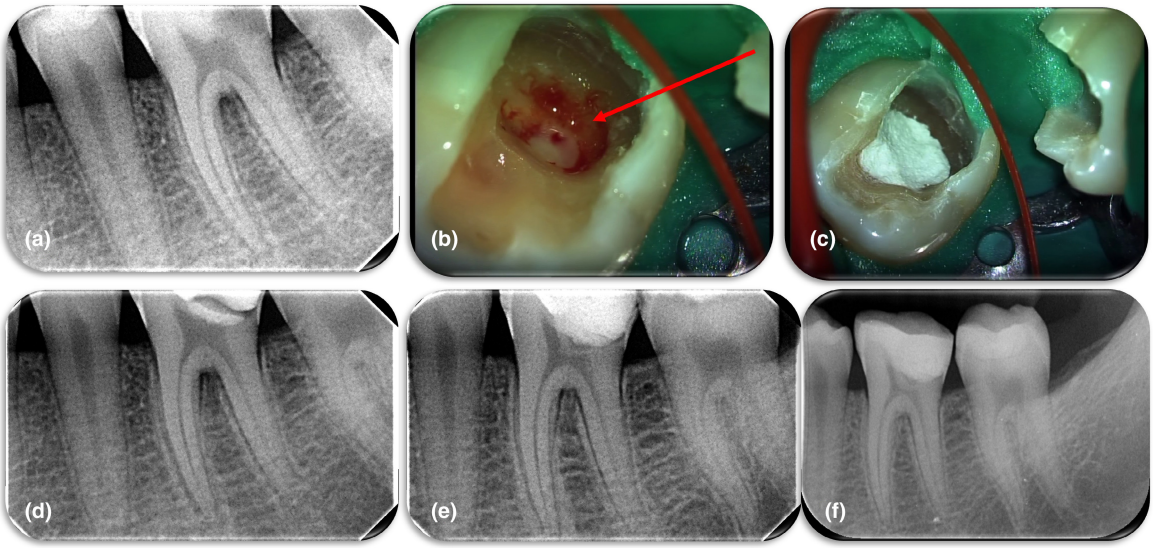

FIGURE 8 (a) Initial radiograph of a mature first mandibular molar of a 19-year-old patient with periapical lesion in mesial root, the patient take analgesics due to spontaneous pain, the tooth also presents pain to percussion, (b) Pus drainage after communication with pulp chamber during caries removal, (c) placement of MTA Angelus over the remaining coronal pulp tissue, (d) postoperative radiograph of the case, (e) 6-month recall radiograph. Formation of dentinal bridge is apparent, note however, the inadequate margins of permanent coronal restoration (f) 36-month recall radiograph. The inadequate restoration has been replaced with a new sufficient restoration. No lesions are present and complete periapical healing has occurred, a thick dentinal bridge has been completely developed.

