Original Article / Özgün Araştırma

Patient-specific Root-analogue Immediate Titanium Premolar Dental Implants: Prospective Evaluation of Fifteen Patients with One-year Follow-up

Kişiye Özel Kök Analoğu İmmediat Titanyum Premolar Dental İmplantlar: On beş Hastanın Bir Yıllık Takiplerle İleriye Dönük Değerlendirilmesi

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Abstract

Objective: This study aimed to evaluate the clinical use and outcomes of the patient-specific root-analogue immediate titanium premolar dental implants (PRIs) that are manufactured by using computer numerical control (CNC) machine.
Materials and Methods: Three-dimensional models of the 15 non-restorable premolar teeth were constructed from cone-beam computed tomography datasets and transferred to a specific modelling software to design the PRIs. PRIs were manufactured from titanium by using a CNC machine and placed immediately after tooth extraction. Implants were evaluated clinically and radiologically one-year after implant placement.
Results: Fifteen patients (five males, 10 females), aged between 18-53 years (average 29.9) were included in the study. The success rate was 80% after one-year follow up. There was no peri-implant radiolucency around survival implants. The 1-year mean marginal bone loss was 1.1 mm (±0.4). Clinically healthy gingival margins were observed without any signs of periodontitis or implant mobility. The mean Periotest® value was -4.7±0.3.
Conclusion: Relatively high success rate was observed for upper premolar PRIs (92.3%) compared to lower premolar PRIs (50%). PRI concept is a new promising treatment modality. Further studies with long-term follow-up are necessary.

Öz

Amaç: Bu çalışmanın amacı, dental bilgisayarlı sayısal kontrol (CNC) cihazıyla üretilen kişiye özel kök analoğu immediat titanyum premolar dental implantların (KÖİ) klinik kullanımını ve sonuçlarını değerlendirmektir.
Gereç ve Yöntemler: On beş adet restore edilemeyen premolar dişin konik ışınlı bilgisayarlı tomografi kesitleri kullanılarak 3 boyutlu modelleri oluşturuldu ve KÖİ tasarımı için özel bir modelleme yazılımına aktarıldı. CNC cihazı kullanılarak titanyumdan KÖİ'ler üretildi ve diş çekiminden hemen sonra yerleştirildi. İmplantlar,

yerleştirilmelerinden 1 yıl sonra klinik ve radyolojik olarak değerlendirildi.
Bulgular: On sekiz - yirmi üç (ortalama 29,9) yaşları arasında 15 (beş erkek, 10 kadın) hasta çalışmaya dahil edildi. Bir yıllık takip sonrasında sağkalım oranı %80 idi. Sağkalan implantlar etrafında peri-implant radyolusensi yoktu. Bir yıllık ortalama marjinal kemik kaybı 1,1 mm (±0,4) idi. Periodontitis bulgusu ya da implant mobilitesi olmaksızın klinik olarak sağlıklı gingival marjinler gözlendi. Ortalama Periotest® değeri -4,7±0,3 idi.
Sonuç: Üst çenedeki implantlarda alt çenedekilere göre daha yüksek sağkalım oranı gözlenmiştir. KÖİ konsepti yeni ve umut vadeden bir tedavi yöntemidir. Daha uzun takip süreli ileri çalışmalara ihtiyaç vardır.

Introduction

Prosthetic rehabilitation of edentulous patients with dental implants is a widely used treatment modality with long-term high success rates (1). Recently, with the development of immediate implant replacement, number of surgical procedures are reduced and overall treatment time is shortened when compared to delayed implant placement (2,3). After immediate implantation, guided bone regeneration is usually necessary due to incongruence between the implant and the extraction socket. Besides, this incongruence may cause the lack of primary stability. Hodosh et al. (4) introduced the patient-specific root-analogue dental implant (PRI) concept in 1969 from the idea of fabricating a more congruent implant to the extraction socket. PRIs are identical copies of the teeth to be extracted. Researchers have taken more interest in PRI concept recently with the advancements in Computer aided design (CAD)/computer aided manufacturing (CAM) technologies.

