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Survival and Radiographic evaluation of Root-Analogue versus Root-Form Zirconia Implants: 18 months follow-up study

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Abstract

Objectives This study evaluated the survival rate and the marginal bone loss of root-analogue compared to root-form zirconia dental implants.

Materials and Methods 28 patients, 35-45 years old, with a free medical history and presenting with a non-restorable mandibular premolar, were selected in this research. Atraumatic tooth extraction and immediate placement of zirconia one-piece implants were performed.

The total number of patients were divided according to the type of implants into the zirconia Root-Analogue group (RA, n=14), which w customized to the exact shape of the extracted root. Retentive features were added to the implant surface with the aid of CAD/CAM on Yttria tetragonal zirconia polycrystal blocks (Y-TZP) (Ceramill Zi, Amann Girrbach, Austeria) and prefabricated Root Form group (RF, n=14)(WhiteSky, Bredent, Germany). After 3-5 months of placement, the two groups were then subdivided according to the type of implant supported restoration (n=7) into zirconia crowns (RAZ and RFZ) and PEEK crowns (RAP and RFP) WhiteSky, Bredent, Germany). Clinical survival rates were evaluated in addition to radiographic measuring of marginal bone loss (MBL) in each group at baseline, 3, 6, 12, and 18 months.

Outcomes Early loss of three RA implants before loading resulted in a cumulative survival rate of 79.5%. However, the RF group showed a survival rate of 100% at all follow-up periods of 18 months. The surviving implants showed mean MBL, 1.7mm(1.5-1.8), 1.35mm(1.2-1.5), 1.2mm(1.0-1.2), and 1.0mm(0.9-1.5) for RAZ, RAP, RFZ, and RFP, respectively at 18 months of follow up. Clinical examination during the follow-up periods did not reveal any parameter influencing MBL.

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Conclusion RA implants should not be recommended as a substitute for prefabricated RF implants due to the increased incidence of premature failure, however using PEEK crowns as supra structure restorations may influence the outcomes related with marginal bone loss.

Keywords: zirconia implants, one piece, custom made implants, root-analogue, root-form.

Introduction

Zirconia dental implants have emerged as a promising alternative to titanium dental implants in recent years, primarily due to their aesthetic appeal and potential biocompatibility advantages [1].

Zirconia possesses several beneficial properties, including high flexural strength (900-1200 MPa), strong corrosion resistance, exceptional durability, and excellent resistance to bacterial adhesion, all of which contribute to the success of dental implants [2-4]. According to literature, Zirconia dental implants exhibit a one-year survival rate of approximately 98.3% and a two-year survival rate of about 97.2%, comparable to the results of titanium implants [1].

Immediate implant placement after tooth extraction was first introduced by fireSchulte and Heimke in 1976 as a substitute to the conventional surgical protocol, which requires a four to six months healing period [6]. This approach has become a common clinical protocol in dental implantology due to its advantages, such as reduced treatment time, reduced number of surgical procedures, and increased patient satisfaction [1,2]. Even though this treatment option had high survival rates (97–98%) [1,2] there was some resorption of the alveolar ridge. Despite early recommendations, implant placement into a newly created extraction socket does not stop the bone remodeling. Nonetheless, maintaining the alveolar ridge is necessary for the stability of the peri-implant mucosa and the aesthetic benefits of replacing missing teeth. Evidence suggests that with appropriate surgical management, the effects of alveolar bone resorption can be reduced [1].

The use of root-analogue implant (RA) adopt the idea of shaping the implant to mimic the bone socket rather than shaping the bone to mimic the pre-fabricated implant reducing the bone and soft tissue trauma related to the classic implant procedures [6]. This idea of replicating the extracted tooth aims to eliminate the need for bone drills, which may potentially induce bone necrosis. Even the heat generated from the hand-piece during drilling can cause tissue damage, which affects osseo-integration [7]. Wheeler et al (2000) [1] demonstrated preservation of hard and soft tissue with enhancement of the esthetic result after immediate placement of tapered root-analogue implants combined with custom healing abutments. Pirker et al (2008) [9] published a case report for an implant placement technique then followed it with a two year case report of using a zirconium custom made replica of an extracted tooth to substitute conventional titanium implants with success [1]. RA implants also demonstrated better stress distribution on the surrounding bone than screwed implants, as disclosed by finite element analysis literature [11,12].

