

Evaluation of the Effect of Type 2 Diabetes Mellitus on the Outcome of Adult Pulpotomy (A Non-Randomized Controlled Clinical Trial)

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Received 27 July 2026, Revised 02 August 2026, Accepted 28 August 2026, Available Online 30 August 2026

Abstract:

Aim: To assess the outcome of the adult pulpotomy procedure in diabetic patients diagnosed with irreversible pulpitis in mandibular molars.

Methods: A total of 60 patients aged between 30 and 65 years were divided into two groups based on their glycemic control assessment: Group (1) Diabetic patients with HbA1c levels ≥ 6.5 . Group (2) non-diabetic patients with HbA1c < 6.5 . Preoperative pulpal and periapical diagnosis was established. After obtaining informed consent, the tooth was anesthetized, isolated using a rubber dam, and coronal pulpal tissues were removed to the level of the orifices. Hemostasis was achieved via a cotton pellet moistened with saline for 2 minutes and repeated for another 2 or 4 minutes if required. After well-root bioceramic putty was placed as a capping material over the pulp stumps, ensuring the capping material was set after 10 minutes, the teeth were restored with resin-bonded composite restoration. Clinical and radiographic outcomes were assessed by the method described by Zanini et al at 3, 6, and 12 months, using the Periapical radiograph and Cone Beam Computed Tomography (CBCT) at 6,12 months

Results: The overall success rate in the diabetic group was 90% at 3 months, decreasing slightly to 82.1% at 12 months. While in the non-diabetic group, the success rate was slightly higher, reaching 93.3% at 3 months and 92.9% at 12 months, with no statistically significant difference. Periapical as well as CBCT evaluations showed no statistically significant differences between the two groups over time ($p > 0.05$).

Conclusion: Within the limitations of this study, the adult pulpotomy procedure is a viable option for the treatment of type 2 diabetic patients diagnosed with irreversible pulpitis.

Keywords: Adult Pulpotomy, Diabetes Mellitus, Irreversible pulpitis, Bioceramics.

How to cite this article: Ahmed Mahmoud Mohamed Sulaiman, Motaz Mahmoud ElSadat, Mohammed Saad Easa, Ashraf Samir Refai. Evaluation of the Effect of Type 2 Diabetes Mellitus on the Outcome of Adult Pulpotomy (A Non-Randomized Controlled Clinical Trial) Ahmed Mahmoud Mohamed Sulaiman1, Motaz Mahmoud ElSadat2, Mohammed Saad Easa3, Ashraf Samir Refai4 . Int J Drug Deliv Technol. 2026;16(79s):1115-1122. DOI: 10.25258/ijddt.16.79s.185

.Background:

Vital pulp therapy (VPT) is a conservative endodontic approach that has emerged as an effective alternative to conventional pulpectomy for the management of pulpitis in permanent mature teeth. The primary objective of VPT is to preserve the maximum amount of healthy pulp tissue and natural tooth structure, thereby maintaining tooth strength, minimizing the risk of fracture, and preserving the pulp's essential biological functions, including immune defense mechanisms and regenerative potential.¹ Adult pulpotomy represents one of the principal VPT procedures and is categorized into shallow, partial, or full (total) pulpotomy according to the amount of inflamed pulp tissue removed.²

Over the past decade, adult pulpotomy has gained increasing acceptance as a definitive treatment option for permanent teeth diagnosed with irreversible pulpitis (3,4).^{3,4} The success of this procedure largely depends on the preoperative condition of the pulp, making careful assessment of pulpal status essential

for appropriate case selection and treatment planning. Clinical studies have demonstrated favorable outcomes for adult pulpotomy, with reported success rates ranging from 85% to 94% .^{3,5} The introduction of bioceramic materials has further improved treatment outcomes because of their excellent sealing ability,

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adequate compressive strength, rapid initial setting characteristics, antibacterial properties, and capacity to stimulate reparative dentin formation^{6,7}.

Diabetes mellitus is one of the most prevalent metabolic disorders worldwide, affecting individuals across all age groups. It has been estimated that approximately 451 million people were living with diabetes globally, with projections indicating an increase to 693 million by 2045⁸.

Historically, the diagnosis of diabetes mellitus relied on fasting plasma glucose or postprandial blood glucose measurements. However, since 2010, the American Diabetes Association has recommended glycated hemoglobin (HbA1c) as a diagnostic marker, with a threshold value of 6.5% for the diagnosis of diabetes⁹.

Diabetes is associated with impaired wound healing, exaggerated inflammatory responses, and numerous systemic and oral complications¹⁰. The most common oral manifestations include gingivitis, periodontal disease, and apical periodontitis¹¹.

The success of adult pulpotomy, similar to other vital pulp therapy procedures, may be affected by various local and systemic conditions that influence pulpal repair and the healing of periapical tissues. Among these, diabetes mellitus has been shown to compromise pulp healing by inhibiting dentin bridge formation and adversely affecting the structural and biological integrity of the dental pulp¹⁰.

Furthermore, diabetic patients have been reported to experience a higher incidence of flare-ups during root canal treatment, an increased risk of persistent post-treatment endodontic disease, delayed periapical healing, and a greater likelihood of tooth extraction compared with non-diabetic individuals^{12,13}. Multiple patient- and disease-related factors contribute to the prognosis of endodontic treatment in individuals with diabetes mellitus¹⁴.

Despite the growing body of evidence regarding vital pulp therapy, limited research has specifically evaluated the outcomes of adult pulpotomy in patients with type 2 diabetes mellitus. Therefore, the present study aimed to investigate the clinical outcomes of adult pulpotomy in patients with type 2 diabetes mellitus. The null hypothesis was that no significant difference would exist in the treatment outcomes of adult pulpotomy between diabetic and non-diabetic patients.

Materials and Methods:

Study design:

This non-randomized controlled study was approved by the Ethical Committee of the Faculty of Dental Medicine. Sixty diabetic and non-diabetic patients, allocated to one of the tested groups, received the

intended procedures, and were eventually evaluated for different outcomes after 6 months of follow up, as illustrated in the flowchart presented in **Figure 2**.

Ethical approval and registration:

This non-randomized controlled study was approved by the Ethical Committee of the Faculty of Dental Medicine. This study was registered on Clinical Trials.gov on 01/06/2023 as first posted dat.

Sample size calculation:

Sample size was calculated based on the study done by Arya et al.¹⁵ with a significance level (α error) of 0.05 (5%) and an actual power (1- β error) of 0.80 (80%) detects a large effect size (w)= 0.747 with a total sample size (n =56; divided to 28 in each group). The sample size was calculated using the G*Power statistical power analysis tool (version 3.1.9.4) and was increased to 30 patients in each group to compensate for the dropouts during follow-ups.

Setting and location:

Sixty out of ninety-three diabetic and non-diabetic patients aged between 30 and 65 years from the outpatient clinic at the Faculty of Dental Medicine, diagnosed by irreversible pulpitis associated with the mandibular permanent first or second molar, were selected for this study, patients were excluded from the study if they had type 1 diabetes, immature teeth, teeth with reversible pulpitis, non-restorable teeth, sensitivity to percussion, grade II or III mobility, tooth with a probing depth of more than 3 mm.

Participants:

Inclusion criteria:

1. Patients with irreversible pulpitis.
2. Patients with mandibular permanent first or second molar.
3. Patients with type 2 diabetes.

Exclusion criteria:

1. Patients with systemic disorders other than DM.
2. patients taking steroids.
3. Patients with type 1 diabetes.
4. patients with cracks/fractures.
5. patients with reversible pulpitis.
6. patients with a history of antibiotic intake in the preceding month
7. patients with pleading time more than 6 minute

Intervention:

Informed consent:

Preoperatively, patients were given the opportunity to read and understand the various steps involved in the study before providing written informed consent, following a clear verbal explanation of the clinical steps in understandable words by the operator. Verbal

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assent was granted from the patients prior to starting the study.

Grouping and allocation:

The enrolled patients in this study were allocated into two groups (n = 30 each) following 1:1 allocation ratio. They were allocated to the two groups founding on diabetes condition:

- Group I (Diabetic group): The patients in this group had HbA1c levels $\geq 6.5\%$.
- Group II (Non-diabetic group): The patients in this group had HbA1c levels $< 6.5\%$.

Blinding:

In the current study, a double blinded design was adopted, involving clinician and outcome assessors. Study outcomes were assessed by an experienced examiner that was blinded to the allocation group related to every participant.

Clinical steps:

Assessment procedure:

Confirming the clinical diagnosis with pulp sensibility test, palpation test, percussion test, periodontal probing test, and mobility test. Radiographic diagnosis with a digital periapical radiograph was obtained for each target tooth using a 70-KVp x-ray unit (Runyes; Unicorn Denmart, New Delhi, India) with a 0.3-second exposure time. A digital sensor (Vatech HD, Gyeonggi, Korea) with a paralleling device (XCP-DS Sensor Holder, Dentsply Sirona, Charlotte, NC, USA) was employed to ensure standardized imaging. Pulp sensibility testing was performed using Endo Ice (-26°C) (Hygienic Corp., Akron, OH, USA) applied to both the target and contralateral teeth. Teeth that responded with severe, acute, and lingering pain were diagnosed with irreversible pulpitis and included in the study. Glycemic control assessment was evaluated using the HbA1c test by Bio-Rad D-10 HbA1c analyzer (Bio-Rad Laboratories, Inc., Hercules, California, USA).

Pulpotomy procedure:

Upon completion of the clinical and radiographic evaluation, local anesthesia was administered using (1.8ml of 2% Mepivacaine HCl with levonordefrin 1:20,000) through a 27-gauge long needle mounted in a metal dental syringe using the inferior alveolar nerve conventional Halstead Technique¹⁶.

Isolation was achieved using a rubber dam and a #26 clamp, followed by crown disinfection with 2% chlorhexidine for 1 minute. Caries and defective restorations were removed with a carbide bur, and missing walls were rebuilt using resin-bonded composite.

Following the preparation of the access cavity, the coronal pulp tissue was removed up to the orifices using Endo-Z burs and a diamond-coated ultrasonic tip

E4D (Woodpecker Co., Ltd, China). The access cavity was flushed with saline, and hemostasis was attempted with saline-soaked cotton pellets for 2 minutes and repeated for another 2 or 4 minutes if required.

Cases that had a bleeding time of more than 6 minutes were excluded from the study. Bio-ceramic putty (Well-Root PT; Vericom Co., Chungcheong, Korea) was applied to pulp stumps using a compule gun and bond brush, followed by placement of a moistened cotton pellet for 10 minutes until the material set.

A layered resin-bonded composite was used to finish the final restoration. Postoperative clinical and radiographic evaluations were conducted at 3, 6, and 12 months using periapical radiographs. CBCT scans (Planmeca, Helsinki, Finland) were taken at 6 and 12 months, used a voxel size of 75 μm . Assessment of outcome was done using the technique described by Zanini et al¹⁷.

Evaluation procedure.

Clinical and radiographic evaluation was completed postoperatively at different time intervals.

Clinical evaluation:

Preoperative Pain assessment was done using a translated modified verbal descriptor scale (VDS) translated into Arabic as described by Hagraas et al.¹⁸ Each patient was given a copy of the modified VDS and instructed by a trained endodontist on how to use it and the description of each level of pain intensity. This manuscript constitutes part of a master's thesis. A separate manuscript reporting the clinical evaluation (including postoperative pain assessment at different follow-up intervals) has been accepted for publication. The present manuscript reports different outcome measures from the same study, and there is no overlap in the reported results beyond the necessary description of the study design and methodology.

Radiographic evaluation:

Periapical and cone beam computer tomography (CBCT) was done pre-operative and post-operative at 6 and 12 months to evaluate the outcome. **Figure (1)**

Assessment of success or failure was done using the technique described by Zanini et al.¹⁷ Each patient was evaluated at different times: (T1): after 6 months, (T2): after 12 months.

Treatment was considered successful if the patient's final restoration was intact and the patient demonstrated no clinical symptoms (spontaneous pain, pain on chewing, swelling, or sinus tract), and had a PAI score of 1.

Treatment was considered uncertain if the patient's final restoration was intact, and the

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patient demonstrated no clinical symptoms (spontaneous pain, pain in chewing, swelling, or sinus tract), and a PAI score of 2.

Treatment was considered a failure in the following situations:

1. Any case in which the final restoration was not intact. Irrelevant clinical and radiographic symptoms.
2. Any case in which the final restoration was intact and the patient demonstrated clinical symptoms. Irrelevant of PAI score.
3. Any case in which the final restoration was intact, and the patient had a PAI score of 3 or above. Irrelevant clinical symptoms.



Figure (1): Radiographs of lower 2nd molar A) preoperative B) after postoperative C) after 3 months D) after 6 months E) after 12 months.

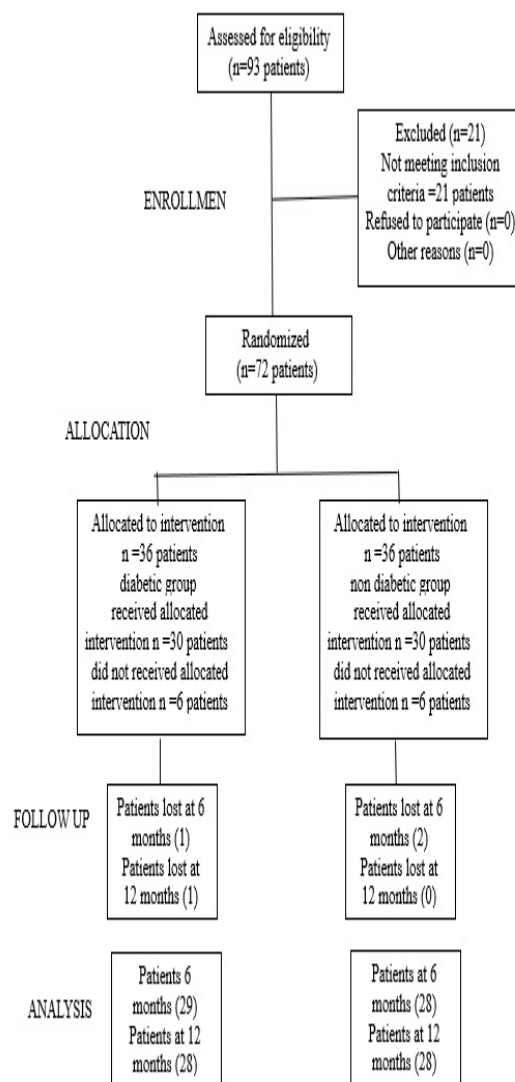


Figure (2): CONSORT flowchart

Statistical analysis:

Data was fed to the computer and analyzed using IBM SPSS Corp., released in 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Qualitative data was described using numbers and percentages. Quantitative data were described using mean and standard deviation for the non-parametric data after testing normality using the Shapiro–Wilk test. The significance of the results obtained was judged at the (0.05) level. We used the Mann-Whitney U Test to compare the different groups at each time interval, while Friedman's Two-Way Analysis of Variance by Ranks was used to compare different time intervals of the study at each group.

Results:

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Patients were distributed regarding the gender. The sixty cases were distributed as 27 males and 33 females. Patients were distributed regarding the age group. The sixty cases were distributed as 10 cases in the age group between (30-35) years, and 6 cases in the age group (36-40) years, and 7 cases in the age group (41-45) years, and 10 cases in the age group (46-50) years, and 11 cases in the age group (51-55) years, and 12 cases in the age group (56-60) years, and 4 cases in the age group (61-65) years.

As regarding to assessment of the outcome by radiograph, results were as the following:

Periapical evaluation:

The success rate in the diabetic group was 82.7% at 6 months and 82.1% at 12 months. There was no significant difference between the success rate in the diabetic group at 6, and 12 months ($P=.0736$). The success rate in the non-diabetic group was 92.8% at 6 months, and 89.2% at 12 months. There was no significant difference between the success rate in diabetic groups between 6, and 12 months ($P=.112$). Table (1)

CBCT evaluation:

The success rate in the diabetic group was 89.7% at 6 months and 82.1% at 12 months. There was no significant difference between the success rate in diabetic group 6 and 12 months ($P=.157$). The success rate in the diabetic group was 92.9% at 6 months and 92.9% at 12 months. There was no significant difference between the success rate in diabetic groups 6 and 12 months ($P=1.00$).

The success rate in diabetic group and non-diabetic group at 6 months and 12 months (periapical methods) was compared with the success rate in diabetic group and non-diabetic group at 6 months and 12 months (CBCT methods) and there was no significant difference between the success rate between them. Table (1)

Table (1) show the success rate of diabetic and non-diabetic groups with the two methods of evaluation at 6 and 12 months.

Method	Groups	6 months		12 months		P value Intragroup
		N	%	N	%	
Periapical	Diabetic	2	8	2	8	$P=.0736$ NS
		4	2.7	3	2.1	
		0		0		
		1		1		
		0		0		
		2		2		
	Non-diabetic	9		8		$P=.112$ NS
		6		2		
		2		5		
		8		0		
		2		2		
		8		8		

CBC T	Non-diabetic	26	92.8	26	89.2	$P=.112$ NS
	Diabetic	26	82.7	26	82.1	$P=.0736$ NS
P value intergroups		$P=.165$ NS		$P=.239$ NS		

N: number of successes, %: percentage of success, $p \leq 0.05$: S: significant, $p > 0.05$: NS: non-significant, $p \leq 0.01$: HS: highly significant

Discussion:

Recent recommendations suggest that adult pulpotomies serve as a more conservative option compared to total pulpectomy. Some studies have been conducted to assess the success rate of adult pulpotomy, which ranges from 78.1% to 98%^{19,20}. This study sought to assess the clinical and radiological outcomes of adult pulpotomies in patients with type 2 diabetes compared to non-diabetic individuals. The null hypothesis of this study posited that there would be no significant difference in the success rates of adult pulpotomy between diabetic and non-diabetic patients. This was a double-blind, controlled clinical trial. A total of 56 patients were assessed over a 12-month period, which aligns with prior studies conducted in this field.^{2,21}

In this study, mandibular molars with irreversible pulpitis in patients aged between 30-65 years were selected as this represents a wide range of ages to evaluate the effectiveness of adult pulpotomies. Furthermore, mandibular molars within this age range are commonly present with carious exposures²² and require intervention. The diagnosis of irreversible

pulpitis was determined according to the diagnostic terminology approved by the American Association of Endodontists. Although there are other classifications of irreversible pulpitis such as Wolters²³ and Hashim²⁴ classifications, the AAE description of symptomatic irreversible pulpitis was used, due to its simplicity, evidence-based approach and it has previously been used in similar research²⁵.

During the pulpotomy procedures, hemostasis was achieved using a sterile cotton pellet moistened with saline, which is similar to other studies²⁰. Although several studies have used hemostatic agents such as sodium hypochlorite and ferric sulfate²⁶. In this study, saline was preferred to allow the clinician to better evaluate hemostasis without any external intervention of other chemicals. With regards to hemostasis time, there is no current standard on the definite time of hemostasis in adult pulpotomy. Patients with bleeding time of more than 6 minutes were excluded from the study, similar to other studies that have been done on this topic^{2,22}. Regarding the choice of capping material, a premixed putty-type bioactive cement, Well-Root PT (WRPT; Vericom Co., Chuncheon, Korea) was used as it is readily available in a premixed capsule form, it provided uniform and adequate consistency and clinical convenience, ease of use and has a shorter setting time, with approximately (5 min for initial setting and 45 min for final setting)²⁷ which allows for completion of the treatment in a single visit.

With regards to periapical evaluation, assessment of success or failure was done using the combined clinical and radiographic examination described by Zanini et al.¹⁷. Although there are other evaluation methods, such as Strindberg & Reit and Grondahl^{28,29}, the Zanini method was used because it is simple, especially designed for pulpotomy evaluation, a clinical and radiographic integrated method unlike other methods, and has been used in other similar research³⁰.

The overall success rate after 12 months evaluated with periapical radiology was (82.1%) in the diabetic group and was (92.9%) in the non-diabetic group, but this difference was not significant ($P = .230$). On the other hand, the overall success rate after 12 months evaluated with CBCT was (82.1%) in the diabetic group and (89.2%) in the non-diabetic group. Still, this difference was not significant ($p = .449$). It seems that diabetes does not significantly alter the outcome of adult pulpotomy. No research to date has been done to evaluate the effect of type 2 diabetes on adult pulpotomy; however, there have been some studies^{10,12} that have investigated the relationship between diabetes and RCT. Most of these studies have shown no significant difference in success rate between diabetic and non-diabetic patients when undergoing RCT.

On the other hand, a few studies¹³ have found a significant difference between diabetic and non-diabetic patients. Although the present study shows similar results to the studies done on RCT. It is not a very balanced comparison because the studies evaluating RCT originally had apical periodontitis or periapical lesions from the beginning, unlike the present study. After a deeper evaluation of the two studies^{12,13} that showed a significant difference in the success rate between diabetic and non-diabetic patients when undergoing RCT, it was found that there was a difference in the number of patients in the diabetic and non-diabetic groups. Furthermore, less restrictions in the inclusion criteria in these studies compared to the other research.

In order to compare periapical and CBCT evaluation methods, both groups were combined to increase the sample size to $n=60$. Furthermore, it has already been established that there was no significant difference between the diabetic and non-diabetic groups. At 6 months, the success rate using periapical radiographs was 91.3%, while with CBCT, it was 87.7%. At 12 months, the success rate using periapical radiographs was 87.5%, while with CBCT, it was 85.7%. Although CBCT has a lower success rate than the periapical method, this difference was not significant. No research to date has been done to compare periapical and CBCT evaluation methods after adult pulpotomy; however, there have been some studies^{31,32} that have shown a significant difference between periapical and CBCT evaluation methods after RCT. Most of these studies have methods. As mentioned, the present study is contrary to this research; this variability in the outcomes may be attributed to the fact that in the present study, the cases did not have periapical disease at the beginning of the study. Furthermore, the length of follow-up time may play a role, as longer follow-up time may result in a significant difference between evaluation methods.

It goes without saying that patients and physicians should be aware of the possible connection between diabetes and the results of root canal treatment, as well as the potential influence that it may have on the prognosis of endodontically treated teeth. Given the growing interest in minimally invasive endodontic procedures and the increasing prevalence of diabetes globally, understanding how diabetes may influence pulpal healing after pulpotomy is of great clinical importance. Evaluating the impact of Type 2 diabetes on the outcomes of adult pulpotomy can help clinicians identify potential prognostic factors, customize treatment protocols, and develop appropriate follow-up strategies. This is particularly important for elderly diabetic patients with comorbidities, as adult pulpotomy

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can provide them with rapid and effective pain relief through a less invasive approach.

Conclusion

Within the parameters of this study, it can be concluded that diabetes in adult pulpotomy didn't affect the outcome. These findings support the viability of the pulpotomy procedure as a conservative alternative to root canal treatment, even in type 2 diabetic patients. Diabetic patients did not experience more postoperative pain than non-diabetic patients after adult pulpotomy.

Funding:

The authors declared that this study was self-funded.

Availability of data and materials:

The datasets generated and/or analyzed during the current study can be gained from the corresponding author upon reasonable request, with all precautions implemented to secure participants' privacy.

Competing interests:

The authors declare no competing interest.

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