Assessment of the Feasibility of Pre-Emptively Fabricated Root Analogue Zirconia Implant from Cone Beam Computed Tomography Scan-A Prospective Pilot Study

Sundaram DS[1], Yadav R[1*], Jain V[2], Roychoudhury A[1], Bhutia O[1] and Yadav P[1]

[1]Department of Oral and Maxillofacial Surgery, Centre for Dental Education and Research, All India Institute of Medical Sciences, New Delhi, India

[2]Department of Prosthodontics, All India Institute of Medical Sciences, New Delhi, India

***Corresponding author:** Rahul Yadav, Department of Oral and Maxillofacial Surgery, Centre for Dental Education and Research, All India Institute of Medical Sciences, New Delhi, 110029, India

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Abstract:

Objective: The objective of the study was to assess the feasibility and clinical effectiveness of pre-emptively fabricated root analogue zirconia implants (RAZI) based on 3-dimensional root surface models obtained from cone beam computed tomography scan (CBCT).

Materials and methods: A prospective pilot study was designed on subjects requiring extraction & immediate rehabilitation of tooth. Virtual tooth preparation and extraction was done on the data obtained from CBCT. RAZIs made of high-strength yttrium stabilised zirconia were made with computer aided designing and computer-aided milling (CAD-CAM). The tooth was atraumatically extracted, and immediate implant placement was done. Clinical parameters including gingival index, plaque index, bone loss, pocket depth, and implant stability were assessed. Surface area and volume analysis were performed comparing extracted tooth and implant. Paired t-test and bivariate Pearson correlation coefficient was applied.

Results: 2 out of 9 implants survived at 1-year follow-up accounting for a low success rate of 22.2%. Surface area and volume of the RAZI were 9.6% and 10.40% higher than the extracted tooth respectively.

Conclusion: The lower success rate of RAZI is attributed to difference in surface area and volume from extracted teeth. Though this technique validates pre-emptive fabrication of RAZIs even before tooth extraction, dimensional error should be minimized to achieve better clinical results.

1. Introduction

Conventional titanium dental implants have been widely used for oral rehabilitation. Hodosh et al were the first to propose a polymethylmethacrylate root analogue implant (RAI) [1]. Later, Lundren et al [2], and Kohal et al [3] developed the concept by RAI made of titanium via in-vitro studies. W.K Pirker popularized the use of zirconia-based RAI as a replacement for conventional titanium implants [4]. Authors have proposed several methods for data acquisition for root analogue zirconia implant, which include data of the optically scanned surface of the extracted socket, extracted tooth and impression of the tooth socket [5-8]. Above mentioned methods, necessitate extraction of the tooth for fabrication of RAI. A unique approach was used by DA et al in which cone beam computed tomography (CBCT) of the tooth was utilized to construct RAI pre-emptively in human mandible cadaver [9]. Although these techniques seem intriguing, no clinical study has focused on the fabrication of RAI pre-operatively to restore the tooth at the time of extraction. The objective of the present study was to evaluate the feasibility of 3D printed RAZI fabricated pre-emptively from CBCT. The authors hypothesized that root analogue zirconia implants do osseointegrate, making it an alternative for conventional zirconia implants. The aim of the study was to evaluate the success rate of custom-made RAZI dental implant at 1-year follow-up.

2. Materials and Methods

2.1. Study Design

A prospective pilot study was conducted after obtaining ethical committee approval (Ref. No.: IECPG-608/19.12.2018, RT-14/28.02.2019). Patients above 16-years of age, fractured tooth, uncompromised periodontal ligaments, single rooted tooth, unsuccessful root canal treatment were included in the study. Patients with compromised oral hygiene status, tooth extraction necessitating surgical intervention, active periodontal infection, any systemic disorder, and smoking were excluded.

