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Original Article

Outcomes and risk factors of pulpotomy in mature permanent teeth with complicated crown fractures: A 12-60-month prospective clinical study

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KEYWORDS
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Abstract *Background/purpose:* Traumatic dental injuries (TDIs), especially complicated crown fractures (CCFs), challenge pulp preservation in mature teeth. This study evaluated outcomes and risk factors in mature permanent teeth treated with pulpotomy using iRoot BP Plus.
Materials and methods: This prospective single-arm clinical trial included 47 mature permanent anterior teeth with CCFs and pulp exposures within 24 h post-trauma. Partial pulpotomy was performed under magnification, involving removal of 2–3 mm of coronal pulp, with hemostasis achieved within 5 min. The exposed pulp was capped with iRoot BP Plus, followed by immediate coronal restoration. Patients were followed for 12–60 months. Success was defined as asymptomatic status, maintained pulp vitality, functional integrity, absence of pathology, and dentin bridge formation $\geq$0.3 mm.
Results: The cumulative clinical and radiographic success rate was 93.6 % (44/47) over a median follow-up of 12–60 months. Three teeth (6.4 %) developed pulpitis and required root

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canal treatment. A pre-operative widened apical periodontal ligament (PDL) space was a significant predictor of failure (Hazard Ratio = 17.9; 95 % CI: 2.4–195.8; $P = 0.007$). Failure occurred in 50 % (2/4) of teeth with widened PDLs versus 2.3 % with normal PDLs ($P = 0.008$). Other factors, including patient age, time to treatment, pulp exposure size, depth of pulp removal, and type of restoration, were not significantly associated with outcomes.

Conclusion: Pulpotomy with iRoot BP Plus is effective in mature teeth with traumatic CCFs (93.6 % success). Apical periodontal ligament space widening represents a significant risk factor requiring intensive clinical and radiographic monitoring.

Introduction

Traumatic dental injuries (TDIs) represent a significant public health issue, accounting for approximately 5 % of all bodily injuries.[1] Their prevalence is notably higher in children and adolescents, particularly in school-aged populations.[2] In these patients, the maxillary central and lateral incisors are the most frequently affected teeth in TDIs, primarily due to their prominent position in the dental arch.[3] In addition, studies have reported that maxillary central incisors are by far the most commonly affected teeth in complicated crown fractures (CCFs), characterized by pulp exposure.[4] The timely and appropriate management of CCFs is crucial for averting a cascade of severe sequelae, including pulp infection and periapical pathology, that may culminate in tooth loss.[5] However, the management of CCFs in children and adolescents presents distinct challenges owing to unique anatomical, developmental, and behavioral factors.

Management options for CCFs in mature permanent teeth include root canal treatment (RCT) and vital pulp treatment (VPT). In recent years, there has been a growing preference for VPT, which aims to preserve pulp vitality through procedures such as full or partial pulpotomy.[6] Full pulpotomy involves the removal of the entire coronal pulp up to the root canal orifices, whereas partial pulpotomy removes only a portion of the coronal pulp.[7] Pulpotomy is especially advantageous in young patients with immature teeth, as maintaining pulp vitality is essential for continued root development.[8] One study reported a 100 % tooth survival rate for immature teeth with CCFs treated by pulpotomy after a median follow-up of 7.3 years.[9] While the benefits of VPT for immature teeth are well-established for continued root development, its application in mature permanent teeth is equally valuable for preserving the tooth's proprioceptive and defensive mechanisms, potentially enhancing its long-term survivability, especially in adult populations. In mature permanent teeth, the use of pulpotomy has become more widespread with the introduction of bioactive materials such as Mineral Trioxide Aggregate (MTA) and iRoot BP Plus.[10] However, most research has focused on pulpotomy in teeth affected by caries rather than TDIs.[11] In addition, case reports have shown successful outcomes for CCFs treated with pulpotomy, with one reporting success at 12 months follow-up.[12] Similarly, a retrospective study found a 93.6 % success rate for CCF cases treated with pulpotomy after at least 12 months of follow-up.[13] The lack of high-quality evidence for pulpotomy in mature permanent teeth with CCFs necessitates more rigorous clinical trials to inform treatment protocols.[8]

This prospective clinical study evaluated the clinical and radiographic outcomes of partial pulpotomy using iRoot BP Plus in 47 mature permanent teeth with CCFs and identified factors associated with treatment failure.

