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ORIGINAL RESEARCH

# Clinical and Radiographic Evaluation of Narrow-Diameter Titanium-Zirconium Implants in Unilateral Atrophic Mandibular Distal Extensions: A 1-Year Pilot Study

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## ABSTRACT

**Background:** The use of endosseous dental implants has led to more sophisticated fixed options when considering treatment of patients with distal extensions. The use of narrow-diameter implants may reduce the necessity for bone augmentation. The mechanical strength of titanium is limited, so titanium alloys with greater tensile and fatigue strength may be preferable.

**Purpose:** The purpose of this study was to evaluate clinically and radiographically the performance of narrow-diameter bone level implants made from titanium-zirconium alloy (TiZr, Roxolid™) in restoring unilateral atrophic mandibular distal extensions with fixed dental prostheses.

**Materials and methods:** Twenty partially edentulous patients with unilateral atrophic mandibular distal extensions received two 3.3 mm diameter bone level TiZr implants (Straumann AG, Basel, Switzerland). The two implants were restored with 3-units ceramo-metal fixed partial dentures. Standardized clinical and radiographic parameters (survival rate, probing pocket depth and marginal bone loss) were evaluated at the time of the completion of the prosthetic treatment (baseline) and after 3, 6 and 12 months of functional loading. Prosthetic complications were also assessed.

**Results:** The survival rate for narrow-diameter bone level TiZr implants was 100% after 1 year of functional loading. There were no statistically significant differences between the values of probing pocket depth over the follow-up period. All implants showed less than 1 mm of marginal bone loss at the end of the follow-up period.

**Conclusion:** Within the limitations of this 1-year pilot study, the use of narrow-diameter bone level TiZr implants appears to be predictable in restoring the unilateral atrophic mandibular distal extensions. This type of implants meets established success and survival criteria after 1 year.


**Keywords:** Atrophic mandible, Distal extensions, Titanium-zirconium, Titanium-zirconium implants, Narrow-diameter.

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## INTRODUCTION

Prosthetic management of partial edentulism remians a challenge due to the variability affecting both the esthetic and functional results. Periodontal conditions, caries susceptibility, the amount of alveolar ridge resorption, as well as other functional and psychosocial factors have to be considered in treatment planning of partially edentulous patients. A removable partial denture (RPD) was often indicated to restore distal extensions.[1] Some of the potential disadvantages of RPD treatment are the risk of developing caries, periodontal involvement of the abutment teeth, continuous ridge resorption and unesthetic appearance of the clasps.[2-5]

The introduction of osseointegrated implants in many instances changed the conventional approach to prosthetic rehabilitation of patients with distal extensions and created treatment options deemed impossible to achieve in the past.[1,6,7] Being a revolutionary treatment approach, implant therapy still has its limitations and requires the presence of a favorable anatomical condition.[8]

Several factors determine whether or not standard-diameter implants can be placed. Reduced mesiodistal space or reduced ridge width due to alveolar bone loss following tooth extraction often result in insufficient bone volume for the placement of a standard diameter dental implant.[9] Bone augmentation procedures can be used to increase bone volume in cases of reduced alveolar ridge width. However, such procedures involve bone harvesting and grafting, which can present increased risks, morbidity and costs.[10,11] To overcome these problems, narrow-diameter implants may be used.

The material of narrow-diameter implants must fulfill high demands on mechanical stability to avoid overload and implant fracture. Titanium is widely used for dental implants because of its corrosion resistance and biocompatibility

superior to titanium-aluminum-vanadium alloys.[12] Titanium alloys containing zirconium show better tensile and fatigue strength than pure titanium.[13] Therefore, a new implant alloy TiZr has been developed that allows SLActive surface modification and that has comparable or better mechanical strength and improved biocompatibility compared with existing Ti alloys.[9] Experimental testing in the development phase showed favorable mechanical strength and corrosion properties of the material, and biocompatibility and enhanced osseointegration has been confirmed in animal studies.[14-17]

Al-Nawas et al[18] in their clinical study confirmed that TiZr small-diameter bone level implants provide at least the same outcome after 12 months as Ti Grade IV bone level implants with overdentures in edentulous mandibles. Chiapasco et al[19] reported that narrow-diameter implants fabricated with the TiZr alloy were reliable in supporting both fixed and removable prosthetic rehabilitations in horizontally deficient ridges. The pilot study by Barter et al[9] demonstrated good performance and tolerability of the TiZr implants over 2 years in partially edentulous patients.

