

Focus on the Clinic: A Novel Titanium-Zirconium Alloy for Reduced Diameter Implants

Eduardo R. Lorenzana, Jason Gillespie

Review of Clinical Concept and Case Report



Eduardo R. Lorenzana, DDS, MS, is a Diplomate of the American Board of Periodontology and maintains a private practice for periodontics and dental implants based in San Antonio, Texas. Dr. Lorenzana earned his Certificate in

Periodontics and Masters in Oral Biology from Baylor College of Dentistry – TAMUS in Dallas, Texas and holds academic appointments at Baylor College of Dentistry – TAMUS in the Graduate Periodontics Department and at the University of Texas Health Science Center – San Antonio Dental School in the Department of Restorative Dentistry. Dr. Lorenzana is a Fellow of the ITI.



Jason Gillespie, DDS, MS, maintains a full-time prosthodontics private practice in San Antonio, Texas. Dr. Gillespie is a graduate of Baylor College of Dentistry – TAMUS in Dallas, Texas

and earned his Certificate in Prosthodontics as well as a Masters in Oral Biology from Baylor College of Dentistry, where he currently holds a position as an Adjunct Assistant Professor in the Department of Restorative Sciences. Dr. Gillespie is a Fellow of the ITI.

INTRODUCTION

Conventional wisdom dictates that a clinician should always use the largest diameter implant that can be placed into a given edentulous space. In certain clinical situations, however, larger or even conventional diameter implants cannot be accommodated without additional augmentation procedures, resulting in increased treatment time and increased treatment cost. These additional procedures and costs in time and finances can become barriers to treatment acceptance by potential implant patients¹⁻⁴. The use of narrow-diameter implants exists as an option for sites with reduced alveolar ridge width. However, their use has been generally confined to narrow spaces with reduced functional load, such as maxillary lateral incisors or mandibular incisors⁵⁻⁷. Although titanium as a biocompatible surface for osseointegration has been up to now a reliable, predictable material, it does have mechanical limitations in situations where narrow-diameter implants might be considered, especially when combined with exposure to high strain forces, such as in posterior applications^{8,9}. Efforts to create stronger implants that would not inhibit osseointegration have met with mixed success and are documented in the literature¹⁰⁻¹³.

A novel titanium-zirconium (TiZr) alloy for use in dental implants (Roxolid™, Straumann USA) has recently been introduced and is reported to have higher fatigue and tensile strength over annealed and cold-worked Grade 4 pure titanium^{14,15}. These characteristics are important when clinicians are considering the use of narrow-diameter implants, but as mentioned previously, these improvements would be irrelevant clinically if the alloy were to diminish osseointegration. Animal studies conducted on TiZr alloys have found better biocompatibility than with titanium alone¹⁶. The Roxolid™ dental implant is also characterized by the SLActive® surface, which has been extensively documented in both bench and clinical publications on traditional titanium implants¹⁷⁻²⁰.

Animal studies conducted by Gottlow and co-workers recently documented improved osseointegration in two out of three

measured parameters in a miniature pig model, concluding that the TiZr SLActive® implant presents an improvement over traditional titanium SLActive® implants²¹. Ongoing human clinical studies report 99% implant survival²² and increasing confidence in using reduced-diameter implants in situations where larger diameter implants would have required bone augmentation²³. This case report aims to detail the application of a reduced diameter TiZr SLActive® implant in a limited bone situation in a patient-enrolled, ongoing non-interventional clinical trial.

CASE REPORT

A 31-year-old female patient was referred for implant-based prosthetic replacement of several missing and failing teeth. Following review of her medical history (non-contributory), examination of the patient revealed the need for several implants, including hard- and soft-tissue augmentation, at several sites. Among these was site #29 where a buccal soft tissue deficiency was suggestive of reduced ridge width for dental implant placement (Figs 1–2). Long-term absence of #29 had resulted in mesial tipping of the first molar, further complicating the proposed implant treatment. A computed tomography (CT) scan was ordered to further confirm the three-dimensional anatomy of the proposed implant sites. Radiographs revealed adequate bone height above the inferior alveolar nerve and mental foramen; however, bone width at the crest of the ridge was noted to be deficient (Fig. 3). The rising cost of her treatment plan led to a proposal for the utilization of a reduced-diameter TiZr SLActive® (Roxolid™) implant at site #29 and enrollment into an ongoing non-interventional clinical trial. It was explained to the patient that use of the reduced diameter TiZr implant would eliminate the need for concomitant bone augmentation and its associated expense at that site.