2.2. Study Variables

Primary outcome variable was osseointegration of the RAZI and secondary outcome variables were implant stability, plaque index, gingival index, pocket depth and crestal bone loss. Primary stability was assessed with periotest. All subjects were followed up for a period of 1-week, 1-month, 3-months, 6-months and 1-year. During each follow-up intraoral periapical radiograph of the implant was taken and following clinical parameters were assessed: 1) Gingival index, 2) Plaque index, 3) Soft tissue integration, 4) Pocket depth, 5) Bone loss, 6) Implant stability. Bone loss was measured on mesial and distal aspect radiographically from IOPA digitally. Implant stability was evaluated by periotest (-8 to 9-grade 0, +10 to 19- grade 1, +20 to 29-grade 2, and +30 to +50-grade 3). Gingival and plaque index score were evaluated by standard technique.

2.3. Study conduction and data collection (Figure 1 represents steps of implant fabrication)

2.3.1. Phase I: Tooth preparation

After oral prophylaxis, the tooth of interest was prepared to construct future abutment. Superstructure was built using silver reinforced GIC (Miracle mix) and few cases with pin retained restoration. Tooth preparation was carried out in standard way and gingival margin was defined to receive future prosthesis in implant.

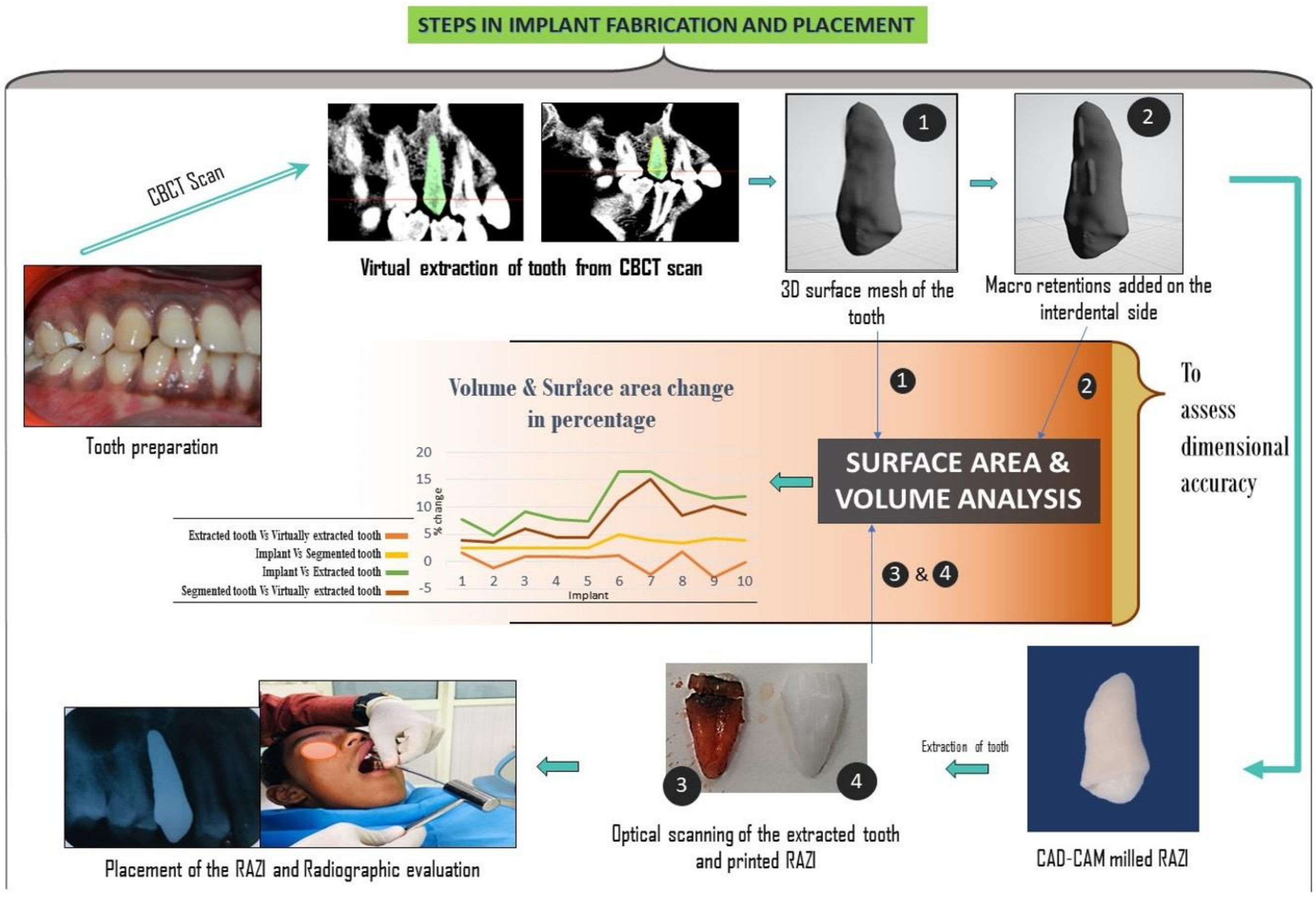

Figure 1: Study workflow describing steps in implant fabrication, placement and data analysis.

2.3.2. Phase II: Implant fabrication, placement and clinical evaluation

A) Data Acquisition and Virtual tooth extraction

CBCT images of the prepared tooth were obtained using standard protocol. Data were exported in DICOM (Digital Imaging and Communications in Medicine) format with an 0.1 mm voxel size. Data sets were exported to Mimics 21.0 (Materialise, Leuven, Belgium) for the purpose of segmentation. Segmentation of the root from imported data sets was done precisely to mimic virtual extraction of the root. The landmarks used were apex of the root inferiorly, CEJ (Cemento-Enamel Junction) superiorly, and periodontal space as lateral boundary.

B) 3D Tooth model:

The virtually extracted tooth data was exported to Autodesk Meshmixer (Computer Assisted Design program) in STL (Standard Triangle Language) format. The tooth roots were smoothened. To provide primary stability, ridges were added limiting to medial and distal surface of each tooth root.