There is very limited evidence for the use of TiZr implants to support fixed prostheses for rehabilitation of patients with free end saddles. Therefore, the purpose of the present study was to evaluate clinically and radiographically the performance of narrow-diameter bone level implants made from TiZr alloy in restoring unilateral atrophic mandibular distal extensions with 3-units ceramo-metal fixed partial dentures.

## MATERIALS AND METHODS

### Patient Selection

Twenty partially edentulous patients, 13 men and 7 women, ranging from 28 to 54 years of age (mean age 41.7 years) were included in this study. These patients were treated in Dammam Dental Centre, Dammam Medical Complex (Dammam, Saudi Arabia). All patients signed an informed consent form. Ethical approval for the project was granted by the Human Research Ethics Committee of the Dammam Medical Complex, Dammam, Saudi Arabia. The primary complaint among the patients referred to the clinic for treatment was related to unsatisfactory conventional acrylic resin removable partial dentures which were fabricated as provisional prostheses.

Inclusion criteria indicated that the patient has unilateral mandibular distal extension and is partially edentulous for at least 1 year, and has sufficient bone for an implant of at least 8 mm length and 3.3 mm diameter. The missing teeth in all patients were the third molar, second molar, first molar and second premolar. The unilateral distal extensions in all patients were opposed by natural teeth. Exclusion criteria included any medical condition contraindicating implant surgery, logistic or physical reasons that could affect follow-up, psychiatric problems and disorders to the implant site related to a history of radiation therapy to the head and neck, or bone augmentation.

### Surgical Procedures

Thorough preoperative clinical assessment was carried out for the quantity and morphology of the bone that would host the implants. Preoperative panoramic and periapical radiographs were used for radiographic evaluation of the placement site to avoid potential complications with important anatomy in this region.

The components used were narrow bone level TiZr implants (Straumann AG, Basel, Switzerland) with a diameter of 3.3 mm and ranged between 8 and 12 mm in length. Each patient received two implants in the second premolar and second molar places. One-stage surgical approach was followed throughout the study for all patients (Fig. 1). Under local anesthesia, a minimal crestal incision (envelope type) with vertical release incision when indicated was made and a mucoperiosteal flap was raised, both on the buccal and the lingual aspects, to enable adequate visualization of both aspects of the mandible and to evenly divide the available keratinized tissue. The osteotomy was prepared using a standard bone drilling protocol, according to the manufacturer's directions. Bone quality was identified, and bone tap was used in types 1 and 2. Initial implant stability was tested manually by hand and insertion torques $\geq$35 Ncm were acceptable. Minor guided bone/tissue regeneration procedures were allowed at implant placement to cover dehiscence and fenestration defects of $\leq$2 mm of the exposed implant surface only. Healing abutments of appropriate length were connected and the mucosa was adjusted and sutured (4-0 Vicryl, Ethicon, Johnson & Johnson, Brussels, Belgium).

