

Original Research Article

Evaluation of clinical efficacy of immediate implant placement into debrided infected sockets using demineralized freeze-dried bone allograft and platelet rich fibrin membrane: a clinical trial

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ABSTRACT

Background: The aim of the study was to evaluate the clinical efficacy of demineralised freeze dried bone allograft (DFDBA) and platelet rich fibrin (PRF) membrane in immediate implant placement into debrided infected mandibular molar sockets.

Methods: A clinical trial was conducted on 15 adult patients requiring tooth extraction and replacement with endosseous implants. Atraumatic tooth extraction was followed by thorough debridement of the socket prior to implant placement. Demineralized freeze dried bone allograft and PRF membranes were used for guided bone regeneration. Pain, signs of infection, vertical bone height measurements (IS-BIC) and stability of implants (torque values) were assessed using paired t test, analysis of variance (ANOVA) and Chi-square test.

Results: Statistically significant reduction in pain from immediate post-operative (post-op) day to 1st post-op day, 7th post-op day to 4 months post-op ($p=0.006$) was seen. Infection was present preoperatively and absent post-op 1st day, 7th day and 4 month in all the subjects. The mean IS-BIC was 2.30 ± 2.27 mm post-op and 0.75 ± 0.74 mm at 4 months. Average height gain on mesial and distal side was 1.55 mm ($p=0.009$).

Conclusions: With proper pre-op and post-op care, immediate implant placement along with DFDBA and PRF membrane in teeth exhibiting periapical pathology, is a cost effective, time saving and reliable treatment option.

Keywords: Immediate implant, Periapical pathology, Bone allograft, PRF membrane

INTRODUCTION

The elusive dream of replacing missing teeth with artificial analogues has been a part of dentistry for a thousand years. However, it was not until the 1960's that the scientific foundation of modern implant dentistry was set when Per-Ingvar Brånemark, a Swedish physician and research professor discovered that osseointegration can occur

between a titanium implant and bone.¹ With the introduction of this "osseointegration technology" to North America at the 1982 Toronto Conference, prosthodontic treatment of patients changed significantly. It became possible to anchor prostheses firmly to osseointegrated implants and significantly improve comfort for those who for so many years were "sentenced" to wearing removable prostheses.²

Since the introduction of immediate implants by Lazzarra in 1989, implant surgery has evolved, and currently, implant placement into fresh extraction sites in a 2-stage fashion has proven to be a viable surgical option.³ The concept of placement of dental implants soon after the removal of a tooth with periapical or periodontal pathologic features, however, is a matter of debate. The placement of implants into the sockets of teeth with periodontal or periapical lesions could offer several advantages. For instance, it minimizes the number of surgical procedures by combining extraction, implant placement, and bone grafting in a single session. One disadvantage of the technique is the potential for implant contamination during the initial healing period owing to remnants of the infection.⁴

To satisfy the goals of implant dentistry, hard and soft tissues need to be present in adequate volumes and quality. This has necessitated development of techniques and materials that promote predictable regenerative treatment. Regeneration refers to the reconstitution of a lost or injured part by complete restoration of its architecture and function.⁵ Augmentation of bone volume has been assisted through different methods, including use of growth and differentiation factors, particulate and block grafting materials, distraction osteogenesis, and guided bone regeneration (GBR). These techniques resulted in comparable long-term implant survival.^{6,7}

Human decalcified freeze-dried bone allografts (DFDBA) are used in periodontal regeneration and in the maintenance and repair of alveolar ridges to provide sufficient quantity of bone for the placement of endosseous implants. DFDBA act as a space maintaining, bone-growth promoting agent and includes the fact that proteins capable of inducing new bone; i.e. bone morphogenetic proteins, can be isolated from bone grafts.⁸

This process is enhanced by the use of platelet rich fibrin (PRF) which is a fibrin matrix in which platelet cytokines, growth factors, and cells are trapped and may be released after a certain time and that can serve as a resorbable membrane. Choukroun's PRF was first described by Choukroun et al in France in 2001. Based on these observations, we evaluated the clinical efficacy of DFDBA and PRF membrane in immediate implant placement into debrided infected mandibular molar sockets. Taking into considerations the advantages of immediate implant placement the aim and objective of the study was to evaluate clinically and radiographically the clinical efficacy of DFDBA and PRF membrane in immediate implants placement into debrided infected mandibular molars sockets.