C) Root Analogue Zirconia Implant:

Finally, 3D tooth model with ridges were exported back to Mimics 21.0 to evaluate the congruence with its surrounding structures. This 3D tooth data was exported in STL format for CAD-CAM (Computer Aided Design & Computer Aided Manufacturing) printing. Aidite (Qinhuangdao - Technology Co., Ltd) high strength medical grade yttrium stabilised zirconia blanks were used for manufacturing of the implants. Implants were milled using 5 axis VHF K5 Plus CAD-CAM milling machine (VHF camfacture AG, Deutschland) with 3-micron repetition accuracy and then sintered using Zircom (KDF, Japan) sintering furnace. The milled implants were subjected to optical scanning using 3Shape (Copenhagen, Denmark) optical scanner with 4-micron accuracy.

D) Sterilization and Surgical technique:

Various authors have used 96% ethanol in an ultrasonic bath for 30 minutes followed by steam sterilization [10]. All the implants in the study were subjected to sand blasting using aluminium oxide (Al_2O_3) particles followed by plasma sterilization.

With the use of periotome, atraumatic extraction of the tooth of interest was carried out under local anaesthesia without flap elevation. The extraction socket was curetted to remove the left-over periodontal ligament fibres and irrigated with isotonic saline.

The implants were placed in extraction socket followed by gentle finger pressure and malleted using hand mallet. Once the desired depth was achieved and abutment region of the RAI reached the infra occlusion level (leaving appropriate clearance of 1.5-2mm for future prosthesis), malleting was stopped. Percussion test was done to assess the implant stability. Metallic sound was heard in all implants confirming firm placement. Later, the extracted tooth roots, similar to their respective 3D printed implants, were subjected for optical scanning. Final preparation was done to the osseointegrated implants during the 4th month and gingival margins were defined. Metal ceramic crowns were fabricated.

2.3.3. Phase III: Data interpretation

The optical scanned data of milled implants and their respective extracted tooth roots were exported to Mimics 21.0 in STL format. With optical scan data of extracted tooth being the “Standard value”, the STL data of Virtually extracted tooth, 3D tooth and the Zirconia implant were superimposed by aligning in all three axes.

