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CLINICAL RESEARCH

Long-term survival and success of zirconia screw-retained implant-supported prostheses for up to 12 years: A retrospective multicenter study

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ABSTRACT

Statement of problem. Despite the broad clinical application of zirconia for fixed implant-supported prostheses, evidence of long-term performance is sparse.

Purpose. The purpose of this retrospective study was to evaluate the long-term clinical and radiographic outcomes of zirconia-based partial and complete screw-retained implant-supported zirconia fixed dental prostheses (ISZFDPs).

Material and methods. Records of patients treated with dental implants and ISZFDPs between December 2004 and June 2017 were screened. Eligible study participants, according to inclusion criteria, were contacted and invited to undergo clinical and radiographic examinations. Outcomes were evaluated as implant and prosthetic survival rates, prosthetic success rate, complications, marginal bone level (MBL) change, and soft tissue condition. Along with the effects of zirconia prosthesis type and level, the effects of implant type and connection, type of loading, and follow-up on MBL were tested with a generalized linear effects model (GLEM) (α=.05).

Results. A total of 118 patients were identified, of whom 20 (16.9%) were not available for clinical examination for various reasons. Ninety-eight participants (mean age 60.7 ±11.7 years) with 337 implants were included, of which 176 (52.2%) had been immediately loaded. A total of 111 ISZFDPs (96 zirconia connection and 15 titanium base) were investigated: 24 complete ISZFDPs with a zirconia connection (12.9 ±0.97 dental units, minimum 12, maximum 14), 72 partial with a zirconia connection (3.11 ±1.12, minimum 2, maximum 7), 15 partial with a titanium base (3.62 ±1.02, minimum 2, maximum 5). Forty ISZFDPs had been in function for ≥10 years (36%), 38 for 5 to 9 years (34.2%), and 33 for 2 to 4 years (22.8%). The mean follow-up time was 7.2 ±3.4 years. No zirconia fractures were identified. Two implants and 2 ISZFDPs failed, with chipping being the most common complication (13.5%). The implant survival rate was 99.4%, and the prosthetic survival rate was 98.2%. The cumulative prosthetic success rate was 91.9%. MBL change was -0.18 ±0.59 mm. Thirteen implants were treated for peri-implantitis (3.8%), and 9 for mucositis (2.7%), but presented healthy peri-implant soft tissues at the follow-up examination. A significant difference was found between the implant-level and abutment-level prostheses (P=.013), with less marginal bone loss observed in ISZFDPs delivered at the implant level.

Conclusions. Zirconia-based screw-retained implant-supported prosthesis can be considered a reliable long-term treatment option for partial and complete edentulism. No zirconia fractures were experienced. Stable bone levels and low peri-implantitis rates were reported regardless of the ISZFDP type and level, implant type and connection, and type of loading. (J Prosthet Dent 2021;■:■-■)

The predictability and success of implant treatment has increased as a result of the continuing evolution of implant designs, bioactive surfaces, and technologies.[1-3] Because of biocompatibility concerns and increased esthetic demand, metal-free dental restorations have become popular.[4,5] In the past, metal-ceramic

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Clinical Implications

Partial and complete edentulism can be rehabilitated with ISZFDPs, and long-term favorable clinical performance may be expected. The use of screw retention at the implant level was not detrimental to bone and soft tissue integration. Zirconia fracture and porcelain chipping can be minimized with appropriately managed clinical and laboratory protocols.

restorations were considered the standard for the fabrication of implant-supported fixed dental prostheses (ISFDPs).[6,7] However, computer-aided design and computer-aided manufacturing (CAD-CAM) technology has contributed to the popularity of implant-supported zirconia fixed dental prostheses (ISZFDPs).[8-12] Zirconia has improved biocompatibility compared with gold casting alloys, with low bacterial surface adhesion, high flexural strength, absence of mucosal discoloration, high toughness because of transformation toughening, and excellent esthetic properties.[5,13-15] Nevertheless, the need for highly accurate impressions, the difficult post-sintering adjustment and polishing, the complex manufacturing protocol because of poor heat conductivity, and the risk of framework fractures and chipping of the veneering ceramic have limited the universal adoption of ISZFDPs.[9,15-17]

Although ISZFDPs have been advocated for complete arches, clinical evaluations of their medium- to long-term follow-up are lacking.[10,16,18] This study aimed to retrospectively evaluate the clinical reliability of industrially fabricated screw-retained ISZFDPs for rehabilitating individuals with partial and complete edentulism after up to 12 years in function. Clinical and radiographic outcomes and biologic and biomechanical complications were assessed. The null hypothesis was that the implant type and connection, ISZFDP type and level, and visit (baseline or last follow-up appointment) would not influence the marginal bone level (MBL) of ISZFDPs.

MATERIAL AND METHODS

This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (http://www.strobe-statement.org).[19] A retrospective chart review was conducted of partially and completely edentulous study participants aged ≥18 years treated with dental implants and ISZFDPs in 3 private dental clinics (A.P., G.F., G.S.) between December 2004 and June 2017. Eligible study participants were contacted and invited to undergo a clinical and radiographic examination and participate in a clinical investigation. All participants provided written informed consent after being informed about the objectives of the study. Participant recruitment and study outcomes were approved and monitored by the Scientific Review Board of the University of Rome Tor Vergata, Italy. The study was conducted in accordance with the tenets of the Helsinki Declaration of 1964 for biomedical research involving human study participants as amended in 2008.

Data were extracted according to the following inclusion criteria: study participants who received industrially manufactured ISZFDPs (NobelProcera; NobelBiocare), either at the implant or the abutment level, with 2 different types of yttria-stabilized tetragonal polycrystal zirconium dioxide, defined by the manufacturer as high-strength monolayer (HS) and high-translucent multilayer (HTML), mean biaxial flexural strength 1402 and 1125 MPa; follow-up of at least 2 years; complete-mouth bleeding index and complete-mouth plaque index ≤25%; stable occlusal relationship. Exclusion criteria were general medical and/or psychiatric conditions preventing surgical treatment; pregnancy or nursing; any interfering medication such as steroid therapy or bisphosphonate therapy; alcohol or drug abuse; heavy smoking (>10 cigarettes/d); radiation therapy to head or neck region within 5 years; untreated periodontitis; acute and chronic infections of the adjacent tissues or natural dentition; severe maxillomandibular skeletal discrepancy; high and moderate parafunctional activity[20]; absence of teeth or denture in the opposing jaw; and cantilever lengths greater than 10 mm. One clinician for each center performed all the surgical and prosthetic procedures, and 3 dental laboratories experienced in CAD-CAM technology designed and manufactured the screw-retained zirconia ceramic implant-supported prostheses.