After Hodosh et al. (4) reported failure of autopolymerizing and heat-processed polymethacrylate PRIs, Lundgren at al. (5) used titanium root analogue implants in an experimental study in beagle dogs and a survival rate of 88% was reported. The major factor for the success of these implants was attributed to close-fitting between the implant and the socket. Therefore, Kohal et al. (6) enlarged the coronal part of the root analogue implants to compensate the width of the lost periodontium for better congruence but, the buccal alveolar bone fracture was occurred while placing the implants. However, direct bone-to-implant contact observed in all evaluated implants. In a prospective clinical study by Kohal et al. (7), 31 custom-made titanium implants were evaluated. During an average observation period of 9.1 months, 15 implants were lost before prosthodontic reconstruction and two were lost after crown insertion. This implant system was not recommended for clinical application, due to this high failure rate over a short time period (7).

Recently, several clinical studies that titanium and zirconia PRIs were manufactured with different CAD/CAM techniques were reported. Direct metal laser sintering (DLMS), an additive manufacturing technology, was used to manufacture PRIs and high success rates were reported (8-10). DLMS technology is widely used in routine dental practice to fabricate the metallic frameworks of removable partial dentures, porcelain-fused-to-metal restorations and implant frameworks. However, these restorations are mostly fabricated from chrome-cobalt alloy powder. Titanium and its alloys are not used as much as chrome-cobalt due to its expense and limited indications. Unlike the DLMS machines, dental computer numerical control (CNC) machines are relatively cheaper, so they can be found in many dental clinics. Subtractive manufacturing of zirconia PRIs with dental CNC machines were also presented (11-16). A hybrid root analogue implant system was introduced recently in a pilot study. Moin et al. (17) fused together a titanium milled root analogue implant and a ceramic milled abutment portion to create one-piece implant.

PRIs with different design and manufacturing techniques and different modifications were evaluated in many experimental and clinical studies. However, there is a few CNC machined titanium PRI studies in the literature. The aim of the study is to show the feasibility of titanium premolar CNC-machined PRIs and to evaluate the clinical use and outcomes of the implants.

Materials and Methods

Patient Selection

This prospective study followed the Declaration of Helsinki on Medical Protocol and Ethics; and it was approved by the Local Ethics Committee of Erciyes University (2014/193). Between July 2015 and December 2016, all patients referred to Erciyes

University Faculty of Dentistry, Department of Oral and Maxillofacial Surgery were considered for inclusion in this study.

Patients who needed premolar tooth extraction due to root caries, vertical/horizontal root fracture, endodontic lesion, and unsuccessful root canal treatment were examined clinically and radiographically. Fractured and/or non-restorable teeth with uncompromised periodontal ligaments were included in the study. Exclusion criteria were uncontrolled systemic disease, bruxism, poor oral hygiene, and active periodontal disease. Chronic apical periodontitis and fenestration/dehiscence defects were not exclusion criteria. In case of chronic apical periodontitis, the area of infection was removed and fenestration/dehiscence defects were restored with alloplastic bone grafts after PRIs were placed. The study protocol was explained to each patient, and a signed informed consent was obtained.

Cone Beam Computed Tomography Scan and Implant Design

Computed tomography (CT) datasets of the teeth were acquired using a CBCT (Cone Beam Computed Tomography) scanner (NewTom 5G, QR, Verona, Italy). CT datasets with voxel size of 0.25x0.25x0.25 mm were transferred in the DICOM format to a specific 3D reconstruction software (Mimics^{R}, Materialise, Leuven, Belgium) and virtual 3D models of tooth, surrounding bone and opposing jaw were constructed for each patient. The tooth models were smoothed for obtaining a regular surface. The virtual models were exported as stereolithographic (STL) files and transferred to 3-matic^{R} Modeling Software (Materialise, Leuven, Belgium). PRIs were designed by using this software. Macro-retentions on interdental surfaces of root were added. Reduction on the buccal and lingual faces of roots (0.1-0.2 mm) was made to avoid fractures on thin alveolar bone walls. The abutments in the shape of a prepared tooth with a taper of 5 degrees and chamfer margins were designed. Finally, all designed parts were merged to create a PRI. PRIs were smoothed and exported as STL files with three different sizes (original size, 5% increased and 5% decreased) to avoid potential distortions or errors related to the 3D projection steps. All these three STL copies were used to manufacture the PRIs using a dental CNC machine (Figure 1).