METHODS

Patient selection and study design

A clinical trial was conducted on 15 adult patients (7 males and 8 females) requiring extraction and tooth replacement

with endosseous implants in the department of oral and maxillofacial surgery, D. J. College of Dental Science and Research, Modinagar, from August 2015 to December 2016. Convenience sampling method was used for data collection. Prior to the commencement of implant surgery a detailed history of the patients was carefully recorded and patients were apprised about the potential risks and benefits of the procedure. An informed consent was obtained on the prescribed format.

Inclusion criteria was ASA class 1 and 2 medically fit patients; teeth requiring extraction due to chronic infection with minimum 3 mm of bone present between the apex of tooth to be extracted and inferior alveolar nerve at the proposed site of implant placement; sufficient mesio-distal and interarch space for implant placement; and patients who were non-smokers or smoked less than 10 cigarettes per day and stopped smoking throughout the surgical and post-operative (post-op) period.

Each case was carefully evaluated by analyzing the diagnostic casts for the intra-arch and the interarch relationship. Periapical radiographs were taken using long cone paralleling technique (Figure 1g and h). After the initial steps for treatment planning, all of the patients underwent scaling, root planning and oral hygiene instructions. Amoxicillin 500 mg 3 times a day was started 2 days prior to implant placement.

PRF preparation

The PRF was prepared in accordance with the protocol developed by Choukroun et al just prior to surgery. 40 ml Intravenous blood from antecubital vein was collected in glass coated sterile tubes without an anticoagulant and centrifuged immediately using a tabletop centrifuging machine for 10 min at 3000 rpm (Figure 1d).

Surgical technique and post-operative management

An aseptic surgical technique was followed. Flap was raised under local anesthesia (2% lignocaine). Atraumatic tooth extraction was performed preserving the alveolar bone integrity followed by thorough debridement and rinsing of extraction socket to remove any remaining granulation tissue. Sequential osteotomy was done according to the manufacturer's instructions. The implant was placed 2-3 mm below the Cemento-enamel junction of adjacent tooth. The bone defect between the implant and socket walls (jumping distance) was packed with demineralized freeze dried bone allograft (particle size 500 μ -1000 μ) (Figure 1c). The extraction socket was covered with the PRF membranes from all sides (Figure 1d and e). Primary closure of soft tissue was achieved. Closure was done with 3-0 non-resorbable silk sutures (Figure 1f).

Patients were prescribed amoxicillin 500 mg 3 times a day for 5 days and chlorhexidine rinses twice a day for 10 days. Suture removal was done after 7 days. Second stage

surgery was performed after 4 months for placement of final provisionalization.