Clinical and laboratory protocol

Before implant placement, all study participants received a comprehensive examination including a cone beam computed tomography (CBCT) scan. The digital imaging and communication in medicine (DICOM) files had been imported into different versions of the same implant planning software program (NobelGuide, NobelClinician, and DTXStudioImplant; NobelBiocare). A double scan protocol[21] or a digitally integrated workflow[2] was used to accurately plan implant positioning according to a prosthetically driven and soft tissue-driven approach (Figs. 1 and 2). Eleven different implant types (NobelActive, NobelParallel, NobelSpeedyGroovy, NobelSpeedyReplace, NobelReplace CC, NobelReplaceSelect, NobelReplaceTapered, BrånemarkSystemMKIII, BrånemarkSystemMKIIIGroovy, BrånemarkSystemMKIIIShorty, BrånemarkSystemMKIV; NobelBiocare) had been placed by means of laboratory or CAD-CAM–fabricated surgical guides (Fig. 3). The surgical protocol was customized to achieve high implant

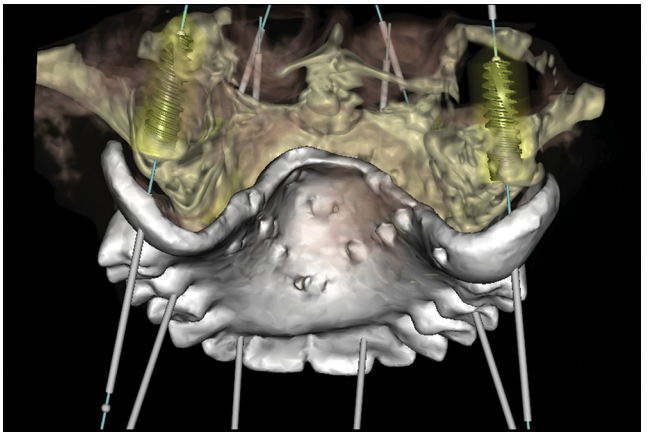

Figure 1. Prosthetically driven implant positioning achieved by means of 3D implant planning software program and double scan protocol. 3D, three dimensional.

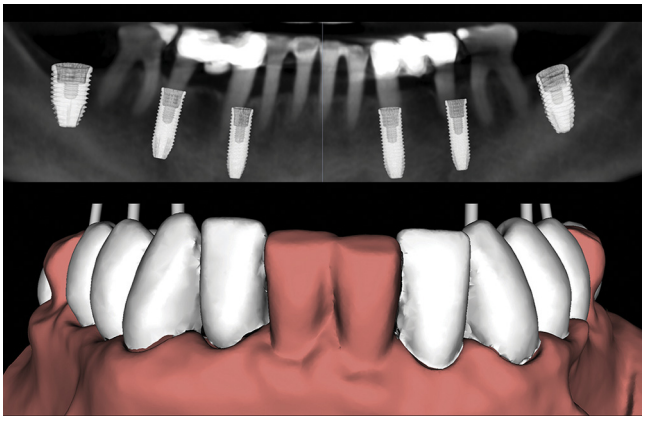

Figure 2. Digitally integrated workflow with virtual waxing to plan implant position according to prosthetically driven and soft tissue-driven approach.

primary stability as previously described,[1] and prefabricated, screw-retained, metal-reinforced, acrylic resin interim restorations were delivered.[1] After an uneventful healing period of 3 and 4 months in the mandible and the maxilla, either definitive impressions were made with a conventional open tray technique according to a previously published protocol[22] or intraoral scans (IOSs) (TRIOS3; 3Shape A/S, or True Definition; 3M). Implant scan bodies (ElosAccurate; ElosDental) were placed for the IOS. The definitive casts were poured in low-expansion Type IV dental stone (FujiRock EP; GC). Three-dimensional (3D) printed casts were designed from the standard tessellation language (STL) file of the IOS scan by using a laboratory software program (DTX Studio Design; Nobel Biocare), a 3D printer (AsigaMax UV; Asiga), and a dedicated resin (DentaMODEL; Asiga). The zirconia design was customized for all the HS-ISZFDPs by a cutback procedure to provide support for the veneering material and minimize biomechanical complications, while the HTML-ISZFDPs were fabricated as either veneered or monolithic (HTML-FC). The minimum connector area of 10 mm^2 recommended by the manufacturer was increased to achieve a mean of 17 ±1.11 mm^2, and the cantilever units were contoured in monolithic zirconia and designed to be 100 μm out of occlusion.

The framework prototype had been scanned with different extraoral scanner (EOS) technologies: tactile (Procera Forte scanner; Nobel Biocare), optical with a conoscopic holographic technique (Nobel Procera 2G; Nobel Biocare), and optical color scanning (Kavo LS3; Kavo). The data obtained were digitized with different laboratory software programs (NobelProcera, NobelDesign, DTXStudioDesign; Nobel Biocare) and subsequently milled at a centralized production facility. The accuracy of all the ISZFDPs was assessed on the definitive casts, as well as intraorally with ×35 magnification

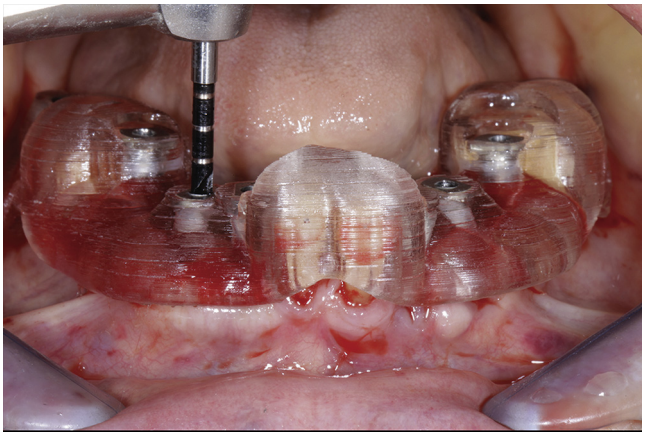

Figure 3. Semiguided tooth-supported computer-aided design and computer-aided manufactured surgical guide in mandible for 2-mm pilot drilling.

and the Sheffield one-screw test.[23,24] The HS-ISZFDPs were designed with a calyx-like shape in cross-section to support the veneering material,[25] and their surfaces were conditioned with aluminum oxide airborne-particle abrasion (50 μm Al_2O_3, <0.2 MPa, 5.0 cm from the framework) and steam cleaned.[18,25]

Four types of porcelain with different coefficients of thermal expansion (CTE) were used for the veneers: NobelRondo zirconia (Nobel Biocare AG); ZI-CT Creation (Willi Geller International); IPS e.max Ceram (Ivoclar Vivadent AG); and CZR (Kuraray Noritake). A ceramic liner (CZR Shade Base Stain; KurarayNoritake) was applied with a maple syrup consistency and a thickness of 0.15 mm. The first firing temperature was set at 1090 °C. An average of 2 subsequent baking procedures (maximum 3) were conducted at 910 °C to complete the veneer. The complete-arch ISZFDPs were manufactured with HS (Figs. 4 and 5), while the partial ones were fabricated with either HS or HTML zirconia (Table 1).

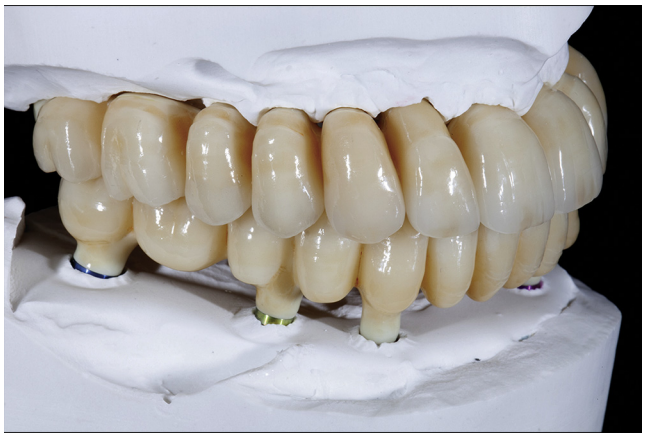

Figure 4. Maxillary and mandibular ISZFDPs anatomically designed to have zirconia surface tightly adhered to scalloped soft tissue architecture. ISZFDPs, implant-supported zirconia fixed dental prostheses.

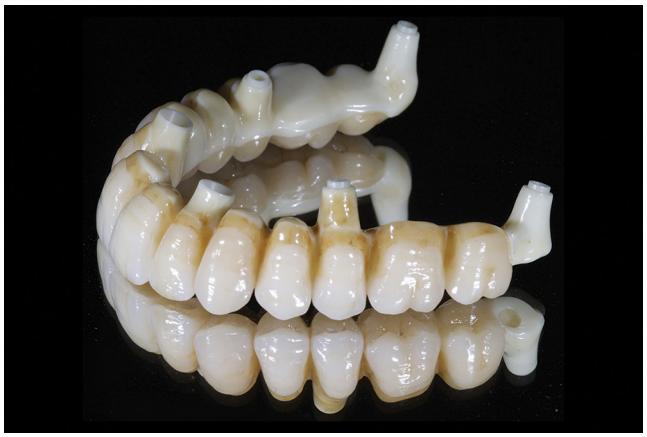

Figure 5. Maxillary ISZFDP delivered at implant and abutment levels with monolithic zirconia at connector and pontic sites. ISZFDP, implant-supported zirconia fixed dental prosthesis.

Table 1. Characteristics of prostheses

Zirconia Type	Fixed Partial Dentures	Dental Units	Number of Implants	Fixed Complete Dentures	Dental Units	Number of Implants
HS-ISZFDP (zirconia connection)	72	3.11 ±1.12 Minimum 2 Maximum 7	2.25 ±0.62 Minimum 2 Maximum 5	24	12.9 ±0.97 Minimum 12 Maximum 14	5.75 ±1.1 Minimum 4 Maximum 8
HTML-FC-ISZFDP (titanium base)	12	3.58 ±0.51 Minimum 3 Maximum 4	2.5 ±0.67 Minimum 2 Maximum 4	–	–	–
HTML-ISZFDP (titanium base)	3	3.66 ±1.53 Minimum 2 Maximum 5	2.33 ±0.58 Minimum 2 Maximum 3	–	–	–

ISZFDPs, implant-supported zirconia fixed dental prostheses.

The occlusion was adjusted, and the screws tightened at 15 Ncm for the abutment-level and 30 Ncm for the implant-level prostheses according to manufacturer instructions. Screw-access holes were acid-etched chairside with 9.8% hydrofluoric acid for 2 minutes, rinsed with water, and cleaned with isopropanol. Then, after having secured the ISZFDP in the mouth, the screw head was isolated with polytetrafluorethylene tape. The zirconia-ceramic surface of the screw-access hole was prepared with 10-methacryloyloxydecyl dihydrogen phosphate containing a bonding and silane coupling agent mixture (Clearfil Ceramic Primer; Kuraray Noritake) and sealed with a dual-polymerizing, radiopaque, 2-component core foundation material supplied in an automix delivery system (Clearfil DC Core Automix; Kuraray Noritake). Fifteen days after prosthesis delivery, the occlusion was adjusted to avoid any contact during eccentric movements and to ensure a mutually protected occlusion with anterior guidance.

Study participants were recalled after 15 days for a further occlusion adjustment and every 4 to 6 months for professional hygiene and occlusion assessment. A rigid, acrylic resin occlusal device, with an occlusal scheme characterized by 1-point occlusal contact per posterior tooth combined with anterior and canine guidance, was delivered to protect the veneering porcelain from any parafunctional habit. The patient was

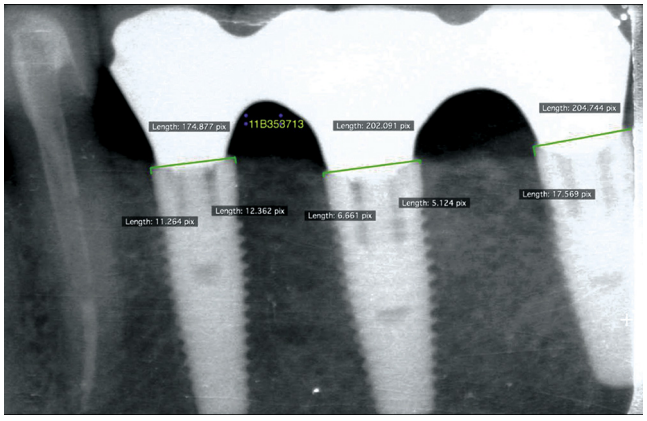

Figure 6. MBL measurement protocol on periapical radiograph made with parallel technique of 3-unit HS-ISZFDP. MBL, marginal bone level. HS-ISZFDP, high-strength monolayer implant-supported zirconia fixed dental prosthesis.

Table 2. Implant and ISZFDP type frequencies per center

Center	Patient, n	Implant, n	ISZFDPs Type Frequencies							
			HS-ISZFDP		HTML-FC-ISZFDP (Titanium Base)		HTML-ISZFDP (Titanium Base)		Total, n ISZFDPs	
AP	48 (49.0%)	141 (41.8%)	35		3		10		48 (43.2%)	
GF	26 (26.5%)	133 (39.5%)	31		-		2		33 (29.7%)	
GS	24 (24.5%)	63 (18.7%)	30		-		-		30 (27.0 %)	
Total	98 (100%)	337 (100%)	96 (86,5%)		3 (2.7%)		12 (10.8%)		111 (100%)	
ISZFDP Level	–	–	91 I-Level	5 A-Level	3 I-Level	0 A-Level	10 I-Level	2 A-Level	104 (93.7%) I-Level	7 (6.3%) A-Level
Cantilever	–	–	12	3	-	-	-	-	13.5% 12 (10.8%) I-Level 3 (2.7%) A-Level	

A-Level, ISZFDP at abutment-level; I-Level, ISZFDP at implant-level; ISZFDPs, implant-supported zirconia fixed dental prostheses.

Table 3. MBL, MBL change, and mean follow-up per implant connection

Implant Connection	Implant Type	Mean Follow-up (y)	MBL* Baseline Minimum - Maximum	MBL* Last Follow-up Minimum - Maximum	MBL* Change Minimum - Maximum
Internal conical	–	**7.2**	-1.29 ±0.92 -4.39 to -0.23	1.38 ±0.95 -5.25 to -0.09	-0.11 ±0.46 -1.25 to 1.63
	43 (12.8%) NobelActive	9.1			
	44 (13.1%) NobelParallel CC	3.8			
	28 (8.3%) NobelReplace CC	8.8			
Internal tri-channel	–	10.5	-1.26 ±0.94 -3.13 to -0.15	-2.03 ±1.86 -5.58 to -0.06	-0.94 ±1.20 2.93 to 0.16
	48 (14.2%) Replace Select Tapered	11.5			
	22 (6.5%) NobelSpeedy Replace	9.2			
	19 (5.6%) NobelReplace Tapered Groovy	10.8			
External hexagon	–	10.6	-1.73 ±1.13 -4.23 to -0.43	-1.75 ±1.35 -4.96 to -0.45	-0.03 ±0.33 -0.73 to 0.48
	70 (20.8%) NobelSpeedy Groovy	10.6			
	63 (18.7%) Brånemark System	11.6			

MBL, marginal bone level. *mm (mean ±standard deviation).

asked to consult the clinic immediately if complications occurred.

Clinical and radiographic outcomes

Primary outcomes were failures of the implants and prostheses biologically (mucositis, peri-implantitis, fistulas, or abscess) or biomechanically (fracture of the implant, prosthetic screw loosening or fracture, porcelain chipping, or zirconia fracture). The implant success and survival criteria used in this study were modifications of criteria suggested by Van-Steenberghe.[26] A failed implant was defined as an implant that had been removed.[26] Prosthetic success was evaluated by using modified criteria suggested by the California Dental Association.[27] A "surviving prosthesis" was a prosthetic reconstruction that was stable and in good function. Secondary outcome measures were MBL changes evaluated on intraoral radiographs made with the parallel technique by means of a custom radiograph holder. Periapical radiographs of ISZFDPs were collected and deidentified by each center and forwarded to 1 independent radiologist who was not informed of the study aims to assess the MBL and MBL change at baseline (on the day of the definitive prosthesis placement) and last follow-up. The periapical radiographs were loaded onto an image diagnosis and analysis software package (Osirix MD 7.5; Pixmeo SARL) on a computer (Mac Pro iOS 10.13.6; Apple Inc), adjusting the density and contrast for optimal visibility of the crestal bone. For measurements, the images were magnified 15 to 20 times, and all distances were measured in pixels. The mesiodistal width of the implant was measured by drawing a reference line from edge to edge along the implant-

Table 4. Life table analysis at prosthesis level

Baseline Prosthesis Delivery	Follow-up Year	n	%
2007	12	13	11.7
2008	11	15	13.5
2009	10	12	10.8
Total prosthesis ≥10y		40	36%
2010	9	8	7.2
2011	8	5	4.5
2012	7	7	6.3
2013	6	6	5.4
2014	5	12	10.8
5≤ Total prosthesis ≤9 y		38	34.2%
2015	4	14	12.6
2016	3	9	8.1
2017	2	10	9.1
2≤ Total prosthesis ≤4 y		33	29.8%
–	Total	111	100%

Table 5. ISZFDPs characteristics per FDP type and level (maxilla)

ISZFDP Type—Level			Maxilla: Definitive Restoration Characteristics per Tooth						
			Third Molar	Second Molar	First Molar	Second Premolar	First Premolar	Canine	Lateral Incisor
HTML-FC	A-level	FDP pontic	-	-	-	-	-	-	1
		Conical connection	-	-	-	-	-	1	-
		External hexagon	-	-	-	-	-	-	-
		Tri-channel connection	-	-	-	-	-	-	-
		All implants	-	-	-	-	-	1	-
		Adjacent tooth	-	-	-	1	1	-	-
	I-level	FDP pontic	-	-	-	3	-	-	-
		Conical connection	-	-	3	-	3	-	1
		External hexagon	-	-	-	-	-	-	-
		Tri-channel Connection	-	-	-	-	-	-	-
		All implants	-	-	3	-	3	-	1
		Adjacent tooth	-	3	-	-	-	4	-
HTML	I-level	FDP pontic	-	-	-	-	-	-	-
		Conical connection	-	1	1	-	-	-	-
		External hexagon	-	-	-	-	-	-	-
		Tri-channel connection	-	-	-	-	-	-	-
		All implants	-	1	1	-	-	-	-
		Adjacent tooth	-	-	-	1	-	-	-
HS	A-Level	FDP pontic	-	-	1	-	2	2	-
		Conical connection	-	-	-	-	-	-	-
		External hexagon	-	-	1	2	-	-	2
		Tri-channel connection	-	-	-	-	-	-	-
		All implants	-	-	1	2	-	-	2
		Adjacent tooth	-	-	-	-	-	-	-
	I-level	FDP pontic	-	5	6	14	5	5	6
		Conical connection	2	2	7	4	7	1	4
		External hexagon	-	2	9	6	1	2	3
		Tri-channel connection	-	4	6	4	9	5	1
		All implants	2	8	22	14	17	8	8
		Adjacent tooth	-	3	-	1	7	11	2
Total			4	29	61	52	55	40	31

A-Level, ISZFDP at abutment-level; FDP, fixed dental prosthesis; I-Level, ISZFDP at implant-level; ISZFDPs, implant-supported zirconia fixed dental prostheses.

abutment junction (IAJ) (Fig. 6). The distance between the outer edge of the implant platform and the first bone-to-implant contact point was measured on both the mesial and distal surfaces of the implant. Positive measurement values were recorded when bone level was coronal to the IAJ reference line, but negative values when apical. Using the correlation between the known (in mm) and measured (in pixels) width of the implant as a calibration reference, all pixel measurements were converted to millimeters. MBL change was subsequently calculated for paired radiographs from baseline (the day of definitive prosthesis delivery) to last follow-up. Bleeding upon probing (BOP) was assessed with a plastic periodontal probe (Plast-o-Probe; Dentsply Sirona) according to the Mombelli Index,[28] and plaque score (PS) and gingival index (GI) were assessed at the abutment-to-restoration complex according to Löe.[29] Patient satisfaction in terms of esthetics, phonetics, masticatory function, and comfort was recorded by means of a questionnaire at the last follow-up.[30]

Statistical analysis

Descriptive data were analyzed by using the mean, standard deviation, and percentage. The data were analyzed on the implant level or prosthesis level depending on the questions. For the bone-level analysis, the significance of the effects of implant type, connection, prosthesis type and level, type of loading, and follow-up visit was tested. A generalized linear effects model (GLEM) with prosthesis and implant type as the subject and prosthesis type as the random effect was used (α=.05). Statistical analysis was performed with a statistical software program (IBM SPSS Statistics, v23.0.0.0; IBM Corp).

RESULTS

The records of 118 study participants fulfilling the inclusion criteria were identified. Twenty study participants (16.9%) were not available for clinical examination for various reasons. Ninety-eight study participants, 59

Table 5. *(Continued)* ISZFDPs characteristics per FDP type and level (maxilla)

Maxilla: Definitive Restoration Characteristics per Tooth									Total	
Central Incisor	Central Incisor	Lateral Incisor	Canine	First Premolar	Second Premolar	First Molar	Second Molar	Third Molar	n	%
-	-	1	-	-	-	-	-	-	2	0.3
1	1	-	1	-	-	-	-	-	4	0.7
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
1	1	-	1	-	-	-	-	-	4	0.7
-	-	-	-	1	1	-	-	-	4	0.7
1	1	-	-	-	-	2	-	-	7	1.2
-	-	1	-	3	3	1	3	-	18	3.1
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	1	-	3	3	1	3	-	18	3.1
-	-	-	3	-	-	-	-	-	10	1.7
-	-	-	-	-	1	1	-	-	2	0.3
-	-	-	-	1	-	-	1	-	4	0.7
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	1	-	-	1	-	4	0.7
-	-	-	1	-	-	-	-	-	2	0.3
2	2	-	2	2	-	1	-	-	14	2.4
-	-	-	-	-	-	-	-	-	-	-
-	-	2	-	-	2	1	-	-	10	1.7
-	-	-	-	-	-	-	-	-	-	-
-	-	2	-	-	2	1	-	-	10	1.7
-	-	-	-	-	-	-	-	-	-	-
9	11	9	6	6	14	7	4	-	107	18.4
-	-	4	1	6	1	6	2	1	48	8.4
2	-	2	2	3	3	8	2	-	45	7.8
3	3	-	4	7	8	5	5	-	64	11.1
5	3	6	7	16	12	19	9	1	157	27.1
-	1	1	11	4	2	-	3	-	46	7.9
24	23	29	39	53	52	53	33	2	580	100

(60.2%) women and 39 (39.8%) men (mean age 60.7 ±11.7 years; median 62 ±1.1; minimum 21, maximum 84) accounting for 337 implants and 111 prostheses were eligible to be included and investigated (Table 2). One hundred ninety-three implants were placed in the maxilla and 144 in the mandible between 2004 and 2017. The implant types were selected according to the practitioner's preference and experience (Table 3). One hundred seventy-six (52.2%) implants were immediately loaded (<48 hours), 161 (47.8%) underwent a delayed loading protocol (>3 months), while early loading (48 hours to 3 months) was not performed.[31] Definitive casts were obtained from a conventional open tray impression technique (85 ISZFDPs; 76.6%) or from an IOS (26 ISZFDPs; 23.4%). The definitive prostheses were delivered between 3 and 6 months (99 ISZFDPs; 89.2%) or between 6 and 12 months (12 ISZFDPs; 10.8%) after implant placement. All the prostheses were delivered between 2006 and 2017, and the last follow-up was between 2016 and 2019 (mean 7.2 ±3.4 years) (Table 4). Tables 5 and 6 show frequencies of pontics, adjacent teeth, and implants by FDP type, level, and total and by location in the maxilla or mandible. Forty-five (45.9%) study participants had been treated for periodontitis. A total of 28 (28.6%) study participants were former smokers, 12 (12.2%) were current smokers, and 58 (59.2%) had never smoked. The opposing dentition was represented by teeth in 69 (62.2%) study participants, implants in 39 (35.1%), and removable dentures in 3 (2.7%). The antagonist material was acrylic resin in 7 (6.3%) prostheses, ceramic in 58 (52.3%), metal in 1 (0.9%), mixed in 10 (9.0%), and natural teeth in 35 (31.5%). At the baseline (prosthesis delivery), the GI was reported as normal gingiva (77.5%), mild inflammation (16.2%), or moderate inflammation (6.3%). At the last follow-up, the GI was reported as normal gingiva (75.7%), mild inflammation (22.5%), or moderate inflammation (1.8%) with a BOP of 11.87% (Figs. 7 and 8). Biologic complications and prosthesis failure characteristics are shown in Table 7. Two implants out of 337 failed: One was removed because of peri-implantitis, and 1 in spite of a minor fracture of the neck portion not

Table 6. ISZFDPs characteristics per FDP type and level (mandible)

Zr-PIB Type and Level			Mandible: Definitive Restoration Characteristics per Tooth						
			Third Molar	Second Molar	First Molar	Second Premolar	First Premolar	Canine	Lateral Incisor
HTML-FC	Abutment	FDP pontic	-	-	-	-	-	-	-
		Conical connection	-	-	-	-	-	-	-
		External hexagon	-	-	-	-	-	-	-
		Tri-channel connection	-	-	-	-	-	-	-
		All implants	-	-	-	-	-	-	-
		Adjacent tooth	-	-	-	-	-	-	-
	Implant	FDP pontic	-	-	1	-	-	-	-
		Conical connection implant	-	1	-	1	1	-	1
		External hexagon	-	-	-	-	-	-	-
		Tri-channel connection	-	-	-	-	-	-	-
		All implants	-	1	-	1	1	-	1
		Adjacent tooth	-	-	-	-	-	2	-
HTML	Implant	FDP pontic	-	-	-	-	-	-	-
		Conical connection	-	-	-	-	-	-	-
		External hexagon	-	-	-	-	-	-	-
		Tri-channel connection	-	-	-	-	-	-	-
		All implants	-	-	-	-	-	-	-
		Adjacent tooth	-	-	-	-	-	-	-
HS	Abutment	FDP pontic	-	-	2	1	3	1	-
		Conical connection	-	-	-	-	-	-	-
		External hexagon	-	-	1	2	-	2	3
		Tri-channel connection	-	-	-	-	-	-	-
		All implants	-	-	1	2	-	2	3
		Adjacent tooth	-	-	-	-	-	-	-
	Implant	FDP pontic	-	2	8	4	9	5	6
		Conical connection	-	4	3	6	-	1	7
		External hexagon	-	3	7	5	4	3	4
		Tri-channel connection	-	1	1	2	1	1	1
		All implants	-	8	11	13	5	5	12
		Adjacent tooth	-	2	-	2	4	12	-
Total			-	22	35	39	28	34	38

A-Level, abutment level; FDP, fixed dental prosthesis; I-Level, implant level; ISZFDPs, implant-supported zirconia fixed dental prostheses.

affecting the integrity of the prosthetic connection remained in function, yielding a cumulative implant survival rate of 99.4%. Two out of 111 ISZFDPs failed, and no fracture of the zirconia framework was experienced, accounting for an overall 98.2% prosthetic survival rate. The 4 different types of veneering porcelains experienced the following chipping rates: ZI-CT Creation Willi Geller (0 out of 6; 0%), CZR (6 out of 77; 7.8%), IPS e.max Ceram (7 out of 26; 26.9%), and NobelRondo (2 out of 2; 100%). The cumulative prosthetic success rate was 91.9% (Fig. 9). One hundred four (93.7%) study participants were satisfied with the outcome of their treatment. None of the ISZFDPs had to be remade because of esthetic reasons over the observation period. Seven study participants (6.3%) were not satisfied with the cantilever and reported food impaction. MBL and MBL change are summarized in Figure 10. At the prosthesis level, the MBL change from baseline to the last follow-up was -0.17 ±0.62 mm (minimum -2.93, maximum 1.63 mm) for implant-level prostheses and -0.20 ±0.43 mm (minimum -1.17, maximum 0.26 mm) for abutment-level prostheses. The effects of implant type, implant connection, FDP type, FDP level, type of loading, and visit on MBL were tested as fixed effects by using GLEM with FDP type and implant type included as random effects. None of these analyses were significant for any of the fixed effects ($P>.05$), implant connection and type, ISZFDP type, type of loading, or visit (baseline or last follow-up) and had no significant effect on bone level, with the exception of implant-level ISZFDPs, which demonstrated less marginal bone loss than abutment-level ISZFDPs ($P=.013$).

DISCUSSION

The null hypothesis that prosthesis type and level, implant type and connection, type of loading, and follow-up would not affect MBL was partially rejected. None of these analyses showed a significant effect of any of the fixed effects ($P<.05$) despite a low significance of implant-

Table 6. *(Continued)* ISZFDPs characteristics per FDP type and level (mandible)

Mandible: Definitive Restoration Characteristics per Tooth									Total	
Central Incisor	Central Incisor	Lateral Incisor	Canine	First Premolar	Second Premolar	First Molar	Second Molar	Third Molar	n	%
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
1	1	-	-	-	1	-	-	-	4	0.9
-	-	1	-	1	-	1	1	-	8	1.7
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	1	-	1	-	1	1	-	8	1.7
-	-	-	2	-	-	-	-	-	4	0.9
-	-	-	-	-	1	1	-	-	2	0.4
-	-	-	-	1	-	-	1	1	3	0.6
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	1	-	-	1	1	3	0.6
-	-	-	1	-	-	-	-	-	1	0.2
3	3	1	1	3	1	2	-	-	21	4.6
-	-	-	-	-	-	-	-	-	-	-
-	-	2	2	-	2	1	-	-	15	3.3
-	-	-	-	-	-	-	-	-	-	-
-	-	2	2	-	2	1	-	-	15	3.3
-	-	-	-	-	-	-	-	-	-	-
15	13	8	4	8	4	6	1	-	93	20.3
1	2	6	1	-	5	6	6	-	48	10.6
1	1	2	4	3	8	7	3	-	55	12
-	1	1	-	1	2	2	1	-	15	3.3
2	4	9	5	4	15	15	10	-	118	25.8
1	-	-	11	6	3	-	3	1	45	9.8
24	25	33	33	29	44	43	28	3	458	100

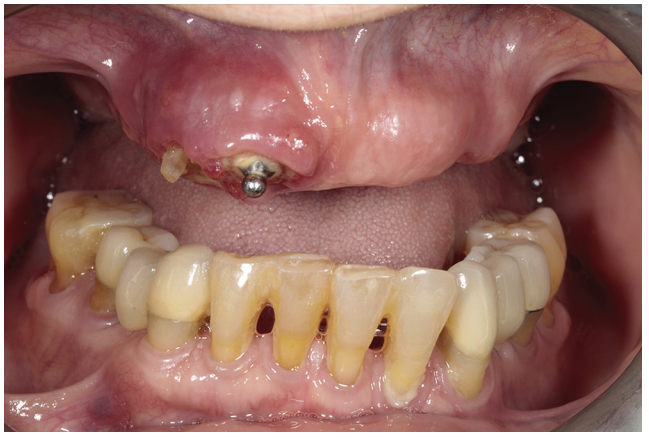

Figure 7. Intraoral preoperative frontal view.

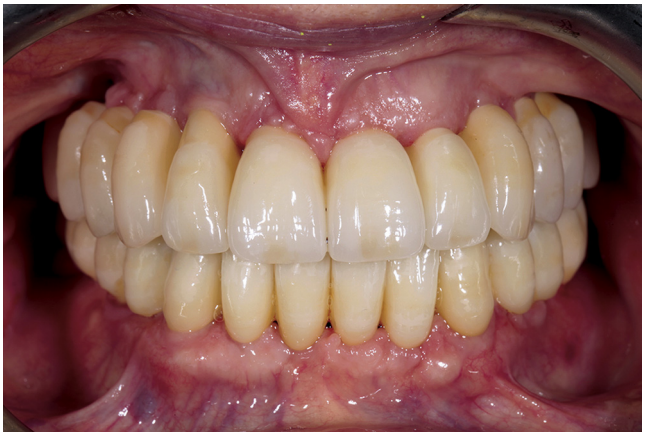

Figure 8. Intraoral frontal view at last visit: 12-year follow-up for maxillary ISZFDP and 6-year follow-up for mandibular ISZFDP. ISZFDP, implant-supported zirconia fixed dental prosthesis.

level ISZFDPs, demonstrating less marginal bone loss than abutment-level ISZFDPs. However, such a positive effect on the bone resorption pattern could not be extrapolated to any concrete conclusions and must be considered with caution because only 14.4% of ISZFDPs were manufactured at the abutment level. Thus, further

Table 7. Complications assessed at FDP and implant levels

	HTML-FC-ISZFDP		HTML-ISZFDP	HS-ISZFDP		Total Complications at FDP Level		Total Complication at Implant-Level	
	Abutment	Implant	Implant	Abutment	Implant				
Complications	**n**	**n**	**N**	**n**	**n**	**n**	**%**	**n**	**%**
Mucositis	-	-	-	3 (4 implants)	3 (5 implants)	5	4.5	3 Brånemark System 2 NobelSpeedy Groovy 2 NobelSpeedy Replace 2 NobelReplace CC	2.7
Peri-implantitis	-	-	-	4 (8 implants)	2 (5 implants)	6	5.4	4 NobelSpeedy Groovy 3 NobelSpeedy Replace 2 Replace Select Tapered 3 NobelReplace CC 1 NobelActive	3.8
Implant removal	-	-	-	-	1	1	0.9	1 NobelSpeedy Groovy	0.3
Implant fracture	-	-	-	-	1 (1 implant)	1	0.9	1 NobelSpeedy Replace	0.3
Prosthesis failed	-	-	-	-	2	2	1.8	–	–
Screw loosening	-	-	-	2	1	3	2.7	–	–
Minor chipping	-	-	-	-	8	8	7.2	–	–
Major chipping	-	-	-	2	5	7	6.3	–	–
Polishing	-	-	-	2	12	14	12.6	–	–
Antagonist wear	-	2	-	-	5	7	6.3	–	–

FDP, fixed dental prosthesis.

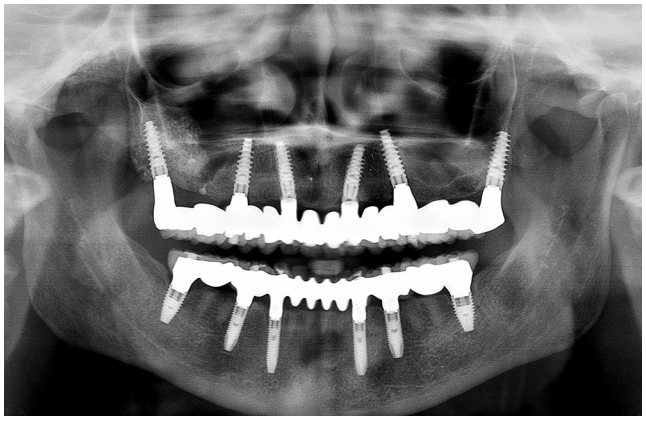

Figure 9. Panoramic radiograph at 12-year follow-up for maxillary prosthesis and 6-year follow-up for mandibular prosthesis.

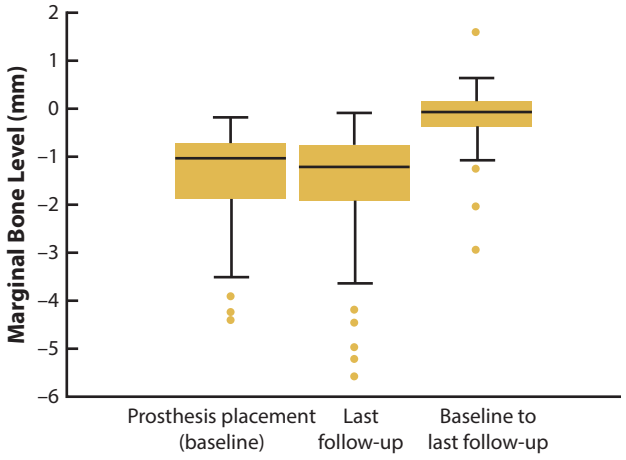

Figure 10. MBL at baseline and last follow-up and MBL change (all implants). MBL, marginal bone level.

RCTs with sample size calculations are needed to draw a conclusion on the potential role of the FDP level on the radiographic outcomes.

Limitations of this study included its retrospective nature and the lack of a control group that may have unidentified some differences. Nevertheless, 98 study participants were treated in accordance with the principles of good clinical practice and documented by strict radiographic measurements. A total of 337 implants and 111 ISZFDPs were eligible to be included and investigated, providing important insights into the clinical reliability of screw-retained zirconia-based FDPs up to 12 years. Although CAD-CAM restorations are showing promising results in the short term, the current scientific evidence is limited because of the restricted quality of the available studies and the paucity of data on long-term clinical outcomes.[32] Recently published systematic reviews with meta-analysis indicated that implant-supported FDPs are a safe and predictable treatment method with high 5-year implant and prosthetic survival rates.[6,7] However, the survival rates of the zirconia ceramics (93%) were significantly lower than those of the metal ceramics FDPs (98.7%), and catastrophic fracture of the ISZFDP framework occurred significantly more often than with metal-ceramic FDPs.[7]

In the present study, only 2 implants and the related prostheses failed, accounting for overall 99.4% and 98.2% implant and prosthetic survival rates, respectively. All the 111 ISZFDPs were structurally intact, and no zirconia framework fractures were experienced. The 6 major chipping fractures determined a cumulative prosthetic success rate of 91.9%, comparing favorably with

previously published studies investigating screw-retained ISZFDPs with a shorter follow-up.[16,33,34] Concerns regarding the risk of fractures of zirconia frameworks or veneering materials still exist, and a passive fit of a screw-retained zirconia-based FDP on osseointegrated implants is difficult to achieve, particularly for complete arches.[35,36] However, industrially manufactured screw-retained complete-arch HS-ISZFDPs fabricated either at implant or abutment level have been reported to achieve consistent accuracy, with a mean vertical microgap of about 15 μm (range 10 to 27 μm).[35,36]

Pozzi et al[15] reported an overall implant and prosthetic survival rate of 100% and prosthetic success of 89% on 26 screw-retained complete-arch ISZFDPs delivered at implant level up to 5 years. The authors concluded that industrially manufactured, complete-arch ISZFDPs were a suitable alternative to conventionally manufactured metal-ceramic FDPs for rehabilitating edentulous patients. Similarly, Worni et al[16] concluded that zirconia-based implant-supported FDPs had exhibited satisfactory treatment outcomes and that screw retention at the implant level was feasible. In the present study, no zirconia framework fractures occurred, and this positive outcome may be because of a meticulous clinical and laboratory workflow for the CAD-CAM restorations. The definitive implant impressions were made with a validated protocol,[22] and the use of the IOS technique was limited to a maximum of 3 implants and 5-unit ISZFDPs[37] to minimize the misfits related to deviations with the IOSs. All the 24 complete-arch ISZFDPs were manufactured as HS-ISZFDP. To minimize the occurrence of biomechanical complications,[38,39] the cross-sectional area of connectors was increased (mean ±standard deviation 17 ±1.11 mm^2), and the cantilever units were in monolithic zirconia and 100 μm out of occlusion, with a maximum mesiodistal length of 10 mm.

The merits of direct screw retention at the implant level without the interposition of an abutment and the interface between implant and prosthetic superstructure are still topics of debate in the dental community. The occurrence of potential biological and biomechanical drawbacks such as unfavorable bone resorption pattern, bacterial and saliva leakage, contamination of the connection, mucositis, peri-implantitis, screw loosening and fracture, fracture of the framework, and chipping of the veneering material have been listed controversial.[16,40-48] However, in the present study, no significant correlations were observed between the bone level (measured at prosthesis and implant level) and the implant type and connection and ISZFDP type characteristics and level. The MBL change (measured at the FDP level) was -0.17 ±0.62 mm for implant-level prostheses (104, 93.7%) and -0.20 ±0.43 mm for the abutment-level prostheses (7, 6.3%), while the MBL change (measured at implant level) was 0.18 ±0.59 mm, indicating stable bone levels with a mean follow-up of 7.2 years for conical connection, 10.5 for tri-channel, and 10.6 for external hexagon implants. The authors assumed that industrial high-quality CAD-CAM–fabricated flat-to-flat interface between the zirconia framework and the implant platform might play a role in these positive outcomes. The chipping fracture of veneering porcelain was the most common complication (13.5%), comparing favorably with previously published results[18,43] and with a recent systematic review and meta-analysis reporting the 11.6% and 50% of extensive ceramic fractures of metal-ceramic and zirconia ISFDPs, respectively.[7]

The positive outcomes of the present study might be related to the use of a 3D implant planning software program that allowed implant positioning according to the definitive prosthetic contour, facilitating prosthesis design and manufacturing. This design process may increase accuracy, precision, and passive fit of screw-retained ISZFDPs. Moreover, the zirconia frameworks were anatomically designed with a calyx-like shape in cross-section, a 120-degree chamfer preparation, and a shoulder width of 1 to 1.2 mm.[15] This ensured a functional porcelain thickness ranging between 1.5 and 2.5 mm to withstand mechanical loading stresses and make the veneering porcelain less prone to failure.[15,49] A dedicated ceramic liner was applied to the zirconia surface to double the bond strength of the veneering porcelain and was fired with a specified protocol in 2 layers at 1090 °C.[50,51] The veneering of the framework was performed with dedicated porcelains closely matching the CTE of the zirconia (25 °C to 500 °C, $10.4\times10^{-6}K^{-1}$) and limited to a mean of 2 firing procedures. In the present study, the prostheses veneered with ZI-CT Creation (Willi Geller International) and the CZR (Kuraray Noritake) experienced the lowest chipping rates.

In agreement with a recently published report on bruxism exerting a higher risk of mechanical complications and prosthesis failures,[39] study participants wore a rigid acrylic resin occlusal device to prevent ceramic fracture. However, heavy and moderate bruxers were not included in the study. A long-term maintenance regimen was useful for evaluating occlusal contacts and to adjust for modified mandibular dynamics after neuromuscular adaptations. No correlations were observed between chipping fractures and different antagonist materials.

The high biocompatibility, low plaque surface adhesion, absence of mucosal discoloration, and esthetic properties of zirconia might have contributed to successful soft tissue integration[52] and patient satisfaction. At the last follow-up visit, the GI was reported as normal gingiva (75.7%), 9 implants experienced mucositis (2.7%), and 13 implants peri-implantitis (3.8%). Such

outcomes can be compared positively with previous studies reporting a 5-year rate of peri-implantitis or soft tissue complications of 3.1% for metal-ceramic implant-supported FDPs and 10.1% for zirconia implant-supported FDPs.[7,34] One hundred four (93.7%) study participants were satisfied with the outcome of their ISZFDP. None of the ISZFDPs had to be remade because of esthetic reasons over the observation period.

CONCLUSIONS

Based on the findings of this clinical study, the following conclusions were drawn:

1. Zirconia-based screw-retained implant-supported prostheses provided a reliable long-term treatment option for partial and complete edentulism with no zirconia fractures experienced.
2. Stable bone levels were reported, regardless of the ISZFDP type and level, implant type and connection, or type of loading.
3. Two implants failed in 2 different study participants accounting for an overall 99.4% implant survival rate. Two prostheses needed to be replaced giving a cumulative prosthetic survival rate of 98.2%. Considering the 6 major chipping fractures, a cumulative prosthetic success rate of 91.9% was reported.
4. Screw retention at the implant level was not detrimental to bone and soft tissue integration.

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