Implant Manufacturing

The PRIs were milled from Ti-6Al-4V alloy blanks (Copra Ti-5 Titanblank, Whitepeaks Dental Solutions GmbH&Co. KG, Essen, Germany) by using a five-axis CNC machine (Yenadent DC40 CAM, Yenadent Ltd, İstanbul, Turkey). Three PRIs (original, 5% increased and 5% decreased sizes) were fabricated for each case. The extraosseous part of each implant was polished. The intraosseous part of the implant was roughened by sandblasting with alumina and acid-etching with a mixture of orthophosphoric acid and nitric acid (15-20% diluted with distilled water) at 65 °C. Then PRIs were washed for 10 min. in distilled water at 45 °C in an ultrasonic bath. Finally, the implants were packaged and sterilized in a steam sterilizer (Getinge HS44, Getinge Infection Control AB, Switzerland) at 134 °C for 45 min.

The surface topography of PRIs was evaluated with scanning electron microscope and energy-dispersive X-ray spectroscopy analysis. The average surface roughness (R_a) was measured with a profilometer (Surftest SJ-301, Mitutoyo Corp, Kanagawa, Japan) and between 1.5-2 µm which is accepted as ideal for osseointegration (18).

Surgical Procedure and Postoperative Evaluation

All patients received nonsurgical periodontal therapy and oral hygiene education before implant placement. To reduce the risk of post-extraction bacteremia, 0.12% chlorhexidine gluconate mouth wash (Klorhex®, Drogsan, Ankara, Turkey) was administered 30 min before surgery. Under local anesthesia by infiltrating articaine 4% containing 1:100,000 adrenaline (Ultracain DS forte, Sanofi Aventis, İstanbul, Turkey) an intrasulcular incision was made and a minimally invasive flap was released to expose alveolar bone margins. Teeth were carefully extracted by applying predominantly vertical forces avoiding any damage to the socket and soft tissue

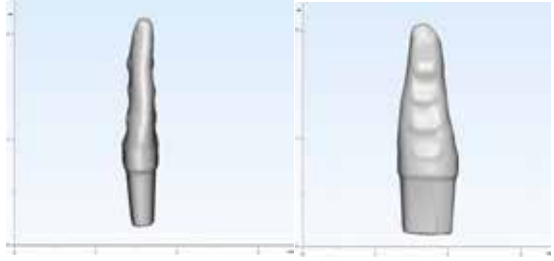

Figure 1. Stereolithographic file of the premolar dental implants, lateral and frontal view

(Figure 2). Then the extraction sockets were carefully debrided and irrigated with saline solution. The PRIs (first original size, but in case of incongruence, undersized-95% or oversized-105% PRIs) were placed in the sockets under finger pressure and gently tapped into the sockets with a hammer and a mallet (Figure 3). Primary stability was checked by percussion and palpation. At the end of the surgical procedure, interrupted sutures (Propilen, Doğsan, İstanbul, Turkey) were positioned and primary stability was measured by using Periotest® M (Medizinteknik Gulden, Modautal, Germany). In case of fenestration/dehiscence defects or minimum trauma of alveolar bone, (if primary stability could be obtained) the defects were reconstructed with particulate bone graft (Tutobone, RTI Biologics, Tutogen, Alachua, Fla, ABD) and collagen membrane (Tutopatch, RTI Biologics, Tutogen, Alachua, Fla, ABD). The patients received postoperative analgesics (Arveles^{R}, Menarini, L'Aquila, Italy) on demand and antibiotherapy (Augmentin^{R} 1 g, GalaxoSmithKline, Beecham, Brentford, UK) for 5 days. Mouth rinses with 0.12% chlorhexidine gluconate (Klorhex^{R}, Drogsan, Ankara, Turkey) were also administered for seven days. Detailed instructions about oral hygiene were given. The patients were instructed to chew predominantly on the contralateral side and avoid hard foods.