Implant and superstructure are a functioning complex that work together to withstand occlusal forces. Maximum occlusal forces are reported to be in the range of 286 N in anterior region and 847 N in molar region [1]. The Early and late implant failure rates have been frequently reported in clinical studies. Successful osseointegration that

is followed by a failure in the implant is associated with implant supra structure. The forces, magnitude and direction of forces applied to the supra structure also affect the success of suprastructe- implant complex. This is related to the implant number and location, prosthetic design, and bone quality [1]. Occlusal material with a low modulus of elasticity, such as acrylic resin lessens the occlusal impact forces, thereby decreasing its effect on the bone-implant interface [2]. PEEK is used as implant supra-structure because its young's modulus near to cortical bone. In pure form, PEEK has a modulus of elasticity around 3.6 GPa. However, Carbon fiber reinforced PEEK is 18 GP and Glass fiber reinforced PEEK is 12 GPa. This feature gives PEEK a favorable stress shielding feature and a cushion effect above dental implants [3,4]. Although numerous researchers have studied RA zirconia implants, [1,2,12] no recent studies clinically compared RA and root-form (RF) one-piece zirconia implants with a more than one-year follow-up period. The null hypothesis of this study was that both types of implants have no significant differences in clinical and radiographic outcomes.

Materials and methods:

A total of 28 female patients aged between 30 and 45 years, all presenting with massive damage to their mandibular premolar teeth, were selected from many patients included in a study conducted at the Faculty of Dentistry, Mansoura University, Egypt. Patient selection criteria involved the following: adequate bone density (D2 or D3) and volume, a healthy periodontium with no signs of periapical pathosis, an intact buccal plate of bone with a minimum 1 mm thickness, conical root in the extracted teeth, and patient compliance and co-operation. Written consents, with approval from the patients regarding all treatment procedures and follow-up visits, was obtained following the recommendation of the Biomedical Ethics Committees of Mansoura University in compliance with the 1964 Helsinki Declaration principles for the involvement of human subjects in clinical experiments.

The selected patients were divided based on the design of the implant type used in the treatment into two groups: Root-analogue (RA, n=7) and Root-form (RF, n=7). Following a comprehensive clinical and radiographic assessment, pre-operative photographs were taken for each case (Figure 1, 2). Then, patients were subjected to atraumatic tooth extraction (Figure 3) using a periostome. Subsequently, the socket was debrided, cleaned from granulation tissue, and thoroughly washed with normal saline. A periodontal probe was used to examine the socket for any fenestrations or fractures.

Root-Form implant placement procedures:

Prefabricated zirconia dental implants commercially available as whiteSKY (Bredent, Germany) were selected. The Surgical protocol followed the manufacturer's instructions and the clinical and laboratory manual of dental implants abutments (Figure 4), to confirm achieving the implants' primary stability [7].

The initial drill was used at a speed of 800 rpm, only to ensure that the socket's most coronal and apical portions were prepared for subsequent drills. The twist drill was used at 300 rpm to replicate the drilling procedure's orientation. The paralleling pen was used to confirm proper inclination with radiographs.
The final drills expanded the cavity's diameter and prepared the implant's central core. The crystal drill was used to prepare the implant cavity coronally to match the width of the implant platform, preventing any stress that could lead to cortical bone degeneration. The implant was unpacked and delivered at first using the rubber holder attached to it.
The implant was securely screwed into the osteotomy site using the holder until it stabilized entirely. Subsequently, the rubber holder was removed from the top of the implant. The implant was threaded clockwise until its apex was stabilized in the osteotomy site. Primary stability achieved immediately after insertion was at least 30 Ncm and not exceeding 45 Ncm, ensuring the bone was protected from undesired forces. The measurement of primary stability was performed using the torque wrench.

Root Analogue Implant Placement Procedures:
According to the technique of RA immediate implants placement suggested by Priker et al, The extracted tooth was soaked in a sodium hypochlorite solution for 20 minutes, followed by ultrasonic cleaning to remove any soft or hard structures adhering to the tooth's cementum. The root was modified with macro-retention features added exclusively on the interdental surfaces. In addition, reduction was carried out on both the buccal and lingual surfaces by 1mm, and a tooth stump was created to work as an abutment for subsequent attachment to the crown.
The macro-retention features were designed as three serrations, each not exceeding 1 mm in thickness, with smoothly rounded angles and starting 2 mm beyond the cemento-enamel junction, with a 2 mm gap between them (Figure 5).
The tooth stump was positioned 1 mm above the CEJ with a finish line of 1 mm. The stump's height was maintained at least 4 mm, with a convergence angle of approximately 3-6 degrees. The modified root surfaces were covered with scan spray (Arti-Scan CAD/CAM Spray; Bausch GmbH & Co. KG, Koln, Germany) and subjected to laser scanning, following the software instructions with ceramill map 400, scanner of Ceramill motion 2 CAD-CAM system (Ceramill motion 2 system, AmannGirrbach GmbH, Germany). After scanning, an animated photo of the implant was designed using Ceramill Match 2 software (Figure 6).
Based on the scanning data, the implants were milled from Ceramill zolid preshades blocks (HT Zirconia) (Ceramill ZI 71; AmannGirrbach GmbH, Germany). The blocks were milled with diamond rotary cutters (Ceramill motion 2 Diamant, AmannGirrbach GmbH, Germany) for dry processing of zolid ceramics (Figure 7). The cutters employed for milling included a 1.0 mm orange diamond cutter (#760624) for gross milling and a 0.4 mm orange diamond cutter (#760627) for finer adjustment. Subsequently, the implants were