Four data sets were used to evaluate the accuracy in fabrication of RAZI (Root Analogue Zirconia Implant) at various steps with Surface Area (SA) and Volume (V) as prime parameters.

1) Extracted tooth root
2) Virtually Extracted tooth root
3) 3D Tooth
4) Zirconia Implant

2.4. Data analysis

Descriptive statistics was performed by calculating mean and standard deviation for the continuous variables. Categorical variables were presented as absolute numbers and percentage. The software used for the statistical analysis was SPSS (statistical package for social sciences) version was 26.0. Paired t-test and bivariate Pearson correlation coefficient was applied.

3. Results

The study included 8 subjects (m:f=0.6:1), (9 implants) with the mean age of 30 ± 10.92 years. Descriptive statistics of the present study is given in Table 1. On comparing the superimposed STL models for surface area and volume, there was an increase in mean between extracted tooth, virtually extracted tooth, 3D tooth and milled zirconia implant in an ascending order.

Table1: Demographic data of the study population.

S.No	Study Variable (N=8 (9))		Descriptive statistics
1	Age		30 ± 10.92 years
2	Gender distribution	Male	3 (37.5%)
		Female	5 (62.5%)
3	Tooth	Central incisor	1 (11.1%)
		Canine	2 (22.2%)
		Premolar	5 (55.5%)
		Molar	1 (11.1%)
4	Condition of tooth	Root stump	1 (11.1%)
		Grossly decayed tooth	4 (44.4%)
		RCT failed	4 (44.4%)
5	Complication while extraction	Root fracture	2 (22.2%)
6	Complication while implant insertion	Buccal cortex fracture	2 (22.2%)

Paired t-test revealed a statistically significant difference between the mean volume and surface area of 3D tooth vs implant, extracted tooth vs implant and segmented tooth vs virtually extracted tooth. ($P<0.001$). However, difference between mean volume and surface area between extracted and virtually extracted tooth was not statistically significant ($p<0.05$). The virtually extracted tooth exceeded the extracted tooth surface area by 0.26% and diminished in volume by 0.29%. The RAZI exceeded the segmented tooth surface area by 3.05% and volume by 3.10%. The 3D tooth exceeded virtually extracted tooth surface area by 6.50% and in volume by 6.77%. The RAZI exceeded the extracted tooth surface area by 9.61% and volume by 10.40% (Table 2).

The clinical parameters were represented in two groups based on survival.

Group 1: Failed implants (7 implants) -Figure 2 showing aseptic loosening with tenderness to percussion. All failed implants showed peri-radicular halo with pressure induced resorption.

Group 2: Surviving implants (2 implants) Figure 3 showing clinical (arrowed) and radiographic image of successful root analogue implant at 1-year follow up after prosthetic rehablitation.