Materials and methods

This single-center study included 47 permanent anterior teeth with CCFs (involving pulp exposure) from patients aged 8–51 years, treated at the Peking University School and Hospital of Stomatology. Inclusion criteria were: participants were required to be systemically healthy; teeth were eligible if they met the following conditions: (1) fractures involving <50 % of the crown structure with pinpoint pulp exposure; (2) no root fractures or displacement; (3) percussion sensitivity $\leq +$ and mobility $\leq$ Grade I; (4) radiographic evidence of an intact PDL space ($\leq$0.5 mm widening acceptable); (5) no signs of periapical radiolucency or resorptive defects (6) non-calcified pulp chambers; (7) pulp exposure within 24 h of trauma; (8) achievable hemostasis within 5 min following superficial pulp removal during pulpotomy. Exclusion criteria were the following: presence of systemic disease or known allergy to materials used in treatment, inability to achieve pulp hemostasis during the procedure, fractures involving more than 50 % of the crown structure, planned orthodontic treatment during the follow-up period.

The study was designed as a single-arm target value clinical trial. Ethical approval was obtained from the Institutional Review Board (Approval No. PKUSSIRB-202169169). The clinical trial registration number was MR-11-23-050481. Written informed consent was obtained from all participants after a thorough explanation of the clinical procedure, possible risks, and follow-up requirements. The sample size was determined based on the primary outcome measure of clinical and radiographic success at 12-month follow-up.

Clinical procedures

All pulpotomy procedures were performed by a single experienced endodontist, with immediate chairside verification by a second clinician, following a standardized protocol under dental operating microscope magnification (Carl Zeiss, Oberkochen, Germany). Local anesthesia was administered using 4 % articaine with 1:100,000 epinephrine, and strict asepsis was ensured through rubber dam isolation and disinfection with 3 % sodium hypochlorite.

Partial pulpotomy was carried out using sterile high-speed diamond burs (TF-21, MANI, Kyoto, Japan) under copious saline irrigation, removing approximately 2—3 mm of exposed pulp tissue. Hemostasis was achieved within 5 min by applying sterile cotton pellets soaked in 2.5 % sodium hypochlorite. Cases in which bleeding could not be controlled within this time frame were excluded from the study and referred for conventional root canal treatment. The exposed pulp was sealed with a 1.5 mm layer of iRoot BP Plus (Innovative Bioceramix Inc., Vancouver, Canada), prepared according to the manufacturer's instructions. This was followed by placement of a base layer of glass ionomer cement (Fuji IX, GC Corporation, Tokyo, Japan). Final restoration was completed within 7 days using composite resin (Filtek Z350XT, 3M ESPE, Saint Paul, MN, USA) and an etch-and-rinse adhesive system (Single Bond Universal, 3M ESPE). Immediate postoperative periapical radiographs were obtained using the paralleling technique to assess treatment outcomes.

During the pulpotomy procedure, comprehensive clinical and radiographic data were recorded. Patient demographics, including age and gender, as well as the time elapsed since the traumatic injury, were obtained through patient or guardian interviews and clinical records. Clinical assessments included percussion sensitivity, evaluated using vertical and lateral tapping with a mirror handle and graded on a scale from 0 (no pain) to +++ (severe pain), and tooth mobility, measured manually using two blunt instruments and classified according to Miller's criteria.[13] The extent of pulp exposure was visually assessed under dental operating microscope magnification and categorized based on surface area, while the depth of pulp removal was estimated during the procedure using a periodontal probe or endodontic file with rubber stopper, targeting 2—3 mm of coronal pulp tissue. Radiographic evaluation was performed immediately postoperatively using standardized periapical radiographs obtained via paralleling technique. Special attention was given to the width of the PDL space, which was measured at the mid-root level using calibrated digital radiographic software (Romexis, Planmeca, Helsinki, Finland), with $\leq$0.5 mm widening considered within the acceptable range for inclusion.