cleaned manually and ultrasonically in alcohol at 70°C for 15 min, packaged, and steam-sterilized at 135o C for 45 minutes.

Placement of the Root Analogue Implant:

Immediately after extraction of the tooth and subsequent removal of any granulation tissue, a piece of cotton gauze soaked with Iodoform was inserted into the socket. The patient was scheduled for a follow-up after 48 hours of extraction. The cotton gauze placed in the extraction socket was removed, and the socket was thoroughly curetted and cleaned with normal saline using a syringe.

The fresh blood was observed to initiate from the socket, and the zirconia implant was inserted in the socket using finger pressure carefully, then gently tapped into the sockets with a dental mallet. Primary stability was checked through percussion and palpation. Immediately after implant placement, a radiographic examination confirmed that the implant had reached the entire length of the extraction socket.

Postoperative care:

Postoperative cold application was recommended to minimize edema and hematoma formation. Additionally, a broad-spectrum antibiotic (Augmentin 625 mg. GlaxoSmithKline Co, Egypt) was administered before surgery and continued for five days after surgery to prevent infection. Appropriate medication for pain control, as a non-steroidal anti-inflammatory drug (Ibuprofen 400 mg. Snafi Aventis, Egypt) and chlorhexidine mouth rinses. Furthermore, Patients were instructed to maintain a relatively soft diet and avoid touching the area of implantation after surgery for the first week.

Prosthetic phase:

a) Fabrication of provisional restoration:

A removable appliance was fabricated for the abutment cover, ensuring a minimum clearance of 1 mm from all directions between the abutment and the fitting surface of the appliance (Figure 8).

The patient was instructed to wear the appliance while eating and sleeping and only removed it for cleaning.

b) Abutment preparation:

After 3-5 months of implant placement, the implants were subjected to radiographic examination (Figure 9) and clinical evaluation (Figure 10).

The abutment portion of the implant was modified, and adjustments were made to the interocclusal space as necessary. The preparation was done according to the manufacturer's instructions, as follows: The height was reduced to a maximum of 1.5 mm. The remaining abutment height was approximately 1/3 of the final crown height. The diameter was reduced by a maximum of 50%. The abutment preparation ensured an occlusal clearance of 2 mm and a finish line contouring of a 1 mm chamfer. Additionally, the angulation of the abutment was also adjusted when needed.

Final impression:

The gingival retraction was obtained using a retraction cord. The color of the crown matched the neighboring teeth using a shade guide. A conventional one-step impression was taken using an additional silicon material (Zhermack Elite HD putty soft and light body). Then, the impression was sent to the laboratory for the fabrication of the implant supra structure. The final restoration was made from either monolithic high translucency material (Zolid HT, Ceramill Systems, AmannGirrbach GmbH, Germany) or PEEK (BioHPP ®, Bredent, UK), according to the group's subdivision (n=7) (figure 11). Following intraoral evaluation of the crowns, they were cemented according to each type of manufacturer's instructions. This paper will exclusively focus on implant survival and marginal bone loss. Other soft and hard tissue clinical observations and Finite Element Analyses of this research will be discussed in separate papers.

Implant survival in this study was related to the absence of clinical mobility, signs of infection, pain, and limited marginal bone loss. Clinical follow-up assessments were carried out at various time points, including implant placement (baseline), 3 months, 6 months, 9 months, 12 months, and finally, after 18 months. During each recall appointment, both clinical and periapical radiographic examinations were evaluated.

Statistical analysis:

Kruskal-Wallis test (a non-parametric statistical test) was used to compare the medians of all 4 independent subgroups in the analysis of marginal bone loss. Friedman test (non-parametric) was used to compare the different follow-up periods within the same dependent subgroup. The decision was based on the p-value obtained from the statistical software (p=0.05). If the test statistics were less than the p-value, it indicated a significant difference between at least one pair of groups. Subsequently, a post-hoc test was then performed to determine which specific groups were significant.

