

Comparative Evaluation of Periapical Healing Outcome Following Non Surgical Endodontic Treatment in Single-visit versus Multiple-visit in Type 2 Diabetes Mellitus Patients: A Randomised Clinical Study

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ABSTRACT

Introduction: Apical periodontitis is very common in those with diabetes mellitus. Diabetes alters immunity, which impacts how periapical tissue heals. The decision between one-visit and multiple-visit root canal therapy is currently up for debate.

Aim: To compare periapical healing following single-visit endodontic therapy and multiple-visit endodontic therapy in type 2 diabetic patients by clinical assessment.

Materials and Methods: The present randomised single-blinded clinical trial was conducted in the Department of Conservative Dentistry and Endodontics, KM Shah Dental College and Hospital, Vadodara, Gujarat, India, from December 2017 to October 2019. A total of 46 patients having type 2 diabetes, indicated for root canal treatment participated in the study and were randomly split into two groups: group I: Single-visit endodontic treatment and group II: Multiple-visit endodontic treatment. Thereafter, endodontic treatment was carried out on all the patients and the patients

were recalled for evaluation at 1-week, 3-month and 6-month time intervals. The clinical assessment was done based on the absence of pain, swelling and sinus tract formation. Statistical analysis was done using Statistical Package for Social Sciences (SPSS) software version 20.0.

Results: Results showed that the success rate based on clinical assessment at one week for a single-visit and multi-visit group was 56.52% for both the groups and at three months 90.47% and 86.36%, respectively. At six months, the single-visit group reported 100% success, while the multi-visit group reported 95% success. However, the difference between the groups was not statistically significant.

Conclusion: Within the limitation of the study, it was concluded that clinically, a higher success rate was found after six months in patients having type 2 diabetes mellitus who were treated in a single-visit, which was not statistically significant.

Keywords: Apical periodontitis, Clinical assessment, Glycated haemoglobin, Intracanal medicament, Strindberg criteria

INTRODUCTION

A genetically diverse collection of disorders known as diabetes mellitus affects protein, lipid and carbohydrate metabolism [1]. It is also characterised by hyperglycaemia and is further classified into type 1 and 2. Among both types, level of the insulin may be normal or reduced in type 2 category of diabetes mellitus. Although a high deficiency of insulin does not occur, the target tissues are resistant to insulin because of the decrease in the number of insulin receptors available in the target cell [2].

Diabetes mellitus causes an alteration in the migration of polymorphonuclear cells, and an increase in the detection rate of anaerobic bacteria in the dental pulp of diabetic patients [3]. High levels of glucose in blood can interfere with macrophage function resulting in wound healing. The vascular system also gets affected by atheromatous deposits, which are deposited in the basal lumen membrane of blood vessels, and could interfere with tissue nutrition and pulp repair [4].

Apical periodontitis is highly prevalent in type-2 diabetes mellitus. The periodontium in the apical region that arises from the pulpal region is inflamed and destroyed and appears as a radiolucency in the periapical area [1]. The periapical tissues' ability to heal is influenced by the non specific immune system. Thus, the preoperative status and altered immune response can have an impact on the dental pulp's capacity for repair and the periapical healing [5].

Teeth having apical periodontitis can be treated by endodontic treatment. The success rate in such teeth is reported to be around approximately 87%. Single-visit endodontics has the advantage of reduced risk of interappointment infection compared to multiple visits, wherein there is a chance of loss of temporary restoration. Hence, the effectiveness of single-visit therapy is 6.3% better than multiple visits [6]. Endodontic treatment typically requires several visits, with the length of the procedure being one of the primary causes [7]. In necrosed teeth, application of an interappointment dressing such as calcium hydroxide should be done and then the canal can be obturated in the following visit [8].

There are conflicting data available in the literature regarding the success of single-visit and multiple-visit endodontics [9,10]. Hence, the current study was aimed to evaluate and compare the periapical healing outcome in both single-visit and multiple-visit endodontic therapy in patients suffering from type 2 diabetes by clinical assessment. The null hypothesis for the study was that no significant difference will be seen in periapical healing outcome for single-visit and multiple-visit endodontic therapy in patients suffering from type 2 diabetes.