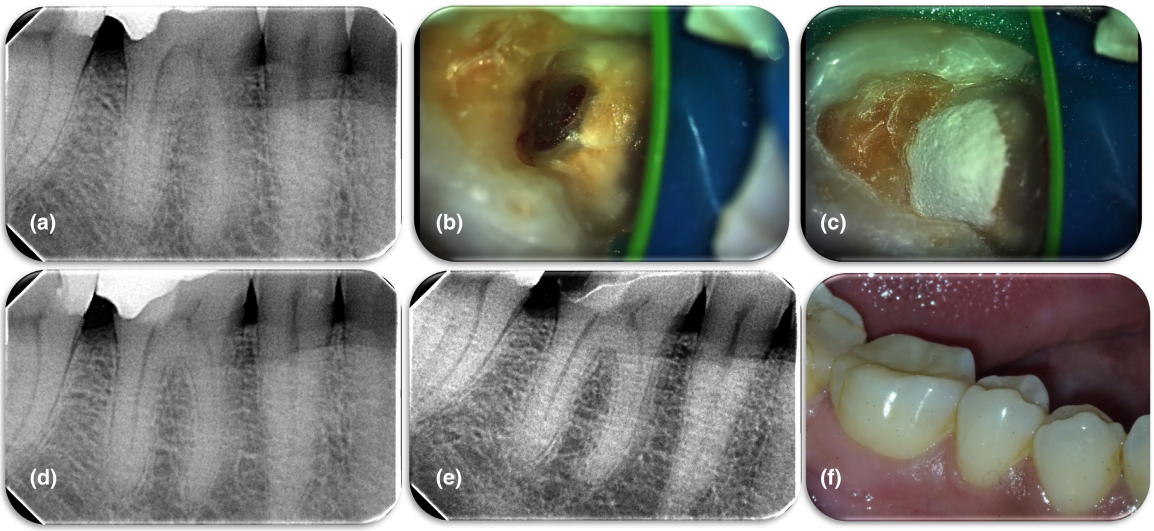

FIGURE 9 (a) Initial radiograph of a mature first mandibular molar of a 35-year-old patient with symptoms of lingering pain to cold stimulus, (b) clinical figure of the tooth after caries removal and communication with the pulp chamber, (c) placement of MTA Angelus over the coronal pulp tissue, (d) postoperative radiograph of the case. (e) 32-month recall radiograph. An onlay has been placed as permanent coronal restoration, (f) clinical figure of the tooth at 32-month recall examination, no crown discolouration is apparent.

because it demonstrates that the pulp remains vital underneath the capping material. In the present study, the formation of the dentinal bridge was observed in a total of 102 cases. A higher percentage was verified for MTA Angelus compared to Total Fill BC. In some cases, minor disagreements emerged between the evaluators, however, a consensus was reached in all cases after thoughtful discussion and consideration.

Response to EPT was achieved in almost half of the examined sample, irrespective of the intervention. This is an important finding since this constitutes a clinical sign of maintenance of pulp vitality. The response to EPT may also be considered a significant advantage of partial pulpotomy since an amount of coronal pulp tissue remains vital in the pulp chamber and may react to electric stimulus during follow-up examinations.

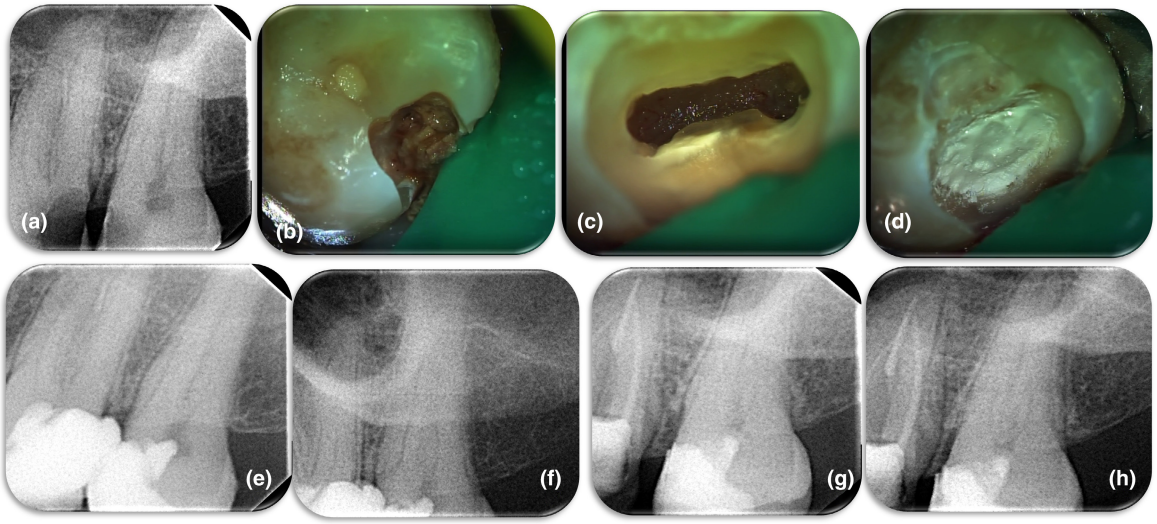

FIGURE 10 (a) Initial radiograph of a mature second mandibular molar of a 43-year-old patient with large caries at the mesial surface, the tooth is very sensitive to percussion, (b) clinical figure of the deep caries after tooth isolation, (c) clinical appearance of the pulp tissue after control of bleeding, (d) placement of Total Fill BC over the remaining coronal pulp tissue, (e, f) Postoperative radiographs of the case, (g, h) 24-month recall radiographs. Formation of dentinal bridge is apparent. Due to great length of the roots, two radiographs were considered essential for the evaluation of periapical tissues and coronal restoration.