Following IRB-approved consent, the patient was entered into the study and prepared for surgery. After achieving local anesthesia, mid-crestal incisions were made and a full-thickness flap reflected to reveal the edentulous ridge and buccal ridge deficiency (Fig. 4).



Fig. 1: Occlusal view, initial presentation, site #29. Soft tissue anatomy is suggestive of underlying buccal alveolar ridge deficiency



Fig. 2: Facial view, site #29



Fig. 3: CT scan, site #29, demonstrating buccal deficiency



Fig. 4: Initial flap reflection confirms reduced alveolar ridge width

Utilizing a surgical guide provided by the patient's prosthodontist (Dr. Gillespie), the implant site was prepared in the traditional manner, beginning with small diameter round burs, followed by a 2.2 mm twist drill and a 2.8 mm twist drill under copious irrigation. A 3.3 mm x 10 mm Narrow CrossFit™ (NC) Bone Level Roxolid™ TiZr SLActive® implant was selected for the site (Figs 5–6) and introduced into the osteotomy site, where Figure 7 documents the hydrophilic nature of the Roxolid™ implant, consistent with the established titanium SLActive® implant (Fig. 7). The correct buccal alignment of the laser markings on the implant transfer mount was confirmed (Fig. 8) as well as the correct three-dimensional position (Fig. 9). No bone augmentation was performed at the site. Non-submerged closure consisted of a Ø 3.3 mm bottle-shaped healing abutment, interrupted sutures, and the site was allowed to heal undisturbed (Fig. 10). A radiograph was taken to document the final implant position (Fig. 11).

At 4 weeks, the healing cap was changed to a Ø 4.8 mm conical healing abutment to facilitate the development of the eventual emergence profile (Fig. 12). The patient was referred back to her prosthodontist for restorative procedures.

Eight weeks after implant placement, impression procedures were initiated. Using the SCS driver, the healing cap was removed and a closed-tray, two-part impression coping was positioned into the implant, hand-tightened and the impression cap placed (Fig. 13). An elastomeric impression material was used to make the impression; the impression coping was removed from the implant and placed back into the impression with an analog attached (Fig. 14). A Narrow CrossFit™ temporary meso-abutment was placed and marked for reduction (Figs 15–16). After extra-oral modification, the abutment was hand tightened and a provisional restoration was fabricated using a bisacrylic resin material. The temporary abutment was removed to allow for marginal adaptation and polishing (Fig. 17). The temporary coping was hand-tightened and the provisional was secured using provisional cement (Fig. 18).



Fig. 5: Implant chosen for #29 was a 3.3 x 10 mm Roxolid™ Narrow CrossFit™ Bone Level implant



Fig. 6: Packaging of the Roxolid™ TiZr implant, identical to titanium SLActive® implants



Fig. 13: Occlusal view of the closed-tray NC impression components in place

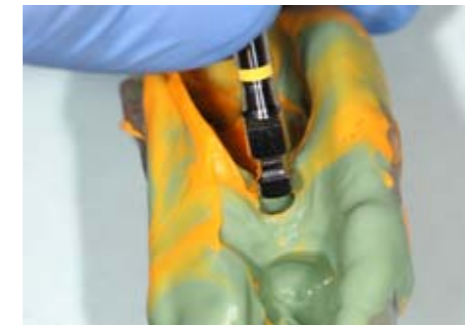


Fig. 14: Placement of the closed-tray impression post and NC implant analog into the impression prior to pouring the master cast



Fig. 7: Photograph demonstrates that the hydrophilic nature of the SLActive® surface is conserved on the Roxolid™ implant



Fig. 8: Final position of the Roxolid™ implant. Note facial position of laser marking on transfer mount



Fig. 15: Placement of the NC temporary abutment prior to modification



Fig. 16: The NC temporary abutment after modification



Fig. 9: Occlusal view of implant #29. Due to the 3.3 mm diameter, at least 1 mm thickness of facial bone was preserved, while ensuring an ideal 3-dimensional implant position. Internal CrossFit™ is also visible



Fig. 10: Transmucosal closure using 3.0 non-resorbable PTFE suture with the Ø 3.3 mm bottle-shaped healing abutment