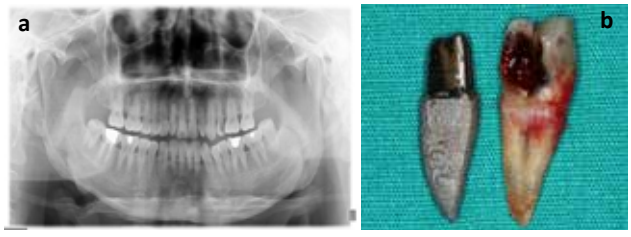

Figure 2. a) Preoperative panoramic radiograph, b) The extracted upper left second premolar tooth and the premolar dental implants before placement

Figure 3. Premolar dental implants was placed in the socket and interrupted sutures were positioned

Immediately after implant placement, periapical radiographs were taken to confirm that PRIs were at the right position in the extraction sockets and to measure the distance between the implant apex and the first visible bone contact in millimeters for later measurement of marginal bone loss. Although parallel cone technique and film holders were used for reproducible radiographs, measurements were compared to the real implant length in case of dimensional distortions. Sutures were removed at seventh day after the surgery. The patients were seen weekly during the first month, then monthly until prosthetic rehabilitation. Three months later, metal-ceramic crowns were cemented (Figure 4). After that patients were seen every six months. In case of alveolar bone damage or incongruence of PRIs with the extraction sockets, conventional screw type implants were placed after bone healing.

After one year of functional loading, PRIs were evaluated clinically and radiographically. Presence of bleeding on probing, pocket depth, suppuration, pain, and mobility were investigated. Stability of PRIs were measured with Periotest® M. Periotest values (PTV) lower than 0 were accepted as well osseointegrated. Radiographically, peri-implant radiolucency and excessive bone loss were evaluated on periapical

Figure 4. The crown restoration 1-year after premolar dental implants placement

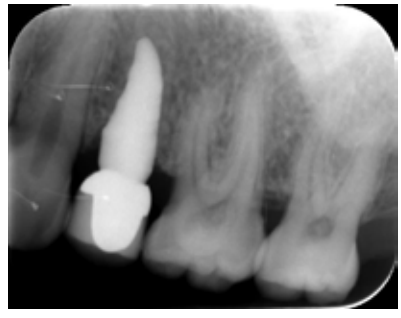

Figure 5. Periapical radiograph at 1-year follow-up

radiographs (Figure 5). Marginal bone level was measured and changes at 1 year were registered.

The success of the PRIs was defined, according to the criteria suggested for determination of success with reference to clinical and radiological parameters by Mangano et al. (9). PRIs that were still functional at the end of the study, after 1 year of functional loading, were categorized as survival. Implants presenting pain on function, suppuration, or clinical mobility were removed and categorized as failures (19). To achieve implant success, the following clinical and radiographic success criteria had to be fulfilled: absence of pain on function; absence of suppuration or exudation; absence of clinically detectable implant mobility; PTV <0; absence of continuous peri-implant radiolucency; and absence of prosthetic complications.

Statistical Analysis

Survival of the implants was computed using the Kaplan-Meier method (SPSS Statistics 17.0, Chicago, IL). An implant survival curve with a 95% confidence interval (CI) was constructed. Data were analyzed descriptively for patients and quoted as mean values ± SD.