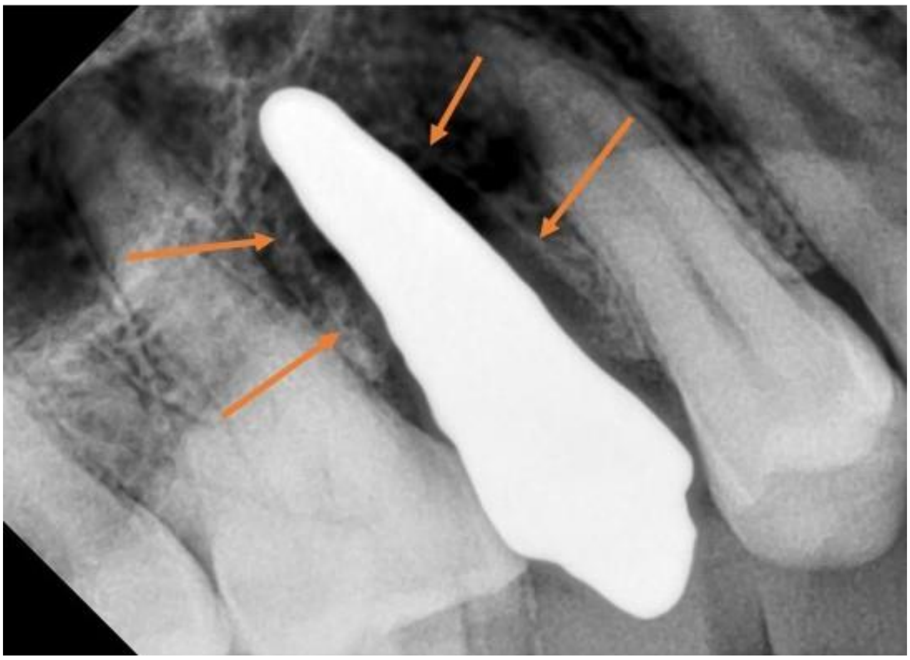

Figure 2: Failed implant showing peri-radicular halo with pressure induced resorption

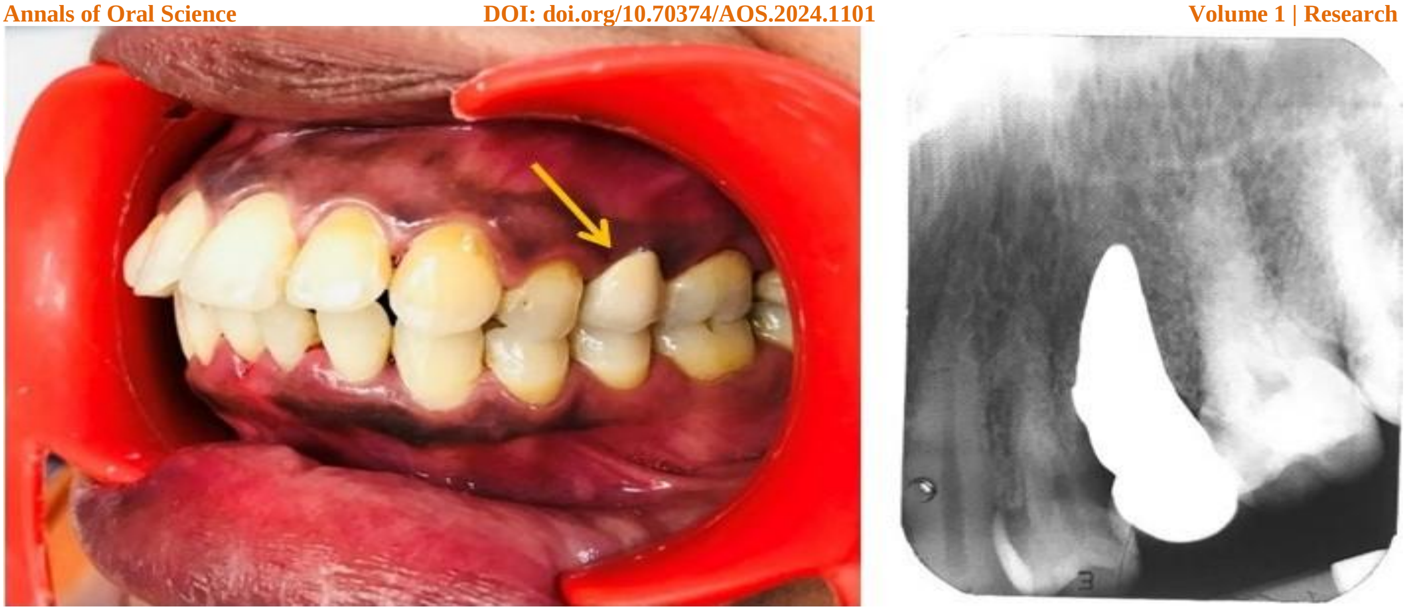

Figure 3: Clinical (arrowed) and radiographic image of successful root analogue implant at 1-year follow up after prosthetic rehablitation.