MATERIALS AND METHODS

This was a randomised single-blinded clinical trial conducted in the Department of Conservative Dentistry and Endodontics, KM Shah Dental College and Hospital, Vadodara, Gujarat, India, from

December 2017 to October 2019. Ethical approval (SVIEC/ON/DENT/BNPG17/D18007) was obtained from Institutional Ethical Committee to conduct the study. All the patients were informed about the benefits, harms, and alternative treatment choices before being included in the study, and informed consent was acquired from all the patients. Preoperative evaluation of periapical lesion was done clinically as well as radiographically.

Inclusion criteria: Patients between the age group of 25-70 years, with controlled diabetes based on Glycated Haemoglobin (HbA1c) level [11], who required endodontic intervention in single as well as multirooted teeth, with sufficient remaining tooth structure, and which could be restored by postendodontic restoration were considered in the study.

Exclusion criteria: Patients with history of smoking, pregnancy, steroid usage, uncontrolled diabetes or any other systemic illness, teeth with internal or external root resorption, non carious lesions, root caries, and cracked or fractured teeth were excluded from the study.

Sample size calculation: A sample size of 40 was achieved with 80% power to determine an effect size (W) of 0.40 using a 1^o of freedom Chi-square test with a significance level (alpha) of 0.05 [6]. Considering 15% drop-out, three extra samples were added to each group. Therefore, a total of 46 patients indicated for root canal treatment having type 2 diabetes participated in the study.

Study Procedure

All the patients were treated by the primary investigator. Sterilisation protocol was maintained and the treatment procedure was thoroughly monitored. Patients requiring endodontic therapy was randomly selected based on the flip coin method and divided into two groups; group I: Single-visit endodontic treatment and group II: Multiple-visit endodontic treatment.

In group I, administration of local anaesthesia (1:200000 lignocaine with adrenaline) was done, followed by rubber dam isolation. Access opening was done and the root canal orifices were located. Working length determination was done using apex locator (Root ZX mini, J Morita), and was confirmed radiographically. Cleaning and shaping were performed based on the canal configuration. The master apical file was determined corresponding to the initial apical file and it was confirmed radiographically. Irrigation was done using 5.25% sodium hypochlorite (Neelkanth), 17% Ethylenediaminetetraacetic acid (EDTA) (Prevest Dent Pro), and normal saline (0.9%w/v Otsuka) after changing each instrument and recapitulation. Chlorhexidine gluconate 2% (V-Concept) was used as a last irrigant. The obturation was completed with AH Plus sealer. The postendodontic restoration was done using nanohybrid composite (GC Solar X).

In group II, the root canal procedure was performed similarly to group I, except that in group II, calcium hydroxide (RC Cal, Prime dental) was the intracanal medicament used in the root canals, and temporary restoration was given for one week between two appointments. In the 2nd appointment, obturation was done followed by postendodontic restoration.

After the endodontic treatment, clinical evaluation and follow-up were carried out after 1-week, 3-months and 6-months. Since, it was a single-blinded study evaluation was done by a co-investigator who was blinded to whether the patient had undergone single-visit or multiple-visit endodontic treatment. Clinical assessment of periapical healing was done based on Strindberg's criteria [12], i.e., the presence or absence of pain, swelling, and sinus tract formation.

Treatment was considered successful when: (a) tooth that had no preoperative periradicular radiolucency of endodontic origin and continued to show no radiographic or clinical abnormalities at the time of follow-up; and (b) tooth that had preoperative periradicular radiolucency but showed bone deposition or no apical rarefaction. The periodontal ligament space was intact or up to twice the width of neighbouring teeth at the time of follow-up examination.

Treatment was considered a failure when: (a) there is periradicular pain, swelling or a sinus tract related to the tooth being evaluated; (b) Periradicular radiolucency has been developed after completion of treatment; and (c) preoperative lesion had not resolved or had partially resolved in six months with or without pain, swelling, a sinus tract or deep isolated probing of endodontic origin [13].

STATISTICAL ANALYSIS

Data were analysed using Statistical Package for Social Sciences (SPSS) software version 20.0 (IBM SPSS, IBM Corp., Armonk, NY, USA). Student unpaired t-test and Chi-square test were used to statistically evaluate the results. For all the analysis, p-value <0.05 was considered statistically significant.

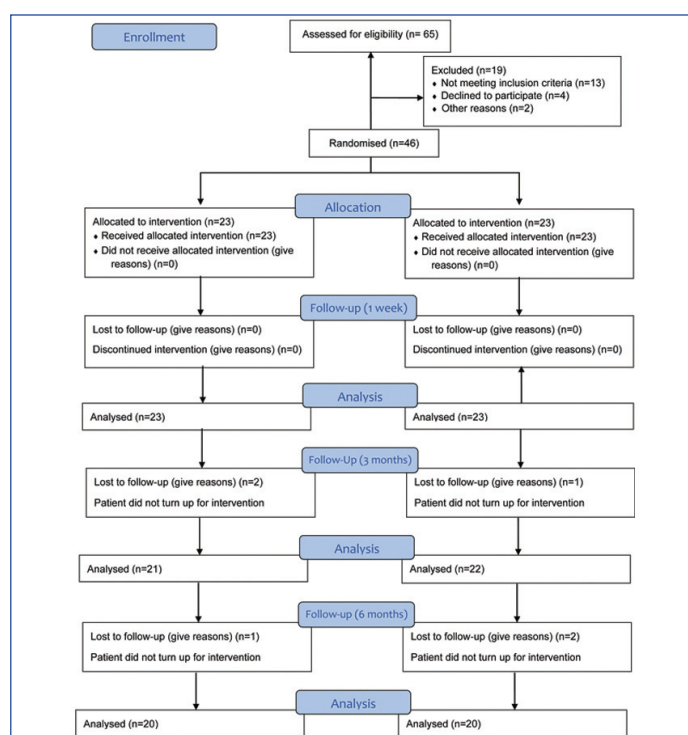
RESULTS

The mean age of group I patients' was 42±14.5 years, whereas in group II, mean age was 47±13 years. No significant difference between the groups was found by unpaired t-test (p-value=0.087). There were 13 males and 10 females in group I, while in group II there were 11 males and 12 females. Chi-square test showed no significant difference between groups (p-value=0.554). On assessment of preoperative glycosylated haemoglobin, mean HbA1c of patients in group I was 7.9%, while in group II was 8.2% [Table/Fig-1]. No significant difference was seen between the two groups (p-value=0.764)

Groups	Mean age (years)	Sex	Mean HbA1c (%)
Group I	42±14.5	Male-13 Female-10	7.9
Group II	47±13	Male-11 Female-12	8.2

[Table/Fig-1]: Mean age, sex and mean HbA1c values.

In group I, 23 patients were examined at one week. Twenty one patients were examined at three months, i.e., 2 (8.69%) subjects lost to follow-up. At six months, 20 subjects were examined, i.e., 3 (13.04%) subjects lost to follow-up. In group II, 23 patients were examined at one week. Twenty one patients were examined at three months, i.e., 1 (4.34%) subject was lost to follow-up. At six months, 20 subjects were examined i.e., 3 (13.04%) subjects were lost to follow-up. [Table/Fig-2] shows a Consolidated Standards of Reporting Trials (CONSORT) flowchart of study enrollment and randomisation.



[Table/Fig-2]: CONSORT flowchart for study enrollment and randomisation.

Comparison between Experimental Groups

The Chi-square test revealed a non significant difference between the two experimental groups in periapical healing at one week (p-value=0.056), three months (p-value=0.189), and six months (p-value=0.966) [Table/Fig-3].

Time interval	Criteria	Group I			Group II		
		Total no. of patients	Yes n (%)	No n (%)	Total no. of patients	Yes n (%)	No n (%)
Healing after 1 week	Pain	23	18 (78.3%)	5 (21.7%)	23	12 (52.2%)	11 (47.8%)
	Swelling	23	7 (30.4%)	16 (69.6%)	23	5 (21.7%)	18 (78.3%)
	Sinus tract	23	5 (21.7%)	18 (78.3%)	23	14 (60.8%)	9 (39.2%)
Healing after 3 months	Pain	21	5 (23.8%)	16 (76.2%)	22	2 (9.1%)	20 (90.9%)
	Swelling	21	0	21 (100%)	22	0	22 (100%)
	Sinus tract	21	3 (14.3%)	18 (85.7%)	22	5 (22.7%)	17 (77.3%)
Healing after 6 months	Pain	20	0	20 (100%)	20	1 (5%)	19 (95%)
	Swelling	20	0	20 (100%)	20	0	20 (100%)
	Sinus tract	20	0	20 (100%)	20	1 (5%)	19 (95%)

[Table/Fig-3]: Frequency of periapical healing at 1-week, 3-months, and 6-months.

The success and failure rate for group I and group II were 56.52% and 43.47%, respectively at one week (p-value=1.000). The success rate at six months for group I and II were 100% and 95%, respectively. While there were no failures in group I after six months, there was a 5% failure rate in group II after six months (p-value=0.311) [Table/Fig-4-6].

DISCUSSION

In the present study, clinical assessment of periapical healing during the course of six months was done using Strindberg criteria [12], and the results showed that the rate of success of clinical assessment at one week for single-visit and multi-visit groups was 56.52%, at three months was 90.47% and 86.36%, respectively. At six months,

the single-visit group showed a 100% success rate however, only 95% success was achieved in the multi-visit group. Statistically significant difference was not observed amongst both the groups over six months, but a clinically higher success rate was found in single-visit group as compared to the multi-visit group. It could result from less bacterial contamination in single-visit group as there was no need for provisional restoration, which might lead to microleakage in-between the appointments. It also minimises the possible chance of iatrogenic errors. However, more randomised controlled studies are required for further clinical and radiographic evaluation [14].

Diabetes mellitus is considered as a metabolic disease, that it is marked by high blood sugar levels brought on by a malfunction in insulin secretion [3]. Among both types, type 2 is more common in which insulin production is diminished due to dysfunction of β-cells [15]. During an inflammatory response, leucocytes get attached to the endothelial cells with the help of adhesion receptors on either of the cells whereas, in the case of diabetes mellitus, due to the down-regulation of adhesion molecules, the interaction between leucocytes and adhesion molecules is disturbed. Hence, the immune system is compromised and wound healing is impaired [16]. Diabetes also promotes a decrease in osteoblast formation, which affects the specific bone matrix secretion. In addition, glucose transportation by osteoclast culture is about two times as high in bone in comparison to cultures from outside the bone. This increases the levels of bone resorption in hyperglycaemic conditions [14].

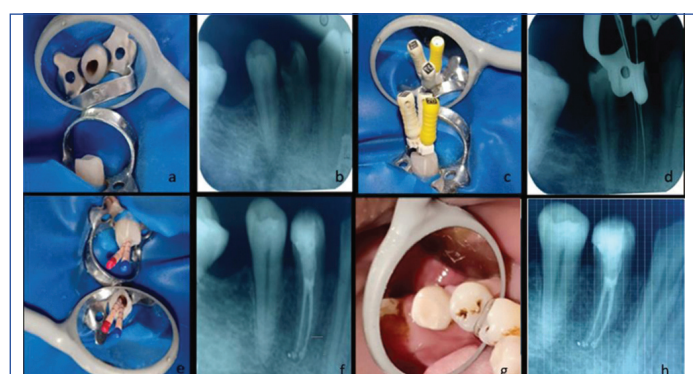
The main aim of endodontic therapy is to eliminate microorganisms by means of cleaning, shaping, disinfecting and filling the root canals, thereby creating a favourable environment for healing of the existing lesion [17]. The rate of success of endodontic treatment of patients with diabetes is 62%, while it is regarded as high as 80% in non diabetic patients. In diabetes, various factors such as altered functions of leukocytes, decreased secretion of microphage growth factors, and increased release of proinflammatory cytokines affect the success rate of the endodontic treatment [15].

In the present study, diagnosis of diabetes was carried out by the estimation of the blood level of HbA1c in all the patients, which provides an accurate and objective measure of blood glucose levels in the previous three months [18].

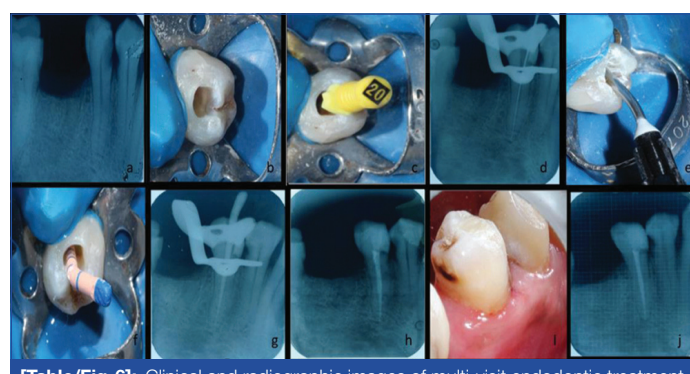
Usually, endodontists favour carrying out a single-visit endodontic treatment for vital teeth. However, a dilemma exists whether to do a single-visit or multiple-visit therapy in cases of pulpal

Duration		1-week		p-value	3-month		p-value	6-month		p-value
Group	Outcome	n	Percentage		n	Percentage		n	Percentage	
Group I	Success	13	56.52%	1.000	19	90.47%	0.674	20	100%	0.311
	Failure	10	43.47%		2	9.52%		0	0%	
Group II	Success	13	56.52%		19	86.36%		19	95%	
	Failure	10	43.47%		3	13.63%		1	5%	

[Table/Fig-4]: Shows the assessment of periapical healing outcomes over six months. Pearson's Chi-square test



[Table/Fig-5]: Clinical and radiographic images of single-visit endodontic treatment group: (a,b) Access opening; (c,d) Working length; (e) Master cone; (f) Obturation; (g,h) Six months follow-up).



[Table/Fig-6]: Clinical and radiographic images of multi-visit endodontic treatment group: (a) Preoperative X-ray; (b) Access opening; (c,d) Working length determination; (e) Placement of intracanal medicament; (f,g) Master cone; (h,i) Obturation; (j) Six months follow-up).

necrosis irrespective of the periapical status. In such cases, only chemomechanical preparation is not effective for the removal of bacteria as it may penetrate the dentinal tubules, lateral canals and apical deltas. Hence, placement of intracanal medicament is necessary for a longer period to decrease or remove bacteria which will lead to better healing [19].

In the present study, the biomechanical preparation technique was performed based on canal configuration and care was taken to avoid the periapical extrusion of debris, which could alter the healing potential [20,21]. Calcium hydroxide was the intracanal medicament used in the root canals of the multi-visit group. Numerous academic works claimed that the placement of intracanal medication increased success rates owing to its benefits, however the present study's findings were in direct opposition to those claims [22].

The results of the present study are in agreement with the study done by Sathorn C et al., in which, single-visit root canal treatments were more effective, and had a recovery rate that was 6.3% greater than that of several visits, with no statistically significant difference between these two therapy modalities [23]. Another study done by Rudranaik S et al., results of which revealed that the clinical and radiographic healing outcome of single visit endodontic therapy was delayed in diabetic patients, which was contradictory to the results of the present study [6]. Su Y et al., in their systemic review stated that the healing rate for an infected tooth is similar for a single-visit as compared to multi-visit endodontic treatment. Patients reportedly suffer less instances of immediate postobturation discomfort after a single-visit endodontic treatment than those treated in multiple visits [24].

Limitation(s)

In the present study, the sample size was relatively smaller, thus more studies are required with a greater sample size, which will give a more accurate idea, regarding the periapical healing outcome. Radiographic assessment of the healing outcome requires a lot of standardisation and precision, which was not followed in the study.

CONCLUSION(S)

Within the limitation of the study, it was concluded that clinically a higher success rate was found in single-visit endodontic therapy in type 2 diabetic patients after six months, which was statistically not significant. However, a greater number of samples and a longer duration of follow-up period are required for a further acceptable and reliable result.

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