Results

Surgical outcomes

An overall failure rate of 21.4% was observed as early as three months after RA zirconia implants were placed. All three participants developed an implant mobility before the placement of the definitive restoration. To enhance osseointegration, the implants were fixed with the neighboring teeth with the aid of composite. However, the implants eventually showed a loss of buccal gingiva and bone level and were lost during the composite removal because of a total absence of osseo-integration. The chi-square test did not show a significant difference between the two main groups, RA and RF (p= 0.053) (table 1,2).

Marginal bone loss evaluation

Marginal bone loss was measured mesially and distally during follow-up periods using periapical radiographs at 6, 12, and 18 months (Figures 12,13,14). The mean mesial marginal bone loss for Root Analogue implants after 18 months of follow-up was 1.5±0.251, while the mean distal marginal bone loss for root analogue zirconia implants was 1.66±0.389. For Root-form implants, the mean mesial marginal bone loss was 1.65±0.33, and the mean distal marginal bone loss was 1.1±0.405. The recorded marginal bone loss between mesial and distal sites in all studied groups did not exhibit any statistically significant difference. Therefore, the average of the two values was used as a single measurement for simplification of statistical analysis.

According to the Kruskal-Wallis analysis, no statistically significant difference was observed between all four groups until the 6-month follow-up visit (approximately 3 months after the final restoration was loaded).

According to the Friedman test, the mean marginal bone loss results significantly differed between all studied groups at all follow-up visits. Notably, Group RAZ exhibited the greatest mean MBL, followed by RAP, RFZ, and RFP, with the least mean MBL (1.7, 1.2, 1.35, and 1.0 mm, respectively).

Discussion

Zirconia is a viable metal-free alternative to titanium within the dental implantology field. It shows several advantages over traditional titanium implants, including higher resistance to corrosion and wear, reduced allergenicity, better compatibility, and superior esthetics [11]. Unlike titanium dental implants, zirconia implants are of the one-piece implant system that has the abutment and the implant body completely attached together in the design [12]. This uncomplicated design offers the benefits of fewer surgical procedures and the absence of micro gaps between the implant and abutment, which promotes an efficient way of tooth restoration.

However, this design has certain limitations. One-piece zirconia implants make it difficult to correct any misalignment that occurs during placement. The only way of correction would be by grinding the abutment, but this should be avoided whenever possible because it may compromise fracture resistance and osseo-integration resulting from potential overheating of the implant [13]. Another limitation of this type of implant is that the implant will be exposed to some loading forces from the tongue and mastication early in the process [14]. In addition, the cementation process accompanying this design may cause cement retention, which increases the risk of peri-implantitis [15].

In our study, any corrections of the abutment preparation were carried out after complete osseo-integration, typically 3-5 months post-placement, using copious water coolant and limited to minimal amount of modifications. Furthermore, immediate one-piece implants in both root analogue and root form designs were restored provisionally with removable

appliances, ensuring keeping the abutments away from any risk of early contact or functional forces, as mentioned in the literature [16].

To the best of our knowledge, until now, no prior study has compared custom-made root analogue zirconia implants with commercially available prefabricated zirconia implants. The only available data about root-analogue zirconia implants was about case reports (17-20) and literature reviews discussing existing data [1,21]. Our research represents the first study examining the difference in survival rates between root--analogue and root-form zirconia implants and marginal bone loss during follow-up periods.

Three RA implants showed early-stage failure before loading the implants; the failure rate is 21.4% vs. 0% of failure in RF groups. Consequently, when comparing survival rates of RA vs. RF implants, the null hypothesis was rejected.

The prefabricated root-form zirconia implants included in this study disclosed a 100% survival rate during the 1.5-year follow-up period. However, a more prolonged follow-up period is needed to confirm this outcome. Spies et al. (2019) assessed 40 patients with immediate zirconia implants restored with zirconia crowns or fixed partial dentures (FPD) for 5 years follow-up, and the survival rates at 3 and 5 years were more than 98% [22].