4. Gingival and Plaque Index Score

There is a statistically significant (p= 0.008) difference in gingival index between preoperative and 3-months follow-up in failed implants. However, there was no significant difference in surviving implants at various intervals. Similarly, there is a statistically significant (p = 0.008) difference in plaque index between preoperative and 3-months postoperative period in group I. However, there was no significant difference in surviving implants at various intervals (Table 2).

Table 2: Comparison of clinical parameters at various time intervals.

Parameters	Group	Interval	Mean difference	p-value
Gingival index	I	T1 – T3	0.71	0.008*
Plaque index	I	T1 – T3	0.71	0.008*
Pocket depth	I	T1 – T3	0.87	<0.001*
	II	T1 – T3	1.94	0.31
		T3-T4	0.06	0.5
		T4-T5	0.5	0.5
		T1 - T5	2.5	0.34
Implant stability (PTV)	I	T1 – T3	16	<0.001*
	II	T1 – T3	1	1
		T3-T4	1	0.5
		T4-T5	2	0.29
		T1 - T5	0	1
Crestal bone loss (Mesial side)	I	T1 – T3	1.14	<0.001*
	II	T1 – T3	1.36	0.084
		T3-T4	0.7	0.177
		T4-T5	0.8	0.284
		T1 - T5	2.86	0.166
Crestal bone loss (Distal side)	I	T1 – T3	1.26	<0.001*
	II	T1 – T3	1.57	0.059
		T3-T4	0.43	0.066
		T4-T5	0.88	0.155
		T1 - T5	2.79	0.087

(Note: Group I: Failed implants, Group II: Surviving implants, PTV – Periotest value, T1- 1 week, T2- 1 month, T3- 3 month, T4- 6 month and T5- 1year).

5. Pocket Depth and Implant Stability

Table 2 shows statistically significant difference (P<0.001) in group I between preoperative and 3-month postoperative pocket depth values. No significant difference was seen in group 2. Similar results were seen for implant stability (table 2). Statistically significant difference (P<0.001) was seen in group I between preoperative and 3-month postoperative period with respect to mesial and distal crestal bone loss and insignificant difference was seen for group 2.

Table 3: Percentage change in surface area and volume between various groups along

Parameters	Mean (SD)		% Change	Paired t test	Pearson correlation	
				p-value	Score	p- Value
Surface Area	Extracted Tooth	Virtually Extracted Tooth	on Extracted Tooth	0.674	0.999	<0.001
	238.84 (77.80)	238.22 (78.15)	0.26			
	Segmented Tooth	Implant	on Segmented Tooth	<0.001	0.995	<0.001
	252.93 (72.65)	261.80 (73.21)	3.5			
	Extracted Tooth	Implant	on Extracted Tooth	<0.001	0.982	<0.001
	238.84 (77.80)	261.80 (73.21)	9.61			
	Segmented Tooth	Virtually Extracted Tooth	on Segmented Tooth	<0.001	0.974	<0.001
	252.93 (72.65)	238.22 (78.15)	6.5			
Volume	Extracted Tooth	Virtually Extracted Tooth	on Extracted Tooth	0.554	1	<0.001
	246.32 (112.60)	247.04 (113.93)	-0.29			
	Segmented Tooth	Implant	on Segmented Tooth	<0.001	0.982	<0.001
	263.78 (113.65)	271.94 (115.31)	3.1			
	Extracted Tooth	Implant	on Extracted Tooth	<0.001	0.994	<0.001
	246.32 (112.60)	271.94 (115.31)	10.4			
	Segmented Tooth	Virtually Extracted Tooth	on Segmented Tooth	<0.001	0.993	<0.001
	263.78 (113.65)	247.04 (113.93)	6.77			

6. Discussion

Since the introduction of dental implants, there has been considerable evolution in the choice of material, surface characteristics, and timing of placement of the dental implant. The titanium owing to its biocompatibility was the choice of material for dental implants. The search for an alternative material for dental implant fabrication paved the way for yttrium stabilized zirconia which has good biocompatibility, reliable mechanical properties, and superior aesthetics. By mimicking the morphology of the tooth root, RAZI adapt to the extraction socket, thereby reducing trauma to the surrounding structures.