Follow-up

Patients were subsequently recalled for clinical and radiographic evaluations according to the predetermined follow-up schedule (mean time 31.7 $\pm$ 14.8 months, Table 1). At each follow-up visit, a comprehensive clinical assessment was performed, including evaluation of symptoms (asymptomatic status), restoration integrity, crown discoloration, percussion sensitivity, tooth mobility, pulp vitality testing (using both thermal and electric pulp tests), and gingival health. Radiographic examinations were conducted using standardized periapical imaging to assess for internal or external root resorption, calcification of the pulp chamber or root canals, periapical pathologies, and the presence of a dentin bridge beneath the pulp capping material. Additionally, changes in dentin thickness were measured to monitor ongoing reparative processes.

Outcome assessment

Treatment efficacy was assessed using standardized clinical and radiographic criteria adapted from the 2020 guidelines of the International Association of Dental Traumatology (IADT). Clinical success was defined by the presence of all of the following: absence of spontaneous pain beyond 72 h postoperatively (asymptomatic status), physiological tooth mobility with a negative or equivocal ($\pm$) response to percussion (functional integrity), a positive response to both cold testing (Endo-Frost, Coltene/Whaledent, Altstatten, Switzerland) and electric pulp testing (Digitest III, Parkell, Edgewood, NY, USA) indicating retained vitality, and normal crown coloration (aesthetic stability). Radiographic success was defined by the presence of a continuous dentin bridge at the pulpal interface with a minimum thickness of 0.3 mm, maintenance of root integrity without signs of internal or external resorption or canal calcification, and periapical health indicated by a Periapical Index (PAI) score $\leq$2, with visible continuity of the lamina dura.

Statistical analysis

Statistical analyses were performed to evaluate treatment success and identify potential predictors of failure. Pulp survival rates were calculated using the Kaplan—Meier method, with time-to-failure defined as the interval from the pulpotomy procedure to the onset of pulp disease requiring root canal treatment (or the last follow-up for censored observations). To assess the influence of various clinical factors on treatment outcome, Cox proportional hazards regression models were employed. These models quantified the association between predictor variables (e.g., patient age, time from trauma to treatment, pulp exposure size, depth of pulp removal, type of coronal restoration, operator experience, pre-operative apical PDL status) and the hazard of treatment failure (i.e., development of pulp disease necessitating RCT). Hazard ratios (HR) with corresponding 95 % confidence intervals (CI) were reported. Statistical significance was set at $\alpha = 0.05$ (two-tailed). All analyses were conducted using IBM SPSS Statistics software, version 20.0 (IBM Corp., Armonk, NY, USA).

Results

Baseline characteristics and treatment parameters

A total of 70 teeth with TDIs between January 2020 and February 2024 were initially screened for eligibility in this study (Fig. 1). Following preliminary evaluation, 15 teeth

Table 1 Follow-up schedule.

Time point (Months)	0	0.5	3	6	12	18	24	30	36	42	48	54	60
Informed consent	√												
Clinical exam	√	√	√	√	√	√	√	√	√	√	√	√	√
Radiographic exam	√		√	√	√		√		√		√		√
Pulp vitality test	√		√	√	√		√		√		√		√

Inter-rater reliability: Initial calibration with 6 sample teeth (Cohen's $\kappa \geq 0.75$ for all parameters).