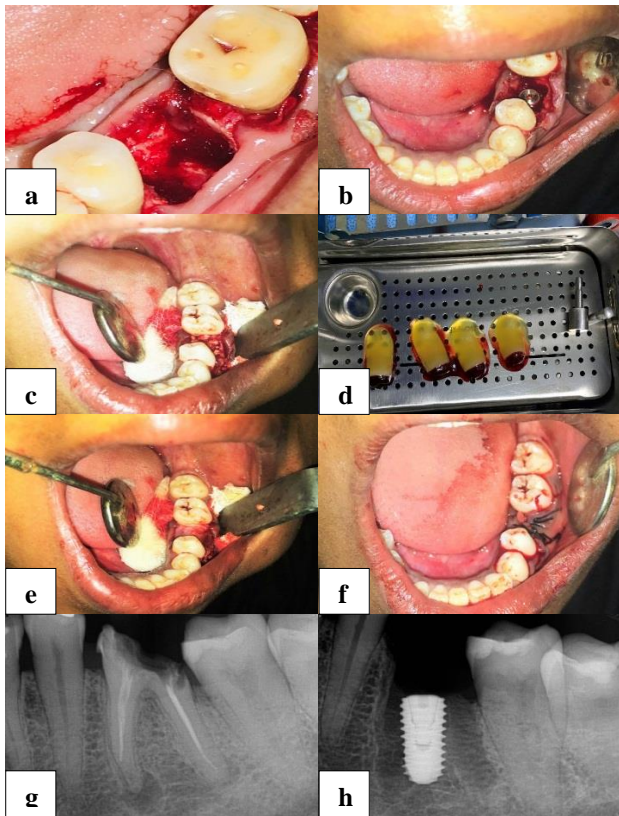


Figure 1: Steps followed for the placement of implant (immediate implant placement in tooth #36) (a) atraumatic tooth extraction preserving alveolar bone integrity, (b) implant placement after sequential drilling, (c) bone graft placement (DFDBA) over the bone defect, (d) PRF membrane prepared, (e) PRF membranes placed over the extraction socket, (f) primary closure achieved using non resorbable silk sutures, (g) preoperative periapical radiograph, and (h) post-operative radiograph.

The follow up period was 1st day, 7th day and 4 months post-op after implant placement during which patients were prospectively evaluated for soft tissue healing or any signs of peri-implantitis clinically (1st day, 7th day, 4th month). Bone height gain and any periapical radiolucency were evaluated radiographically (post-op, 4 month).

All the patients were assessed clinically and radiographically for following parameters: pain was assessed using numeric pain scale; signs of infection (purulent discharge, swelling and redness, fever, abscess/other evidence of infection); vertical measurements from mesial and distal shoulders of implant to first bone to implant contact level in axis parallel to the implant (IS-BIC) via intra oral periapical radiographs taken using the long cone paralleling technique; and stability of the Implant at the time of placement (insertion torque >30 N) and during 2nd stage surgery (Figure 2).

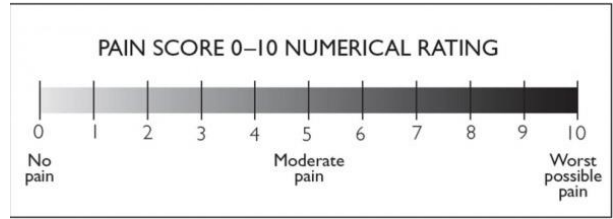


Figure 2: Numeric rating pain scale.

Statistical analysis

The data for the present study was entered in the Microsoft excel 2007 and analyzed using the statistical package for the social sciences (SPSS) statistical software 19.0 version. The descriptive statistics included mean, standard deviation and the calculation of frequency (percentage). The intragroup comparison for the different time intervals was done using paired t test and analysis of variance (ANOVA) was used for the quantitative data and Chi square test for the qualitative data. The level of the significance for the present study was fixed at 5%.

RESULTS

A total of 15 patients exhibiting periapical radiolucencies were included in our study. The mean age was 23.40 years. There were, 07 were male (46.7%) and 08 were female (53.3%) (Figure 3). Out of 15 implants, 07 were placed into left mandibular 1st molar, 03 into right mandibular 1st molar, 02 into left mandibular 2nd molar and 03 implants were placed in right mandibular 2nd molar. The average size of periapical radiolucency seen in left mandibular 1st molar was 1.92 mm, in right mandibular 1st molar was 1.50 mm, in left mandibular 2nd molar was 1.37 mm and in right mandibular 2nd molar was 1.41 mm (Figure 4).

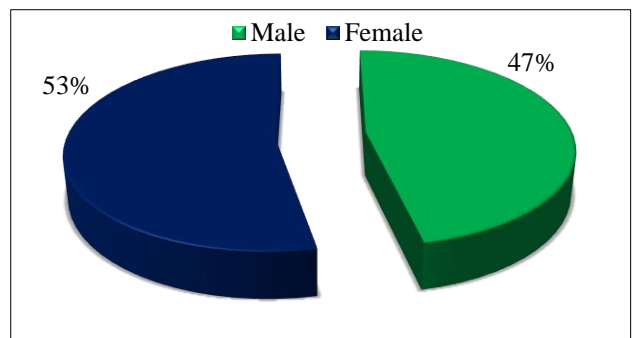


Figure 3: Gender distribution of the study subjects.