Fig. 17: The provisional on a NC implant analog after final shaping



Fig. 18: The provisional delivered and cemented

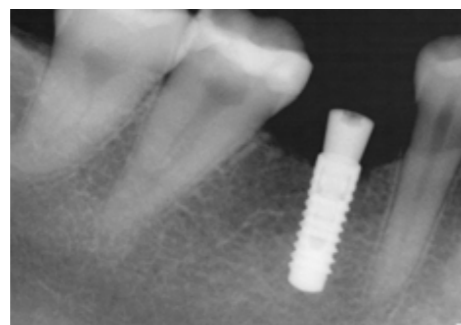


Fig. 11: Radiograph demonstrating final implant position



Fig. 12: Occlusal view of healed site with the larger diameter Ø 4.8 mm conical healing abutment to facilitate development of eventual emergence profile



Fig. 19: The final crown with a Ø 5.5 mm NC cementable abutment



Fig. 20: Delivery of the Ø 5.5 mm NC cementable abutment. The abutment is torqued to 35 Ncm

At 10 weeks post-surgery, the final restoration was ready for delivery (Fig. 19). The provisional and temporary abutment were removed (Fig. 20) and an NC cementable abutment was placed (Fig. 21). The final restoration was tried in and adjusted where necessary. The abutment was then torqued to 35 Ncm without event and the final restoration was delivered using a glass ionomer cement (Fig. 22). A final radiograph was taken to verify cement removal and to assess baseline bone levels the day of delivery (Fig. 23).

DISCUSSION

This case report documents the successful replacement of tooth #29 with a reduced diameter TiZr SLActive® dental-implant-based restoration. Time to treatment completion and cost of treatment are two commonly cited barriers to implant case acceptance by patients^{2,3}. Time as a factor can be further subdivided into two arms: (a) time to allow for osseointegration, and (b) additional time necessary for bone augmentation procedures to rebuild lost bony architecture. The development of the SLActive® surface has helped address the former, with recommendations of three to four weeks of healing in Type I–III bone now considered routine^{17–19}. Bone augmentation procedures, however, can add significant time to treatment depending on the type and amount of augmentation required. Implant placement into fresh extraction sockets can require three to six months healing time prior to final restoration insertion, depending on the situation^{24,25}, while lateral, vertical and sinus augmentations can often add four to nine months additional treatment time^{26,27} for patients, not to mention the morbidity and costs accompanying these procedures.

In regard to cost, Tepper and co-workers found in a survey of 1,000 Austrian adults that while the majority of respondents (61%) would accept implants if the need arose, all respondents perceived implant-supported rehabilitations to be expensive². Yet recent research by Bouchard and co-workers found that due to dental implants' higher success rate, single-tooth implant restorations are more cost-effective than fixed partial dentures⁴.



Fig. 21: Occlusal view of the final abutment position



Fig. 22: The final crown on the day of delivery



Fig. 23: Radiograph of the final prosthesis on the day of delivery

Previously, the use of reduced-diameter implants in posterior deficient bone-width situations would not have been considered advantageous due to the lack of strength and resistance to high strain forces^{8,9}. In fact, the published indications for Straumann 3.3 mm diameter Narrow-Neck and Bone Level implants include maxillary lateral incisors and mandibular incisors, but posterior applications require splinting to larger diameter implants⁵. Single-tooth posterior restorations are explicitly contraindicated⁵. Nevertheless, real-world financial concerns expressed by patients present an opportunity for clinicians and researchers to devise a way to reduce or altogether eliminate the need for grafting to obtain additional bone width in certain situations.

TiZr alloy has demonstrated significantly higher fatigue and tensile strengths than conventional titanium implants^{14,15}. Combined with the SLActive[®] surface, TiZr implants can help expand indications and reduce the possibility of fracture of reduced-diameter implants, as has been previously reported^{9,28,29}. A radiographic study in dogs examining the early bone level changes (two to eight weeks) of TiZr SLActive[®] Bone Level implants vs. Ti SLActive[®] Bone Level implants found no significant differences between the two implant types at any of the timepoints tested³⁰. Gottlow and co-workers²¹ tested the osseointegration properties of specially designed TiZr and Ti implants with an SLActive[®] surface in an animal model. Four weeks following implantation into 12 miniature pigs, removal torque values and histological observations were made by blinded investigators. Maximum removal torque was significantly greater for TiZr implants than Ti implants (231 ± 22 Ncm versus 205 ± 24 Ncm; $p=0.013$). Bone was observed histologically in both TiZr and Ti implants and bone area in the total area was significantly higher in TiZr as compared to Ti implants ($45.5 \pm 13.2\%$ versus $40.2 \pm 15.2\%$; $p=0.037$), while no significant differences were noted in bone-to-implant contact. The authors concluded that the TiZr SLActive[®] implant surface improved osseointegration compared to Ti implants with the SLActive[®] surface. In addition, the authors stated that future studies should be conducted to discern if these differences are due to any

surface property that may differ between TiZr SLActive[®] and Ti SLActive[®].