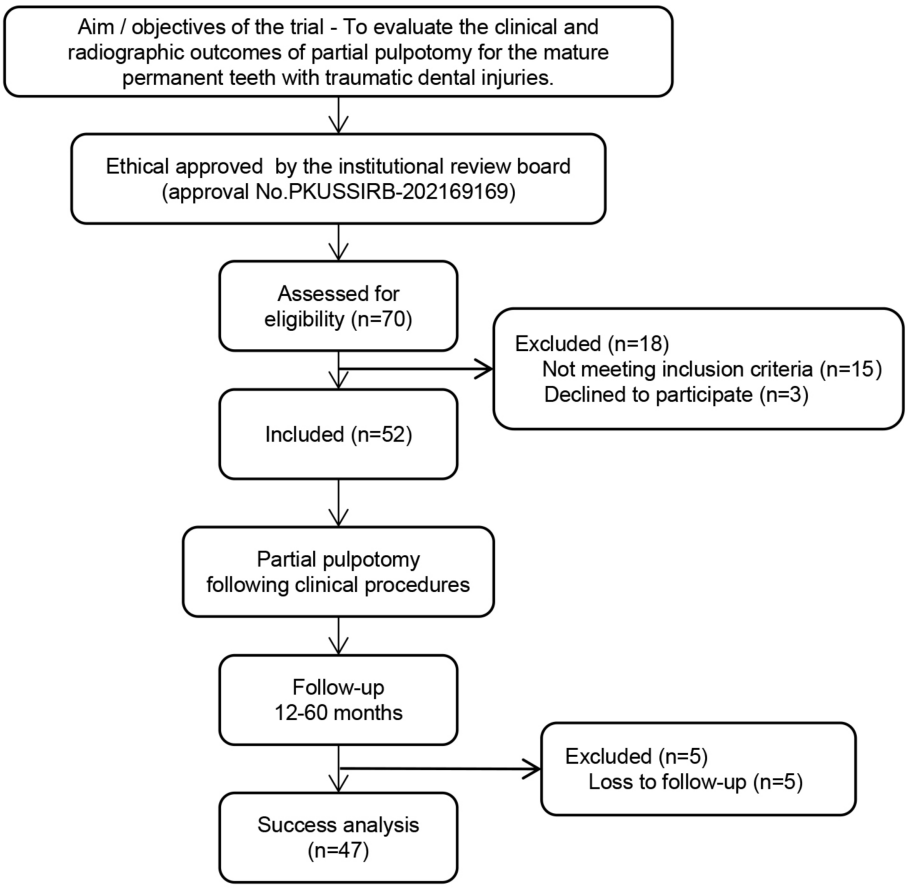

Figure 1 Flowchart of participants throughout the trial.

were excluded based on the predefined inclusion criteria: 3 teeth presented with fractures involving ≥50 % of the crown structure, 5 teeth exhibited mobility greater than Grade I, and 7 teeth demonstrated uncontrolled pulpal bleeding exceeding 5 min. In addition, 3 patients voluntarily withdrew from the study, and 5 patients were lost to follow-up. Ultimately, 47 teeth from 41 patients met the inclusion criteria and were enrolled for analysis (Table 2).

Of the 47 included teeth, 47 % (mean age 12.3 ± 1.9 years; n = 22) belonged to patients aged 18 years or younger, while 53 % (mean age 31.3 ± 7.4 years; n = 25) were from patients over 18 years of age. Regarding operator experience, 40 teeth (85 %) were treated by general practitioners or less-experienced clinicians, whereas 7 teeth (15 %) were treated by experienced or specialist clinicians. The time interval between injury and treatment varied: 51 % teeth (mean time 2.9 ± 1.3 h; n = 24) were treated within 4 h, 28 % teeth (mean time 8.5 ± 2.9 h; n = 13) between 4 and 12 h, and 21 % teeth (mean time 22.2 ± 9.6 h; n = 10) more than 12 h after trauma. Pulp exposure size was classified as pinpoint in 33 teeth (70 %) and more than pinpoint in 14 teeth (30 %). The depth of pulp removal was 2 mm or less in 17 teeth (36 %) and greater than 2 mm in 30 teeth (64 %). Regarding coronal restoration, 43 teeth (91 %) received full-coverage composite restorations, while 4 teeth (8 %) received either partial or no definitive coverage.

Factors associated with pulp complication after the treatment of pulpotomy

Analysis of the apical PDL status revealed a significant correlation with treatment outcomes (χ^2 = 7.08,

Table 2 Distribution and statistical analysis of relevant factors of 47 teeth with traumatic dental injuries.