With recent advancements like rapid prototyping, pre-emptive fabrication of the implant is possible, reducing the intra-operative time. Various authors have used laser scanning of the extracted tooth for the fabrication of the implants. These implants had a delay period of 10 days between the day of extraction and placement of the implant [4,5,7,10]. However, in the present study, all pre-emptively constructed zirconia implants were placed on the day of extraction using finger pressure and malleting technique to aid in immediate rehabilitation of the extraction socket.

Achieving primary stability in such patient-specific RAI demands accuracy in root anatomy. Few authors suggest the addition of macro retentions to the root surfaces for improved stability and osseointegration. The addition of macro retentions to the root surface using light cure composite before subjecting to laser scanning process is one method [4,7,10]. Pirker et al [4] reduced the cervical regions by 0.12-0.2mm on the buccal and lingual sides and added macro retentions to the interdental root areas. This was thought to reduce the chances of pressure-induced resorption and avoid fracture of the thin buccolingual cortex during implant insertion. As suggested by Pirker et al, macro retentions were limited to the interdental areas in the present study. According to the geometric analysis in the current study, the macro retentions contributed to just 3%-dimensional change in the virtually extracted tooth, rendering them inconsequential.

Surface area and volume analysis showed a difference of 0.26% and 0.29% between the extracted tooth and the virtually extracted tooth, respectively. However, the implant surface area and volume were 9.6% and 10.40% higher than that of the extracted tooth, respectively, suggesting a significant discrepancy. The discrepancy in the size of the RAZI caused pressure-induced resorption, leading to decreased stability in the long term. Thus, after sintering, the dimensional change in the RAZI explains the higher failure rate of the study.

All the failed implants showed clinical mobility and yielded fibrous tissue on curettage of the socket. Histopathological examination revealed parakeratotic stratified squamous epithelium and dense collagen fibers with interspersed fibroblasts, endothelial lined blood vessels, hemorrhagic areas in the connective tissue, all of which were suggestive of mild inflammatory fibrous tissue. The inflammatory fibrous tissue is the result of pressure-induced resorption caused by the oversized implant that were positive for percussion.

The probing depth was 4mm in group II which progressed to 4.56 at the end of one year. Mucosal recession was observed in three cases, accounting for 33.3% (3 out of 9 implants). To the best of our knowledge, no studies have documented the periodontal status and recession of RAI. Immediate implants are more likely to result in marginal bone loss. A bone loss of 2.4mm and 2.46mm at three months on mesial and distal aspects, respectively, on surviving implants. The bone loss progressed up to 3.91mm and 3.68mm at one year period. The failed implants had an average bone loss of 2.07mm and 2.26mm on mesial and distal aspects, respectively, at the end of 3-months. The current study found a considerable amount of bone loss even among surviving implants, raising concerns about their long-term prognosis.

The overall survival rate of the RAI fabricated pre-emptively using CBCT data by the method proposed in the study is 22.2% (2 out of 9) at the end of 1-year. On the contrary, Pirker and Kocher et al [8] documented 92% of the overall success rate in root analogue zirconia implant fabricated with laser scanning over a 2-year period. Since the implants were placed on the day of extraction, the geometric (volumetric) resemblance of the tooth and the pre-emptively constructed implant could not be compared before implant placement. The geometric shrinkage of the zirconia implants during sintering has to be predetermined for achieving accuracy in fabricated implant design. The surface characteristics of root analogue zirconia implants should be improved either by addition or subtraction to improve osseointegration.

The current study has shown that the clinical time can be reduced by rehabilitating the socket on the day of extraction. However, studies with a large sample size, and standardization of protocol for designing such implants, their path of insertion, surface modifications and method of placement is essential. If an effort is taken to mitigate the shrinkage occurring during milling, the clinical effectiveness can be significantly improved.

7. Conclusion

The present study demonstrated the feasibility of using root analogue zirconia implants if dimensional accuracy is maintained while fabrication.

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