In light of these findings, present indications for the Roxolid[™] implant include two or more Roxolid[™] implants to anchor a fixed-detachable or removable denture via bar, Locator[®], or synOcta[®]; two single non-splinted crowns in a double-tooth gap, including premolars; two or more implants for a cemented or screw-retained fixed partial denture; one implant for either cemented or screw-retained single crowns from premolars to anterior teeth. The only contraindication that still stands is that the use of Roxolid[™] reduced-diameter implants is not recommended in either maxillary or mandibular molars³¹.

The Roxolid[™] implant had reportedly undergone an unprecedented degree of clinical evaluation prior to its recent market release, dating back two years^{22,23}. These include a pilot clinical trial in 22 patients, an ongoing multi-center double-blind study in eight European centers, as well as a non-interventional multi-center clinical trial in the US, from which the present case report is drawn. Current reports state implant survival exceeds 99% but one-year reports will be forthcoming and additional long-term clinical evaluations are necessary to further document and establish the efficacy of the novel composition of this implant.

CONCLUSION

By expanding the indications of reduced-diameter implants through a combination of a proven implant surface and increased fixture strength, the Roxolid[™] TiZr implant may provide clinicians with the additional flexibility to further reduce the cost of implant-based reconstructions for their patients.

REFERENCES

- McNutt MD, Chou CH. Current trends in immediate osseous dental implant case selection criteria. *J Dent Educ.* 2003 Aug;67(8):850-9.
- Tepper G, Haas R, Mailath G, Teller C, Bernhart T, Monov G, Watzek G. Representative marketing-oriented study on implants in the Austrian population. II. Implant acceptance, patient-perceived cost and patient satisfaction. *Clin Oral Implants Res.* 2003 Oct;14(5):634-42.
- Zimmer CM, Zimmer WM, Williams J, Liesener J. Public awareness and acceptance of dental implants. *Int J Oral Maxillofac Implants.* 1992 Summer; 7(2):228-32.
- Bouchard P, Renouard F, Bourgeois D, Fromentin O, Jeanneret MH, Beresniak A. Cost-effectiveness modeling of dental implant vs. bridge. *Clin Oral Implants Res.* 2009 Jun;20(6):583-7.
- Straumann Narrow Neck Implant Instructions for Use.
- Cordaro L, Torsello F, Mirisola Di Torosanto V, Rossini C. Retrospective evaluation of mandibular incisor replacement with narrow neck implants. *Clin Oral Implants Res.* 2006 Dec;17(6):730-5.
- Vailati F, Belser UC. Replacing four missing maxillary incisors with regular- or narrow-neck implants: analysis of treatment options. *Eur J Esthet Dent.* 2007 Spring;2(1):42-57.
- Cehreli MC, Akça K. Narrow-diameter implants as terminal support for occlusal three-unit FPDs: a biomechanical analysis. *Int J Periodontics Restorative Dent.* 2004 Dec;24(6):513-9.
- Zinsli B, Säggerer T, Mericske E, Mericske-Stern R. Clinical evaluation of small-diameter ITI implants: a prospective study. *Int J Oral Maxillofac Implants.* 2004 Jan-Feb;19(1):92-9.
- Wataha JC. Materials for endosseous dental implants. *J Oral Rehabil.* 1996 Feb;23(2):79-90.
- Johansson CB, Han CH, Wennerberg A, Albrektsson T. A quantitative comparison of machined commercially pure titanium and titanium-aluminum-vanadium implants in rabbit bone. *Int J Oral Maxillofac Implants.* 1998 May-Jun;13(3):315-21.
- Stenport VF, Johansson CB. Evaluations of bone tissue integration to pure and alloyed titanium implants. *Clin Implant Dent Relat Res.* 2008 Sep;10(3):191-9. Epub 2008 Jan 30.
- Han CH, Johansson CB, Wennerberg A, Albrektsson T. Quantitative and qualitative investigations of surface enlarged titanium and titanium alloy implants. *Clin Oral Implants Res.* 1998 Feb;9(1):1-10.