Category/Variable	n (%)	Follow-up		χ^2	*P* value
		Success	Fail		
Total	47 (100)	44 (93.6)	3 (6.4)		
Gender				2.87	0.234
Male	23 (49)	23 (100)	0		
Female	24 (51)	21 (88)	3 (12)		
Age, years				1.17	0.28
≤ 18	22 (47)	22 (50)	0 (0)		
> 18	25 (53)	22 (50)	3 (100)		
Operator				0	1.00
Experienced/Specialist	7 (15)	7 (16)	0 (0)		
Inexperienced/General	40 (85)	37 (84)	3 (100)		
Time of injury (hours)				0.45	0.797
Time≤4	24 (51)	23 (52)	1 (33)		
4<Time≤12	13 (28)	12 (27)	1 (33)		
Time>12	10 (21)	9 (21)	1 (33)		
Percussion				0.04	0.84
Normal	10 (21)	10 (23)	0 (0)		
Painful	37 (79)	34 (77)	3 (100)		
Mobility				0	1.00
No	42 (89)	39 (89)	3 (100)		
Yes	5 (11)	5 (11)	0 (0)		
Exposure size of pulp				0	1.00
Pinpoint	33 (70)	31 (71)	2 (67)		
More than pinpoint	14 (30)	13 (30)	1 (33)		
Depth of pulp removal				0.53	0.467
≤ 2 mm	17 (36)	17 (39)	0 (0)		
> 2 mm	30 (64)	27 (61)	3 (100)		
Coronal restoration				0	1.00
Full coverage	43 (91)	40 (91)	3 (100)		
No/Partial coverage	4 (9)	4 (9)	0 (0)		
Periodontal ligament of apical area				7.08	0.008
Normal	43 (91)	42 (96)	1 (33)		
Widened	4 (9)	2 (4)	2 (67)		
Full coronal pulpotomy				1.34	0.248
No	24 (51)	21 (48)	3 (100)		
Yes	23 (49)	23 (52)	0 (0)		

$P = 0.008$; Table 2). Of the 47 teeth with traumatic dental injuries, 43 teeth (91 %) exhibited normal PDL space on baseline radiographs, among which 42 teeth (96 %) achieved successful outcomes and only 1 tooth (4 %) failed. In contrast, 4 teeth (9 %) presented with widened PDL space, and among these, only 2 teeth (50 %) were successful, while the remaining 2 (50 %) resulted in treatment failure. These findings suggest that widening of the apical PDL is associated with a markedly increased risk of pulpotomy failure.

Further analysis using the Cox proportional hazards model confirmed this association, revealing a hazard ratio (HR) of 17.9 (95 % CI: 2.4—195.8; $P = 0.007$; Table 3), indicating a significantly elevated risk of failure when PDL widening is present. Additionally, receiver operating characteristic (ROC) curve analysis was performed to assess the predictive value of PDL widening for pulpotomy failure at 1-year and 2-year follow-ups. The area under curve (AUC) was 0.811 (95 % CI: 0.539—1.082) for predicting 1-year failure and 0.833 (95 % CI: 0.564—1.103) for 2-year failure, demonstrating good predictive accuracy of this radiographic parameter (Fig. 2).

Treatment outcome

Over a follow-up period ranging from 12 to 60 months, 3 out of 47 treated teeth developed pulp disease, resulting in an

Table 3 Analysis of periodontal ligament of apical area using cox proportional hazards modeacrtlNormal.

Periodontal ligament of apical area	N	n (%)	Single factor	
			HR (95 % CI)[a]	*P*
Widened	43	1 (2.3)		
Nornal	4	2 (50.0)	17.9 (2.4,195.8)	0.007

[a] HR: Hazard ratio; CI: Confidence interval.

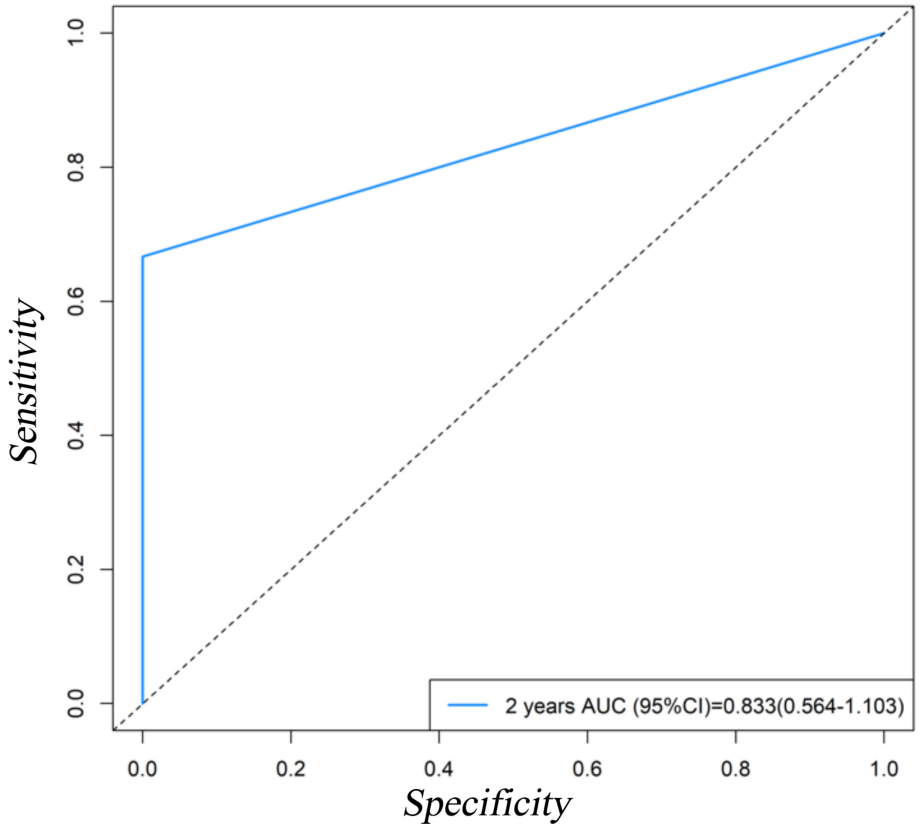

Figure 2 Receiver operating characteristic (ROC) curve analysis was performed to assess the predictive value of PDL widening for pulpotomy failure at 1-year and 2-year follow-ups. AUC: Area under curve. CI: Confidence interval.

Table 4 The specific information of the 3 patients with pulp complication after pulpotomy.

	Patient 1	Patient 2	Patient 3
Age (years)	>18	>18	>18
Operator	Specialist	Specialist	Specialist
Time of injury (hours)	>12	12	<4
Location of tooth	21	21	11
Percussion	+	+	±
Mobility	No	No	No
Exposure size of pulp	Pinpoint	More than pinpoint	More than pinpoint
Depth of pulp removal (mm)	>2	>2	>2
Coronal restoration	Partial coverage	No coverage	No coverage
Periodontal ligament of apical area	Widened	Widened	Normal
Full coronal pulpotomy	No	No	No
Symptom	Spontaneous pain	Spontaneous pain	Spontaneous pain
Time after treatment (months)	0.5	1	1
Pulp status	Pulpitis	Pulpitis	Pulpitis
Treatment plan	Root canal treatment	Root canal treatment	Root canal treatment

overall success rate of 93.6 % (Table 4). The first failure case involved a 25-year-old female who reported spontaneous pain two weeks after treatment. The tooth (position 21) had experienced trauma more than 12 h prior to pulpotomy and presented with pinpoint pulp exposure and a pulp removal depth greater than 2 mm. The coronal restoration was partial, and the apical PDL space was widened. The second case involved a 29-year-old female who developed symptoms one month postoperatively. The affected tooth, also at position 21, had a pulp exposure larger than pinpoint, a pulp removal depth exceeding 2 mm, no coronal coverage, and radiographic evidence of widened apical PDL space. The third case involved a 28-year-old female who presented with spontaneous pain one month after treatment. The trauma had occurred less than 4 h prior to intervention, and the affected tooth

(position 11) had pinpoint pulp exposure, a pulp removal depth greater than 2 mm, no coronal coverage, but a normal apical PDL on radiographic examination. Following a clinical diagnosis of pulpitis, all three teeth underwent conventional root canal therapy.

Discussion

This prospective clinical study confirms that partial pulpotomy with iRoot BP Plus is a highly effective treatment for complicated crown fractures in mature permanent teeth, achieving a 93.6 % cumulative success rate over a 60-month follow-up. These findings validate vital pulp therapy as a conservative and reliable biological approach to preserving pulp vitality after traumatic injury.