Statistically significant reduction in pain from immediate post-op day to 1st post-operative day (p=0.006), from immediate post-op day to 7th post-op day (p=0.006) and from immediate post-op day to 4 months post-op (p=0.006) was seen (Table 1).

Preoperatively swelling was absent in all the 15 subjects. On 1st post-op day 1 subject reported swelling (6.7%). No swelling was reported on 7th day and 4th month post-op.

The result is statistically non-significant ($p=0.384$) (Table 2). Infection was present preoperatively and absent post-op 1st day, 7th day and 4 month in all the subjects. The value is statistically significant ($p=0.001$) (Table 3). Mobility was absent in all the subjects post operatively as well as during 2nd stage surgery. The result is statistically non-significant ($p=1.000$) (Table 4).

Table 5 shows bone height from implant shoulder to first bone to implant contact. IS-BIC on mesial side was 2.10 ± 3.03 mm postoperatively and 0.73 ± 0.67 mm at 4 month interval. On an average, 1.36 mm height gain ($p=0.046$) was seen (Table 5).

Table 6 shows insertion torque values. There was statistically significant difference in the values ($p=0.001$). Postoperatively mean torque value was 37.33 N cm

(SD=2.58), at loading (4 months post-op) average torque value was 67.33 N cm (SD=4.96). The mean difference in the torque post-op and at loading was 29.99.

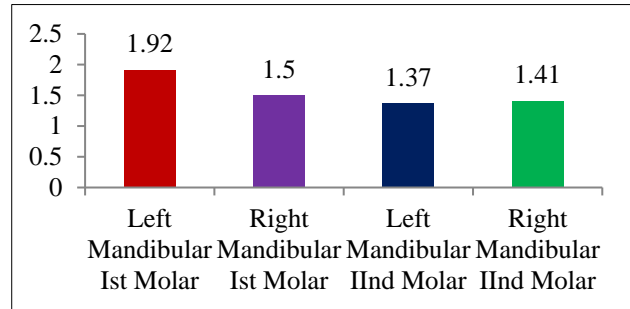


Figure 4: Size of periapical radiolucency according to tooth (in mm).

Table 1: Pain between different intervals.

Interval	Immediate post-op	1 day post op	Difference	P value
Immediate post-op – 1 day post-op	0.53±0.63	0.00±0.00	0.53±0.63	0.006*
Immediate post-op – 7 day post-op	0.53±0.63	0.00±0.00	0.53±0.63	0.006*
Immediate post-op – 4 month post-op	0.53±0.63	0.00±0.00	0.53±0.63	0.006*
1 day post-op – 7 day post op	0.00±0.00	0.00±0.00	0.00±0.00	1.000
7 day post-op – 4 months post op	0.00±0.00	0.00±0.00	0.00±0.00	1.000

*P value <0.05 – significant.

Table 2: Swelling between different intervals.

Intervals	Absent	Present	Chi square value	P value
Pre-op	15 100.0%	00 00.0%	6.731	0.384
1 day post-op	14 93.30%	01 6.7%		
7 day post-op	15 100.0%	0 0.0%		
4 months post-op	15 100.0%	0 0.0%		

*P value <0.05 – significant.

Table 3: Infection between different intervals.

Intervals	Absent	Present	Chi square value	P value
Pre-op	0 0.0%	15 100.0%	60.000	0.001*
1 day post-op	15 100.0%	0 0.0%		
7 day post-op	15 100.0%	0 0.0%		
4 months post-op	15 100.0%	0 0.0%		

P value <0.05 – significant.

Table 4: Implant mobility between different intervals.

Intervals	Absent	Present	P value
Immediate post-op	15	00	1.000
	100.0%	00.0%	
4 months post-op	15	0	
	100.0%	0.0%	

P value <0.05 – significant.

Table 5: Bone height.

Parameters	Post-op	4 month post-op	Height gain	P value
Mesial side	2.10±3.03	0.73±0.67	1.36	0.046*
Distal side	2.50±2.28	0.76±0.90	1.73	0.003*
Mean of mesial and distal	2.30±2.27	0.75±0.74	1.55	0.009*

P value <0.05 – significant.

Table 6: Insertion torque (Nm).