A speculated limitation of the present study might be the fact that no actual control and standardization of the permanent restoration could be achieved since the patients returned to the referral dentists to complete the restoration after the pulpotomy procedure. However, this rather reflects a real case scenario, where patients are mostly referred to the endodontist by referral dentists; certainly, this cannot have an impact on the expected outcomes of the present study, due to the nature, design and sufficient sample of the present work. Furthermore, no cut-off point of bleeding control during the procedure was defined and used in the present trial; rather than that, bleeding control and timing was dictated by intraoperative examination of tissue inflammation and its control. Last, the procedure of simple randomization we followed, apparently resulted in small inequalities in the number of recruited units per arm due to chance. However, although a restricted randomization scheme could have eliminated these, one cannot consider such small differences likely to impact the overall power of the study, additionally due to the fact that the size of the overall sample is adequate. Generalisability of the findings of the present study follows the pre-established eligibility criteria, mostly defined by the signs and symptoms of irreversible pulpitis in mature teeth, while further research, multi-centre in nature might provide validation of the identified evidence in this respect.

In the end, some empirical observations are also reported and presented from a clinical standpoint, for mature teeth with signs and symptoms of irreversible pulpitis, treated with partial pulpotomy. First, no tooth that had spontaneous pain and the symptoms were alleviated by the cold stimulus was a viable candidate for partial or full pulpotomy as it was revealed after communication with the pulp chamber and the complete degeneration of the pulp tissue. Second, teeth with advanced symptoms may present with pus drainage after the first communication with the pulp chamber. The presence of pus evidently shows that irreversible pulpitis has been established in the pulp tissue and an area of pulp necrosis is present most probably at the upper layers of the tissue. However, pus drainage does not necessarily indicate that partial pulpotomy is not feasible as it is shown in cases of Figures 5, 7 and 8 of the present study. In such cases, a deeper cut is directly indicated to reach an area of pulp tissue free of inflammation. Third, if continuous bleeding was confirmed after the first effort of haemorrhage control, a second cut of the pulp tissue is indicated and should be immediately performed rather than a second effort of bleeding control. Fourth, if an area of pulp inflammation remains within the tissue but control of bleeding has been achieved, haemorrhage will be observed after the placement and compaction of the capping material. Then, the procedure should be repeated with a second cut of pulp tissue. In case of the MTA material, the blood is likely to perforate the mass of the material, whereas in case of the Total Fill an inflation of the material will be initially observed, under the microscope, probably due to the increased pressure of the underlying tissue and thereafter, the blood will perforate the material. This observation has not been noticed in cases of MTA.

In conclusion, the present study showed that partial pulpotomy may be a viable treatment option in some carefully selected caries exposed cases of mature teeth with symptoms of irreversible pulpitis. The survival rate is considered quite satisfactory, and it seems that time passage is in