An Egyptian study about root analogue zirconia implants, published by **Elkhouly et al. (2020)**, reported an early failure of all the cases (8 root analogue cases) included in the study before loading.[23] The reasons for this are not entirely clear, but it was assumed that the shape of the root analogue implant maintains the force distribution as it mimics the socket of the extracted tooth. However, stress concentration in the implant-bone area is higher than the tooth-bone level because of the absence of periodontal ligaments.[24] Additionally, it was assumed that the failure may be related to the biomechanical properties of zirconia, characterized by a higher modulus of elasticity (240-260 GPa) compared to the surrounding bone (10-20 GPa), making it susceptible to stress shielding and associated bone resorption. Notably, this study was carried out in the anterior upper maxillary region without provisional restoration protecting the abutment from early loading.

According to Pirker and Kocher (2009) the approach of immediate placement of RA implants in the fresh socket has specific requirements for successful osseointegration. While replicating the shape of the extracted root will obtain excellent primary stability, it may lead to bone resorption due to the forces applied to the alveolar bone. Therefore, macroretention features should be added at the proximal aspects of the implants to ensure the interlock between ingrowth bone and the RA implant [18].

The failure of three RA implants in our study may be attributed to the patient's disobedience in wearing the removable provisional restorations. However, when compared to the RF implants, the 21.4% failure rate of RA implants should be taken into consideration.

Marginal bone loss associated with root analogue implants exceeded the root form implants during all follow-up periods. This could be due to the slight miss fit of the implant

with the dilated bony socket at the extraction time. According to an animal study conducted by Caneva M et al (2010) found root analogue implants exhibit greater marginal bone loss than the standard prefabricated implants [25].

In terms of crown materials used to restore the implants in this study, we selected two types of crown materials. Monolithic zirconia crowns were chosen following the recommendation of a published paper to use all ceramic crowns as zirconia implant-supported restorations. This is believed to result in a uniform distribution of occlusal forces around the implant through a monoblock implant-restoration system [26].

PEEK crowns were also chosen due to their modulus of elasticity, which is like cortical bone, which results in less force over zirconia implants [27]. This was obvious in the mean marginal bone loss showed in zirconia crowns in both RA and RF implants, which was greater than those restored with PEEK crowns in all follow-up periods.

The greatest mean MBL was observed in RAZ group (1.7 mm) at the 18 months follow-up visit. This could be due to the specific design of RA combined with zirconia crown, which has a modulus of elasticity exceeding that of bone. In contrast, the lowest mean MBL was found in the RFP group (1.0 mm). Over all, the greatest bone loss showed in this study was still less than that reported for other types of Zirconia implants, such as the NobelDirect implant design (Nobel Biocare) reported in other investigations (**Albrektsson et al 200[illegible] O¨ stman et al 2007; Sennerby et al 2008; Zembic et al 2012**) where more severe bone loss was observed after only one year of follow-up (≥2 mm).[28-31] However, **Kohal R-J, et al (2012)** reported a 1.3 mm MBL, which to some extent, is a coincidence with our results. Although MBL was observed in all zirconia implant groups in this study, the null hypothesis that all groups would not show a significant difference was rejected [24].

Conclusions

Root Analogue implants should not be recommended as a substitute for Roof-form prefabricated implants in routine clinical practice because of the increased incidence of early failure and the associated marginal bone loss compared to traditional root-form implants. PEEK crowns are recommended as a suitable supra-structure restoration for zirconia implants; however, further clinical evaluations for longer follow-up periods should be considered in the following investigations.

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Tables

Table (1): Showing survival and failure numbers of implants:

	Survival number (%)	Failure number (%)
Root analogue group	11 (78.6)	3 (21.4)
Root form group	14 (100)	0 (0)

Table (2): showing time of implant loss:

Patient number	Subgroup	Time of implant loss
1	RA	Week no. 11
2	RA	Week no. 2
3	RA	Week no. 3

Table (3): comparison of marginal bone loss between studied groups and during follow up:

		RAP N=6	RAZ N=5	RFP N=7	RFZ N=7	Test of significance
Marginal bone loss	Baseline	0(0-0)	0(0-0)	0(0-0)	0(0-0)	Kw =0.0 P=1.0
	3 months	0.35(0.2-0.6)	0.50(0.4-0.60)	0.3(0.3-1.0)	0.4(0.3-0.6)	Kw=0.283 P=0.252
	6 months	0.75(0.6-1.0)	0.9(0.7-1.0)C	0.5(0.40-1.3)B	0.7(0.5-.9)	Kw =2.94 P=0.039*

	12 months	1.2(1.2-1.3)BC	1.5(1.4-1.6)ACD	0.7(0.7-1.2)ABD	1.0(0.7-1.3)[eABC]	Kw =5.14 P=0.001*
	18 months	1.35(1.2-1.5)	1.7(1.5-1.8)	1.0(0.9-1.5)	1.2(1.0-1.2)[d]	Kw =4.03 P=0.001*
Freidman test P value		<0.001*	<0.001*	<0.001*	<0.001*	