Results

Fifteen patients (five males, 10 females), aged between 18-53 years (29.9±10.9, mean ± SD) were included in the study (Table 1). A PRI was placed into fresh extraction socket immediately after premolar tooth extraction for each patient. Primary stability was achieved, PTVs were between -1.4 and -6.2 (3.9±1.4). Four PRIs were placed in the mandible and 11 were in the maxilla. Bone grafts were used for dehiscence defects in 3 patients and fenestration defects in two patients and none of those implants were failed. At first week control visit, no complications, such as swelling, inflammation, bleeding and pain, were observed. The mean initial PTV was -2.1±1.8 for lost implants and -4.5±0.8 for survival implants. Three of 15 (20%) implants were lost within 24-53 days (40±19, mean ± SD), before functional loading (Figure 6). Implants

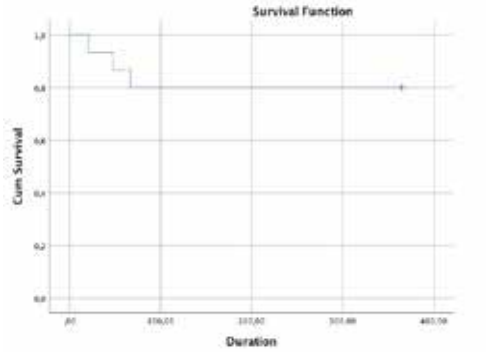

Figure 6. Kaplan-Meier estimate of implant survival

Table 1. Summary of patient information and clinical results of implant placement

Patient	Age (years)	Gender	Extracted tooth number	Implant status	Implant size (%)	Initial PTV	PTV at first year
1	34	F	25	Survival	100	-4.5	-5.4
2	40	F	15	Survival	100	-4.3	-5.4
3	22	F	25	Survival	100	-4.2	-4.4
4	38	M	24	Survival	100	-6.2	-5.6
5	20	M	24	Survival	100	-4	-5.8
6	49	F	15	Survival	100	-4.3	-3.7
7	30	F	15	Survival	95	-5.1	-6.0
8	19	F	25	Fail	95	-3.7	N/A
9	30	F	35	Survival	95	-4.4	-4.0
10	29	M	44	Fail	95	-1.4	N/A
11	23	F	24	Survival	95	-3.5	-4.1
12	21	M	25	Survival	95	-3.4	-3.5
13	23	M	35	Survival	100	-5.4	-5.5
14	53	F	25	Survival	100	-4.4	-2.7
15	18	F	35	Fail	100	-0.5	N/A

PTV: Periotest values, F: Female, M: Male, N/A: Not available, 100: Original size implant, 95: 5% decreased size implant

were loosened and suddenly lost without any pain, infection, noticeable bone resorption or soft tissue inflammation. After failed implants were removed, a soft tissue capsulation surrounding the socket walls was seen.

Three months later, metal-ceramic crowns were cemented. Patients were followed for 15-26 months. There was no peri-implant radiolucency around survival implants. Survival rate was 80% at the end of the observation period. The 1-year mean marginal bone loss was 1.1±0.4 mm (median, 0.5; CI 95%, 0.1-4.4). Clinically healthy gingival margins were observed without any signs of periodontitis or implant mobility. The mean PTV measured at one-year follow-up was -4.7±0.3. PTVs for each survival implant were lower than 0 at the end of the study. No prosthetic complications were observed. The prosthetic restorations were stable with good functional and esthetic results.

Discussion

In recent years, the CAD/CAM technology has been widely used in dentistry with the advantages of improving the patient's comfort, reducing treatment time and amount of visits. New techniques for design and manufacturing of PRI were also developed with the advancements in this technology. In a clinical study, Pirker and Kocher (15) evaluated 18 zirconia PRIs that were placed in premolar/anterior region. In one group (n=6), PRIs were roughened by sandblasting only, however all of the PRIs were lost. In the second group (n=12), root was modified by adding microretentions, strictly limited to the interdental space, and by reducing the buccal and lingual face by approximately 0.1-0.2 mm, preventing fractures of the thin cortical bone layer at insertion before laser scanning and all of the PRIs in this group were survived. The authors concluded that by introducing significant modifications, primary stability and excellent osseointegration of immediate PRIs can be achieved, while preventing unaesthetic bone resorption. In the present study, these modifications were also applied digitally on implants with the help of a specific software before tooth extraction. In this manner, we are of the opinion that these modifications could be done in a more standardized way for each implant. In addition to these modifications, the abutments in the shape of a prepared tooth with a taper of 5 degrees and chamfer margins were designed by using the same software. This design provided ease of prosthodontic procedures and resistant and retentive restorations with aesthetic results. In another study by Mangano et al. (9), 15 DLMS titanium premolar PRIs (eight in maxilla, seven in mandible) were evaluated. At the 1-year follow-up, a survival rate of 100% was reported. All implants were stable, with no signs of infection. In this study, there were no microretentions on root surface but, the authors also made a reduction of the diameter (0.1-0.3 mm) of the implant neck next to the thin vestibular cortical bone.

In the present study, survival rate was 80% which is lower than previously reported success rates in other studies. The primary and secondary stabilities were measured by using Periotest® M which is a quantitative test method. PTV ranges between -8 (clinically rigid) and +50 PTVs (very mobile). Lower PTVs indicate more stable implants. The mean initial PTV was -2.1±1.8 for lost PRIs and -4.5±0.8 for survival PRIs. These results indicate the importance of primary stability for implant survival.

Even though unchanged peri-implant marginal bone levels after 1 to 2.5 year follow-up were reported in several PRI studies (8,9,11-16), mean marginal bone loss was 1.1±0.4 mm (median, 0.5; CI 95%, 0.1-4.4) at first year in the present study. Nevertheless, all of the survival implants were stable and on function without any signs of peri-implantitis or implant mobility. Healthy gingival margins were observed with good esthetic results.

According to our previous clinical experience, molar or incisor/canine teeth were not included in the study. Titanium is a very hard material which makes it difficult to be milled with CNC-machines. The bifurcation of the molar implants was not milled accurate enough, so the implants were interfering with interradicular septum. Primary stability was achieved by adapting the septum to the implants. However, it resulted in high PTVs and initiation of bone resorption in the furcation area. Hence the most of the titanium molar PRIs were lost within 2-3 weeks. Despite this, the successful upper and lower molar zirconia PRIs were reported in the literature (12-14). Pre-sintered zirconia is a relatively softer material and easy to mill with CNC-machines. The grey color of titanium may

be reflected by the gingiva or it may get exposed in case of gingival recession, so it may not be favorable in the anterior region. Because of all of these, only premolar teeth were included in the study.

Implants were manufactured in three different sizes (original size, 5% increased and 5% decreased) to avoid potential distortions or errors related to the 3D projection steps. Differently from other studies in the literature (8,9,13,15,16), 5% decreased size implants were created instead of %10 increased-sizes. Because, in some cases a smaller implant which is more compatible with the extraction socket may be necessary, not only larger ones. In fact, none of the 5% increased-size CAIs were used in this study.

There are some conditions limiting the application of PRI technique. In the presence of curved and divergent roots, atraumatic tooth extraction and implant placement is difficult. Malposition, large periapical lesions, inadequate alveolar socket height also limits the feasibility. Even if this technique has high success rates, the precise patient selection criteria limit the feasibility of the technique.

Conclusions

This study differs from other studies in terms of PRI design and manufacturing techniques. CNC machined premolar PRIs were placed and evaluated. Relatively high success rate was observed for upper premolar PRIs (92.3%) compared to lower premolar PRIs (50%). PRI concept is a new promising treatment modality. Further studies with long-term follow-up are necessary.

Ethics

Ethics Committee Approval: This prospective study followed the Declaration of Helsinki on Medical Protocol and Ethics; and it was approved by the Local Ethics Committee of Erciyes University (2014/193).

Informed Consent: The study protocol was explained to each patient, and a signed informed consent was obtained.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: E.F.A., A.E.D., H.Ö.G., A.A., A.A., Concept: E.F.A., A.E.D., H.Ö.G., A.A., Design: E.F.A., A.E.D., A.A Data Collection or Processing: E.F.A., A.E.D., Analysis or Interpretation: E.F.A., A.E.D., A.A., B.A.A., Literature Search: E.F.A., A.E.D., A.A., Writing: E.F.A., A.E.D.

Conflict of Interest: No conflict of interest was declared by the authors.

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