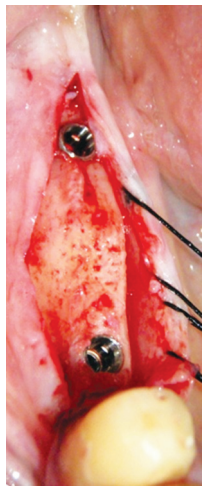

**Fig. 1:** Surgical placement of two narrow-diameter implants in the unilateral distal extension

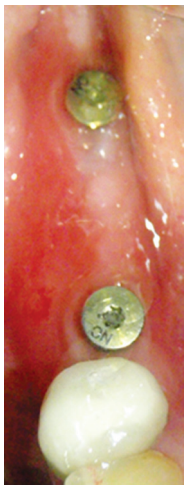

**Fig. 2:** Healing abutments in place 10 weeks after implant placement

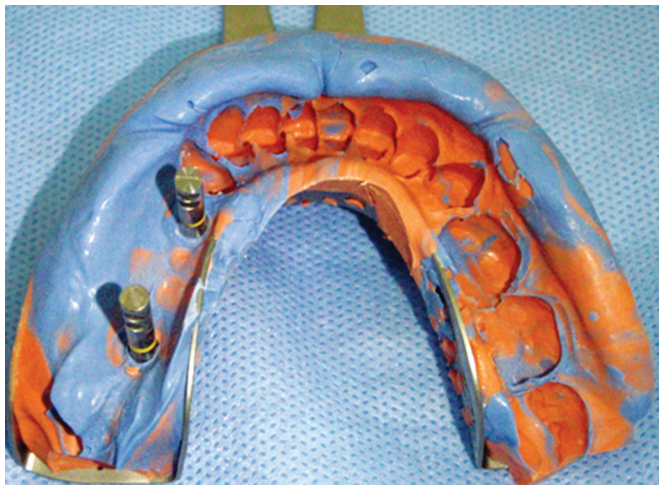

**Fig. 3:** Final impression of the mandible with the impression posts and implant analogs before pouring

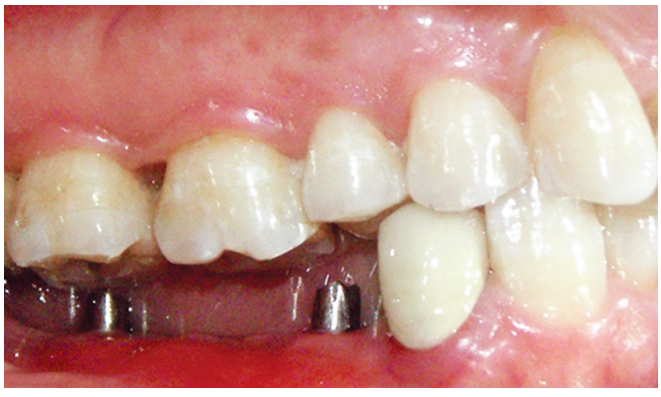

**Fig. 4:** Appropriate abutments screwed into the implants immediately before insertion of the final prosthesis

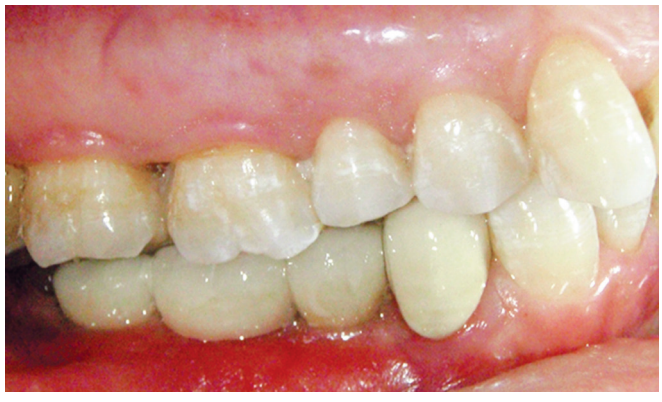

**Fig. 5:** Finished implant-supported FPD cemented in the patient's mouth 12 weeks after implant placement

Antibiotic (Augmentin 625 mg) and non-steroidal anti-inflammatory (Ibuprofen 400 mg) medications were given to the patients every 8 hours for 5 days postoperatively. All patients were limited to a soft diet for 10 days. The patients were instructed in a plaque control protocol at the time of implant placement and this was reinforced at subsequent reviews.

## Prosthetic Procedures

The healing abutments (Fig. 2) were removed 10 weeks after implant placement and impression posts were inserted for taking the final impression (Fig. 3) using vinyl polysiloxane impression material (Express, 3M ESPE Dental Products, USA). Ceramo-metal fixed partial denture was fabricated using recognized rules of fixed prosthodontics. A torque of 35 Ncm was used for tightening the selected abutments (Fig. 4). The final prosthesis was checked in the patient's mouth and the required adjustments were carried out. The fixed partial denture (Fig. 5) was delivered to the participants approximately 12 weeks after implant placement. All restorations used in the study were cement-retained restorations.