KW: Kruskal Wallis test, *statistically significant

[a] non-significant with baseline , [b] non-significant with 3 months , [c] non-significant with 6 months , [d] non-significant with 12 months , [e] non-significant with 18 months

Figure1: Preoperative photos:

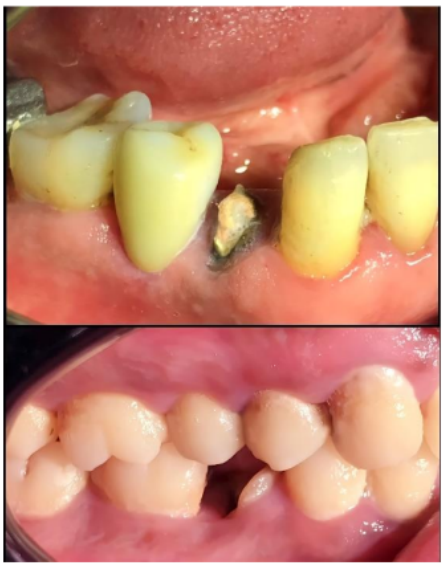

Figure 2: Pre-operative radiographs:

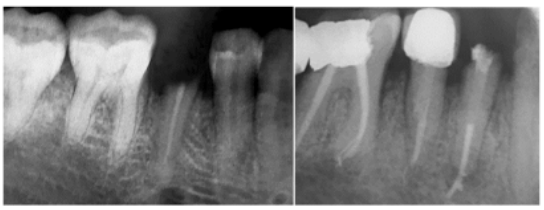

Figure 3: atraumatic extraction

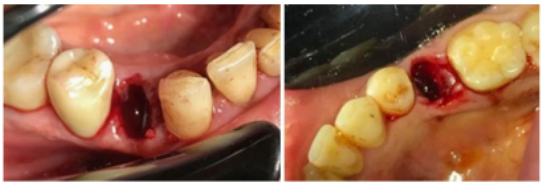

Figure 4: Surgical Protocol of Root form whiteSKY Implant placement:

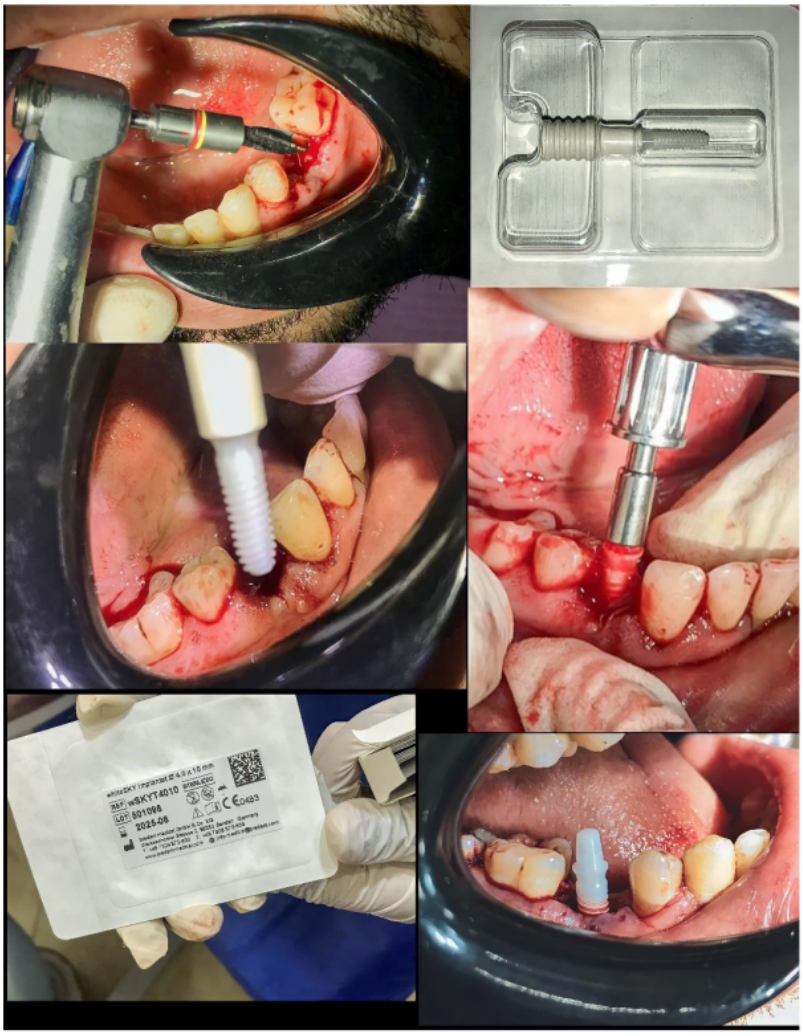

Figure 5: Extracted root preparation for Root analogue implants:

Figure 6: Design of the RA implant:

Figure 7: Milled implant before sterilization:

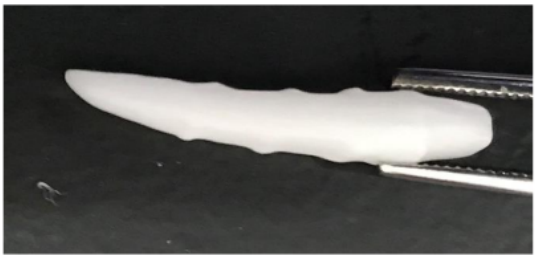

Figure 8: provisional removable appliance for protection of one-piece implant:

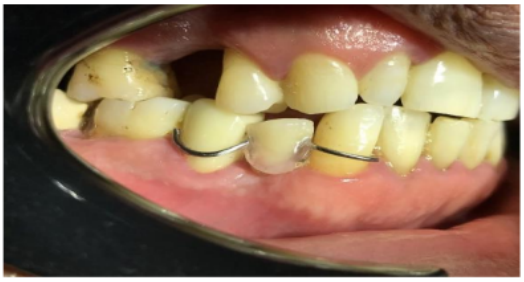

Figure 9: radiographic check of the implant after 3-5 months of placement:

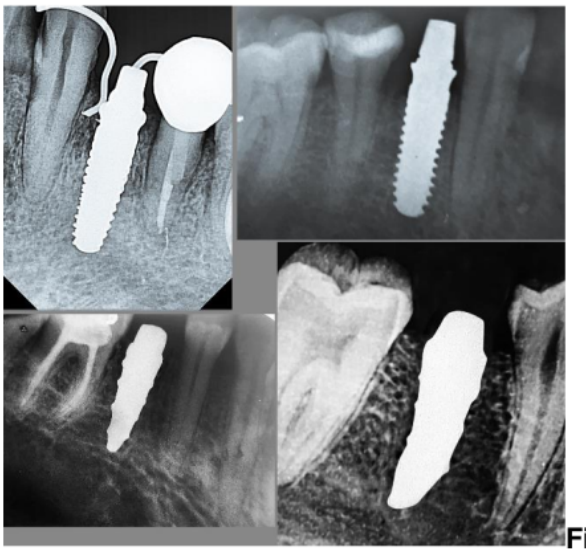

Figure 10: Clinical check of the implant after 3-5 months of placement:

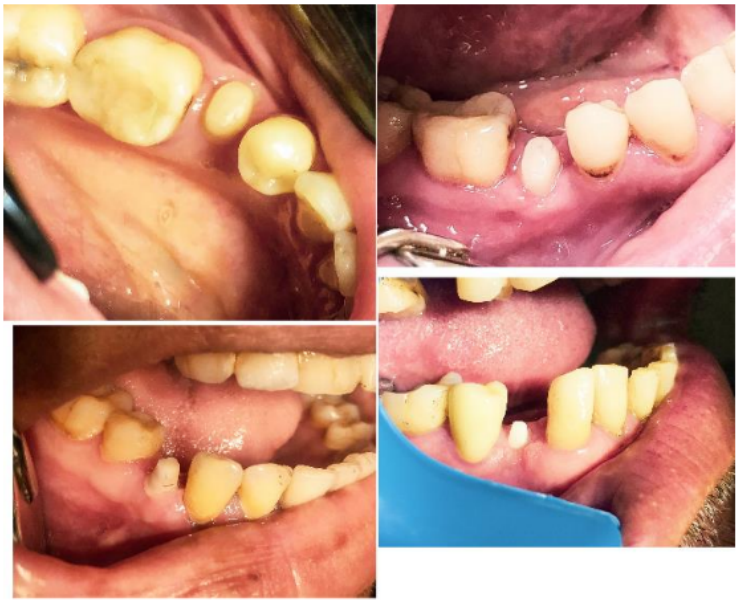

Figure 11: final restorations immediately after cementation:

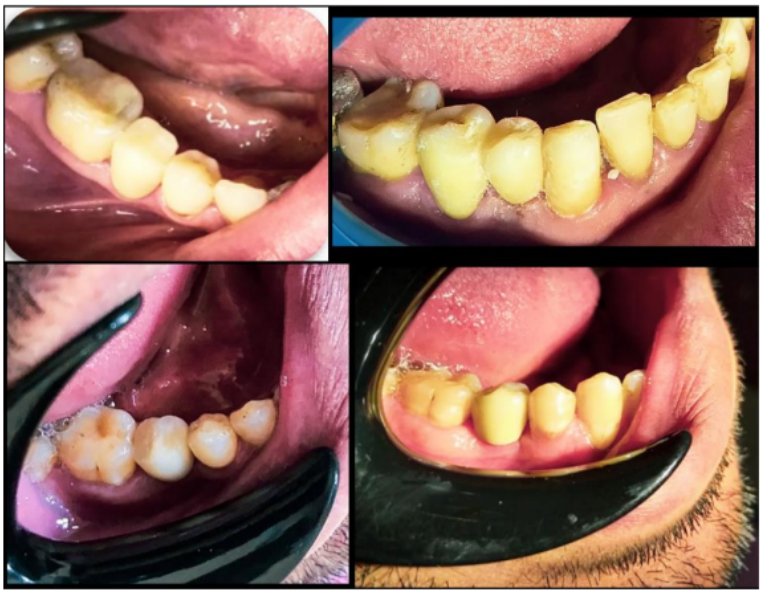

Figure 12: Marginal bone loss radiographic measuring at 6 months follow up visit:

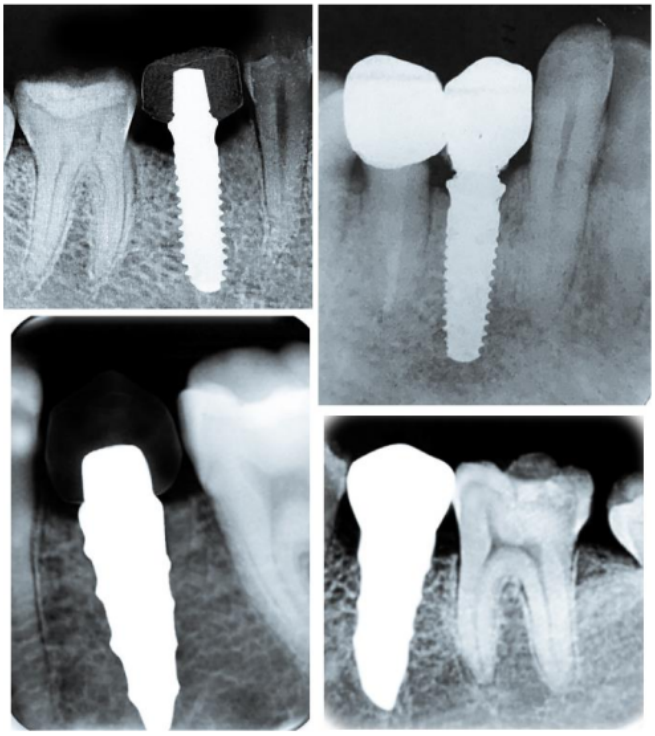

Figure 12: Marginal bone loss radiographic measuring at 12 months follow up visit:

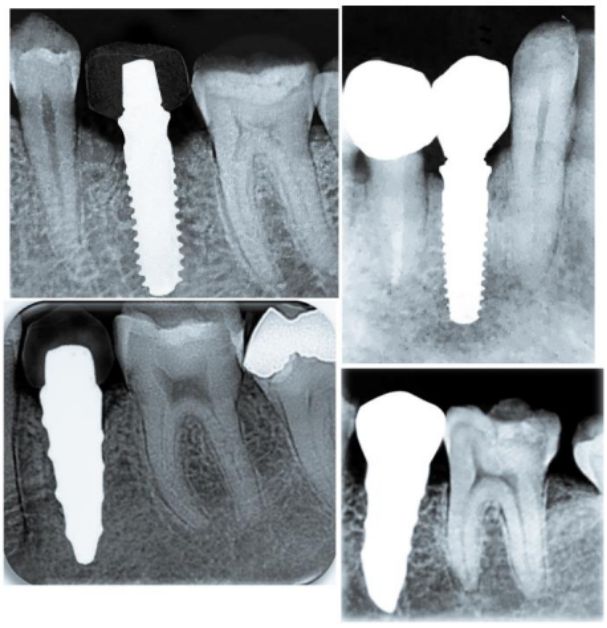

Figure 12: Marginal bone loss measuring radiographic at 18 months follow up visit: