Soft and Hard Tissue Response to Zirconia versus Titanium One-Piece Implants Placed in Alveolar and Palatal Sites: A Randomized Control Trial

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ABSTRACT

Background: Titanium (Ti) implants have been used in the last four decades to replace missing teeth. Alternatives to Ti such as zirconia (Zr) may offer aesthetic advantages and be more acceptable to patients and clinicians concerned about Ti allergy but must show equivalent biological acceptability to Ti.

Purpose: The research aimed to investigate soft and hard tissue response to Ti and Zr implants in edentulous patients.

Materials and Methods: The research included 24 participants (Ti = 12, Zr = 12) restored with one-piece ball-abutment implants to support overdentures. Participants received four maxillary implants (two in the premolar alveolus, one off center in the alveolar midline, and one wide-diameter implant in the anterior median palate) and three mandibular implants (one in the midline and bilateral posterior implants).

Results: Success rates for both Ti and Zr implants were low, 67.9% for all alveolar implants and a survival rate of 50.0% for the palatal implants. Only 11 (52.4%) of 21 palatal implants survived the follow-up period. Peri-implant health was equivalent for Ti and Zr implants and showed no statistically significant changes from loading to the 1-year follow-up. Statistically significant differences were noted in radiographic bone level between Ti and Zr implants (p = .02), with Zr showing greater bone loss.

Conclusions: Although the failure rates with the one-piece Zr implants were higher than with the Ti ones, suggesting that the former's clinical usage as in this study cannot be recommended, it should be borne in mind that the fault may also lie with the novel prosthodontic design which was used.

KEY WORDS: crestal bone loss, edentulous mandible, edentulous maxilla, randomized controlled trial, success rate, survival rate, titanium, zirconia

Edentulism has been described as an oral handicap with adverse functional, aesthetic, and psychosocial

sequelae for the affected individual.¹ Although it may be treated by the fabrication of full dentures, these prostheses are often unstable and unaesthetic, and fail to restore full oral function. For this reason, a modern approach has emerged where the dentures are stabilized using dental implants, with the latter usually being made of

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titanium (Ti).^{1,2} Implant dentistry has evolved tremendously over the past 25 years, and implant-supported overdentures have now improved the quality of life of elderly edentulous patients in a number of countries and hence have become a predictable treatment for the oral rehabilitation of edentulous patients.^{3–6}

Ti is a reactive material and is classified into two categories: commercially pure (cpTi) and Ti-alloy. The cpTi (of different grades), with its superior biocompatibility, high corrosion resistance, and good mechanical properties, has been used to anchor dentures and restore function for elderly patients since the late 1960s.² Hypersensitivity to Ti as an implant material in the oral and maxillofacial area may be more common than has been reported in the literature.⁷⁻¹⁰ Some patients have raised concerns about using Ti in the body because it may induce allergic reactions.^{9,11–13} Patients are increasingly requesting a metal-free approach for their treatment needs for reasons other than aesthetics.⁹

Zirconia (Zr) represents an alternative material to Ti because of its biocompatibility, good mechanical properties, and aesthetically acceptable color.^{14–16} In vitro animal studies investigating different aspects of Yttria-stabilized Tetragonal Zirconia Polycrystal (Y-TZP) implants have shown promising findings, which strongly support the use of Zr in human clinical trials.^{14–17} Furthermore, there is evidence that Ti can be as corrosive as any other base metal under conditions of mechanical stress, oxygen deficit, or low pH. A variety of adverse effects (ranging from mild facial erythema, hyperplasic tissues, and inexplicable implant failure up to nonspecific Ti induced autoimmune and immunemodulation reactions) has been reported with Ti.^{7,8,13}

Resorption of the anterior maxilla following extraction takes place in both vertical and horizontal directions,¹⁸ reportedly up to 23% after tooth extraction in the first 6 months, with a further 11% between 6 months and 5 years.¹⁹ This results in a residual ridge that is more palatally and apically located, making it more difficult to place an implant in a favorable position. Thus, implants are often placed somewhat palatally to the original tooth location, making it difficult to achieve acceptable aesthetics and adequate lip support without modifying the prosthesis.

It has been suggested that the midline of the palate (anterior median palate) may be suitable for implant to support overdentures.^{20–22} Mini-implant anchorage is a significant part of orthodontic treatment.²³ Wehrbein

evaluated the histological characteristics of palatal bone and found that the midpalatal bone was a suitable site for mini-implant placement because it has a relatively compact bone, which, from a morphological point of view, provides good primary stability.²⁴ Männchen and Schätzle,²⁵ in reporting on a prospective longitudinal study, concluded that the survival and success rates of palatal orthodontic implants (98.5% after 19 months) are comparable with those of implants placed for dental prostheses.²⁵ In a unique case report, a strategically positioned palatal implant was used to improve the retention and stability of a maxillary implant overdenture.²⁰ A triangular prosthodontic design was used by placing two conventional implants in the canine areas of the maxillary ridge together with a single implant in the midpalatal region.20

Our research team has conducted a randomized, controlled clinical trial evaluating one-piece Zr (Y-TZP) implants supporting overdentures in fully edentulous human subjects. Our trial incorporated a novel distribution of implants sites in both arches, including palatally placed implants, and matched the Zr implants with identical Ti one-piece implants.²⁶ Our research team has recently presented 1-year outcomes of pilot study involving four patients with one-piece Zr implants supporting overdentures.²¹ Here, we report the surgical protocol in detail and analyze soft and hard tissue responses to Ti (Ti) and Zr implants using accepted success criteria. To date, there appear to be no other reports of similar randomized control trials using Zr implants to support overdentures in edentulous patients.

METHODOLOGY AND STUDY DESIGN

This in vivo human study involved surgical and prosthodontic rehabilitation of 24 completely edentulous participants with implant overdentures. Although a formal power study was not conducted, the sample size for the trial was based upon the team's previous experience with similar trials.^{27,28} Participants who met the inclusion criteria (Table 1) were randomly allocated to one of two groups (control or test group) depending on the type of implants they had received (Figure 1). In the control group (Group I), the implants were made from Ti, and the implants' surfaces were acid etched and sandblasted with surface R_a values of 1 to 2 μ m. In the test group (Group II), Zr implants with surface roughness R_a values of 0.5 to 0.8 μ m were used (Figure 2). Cone beam computed tomographic radiographs

TABLE 1 Inclusion and Exclusion Criteria for	the Research
Inclusion Criteria	Exclusion Criteria
Patients with complete edentulism Bone quality type 1–3 (Lekholm and Zarb, 1985) Bone quantity Class II–V (Cawood and Howell, 1988)	 Patients with poor bone quality (i.e., Lekholm and Zarb [1985] bone type 5 and Cawood and Howell [1988] bone quantity Class I and VI in either jaw as revealed by radiographs) were not included in the study Smokers Patients with existing implants in the jaws Patients with diagnosed medical problems that interfere with implant surgery Patients with previous bone grafting in either the maxillary or mandibular jaws Patients receiving intravenous forms of bisphosphonates Patients who have had radiation therapy to the head and neck region

(Galileos®, Sirona Dental Systems GmbH, Bensheim, Germany) were taken using diagnostic stents to investigate bone quantity and to identify any undiagnosed bone pathology before implant surgery. Planning for the implant surgery was performed using Galaxis® software (Sirona Dental Systems GmbH) (Figure 3). For the maxilla, each participant received two narrow or regular diameter one-piece implants with ball abutments in the premolar region, one narrow diameter or regular diameter implant in the maxillary off center region



Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.



Figure 2 Prototype one-piece implants. *A*, One-piece titanium. *B*, One-piece zirconia implant.

(between the maxillary central and lateral incisors), and one wide-diameter implant in the anterior median palate. For the mandible, each participant received three wide-diameter one-piece implants with ball abutments, a midline implant, and bilateral distal implants in the posterior mandible (Figure 4). In the control group (Group I), the implants were made from Ti. In the test group (Group II), Zr implants were used. The decision on length and diameter of implants was customized to each participant depending on the radiographic analysis of available bone at each potential implant site.

The randomization process was in accordance with items 8 to 10 of the Consolidated Standards of Reporting Trials statement checklist for randomized control trials.²⁹ Block randomization was used as presented by Roberts and Torgerson.³⁰ The principal investigator blindly assigned participants to either of the two groups by asking them to pick one of the sequentially numbered, opaque, sealed envelopes containing one of the two interventions. In this way, each participant had an equal chance of being assigned to one of the two groups.

The surgical team met with the selected patients about 4 weeks before, and patients were provided with written and verbal information about the surgical procedure and possible complications. Each participant signed the informed consent for the implant surgery on the day of the surgical procedure. Surgery was performed in one jaw at a time with a delay of a minimum of 3 weeks for the second procedure. Preoperative antimicrobial prophylaxis was provided by giving each participant a single oral dose of 1 g amoxicillin (or 600 mg clindamycin in the event of allergy to penicillin) 1 hour prior to surgery as used in other studies.³¹ Additionally, 1 g of paracetamol was given orally to provide postoperative analgesia. Prior to the surgical procedure, each participant was instructed to rinse his or her mouth twice with 10 ml of 0.2% chlorhexidine gluconate (Savacol®, Colgate, Madison County, NY, USA) for 1 minute each time.³² Before administration of local anesthesia, a surgical skin marker (Viscot All Skin[™]; Viscot Medical, LLC, East Hanover, NJ, USA) was used to mark the implant site on the alveolar mucosa with the help of an acrylic resin surgical stent (Palavit G, Heraeus Kulzer GMBH, Wehrheim, Germany). Local anesthesia was gained by infiltration of Mepivacaine hydrochloride 2% with adrenaline 1:100000 (Scandonest 2% special, Septodont®, Cedex, France) at the implant site in the maxilla and inferior alveolar block in addition to infiltration at the implant site in the mandible. Incisions were made along the keratinized mucosa of the alveolar ridges with no. 15 BP (Bard-Parker®; BD, NJ, USA) surgical blades to reflect full-thickness mucoperiosteal flaps to expose the alveolar bone. Implant sites were flattened, and any sharp areas of the ridge or bone irregularities were removed with wide-diameter carbide burs. In the midpalatal regions, ring of mucosa was removed from the implant sites with the use of 5-mm mucosal punches. All implant osteotomies were prepared according to the guidelines provided by the manufacturer (Southern Implants®, Irene, South Africa). Direction indicators were used to ensure parallelism of the implants. In the patients with insufficient bone width, osteostomes were used to widen the osteotomy site after initial 2-mm implant drill.³³ Bone quality was evaluated for each participant at the time of preparation for the osteotomy, as described by Lekholm and Zarb.³⁴ Implants were inserted with a machine driver with a speed of 15 to 20 rpm using 35 Ncm torque (Figure 5). Final positioning of the implants was performed using a hand torque wrench as provided by the implant manufacturer. During implant osteotomy procedures, bone chips were collected to cover any exposed implant threads. All incisions were closed with a synthetic resorbable sutures (4/0 vicryl, ETHICON™, Cincinnati, OH, USA). Postoperatively, all patients were prescribed with paracetamol 1 g to be taken 6 hourly and ibuprofen 400 mg to be taken 8 hourly for



Figure 3 Cone Beam Computed Tomography (CBCT) treatment planning report (for mandible implant surgery) generated through CBCT using Sirona's Galaxis software. *A*, main OPG view – thin vertical radio-opaque lines represent implant markers (Guttapercha points within the diagnostic stent). Mandibular nerve tracing (thick purple line represents mandibular nerve). Mandibular barrel-shaped implants at 36, 31, and 46 region. *B*, Axial view of the mandible showing bone width at the implant sites (purple circles represent nerve emergence from the mandibular foramen). *C*, Coronal view of the implant sites at 36, 46, and 31 sites. A wide-diameter implant (5 × 10 mm) can be seen. Approximation of the mandibular nerve (purple). *D*, Axial view at implant site 46.

5 days to minimize pain and inflammation. They were also prescribed with 0.2% chlorhexidine gluconate solution to rinse their mouth twice a day for 2 weeks. Recall appointments were scheduled in 4 days after surgery to assess the state of healing and comfort. All patients were recalled 2 weeks after surgery to evaluate their oral hygiene, remove sutures, and arrange their second surgical procedure.



Figure 4 Novel implant distribution in the maxilla and mandible. *A*, In the maxilla, three narrow-diameter one-piece implants $(3.8 \times 10 \text{ mm}/3.8 \times 11 \text{ mm})$ in the alveolar region (one off-center and two premolar implants) and one wide-diameter implant $(5 \times 6 \text{ mm})$ in the anterior median palate. *B*, In the mandible, two wide-diameter implants in the molar region and one midsymphyseal implant $(5 \times 8 \text{ mm}/5 \times 10 \text{ mm}/5 \times 11.5 \text{ mm})$.



Figure 5 Surgical pictures of implant placement. *A*, Preparation the implant site (smoothing of the ridge with a wide carbide bur). *B*, Implant osteotomy site with the direction indicator at 14 region. *C*, Expanding the 11 osteotomy site with the osteotome. *D*, Insertion of a narrow-diameter $(3.8 \times 10 \text{ mm})$ zirconia implant. *E*, Palatal implant insertion with a flapless approach. *F*, Postoperative image of maxillary implants. *G*, Mandibular implant osteotomy site with the direction indicators. *H*, Insertion of a wide-diameter $5 \times 10 \text{ mm}$ titanium implant in the mandible. *I*, Postinsertion image of mandibular implants.

At the completion of the maxillary and mandibular implant placement, complete diagnostic conventional dentures were made by the prosthodontic team for the participants in each group, with the dentures adjusted by removing acrylic at the implant sites. Immediately following the surgery, the fitting surfaces of the complete dentures were relieved and relined with a tissue conditioner (Visco-gel, Dentsply, Dentsply, York, PA, USA). After 3 to 4 months of healing, closed mouth impressions were made with polyether material (Impregum Penta, 3M ESPE, Norristown, PA, USA) to incorporate the respective matrices into the intaglio surfaces of the prostheses (overdentures). Details of prosthodontics treatment and outcomes have been presented elsewhere.^{21,26}

Soft tissue parameters were recorded at baseline (at the time of loading) and after 12 months of function. For the purposes of this study, baseline was taken to mean at the time of definitive loading after 3 to 4 months. Probing depths, recession, and width of keratinized tissue were recorded at four sites (midmesial, mid-distal, midbuccal, and midlingual) per implant.

The presence or absence of plaque around the implant was recorded using a modified plaque index, and sulcular bleeding was evaluated using a modified bleeding index.35 In addition, probing depth, recession, and the width of keratinized tissue were recorded at four sites per implant (midmesial, mid-distal, midbuccal, and midlingual) using a periodontal probe (Williams's markings, Hu-Friedy, Chicago, IL, USA). The probing depth was measured by inserting the probe (with a 0.5-mm ball end and a probing force of 0.5 N) into the midmesial and mid-distal aspects of the implant. The width of the keratinized mucosa around the implant was measured using the same periodontal probe, moving from the mucogingival junction to the free gingival margin.³⁶ Implant success criteria, as described by Albrektsson and Zarb,³⁷ were used for the alveolar implants (maxillary and mandibular), and the survival rate was evaluated for palatal implants.



Figure 6 Radiographic image of a mandibular zirconia implant scanned with intraoral digital imaging plate system for Digora. The image was then calibrated using Image J analysis software. The blue line on the top of the implant head (ball) represents the top reference point, and the red line represents the measurement of the set scale. The green lines on the right (mesial) and left side of the implant represent the mesial and distal bone levels.

Standardized radiographs were taken using phosphor plates (Digora® Optime System, Soredex Ltd, Tuusula, Finland) positioned using modified film holders.³⁸ Tiff images were exported from the Digora for Windows® software (Microsoft, Redmond, WA, USA) and imported into public domain image analysis software (NIH Image J, US National Institutes of Health, Bethesda, MD, USA). The distance from the top of the implant (head of ball) to the first crestal bone contact at the mesial and distal aspect of the implant was measured³⁹ (Figure 6). A mean bone level value was calculated for each implant from the mesial and distal measurements. The difference between mesial and distal sides for each linear measurement was not significant, so they were combined into one value per implant. Additionally, conventional radiographs³⁸ were also taken and analyzed independently by another researcher in order to provide an estimate of interexaminer measurement error. The mean difference was not significant (0.2-0.3 mm).

Statistical Analysis

The data were tabulated on an Excel[®] spread sheet (Microsoft) and analyzed using a commercially available

statistical software package (SPSS® 17.0, SPSS Inc, IBM New Zealand Ltd, Wellington, New Zealand). The groups were compared using independent samples *t*-tests or, in case of non-normality, the Mann–Whitney U test. Spearman's correlation coefficient was used to quantify the association between the implant failure and the type of bone in each group. A p value of <.05 was considered to be statistically significant. Intraexaminer variation was evaluated by means of reassessment (double assessment) of the soft tissue parameters of three participants. The difference between the pairs of linear evaluation was within the accepted range of <1.

RESULTS

Three participants died due to systemic medical conditions and did not finish the trial (one died of pneumonia, one of carcinoma of the prostate, and one of a myocardial infarction). Two participants withdrew from the trial for personal reasons. A total of 19 participants, 15 men (73.7%) and four women (26.3%) completed the trial. Group I consisted of eight participants (42.1%), and Group II consisted of 11 (57.9%). Participants' ages ranged from 50 to 79 years (mean age 62 years, SD 11). Twenty-two participants received 150 implants.

Alveolar Implants

In the Ti group, 40 (66.7%) implants fulfilled the success criteria after 1 year of function, whereas seven implants (11.7%) failed to osseointegrate. Twelve implants were unaccounted for because of the withdrawal of two participants. On the other hand, 46 (67.6%) Zr implants fulfilled the success criteria after 1 year of function, and six implants remained unaccounted for. There were more failures in the Zr (16, or 23.5%) than the Ti (7, or 11.7%) group (p = .166) Table 2.

Palatal Implants

Marginal bone level measurements for the palatal implants could not be obtained because of the anatomical limitations, so the survival of those implants was evaluated. Out of 21 palatal implants placed (in 21 participants), only 11 (50%) survived. Five from the Ti (50%) group and six from the Zr (50%) group completed the 1-year follow-up. A higher failure rate was noted in the Zr group than in the Ti group (Table 2).

Of 150 implants, 21 remained unaccounted for because of the dropout of three participants (deceased).

TABLE 2 Life Table of Impla	ant Success/Surv	vival (Adapted fro	om Albrektsson a	nd Zarb 1998)	
	Implant (<i>n</i>)	Success (%)	Survival (%)	Unaccounted (%)	Failure (%)
Alveolar implants titanium	60	40 (66.7)	1 (1.7)	12 (2)	7 (11.7)
Zirconia	68	46 (67.6)	0	6 (8.8)	16 (23.5)
Total	128	86 (67.2)	1(0.8)	18 (14.1)	23 (18)
Median palatal implants			5 (50)	2 (20)	3 (30)
Titanium	10				
Zirconia	12		6 (50)	1 (8.3)	5 (41.7)
Total	22		11 (50)	3 (13.6)	8 (36.4)

Fifty-eight standard diameter 3.8-mm implants were placed in the maxillary alveolar region, and 51 widediameter 5-mm implants were placed in the mandibular region. In the Ti group, two implants failed during the early healing period (2-3 months). On the other hand, in the Zr group, 12 implants failed during the early healing period (2-3 months). There were more failures with the Zr (n = 21) than with the Ti (n = 10). A higher failure rate was noted with the implants placed in the midpalatal region than with the alveolar implants (42.1% and 20.9%, respectively; $\chi^2 = 3.99$; p = .046). Table 3 shows the details of the failed implants in two groups and the associated implant length. Among the 23 (18%) failed implants, 19 (82%) were in the maxilla, 13 (56.5%) in the posterior maxilla, and 6 (26.1%) in the anterior maxillary region. On the other hand, only four (7.4%) implants failed in the mandibular region (one in the Ti and three in the Zr group) (Table 4). Most of the patients were assessed by the surgeon as having type 2 or type 3 bone in the maxillary region, and type 2 bone quality in the mandible (Table 5). There was a high correlation between implant failure and type 3 bone in the Zr group (rho = 0.79; p = .01) and the Ti group (rho = 0.97; p < .01).

TABLE 3 Ty	pe of Fa	ilure (E	arly/La	ate) by (Group	
Implant	Т	itanium		Z	irconia	
Dimensions	Failed	Early	Late	Failed	Early	Late
3.8×10	4	1	3	8	4	4
3.8×11.5	3	1	2	5	5	0
5×6	3	0	3	6	3	3
5×8	0	0	0	1	0	1
5×10	0	0	0	0	0	0
5×11.5	0	0	0	1	0	1
Total	10	2	8	21	12	9

The peri-implant health of the participants remained the same, and no statistically significant differences were observed with respect to each evaluated peri-implant parameter between the Ti and Zr group from loading to the 1 year follow-up (Table 6). With reference to the hard tissue response, statistically significant differences were noted between the Ti and Zr implants (p = .02). Zr showed greater bone loss than the Ti group (Table 7). Similarly, no statistically significant differences were observed in the two groups in either the maxilla (p = .28) or the mandible (p = .06). Failed implants were replaced after 3 to 4 months of its removal. Although most of the replaced implants were successful, they were not included in the study.

DISCUSSION

The aim of this clinical trial was to compare the surgical and peri-implant (soft and hard tissue) response with one-piece Zr or Ti or implants in human participants. A number of preclinical animal and in vitro lab experiments have investigated the osseointegration of Zr implants, but human clinical trials remain scarce.^{14,17} There have been no randomized controlled trials comparing the outcomes of one-piece Zr and one-piece Ti implants supporting overdentures. The current research did not find significant differences between the success

TABLE 4 (Maxilla, Indicates	Implant Mandik Unacco	Failure ble, and bunted	e accord Mediaı for Impl	ing to F n Palate ants	Region e). Brack	et
Implant	Max	killa	Man	dible	Pala	atal
Туре	Placed	Failed	Placed	Failed	Placed	Failed
Titanium	24 (6)	6	24 (6)	1	8 (2)	3
Zirconia	29 (3)	13	33 (3)	3	11 (1)	5
Total	53 (9)	19	57 (9)	4	19 (3)	8

TABLE 5 Number of	Implants and	Corresponding B	one Quality in th	ne Two Groups		
	١	īi (<i>n</i> = 8 Participants	5)	Z	r (<i>n</i> = 11 Participant	:s)
Implant Site/		Bone Quality			Bone Quality	
Number	Type 1	Type 2	Туре 3	Type 1	Type 2	Type 3
14	0	3	5	0	3	7
11/12	0	3	5	0	2	7
24	0	3	5	0	2	8
Median palatal	0	8	0	0	10	1
36	0	7	1	0	10	1
31/41	2	5	1	0	11	0
46	0	6	2	0	10	1
Total	2	35	19	0	48	25

Ti, titanium; Zr, zirconia; 14, right first maxillary premolar; (11/12), offset maxillary central; (24) = Left first maxillary premolar; (36), left first mandibular molar; (31/41), midsymphyseal; (46), right mandibular first molar.

rate and peri-implant outcomes of the Ti and Zr (test group) implant overdentures after 1 year of functional loading.

This is the first randomized clinical trial where an implant was placed into the median palatine region to provide additional support to the maxillary prosthesis. Because of the anatomical limitations of this site, standardized radiographs of crestal bone could not be obtained; thus, only the survival rate could be recorded. The survival of Ti and Zr implants in palatal sites was evaluated separately from implants placed into conventional sites.

The main limitation of the research was the small sample size. Because of the nature of the trial, it was difficult to find a statistically valid number of participants. Only 12 participants per group were included instead of 18 as intended at the beginning of the project. Additionally, three participants died during the trial,

TABLE 6 Mean Values for Clinical Parameters (Brackets Contain SD Unless Otherwise Indicated)

				Impla	nt Type		
			Ti	Z	r	Both Combine	ed (Ti and Zr)
Jaws	Outcome	Loadin	g 1 Year	Loading	g 1 Year	Loading	g 1 Year
Maxilla, mandible,	Plaque index	0.58 (0.50)	0.71 (0.58)	0.37 (0.45)	0.25 (0.33)	0.46 (0.47)	0.44 (0.49)
and palatal site	Bleeding index	0.13 (0.17)	0.493 (0.50)	0.35 (0.44)	0.22 (0.32)	0.26 (0.36)	0.34 (0.42)
	Probing depth	1.59 (0.33)	2.23 (0.53)	1.59 (0.61)	2.23 (0.69)	1.59 (0.50)	2.23 (0.61)
	Recession	0.74 (0.25)	0.86 (0.68)	0.48 (0.54)	0.56 (0.68)	0.59 (0.45)	0.69 (0.68)
	Keratinized mucosa	2.47 (0.87)	2.34 (0.95)	2.20 (0.97)	2.21 (1.04)	2.31 (0.91)	2.27 (0.98)
Maxilla	Plaque index	0.36 (0.42)	0.30 (0.37)	0.32 (0.58)	0.16 (0.32)	0.34 (0.50)	0.22 (0.34)
	Bleeding index	0.12 (0.24)	0.25 (0.38)	0.49 (0.81)	0.15 (0.27)	0.32 (0.64)	0.19 (0.31)
	Probing depth	1.66 (0.45)	2.15 (0.69)	1.66 (0.52)	2.09 (0.76)	1.66 (0.48)	2.11 (0.71)
	Recession	1.03 (0.59)	1.19 (0.50)	0.51 (0.49)	0.97 (1.16)	0.74 (0.56)	1.06 (0.93)
	Keratinized mucosa	3.09 (1.03)	1.93 (0.86)	2.72 (1.15)	1.95 (0.96)	2.89 (1.08)	1.90 (0.90)
Mandible	Plaque index	0.85 (0.69)	0.90 (0.55)	0.36 (0.48)	0.27 (0.39)	0.57 (0.62)	0.54 (0.55)
	Bleeding index	0.12 (0.23)	0.58 (0.56)	0.22 (0.38)	0.21 (0.40)	0.18 (0.32)	0.37 (0.50)
	Probing depth	1.46 (0.39)	2.20 (0.54)	1.59 (0.83)	2.37 (0.83)	1.54 (0.67)	2.3 (0.7)
	Recession	0.53 (0.18)	0.67 (0.95)	0.53 (0.86)	0.38 (0.83)	0.53 (0.65)	0.5 (0.87)
	Keratinized mucosa	2.0 (0.94)	1.85 (0.96)	2.04 (1.03)	2.09 (1.17)	2.03 (0.97)	1.99 (1.06)

Ti = titanium, Zr = zirconia.

TABLE 7	Mean C	restal Bone Lev	vel at Baseline a	and after 1 Year o	of Loading amo	ong the Two Gr	oups (Brackets C	ontain SD)		
Implant		ž	esial Mean (mm)	(SD)	D	istal Mean (mm) ((SD)	Ō	erall Mean (mm)	(SD)
Type	Site	BL	1 Year	Change	BL	1 Year	Change	BL	1 Year	Change
Ti	14	7.35 (0.68)	7.53 (0.74)	-0.18 (0.29)	6.82~(1.06)	7.23 (1.02)	-0.42(0.62)	7.08(0.80)	7.19(0.74)	-0.30(0.26)
	11	7.20 (0.29)	7.40(0.44)	-0.20(0.46)	6.98(0.54)	7.22 (0.60)	-0.23(0.24)	7.09 (0.38)	7.35 (0.51)	-0.22(0.34)
	24	7.58 (0.69)	7.57 (0.81)	0.02(0.48)	7.40(0.30)	7.28 (0.57)	0.12(0.47)	7.49(0.46)	7.49 (0.66)	0.07~(0.47)
	36	7.71(0.41)	7.73 (0.21)	-0.01(0.25)	7.13 (0.87)	7.30(0.74)	-0.18(0.31)	7.42(0.60)	7.49(0.49)	-0.09(0.23)
	31	7.40(0.89)	7.50 (0.70)	-0.10(0.36)	7.29 (1.05)	7.37(0.84)	-0.09(0.39)	7.34(0.90)	7.39 (0.73)	-0.09(0.36)
	46	7.91 (0.60)	8.03(0.68)	-0.11(0.33)	7.60 (0.61)	7.73 (0.69)	-0.13(0.36)	7.76 (0.56)	7.84 (0.63)	-0.12(0.35)
Zr	14	7.75 (1.51)	8.10(1.69)	-0.35(0.32)	7.65 (1.26)	8.02 (1.22)	-0.37(0.36)	7.70 (1.39)	8.06(1.45)	-0.36(0.32)
	11	7.50(0.80)	7.78 (0.68)	-0.28(0.33)	7.62(1.04)	7.80(1.08)	-0.18(0.26)	7.56 (0.92)	7.79 (0.88)	-0.23(0.12)
	24	7.52 (1.75)	7.74(1.66)	-0.22 (0.23)	7.44(1.25)	7.58 (1.28)	-0.14(0.21)	7.48(1.50)	7.66(1.47)	-0.18(0.21)
	36	7.19(1.51)	7.33 (1.54)	-0.14(0.30)	7.21(1.49)	7.39(1.48)	-0.18(0.36)	7.20(1.50)	7.63(1.51)	-0.16(0.26)
	31	7.51 (1.51)	7.82 (1.71)	-0.31(0.30)	7.69 (1.67)	7.91 (1.76)	-0.22 (0.27)	7.60(1.59)	7.87(1.74)	-0.27(0.23)
	46	7.64(0.99)	8.05(0.95)	-0.41(0.31)	7.58 (1.33)	7.76 (1.32)	-0.18(0.19)	7.61(1.16)	7.91 (2.23)	-0.30(0.16)
A negative v Ti, titanium;	alue represe ; Zr, zirconie	a; BL, baseline; 14, ri	eas a positive value s ight maxillary first pr	shows bone gain. emolar; 11, maxillary	off central; 24, left m	axillary first premol	lar; 36, right mandibul	lar first molar; 31, mi	dsymphyseal; 46, lefi	t mandibular molar.

and the data were excluded from the research, further compromising the findings. However, those 18 (14.1%) unaccounted alveolar implants were reported (by each participant's family) to have been functional and problem-free at the time of death.

Zr implants showed a comparable success rate to the Ti group after 1 year of functional loading, with about two-thirds in each group being successful. It is important to note that none of the failed implants presented any sign of infection or inflammatory exudate at the time of removal. This is consistent with findings from other studies.^{40,41} A possible explanation for the high implant failure rate in the current study is the quality of bone (type 3 - large marrow-filled spaces between trabecular bones) and the one-piece design of the implant. Those early failures could be attributed to patient-associated factors (such as bone quality and quantity), implantassociated factors (such as surface/size of implant), initial implant stability, and intraoperative (implant surgery) factors.⁴² Similar high failure rates for one-piece implants have been reported in other studies.43-45 However, all observed failures in the study by Östmann and colleagues were in the mandible.⁴³ In the Ti group in our research, one patient lost all of the maxillary implants, and one patient lost three implants (two in the maxilla and one in the mandible). In the Zr group, one patient lost all of the maxillary implants and a posterior mandibular implant (five in total, including the palatal one).

Histomorphometric and micro-computed tomography (μ CT) analysis of the median palatine bone have demonstrated a type 2 bone (thick layer of trabecular bone with dense cortical bone underneath) in most of the studies.^{46–48} A recent finite element analysis investigation of the median palatal region in respect of support for maxillary overdentures has concluded that the midpalatal implant used along with three alveolar implants could have a substantial load-bearing capacity.²² Our research group showed comparable stress and strain values between conventional overdenture design and a new quad overdenture design. It was hypothesized that with the introduction of the median palatal implant, a more stress-bearing maxillary overdenture could be constructed, especially in patients where anatomical limitations preclude placement of alveolar implants.²² Of the eight failed palatal implants in the current study, five (62.5%) failed during a functional loading period of 1 to 10 months. Early failure of implants is multifactorial. It is possible that further

modifications to both the surgical protocol and the prothodontic loading protocol may be needed to optimize the success of implants in the midpalatal location. It is also necessary that conclusions based on Finite Element Analysis (FEA) be validated by biological data. Our results suggest that our original FEM analysis may need further refinement to more accurately reflect the response of implant placed into this site.

In the present research, most of the Zr implant failures were observed in the maxilla. Additionally, short implants (5 mm wide and 6 mm long) used in the palatal region would also have contributed to this low success rate. A low success rate for maxillary-implant-supported overdentures is a feature of the literature.^{49,50} This is primarily because of anatomical (poorer bone quality and quantity) and biomechanical reasons.⁵¹ It is clear in that a number of factors could have influenced the implant success rate in the current study.

Kohal and colleagues⁵² have presented 1-year clinical and radiographic outcomes for 65 one-piece Zr implants for single-tooth replacement with one-stage implant surgery. They noted a cumulative survival rate of 95.4% for Zr implants, but they observed an excessive rate of radiographic bone loss (>2 mm) after 1 year of function.⁵² Another study, with a sample size of 20 implants, reported significant bone loss of 1.0 mm within the first year after implant placement (p < .001) and 1.3 mm after 2 years of function in an immediate interim restoration of one-piece Zr implants. The authors reported a survival and success rate of 95%.⁵³

A similar high failure of Zr implants was reported from a multicenter pragmatic randomized control trial by Cannizzaro and colleagues,54 who investigated immediate occlusal versus nonocclusal loading of single Zr implants in 40 partially edentulous patients. They noted statistically significant differences between the immediate postextraction implant group (in whom 40% of implants were lost) and the delayed-placement group where 3% of the implants placed in healed sockets were lost.54 Our study did not find statistically significant differences in peri-implant bone levels (in either the Ti or Zr groups) between the baseline and after 1-year of function. No sign of peri-implant pathology was noted in any radiographs, and excessive bone loss around implants was not observed. The observed radiographic bone loss was comparable with earlier reports from studies of marginal bone loss associated with overdentures: Turkyilmaz and colleagues⁵⁵ reported 0.3 mm; Payne and colleagues⁵⁶ reported 0.2 to 0.3 mm, De Smet and colleagues⁵⁷ reported 0.4 mm, and Naert and colleagues⁵⁸ reported 0.7 mm.

A recent review on Zr implants indicated lower success and survival rates with Zr than with conventional Ti implants.⁵⁹ However, it should be noted that all of the reported studies had potential variables with limited sample size and varying follow-up periods. Most of the studies have used Zr implants in the anterior (maxillary or mandibular) regions where the bone quality and biomechanical conditions are more favorable than in the posterior regions.

We found comparable peri-implant soft tissue response around Ti and Zr implants, suggesting that neither the implant biomaterial nor the design had a detectable influence on peri-implant soft tissue parameters. The soft tissue findings are comparable with those of Kohal and colleagues⁶⁰ and Blaschke and Volz.⁶¹ It should be acknowledged that the participants in the current clinical trial followed the oral hygiene maintenance instructions very well, with observed improvements in the plaque index between baseline and 1-year of function.

In summary, the current research demonstrated a low success rate for one-piece Ti and one-piece Zr implants. A considerably higher failure rate was noted with the maxillary alveolar implants than with the mandibular implants, with a strong influence of bone type. A failure in the first 6 months of loading suggests a compromised healing response in the bone, with it failing to respond to the functional challenges.⁶² The results of our research reinforce the evidence for a low success rate of both Zr and for one-piece implant systems. It is difficult to attribute this high failure rate to the implant biomaterial alone, as implant macrodesign (one-piece) and patient-associated factors are likely to have contributed to these failures.

CONCLUSION

Although the failure rates with the one-piece Zr implants were higher than with the Ti ones, suggesting that the former's clinical usage as in this study cannot be recommended, it should be borne in mind that the fault may also lie with the novel prosthodontic design which was used. Though palatal bone was of good quality (type 2 bone), 8/11 palatal implants failed to osseointegrate. Many variables may have influenced the outcomes of palatal implants, including surgical protocol,

prosthodontic design, implant morphology (one-piece), and patient-related factors. Further research should focus on two-piece Zr designs in large-scale, welldesigned, controlled clinical trials.

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