- Norm AsTm F67 (states min. tensile strength of annealed titanium).
- Kobayashi E, Matsumoto S, Doi H, Yoneyama T, Hamanaka H. Mechanical properties of the binary titanium-zirconium alloys and their potential for biomedical materials. *Journal of Biomedical Materials Research.* 1995;29:943-50.
- Ikarashi Y, Toyoda K, Kobayashi E, Doi H, Yoneyama T, Hamanaka H, Tsuchiya T. Improved biocompatibility of Titanium-Zirconium (Ti-Zr) Alloy: Tissue Reaction and Sensitization to Ti-Zr Alloy compared with Pure Ti and Zr in Rat Implantation Study. *Materials Transactions.* 2005;46(10):2260-7.
- Morton D, Bornstein MM, Wittneben JG, Martin WC, Ruskin JD, Hart CN, Buser D. Early Loading after 21 Days of Healing of Nonsubmerged Titanium Implants with a Chemically Modified Sandblasted and Acid-Etched Surface: Two-Year Results of a Prospective Two-Center Study. *Clin Implant Dent Relat Res.* 2009 Sep 9. [Epub ahead of print]
- Zöllner A, Ganeles J, Korostoff J, Guerra F, Krafft T, Brägger U. Immediate and early non-occlusal loading of Straumann implants with a chemically modified surface (SLActive) in the posterior mandible and maxilla: interim results from a prospective multicenter randomized-controlled study. *Clin Oral Implants Res.* 2008 May;19(5):442-50.
- Ganeles J, Zöllner A, Jackowski J, ten Bruggenkatte C, Beagle J, Guerra F. Immediate and early loading of Straumann implants with a chemically modified surface (SLActive) in the posterior mandible and maxilla: 1-year results from a prospective multicenter study. *Clin Oral Implants Res.* 2008 Nov;19(11):1119-28.
- Schwarz F, Sager M, Ferrari D, Herten M, Wieland M, Becker J. Bone regeneration in dehiscence-type defects at non-submerged and submerged chemically modified (SLActive) and conventional SLA titanium implants: an immunohistochemical study in dogs. *J Clin Periodontol.* 2008 Jan;35(1):64-75. Epub 2007 Nov 21.
- Gottlow J, Dard M, Kjellson F, Obrecht M, Sennerby I. Evaluation of a new titanium-zirconium implant: A biomechanical and histological comparative study in minipigs. *Academy of Osseointegration 23rd Annual Meeting, Boston, MA, USA.* 28 February – 1 March 2008; abs OS-5.
- Stone P. Clinical data presented at the EuroPerio 2009, Stockholm, June 2009.
- Non-interventional study, status July 2009, data on file, Straumann USA.
- Hämmerle CH, Brägger U, Schmid B, Lang NP. Successful bone formation at immediate transmucosal implants: a clinical report. *Int J Oral Maxillofac Implants.* 1998 Jul-Aug;13(4):522-30.
- Wilson TG Jr, Schenk R, Buser D, Cochran D. Implants placed in immediate extraction sites: a report of histologic and histometric analyses of human biopsies. *Int J Oral Maxillofac Implants.* 1998 May-Jun;13(3):333-41.
- Valentini P, Abensur DJ. Maxillary sinus grafting with anorganic bovine bone: a clinical report of long-term results. *Int J Oral Maxillofac Implants.* 2003 Jul-Aug;18(4):556-60.
- Yamamichi N, Itose T, Neiva R, Wang HL. Long-term evaluation of implant survival in augmented sinuses: a case series. *Int J Periodontics Restorative Dent.* 2008 Apr;28(2):163-9.
- Vigolo P, Givani A, Majzoub Z, Cordioli G. Clinical evaluation of small-diameter implants in single-tooth and multiple-implant restorations: A 7-year retrospective study. *Int J Oral Maxillofac Implants.* 2004;19:703-709.
- Comfort MB, Chu FC, Chai J, Wat PY, Chow TW. A 5-year prospective study on small diameter screw-shaped oral implants. *J Oral Rehabil.* 2005;32:341-345.
- Thoma DS, Jones AA, Wieland M, Dard M, Buser D, Hammerle C, Cochran DL. Evaluation of a new titanium-zirconium implant. *Academy of Osseointegration 24th Annual Meeting, San Diego, CA, USA,* 26-28 February 2009; Abs. SO4.
- FDA 510(K) Submission K083550, November 26, 2008.