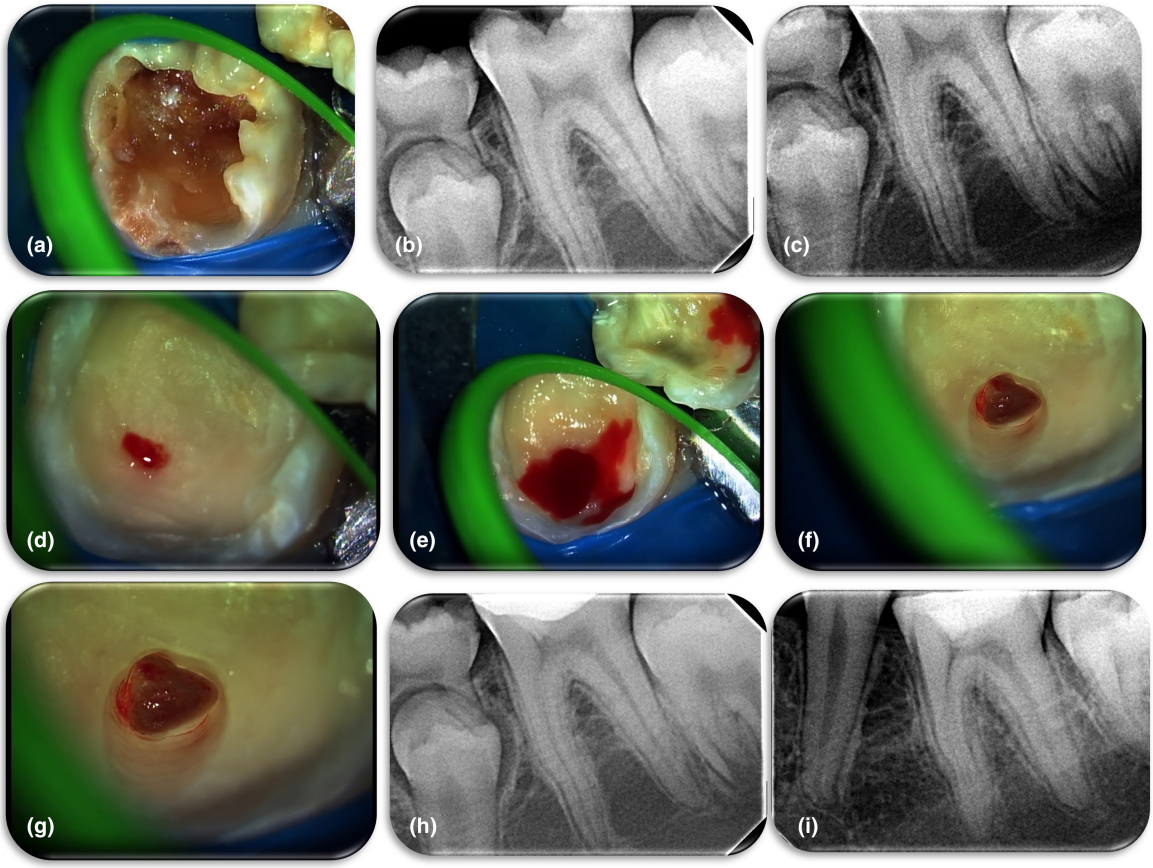

FIGURE 11 (a) Clinical figure of a deep caries in a left mature first mandibular molar of a 14-year-old patient after tooth isolation, (b, c) initial radiographs of the tooth for the evaluation of caries depth and the condition of periapical tissues, the patient take analgesics due to spontaneous pain and clinically the tooth presents pain to percussion, (d) extravasation of blood serum fluid after communication with the pulp chamber following complete caries removal, (e) excessive bleeding after the first cut of pulp tissue, (f, g) clinical appearance of the pulp tissue after control of bleeding (two different magnifications), (i) postoperative radiograph of the case with Total Fill BC in place over the coronal pulp tissue, (f) 24-month recall radiograph. Formation of a thick dentinal bridge is apparent.

favour of such cases if an adequate coronal restoration is present. During the present study, an attempt to standardize and evaluate all preoperative and intraoperative factors that could affect the procedure was made. Despite all difficulties encountered, the present study provides important evidence, gives answers to critical questions on partial pulpotomy and defines the conditions under which similar studies should be carried out in the future.

AUTHOR CONTRIBUTION

Giorgos N. Tzanetakis: Conceptualization (lead); writing – original draft (lead); Methodology (lead); writing – review and editing review. **Despina Koletsi:** formal analysis (lead); Software (lead); writing – review and editing. **Maria Georgopoulou:** Conceptualization (supporting); Writing – original draft (supporting); writing – review and editing.

ACKNOWLEDGEMENTS

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CONFLICT OF INTEREST STATEMENT

The authors deny any conflict of interest related to the present study.

ETHICS STATEMENT

The research was approved by the Ethics Committee of the School of Dentistry of National and Kapodistrian University of Athens, Greece (protocol no. 459/01.03.2021).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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