Parameters	Mean	Standard deviation	Mean difference	T value	P value
Immediate post-op	37.33	2.58	29.99	23.238	0.001*
4 months post-op	67.33	4.96			

P value <0.05 – significant.

DISCUSSION

Since the introduction of immediate implants by Lazzarra in 1989, implant surgery has evolved, and currently, implant placement into fresh extraction sites in a 2-stage fashion has proven to be a viable surgical option.³ With the establishment of immediate implant protocols, we are able to preserve precious anchoring bone at the same time reducing treatment duration by 4-6 months in most cases.³

However the procedure cannot be used in every clinical situation. The presence of chronic infection has been considered unfavourable by many authors. Barzilay reported that teeth with periapical pathosis or active periodontal diseases are not ideal candidates for immediate implants.² Quirynen and coworkers in their review stated that retrograde peri-implantitis, might be provoked by the remaining scar or granulomatous tissue after immediate implant placement into extraction sockets.²³

But this predicament was challenged in 1995 when Novaes and Novaes published a case report of 3 endosseous implants placed immediately into chronically infected sites, after thorough debridement and rinsing of extraction socket and pre and post-operative antibiotic coverage.²⁵ They suggested that if surgery is adequately performed and proper preoperative and postoperative care is provided, immediate implants can be placed successfully into chronically infected sites. Since then, various authors have demonstrated similar results in various clinical studies over the years.^{10,13,14,16,17,20-22}

Based on the observations of above mentioned authors, we conducted a clinical trial to evaluate the clinical efficacy

of immediate implants placed into debrided infected dentoalveolar sockets.

In this study, the age of subjects ranged between 18 years and 37 years with a mean of 23.4. Of total 15 subjects, 07 were male (46.7%) and 08 were female (53.3%). Teeth with hopeless prognosis exhibiting type 1 or type 2 periapical lesions according to Fugazzoto classification of periapical lesion and bone available to effect ideal implant positioning were included for immediate replacement with endosseous implants.¹⁵

Osseointegration is also a measure of implant stability, which can occur at 2 different stages: primary and secondary.²⁶ Primary stability of an implant mostly comes from mechanical engagement with cortical bone. Secondary stability, on the other hand, offers biological stability through bone regeneration and remodeling. Primary stability is vital for successful secondary stability.²⁴

Primary stability (insertion torque >30 Ncm) was achieved for all the patients. There was statistically significant increase in Insertion Torque values (p=0.001) immediate post-op to 4 months post-op. Post-operatively mean torque value was 37.33 Ncm (SD=2.58). At the time of loading (4 months post-op), average torque value was 67.33 Ncm (SD=4.96). The mean difference in the torque post-op and at loading was 29.99.

Implant stability was assessed using implant mobility test post operatively and at 4 months. The clinical perception of primary implant stability is frequently based on the mobility detected by blunt ended instrument. Mobility was absent in all the subjects post operatively as well as during

2nd stage surgery. The result was statistically non-significant ($p=1.000$).

In the present study demineralized freeze-dried bone allograft (DFDBA) was used for augmentation of sockets in all the 15 subjects. DFDBA has been used extensively for grafting of extraction sockets. Healing following the use of DFDBA follows a highly regulated cascade of events, ultimately resulting in cellular migration, differentiation, and synthesis of bone. Although the precise origin of these progenitor cells remains unknown, it is clear that they have the capacity to migrate and differentiate into synthetically specialized cell types in response to signals, such as bone morphogenic proteins, present within DFDBA. The rationale for use of DFDBA includes the fact that proteins capable of inducing new bone; i.e., bone morphogenetic proteins, can be isolated from bone grafts. Koutouzis and Lundgren in their study suggested that Implants placed in post-extraction sockets augmented with DFDBA experienced minimal bone loss and were similar to implants placed in native bone.¹⁸ Baron and coworkers described that the combination of guided bone regeneration and augmentation with demineralized freeze-dried bone resulted in most favorable results as compared to hydroxyapatite regarding bone gain and reosseointegration in treatment of peri-implantitis.²⁸

Choukroun et al developed PRF which is an immune and platelet concentrate collecting all the constituents of a blood sample favorable to healing and immunity on a single fibrin membrane.⁹ PRF membrane promotes angiogenesis, immunity, and epithelial cover which are the 3 keys to healing and soft tissue maturation. With the fundamental considerations, PRF can be considered as a natural fibrin-based biomaterial favorable to the development of a microvascularization and able to guide epithelial cell migration to its surface. The interest of such a membrane is evident, namely, to protect open wounds and to accelerate healing. Furthermore, this matrix contains leukocytes and promotes their migration. Its utilization seems to be of high interest in the case of infected wounds.