## Clinical Analysis

Implant survival was defined as the implant being still in place at the 1-year follow-up. Implant success was defined according to Buser et al[20] as the absence of: (i) persistant pain, foreign body sensation and/or dysesthesia; (ii) recurrent peri-implant infection; (iii) implant mobility; and (iv) continuous peri-implant radiolucency.

Probing pocket depth (PPD) was measured at four sites of each implant (mesiobuccally, distobuccally, distolingually and mesiolingually) by using a periodontal probe. The distance between the marginal border of the mucosa and the tip of the periodontal probe was scored as the probing pocket depth.

## Radiographic Analysis

Standardized intraoral radiographs using a long cone technique of the two implants were obtained. To provide a geometrically reproducible alignment; an index was recorded for each patient on the inserted fixed partial denture with the use of vinyl siloxane material. With the aid of Hawe's sensor holder system (Kerr, KerrHawe SA, Switzerland), the

radiographs were taken using direct digital imaging system (Trophy RVG, William Green Pty Ltd, Australia). Images were displayed on a computer screen with such a dimension and brightness that the observer could read comfortable and accurately the image. On each image, the implant abutment interface and the first bone-to-implant contact were identified and marked with a cursor on the mesial and distal sides of the implant. The analysis program calculated and reported the distance between the two points with a degree of accuracy of ± 0.01 mm. The same procedure was performed with all of the follow-up radiographs. The initial postoperative radiographs immediately after insertion of the final prosthesis (baseline radiography) were compared with the follow-up radiographs 3, 6 and 12 months of functional loading. The vertical bone loss was calculated by subtracting the bone heights in the baseline radiographs from those of follow-up radiographs. Data were collected blindly by one experienced observer throughout the entire study.

### Prosthetic Complications

The fixed partial denture was considered successful if it was stable, functional and there was no associated patient discomfort. Any prosthodontic complications/intervention during the 1-year follow-up were recorded according to the following events: veneer fracture, mobility of the restoration due to loosening of the abutment or decementation of the restoration.

### Data Collection

The data collection (clinical and radiographic outcomes, and prosthodontic maintenance requirements) of all patients was performed as follows: at the completion of the prosthetic treatment (basline) and after 3, 6 and 12 months of functional loading.

### Statistical Analysis

Probing depth was measured at four sites around each implant and bone height measurement was taken mesially and distally on the radiograph for each implant and the mean was taken. The data were statistically analyzed using one-way repeated measures ANOVA followed by Tukey's test at 95% confidence level (SPSS for Windows, version 10.0, SPSS Inc., Chicago, IL, USA).

## RESULTS

### Clinical Parameters

The survival rate for the 40 implants included in the present study was 100% after 1 year of functional loading. The mean probing pocket depth (PPD) values did not markedly increase from the time of loading to the end of the 1-year, with ranges from 1.30 to 1.53 mm at loading (baseline), from 1.48 to 1.76 mm after 3 months, from 1.60 to 1.88 mm after 6 months and from 1.79 to 1.98 mm after 12 months. Comparison between the mean values at the baseline and the mean values at the three recall visits was not statistically significant ($p > 0.05$).

### Radiographic Parameter

The mean change in the marginal bone level was less than 1 mm at the end of 1-year of functional loading with ranges from 0.19 to 0.30 mm at loading (baseline), from 0.31 to 0.44 mm after 3 months, from 0.42 to 0.56 mm after 6 months and from 0.49 to 0.60 mm after 12 months. Comparison between the mean values at the baseline and the mean values at three recall visits was not statistically significant ($p > 0.05$).

### Prosthetic Complications

The prosthetic restorations for all patients included in the study were stable, functional and well tolerated. The only prosthetic complication occurred was decementaion of the restoration in only one patient after 9 months of functional loading.