The most salient finding of this investigation is the identification of a pre-operatively widened apical periodontal ligament (PDL) space as a significant prognostic factor. The Cox regression model revealed a formidable hazard ratio of 17.9, indicating that teeth exhibiting this radiographic feature at baseline faced a drastically elevated risk of failure. While the sample size of this subgroup was limited ($n = 4$), the statistical significance of this association is compelling. This finding necessitates a critical reappraisal of preoperative radiographic assessment in trauma cases. Apical periodontal lesion was defined by previous studies as a PDL width more than twice the normal measurement.[14] A widened PDL space within twice the normal width, may indicate abnormal dental pulp health status as well as occlusal trauma.[15,16] In the context of TDIs, however, its presence likely signifies a more severe initial injury. The impact force causing the crown fracture may have simultaneously delivered a significant concussive force to the pulp and its neurovascular supply, leading to extensive pulp concussion and potential microvascular damage that compromises the organ's inherent healing capacity.[17] Consequently, despite the successful removal of superficially inflamed tissue and the application of a bioactive capping material, the underlying compromised state of the pulp may preclude its recovery, ultimately leading to necrosis. This pathophysiological explanation aligns with our results and underscores that the preoperative status of the periradicular tissues could be a critical indicator of underlying pulp health beyond the coronal exposure.

This highlights a fundamental dichotomy between traumatic and carious exposures that must be emphasized when interpreting VPT outcomes. While recent studies have reported high success rates for pulpotomy in carious teeth with even periapical lesions (e.g., symptomatic irreversible pulpitis with apical periodontitis),[18] the etiology of pulp inflammation in these contexts is markedly different. Caries represents a slow, chronic bacterial challenge, whereas trauma is an acute, high-energy physical insult that can cause instantaneous and widespread damage to the pulp and its supporting structures. For trauma cases, preoperative radiographic assessment of the PDL space is of paramount importance. Unlike the localized inflammation in caries, traumatic injuries can cause widespread, irreversible pulp damage, for which PDL widening serves as a highly sensitive indicator.

Previous study reported that mature permanent teeth with complicated crown fracture treated with pulpotomy reached 100 % successful rate during 12−24 month follow-up period.[19] However, their study was a retrospective study focusing on the young patients with an age of 9.0 ± 1.1. The age of patients in our study ranged from 11 to 51 with an average of 22 years old. For the study of vital pulp treatments, results showed that age do not impact significantly on pulpotomy outcome in the research field of carious treatment.[20] For TDI, most studies recruited young patients. Therefore, it needs more data on the pulpotomy of mature permanent teeth with TDI.

The size of pulp exposure was an important record during pulpotomy. In our study, 70 % of the teeth had pinpoint pulp exposure, while 30 % had larger exposures. While the factor did not show a direct correlation with treatment failure in our study, previous research has suggested that larger pulp exposures may increase the risk of pulp complications.[21] This may be due to the capping material changed to hydraulic calcium silicate cements instead of calcium hydroxide. Also, it is more accurate using dental operator microscope during pulpotomy.

Several other factors were analyzed, factors such as time to treatment (<24 h) and the type of final restoration, did not demonstrate a statistically significant correlation with the outcome in our cohort. At present, the type of final restoration of teeth with pulpotomy was always composite.[22] However, patients with complicated crown fracture encountered aesthetic problems. In our study, 91 % (43/47) of the teeth had full coverage restorations, while 9 % (4/47) had partial coverage 1 week after pulpotomy. Results showed that the type of restoration had no relationship with treatment outcome of TDI. This suggested that teeth with complicated crown fracture restored by full coverage restoration after pulpotomy was feasible.

Despite the encouraging results, certain limitations of this study warrant acknowledgment. The single-arm design lacks a direct comparative group (e.g., root canal treatment). Most notably, the number of teeth with a widened PDL space was small ($n = 4$), which, despite yielding a statistically significant result, limits the generalizability of the effect size estimate. Future large-scale, multi-center studies are warranted to confirm the predictive value of this radiographic parameter and to refine the criteria for case selection in traumatic pulpotomy. Furthermore, incorporating advanced imaging like cone-beam computed tomography (CBCT) would be invaluable for detecting subtle dislocations or fractures that are missed by conventional radiographs but may explain subsequent PDL widening and treatment failure.

Declaration of competing interest

The authors declare that they have no conflicts of interest related to the authorship or publication of this article.

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