Mazor and coworkers in their study added to the benefits of PRF by using it as a sole filling material during a simultaneous sinus lift and implantation procedure which stabilized a high volume of natural regenerated bone in the subsinus cavity up to the tip of the implants.¹⁹ Hsu et al suggested the application of a PRF as a barrier membrane when performing simultaneous implant placement and ridge augmentation procedures.¹¹ However Baslarli and coworkers did not find significant difference in healing of mandibular 3rd molar sockets augmented with PRF and suggested that to better understand the effects of PRF on healing; further research is warranted with larger sample sizes.¹²

In the present study, PRF and DFDBA was used for the purpose of guided bone regeneration. Clinical effectiveness of PRF membrane and DFDBA was

evaluated on the basis of postoperative pain, swelling and any signs of infection clinically (1st day, 7th day, 4th month post-op) and bone height gain and any signs of periapical pathology radiographically (post-op, 4 month).

Pain was assessed using numeric pain scale rating.²⁷ Statistically significant reduction in pain scores from immediate post-op day to 1st post-op day ($p=0.006$), from immediate post-op day to 7th post-operative day ($p=0.006$) and from immediate post-operative day to 4 months post-op ($p=0.006$) was seen. Statistically non-significant difference in pain from 1st day post-op to 7th day post-op ($p=1.000$) and from 7th day post-op to 4 month post-op ($p=1.000$) was observed.

Swelling between different intervals was assessed clinically. Preoperatively swelling was absent in all the 15 subjects. On 1st post-op day 1 subject reported swelling (6.7%) which resolved itself. It could have been the result of tissue reaction to osteotomy done for implant placement or periosteal ribboning that was performed to achieve primary closure in the patient. No swelling was reported on 7th day and 4th month post-op. The result is statistically non-significant. Soft tissue healed uneventfully in all the subjects.

Signs of infection (purulent discharge, swelling and redness, fever, abscess/other evidence of infection by direct visualization or radiographically) was assessed both clinically and radiographically between different intervals. Statistically significant ($p=0.001$) reduction in infection was seen. Infection was present preoperatively in all the subjects and absent post-op 1st day, 7th day and 4 month in all 15 subjects.

Vertical measurements from mesial and distal shoulders of implant to first bone to implant contact level in axis parallel to the implant (IS-BIC) were measured using intra oral periapical radiographs.¹⁷ Statistically significant gain in bone height is seen. Bone height from implant shoulder to first bone to implant contact IS-BIC on mesial side was 2.10 ± 3.03 mm postoperatively and 0.73 ± 0.67 mm at 4 month interval. On an average, 1.36 mm height gain ($p=0.046$) was seen. IS-BIC on distal side was 2.50 ± 2.28 mm post-op and 0.76 ± 0.90 mm at 4th month. Height gain of 1.76 mm ($p=0.003$) was seen. The mean IS-BIC was 2.30 ± 2.27 mm post-op and 0.75 ± 0.74 mm at 4 months. Average height gain on mesial and distal side was 1.55 mm ($p=0.009$).

Limitations

In our study there were few drawbacks. To begin with, study involves small sample size, marginal bone loss was not included in our criteria as our study only focused on the success of bone augmentation and soft tissue healing. Longer follow ups are required to further confirm the successful osseointegration of the implants.

CONCLUSION

Within the limitations of the study, it was concluded that, socket augmentation using DFDBA and PRF membrane in immediate implants placed into mandibular molar extraction sockets exhibiting periapical pathology is a valid operative technique that leads to predictable outcomes if adequate pre-operative and postoperative care is taken. It is a cost effective, time saving and reliable treatment option in terms of patient satisfaction.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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