## DISCUSSION

Management of partially edentulous patients with unilateral distal extensions can still be a prosthodontic challenge. Replacing the missing teeth with conventional RPDs is the traditional method for the treatment of those patients; however, there are many potential disadvantages associated with these RPDs, such as the risk of developing caries, periodontal involvement of the abutment teeth, continuous ridge resorption, and unesthetic appearance of the clasps.

The absence of distal abutment teeth in the lower arch creates problems with support and retention. The mucosa of the distal extension is more displaceable and offers less support than the abutment teeth. This support differential causes a removable prosthesis to sink out of occlusion under load, eliminating effective occlusion and mastication.[21,22] This has been reported to accelerate bone resorption owing to the denture relying entirely on the resdiual alveolar ridge for its support.[21,22] Additionally, the absence of distal abutment teeth makes direct retention of the distal end of the saddle impossible. The denture is able to rotate around the abutment tooth and has a tendency to drift with the potential to cause injury to the abutment tooth and soft tissues, producing discomfort.[21,22] The development of predictable osseointegrated implants has led to more sophisticated fixed options when considering treatment of patients with distal extensions. Studies indicate good long-term survival rates and high levels of patient satisfaction.[6,7,9]

Narrow-diameter implants are usually recommended for the ridge with reduced width due to alveolar bone loss.[23] The increasing clinical success of these implants might reduce the necessity of invasive bone augmentation procedures, which would enhance patient acceptance of implant interventions and reduce the treatment cost. Implants with small diameters must withstand a high mechanical load to avoid implant fracture. However, the mechanical strength of pure titanium is limited,[12,13] therefore, new materials for implant production with more favorable mechanical properties have been developed. Titanium alloys containing zirconium show better tensile and fatigue strength than pure titanium.[13] Several animal studies[14-17] showed favorable mechanical strength and corrosion properties of the titanium-zirconium alloy with enhanced biocompatibility and osseointegration.

The present study was a clinical pilot study on the use of narrow-diameter (3.3 mm) bone level implants made from TiZr alloy in restoring unilateral atrophic mandibular distal extensions with 3-units ceramo-metal fixed partial dentures. The results showed acceptable performance in terms of the 1-year survival and success rates and were generally well tolerated.

The survival rate of the narrow-diameter TiZr implants in the present study was 100%. This percentage is comparable with other clinical studies, which have reported survival rates of narrow-diameter TiZr implants supporting fixed and removable prostheses ranging from 95.2 to 100%.[9,18,19] No implant fracture was recorded in the present study. Zinsli et al[23] concluded that fatigue fracture may occur after a long period of function. The data recorded in the present study with short follow-up period (1-year) do not yet allow a final judgment on long-term success and implant fracture.

No statistical significant differences between the probing pocket depth values were recorded over the follow-up period. The strict oral hygiene regime to which the patients were subjected provided healthy peri-implant tissues. These findings are in agreement with other studies.[1,9]

The baseline for the assessment of the changes in bone height in the present study was the time of insertion of the fixed dental prosthesis, which occurred 12 weeks after implant placement. The overall mean marginal bone loss after 1 year of functional loading in the present study was less than 1 mm which is in agreement with previous studies.[9,18,19]

All of the fabricated restorations in the present study were cement-retained restorations. It was the prosthodontist's decision to use this kind of restoration due to ease of fabrication, better esthetics and lower prosthodontic costs compared to screw-retained restoration.

Rehabilitation of atrophic distal extensions with narrow-diameter endosseous dental implants is an excellent alternative for patients who are unable to tolerate RPDs. Treatment is lengthy and involves careful planning with regard to implant positioning, placement, design of the fixed prosthesis and maintenance. The finished prosthesis should restore function and esthetics whilst limiting the occlusal loads distributed to the supporting implants to be within the physiological limits.

## CONCLUSION

Within the limitations of this 1-year pilot study, it may be concluded that fixed partial dentures supported by narrow-diameter bone level implants made from titanium-zirconium alloy (Roxolid™) may be a highly safe treatment option in restoring the atrophic mandibular distal extensions. Further investigations and long-term evaluations are certainly needed to confirm the encouraging results of this clinical study.

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