Clinical Performance of Two-Piece Zirconia Dental Implants After 5 and Up to 12 Years

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Purpose: To assess the clinical performance of a two-piece zirconia implant system, with a focus on biologic complications. ***Materials and Methods:*** A total of 39 patients received 91 two-piece zirconia implants. The patients were recruited from two private clinics and were monitored for 5 to 12 years (median: 5.6 years). The primary outcomes were biologic complications, such as peri-implant infections (peri-implant mucositis and peri-implantitis), and the secondary outcome was radiographically evident marginal bone loss (MBL). ***Results:*** Three patients (7.7%) with 9 total implants (9.9%) presented with peri-implant mucositis. MBL that did not exceed the first thread was evident at 32 mesial sites (35%) and 25 distal sites (27.4%). MBL exceeding the first thread but not the third thread was evident at 6 mesial and 5 distal sites (thread pitch: 0.7 mm). Only one peri-implant pocket deepened (4 mm) and showed bleeding; however, the estimated MBL did not exceed 1.65 mm. No peri-implantitis occurred, and no implant was lost. ***Conclusions:*** This prospective study shows high survival rates and a seemingly low prevalence of biologic and prosthetic complications for this two-piece zirconia implant system over an observation period of up to 12 years. *Int J Oral Maxillofac Implants 2023;38:1105–1114. doi: 10.11607/jomi.10284*

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Titanium dental implants are medical devices used widely in contemporary dental practice. Nonetheless, biologic complications such as peri-implant infections can occur with their use.[1] These infections are categorized as *peri-implant mucositis*, a reversible inflammatory reaction in the soft tissues surrounding the implant, and *peri-implantitis*,[2] an irreversible inflammatory reaction associated with peri-implant pocket formation and progressive bone loss.[3] Both infections are prevalent; peri-implant mucositis occurs in approximately 80% of patients and 50% of implants, and approximately 18% to 44% of cases progress toward peri-implantitis within the first 5 years of function.[4]

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Alternative materials such as ceramics were already in use in the 1960s when Sandhaus developed the first ceramic implant, the Crystalline Bone Screw implant, which was made out of aluminum oxide.[5] In the late 1990s to early 2000s, zirconia was used as an implant material. However, failures (eg, frequent implant fractures and lack of osseointegration)[6–8] forced many early zirconia systems to withdraw from the market. The processing and design have advanced greatly since then; modern zirconia implant systems come in varying designs and surface topographic characteristics, have been tested extensively in various preclinical models, and show excellent properties, as demonstrated by Roehling et al.[9] According to their systematic review, zirconia appeared to have comparable interactions with hard and soft tissues except for a slight delay in osseointegration for some systems.

The material properties of titanium differ in some ways from those of zirconia; for example, zirconia has a hardness of 1,600 to 2,000 HV while titanium's hardness is 258 HV, and zirconia has a surface charge of 0 V while titanium's charge is –1.32 V. Thus, zirconia is a galvanically inert, corrosion-free material, whereas titanium is a galvanically active and corrosion-prone material.[10] Zirconia has seemingly less particle release than titanium,[11,12] and titanium has four to five times more thermal conductivity than zirconia.[13] To properly inform patients about potential complications with both materials, clinicians should be aware of the properties of each. The extent to which these fundamental differences in material properties may affect the long-term

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clinical performance of either material remains to be clarified in future randomized clinical investigations.

Two potential advantages of zirconia are the reduced in vitro formation of bacterial biofilm and reduced numbers of inflammatory cells in peri-implant soft tissues around healing caps and abutments.[14–16] Moreover, Roehling et al[17] described a significantly lower incidence of ligature-induced inflammation and bone loss for zirconium dioxide (ZrO_2)–large-grit sandblasted and acid-etched implants compared to sandblasted/acid-etched titanium implants in a canine model.[17] These experimental findings supported the notion that zirconia implants could also present lower rates of biologic complications and peri-implant infection in clinical settings than titanium implants.

The aim of this prospective study was to evaluate the clinical performance of a two-piece, equigingival zirconia implant system (Patent, Zircon Medical Management) in which glass fiber posts are cemented and prepared through a specific process of prosthetic rehabilitation and to assess the prevalence of biologic and prosthetic complications, with a focus on the occurrence of biologic complications during at least 5 years of follow-up after placement.

MATERIALS AND METHODS

Study Design and Participants

Data from a group of patients consecutively treated at two independent clinics in two countries (Austria and Greece) were studied. Both clinicians (S.K. and H.F.) who undertook the treatments became familiar with the implant system as well as the manufacturer's recommendations and guidelines after receiving theoretical and hands-on training offered by the manufacturer. The surgical and prosthetic protocols were followed as instructed in the training.

Patients were excluded from the study if they were younger than 17 years old or had insufficient bone volume (< 8 mm crestal width and < 7 mm height). In both clinics, zirconia implants were used instead of conventional titanium implants upon discussion with the patients and under the condition that the patients met the inclusion criteria (age > 18; single or multiple tooth gaps in the molar, premolar, or anterior areas in the mandible or maxilla; bone quality I to III; sufficient quantity of bone to allow implant placement; and substantially healed extraction sockets). Informed consent was obtained from all patients prior to treatment. The study protocol was registered and approved by the local regulatory body (Athens Dental Association) in one of the two countries (Greece). The protocol approval was valid in the second country (Austria) by extension under the common EU legislation that covers the EU members (protocol no. 889). The study protocol was only a priori registered with the above regulatory body and not in a scientific database. Both the surgical and prosthetic components of the treatment and follow-up sessions were provided in the two clinics and by two clinicians (H.F. and S.K.).

Patients missing one or more teeth were initially treated for caries and periodontal disease when needed, and the placement of one or multiple two-piece zirconia implants was planned.

Initially, 47 patients received this treatment, and a total of 108 implants were placed. Prior to final analysis, 2 patients died (3 implants), 1 patient (1 implant) could not attend follow-up sessions due to health restrictions, 2 patients (3 implants) left the country, and 3 patients (10 implants) could not attend follow-up sessions due to personal restrictions. The final analysis comprised 39 patients (21 women, 18 men) with a total of 91 implants.

All patients were encouraged to participate in two follow-up reviews per year after completing the restorative phase, which included clinical and radiographic examinations. Compliance with follow-ups was irregular. Two time points (eg, the day of implant placement and the last day of follow-up) were chosen to extract data for analysis. Periapical radiographs were taken at implant insertion and at the final examination. The periapical radiographs taken at implant placement were considered the baseline for marginal bone level assessment. These were later compared to the marginal bone levels at the final examination. The difference in marginal bone levels was defined as marginal bone loss (MBL).

The implants were placed between 2009 and 2016, and the last follow-up assessment took place in May 2021, for a median follow-up period of 76 months (Figs 1 and 2). The research protocol was approved before handling and analyzing patient data.

Surgical and Prosthodontic Procedures

The implant design is shown in Fig 3. The design includes a rough endosseous part with threads and a 1-mm rough, nonthreaded part. The transmucosal part has a machined surface. The nonthreaded part was partially or completely inserted in the bone based on patient anatomy, and it could vary between the mesial and distal sides. All implants had a standard design except one, which was customized on the basis of the available host bone volume, milled, and subsequently sintered.

Implants were placed in healed sites or into sockets immediately after tooth extraction, without flap elevation. When a full-thickness flap was raised, it extended 5 mm mesially and distally from the transmucosal part of the implant without vertical incisions. Drills of increasing diameter were used according to the implant manufacturer's guidelines, and the implants were

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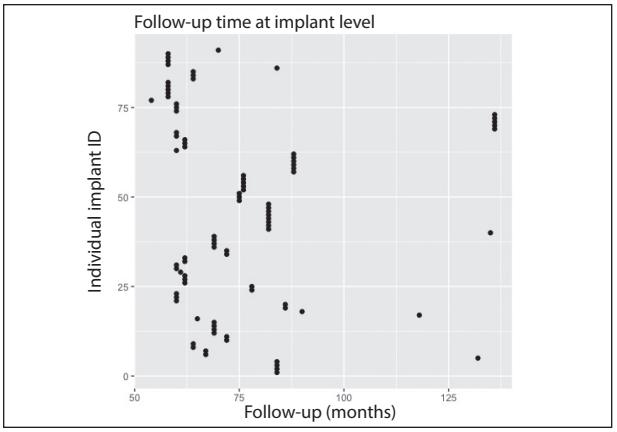

Fig 1 Follow-up time at the implant level.

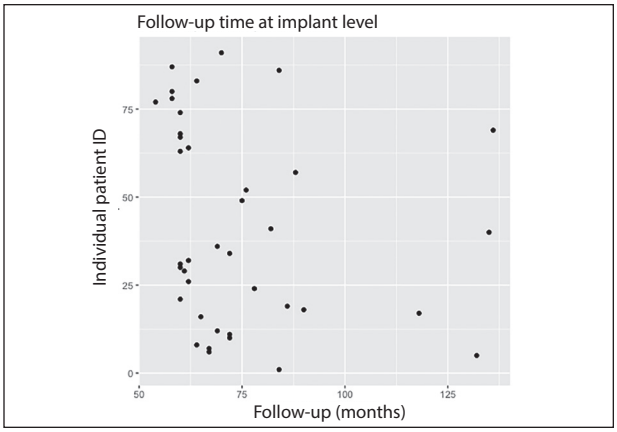

Fig 2 Follow-up time at the patient level. Patient ID corresponds to the patient's lowest implant ID number.

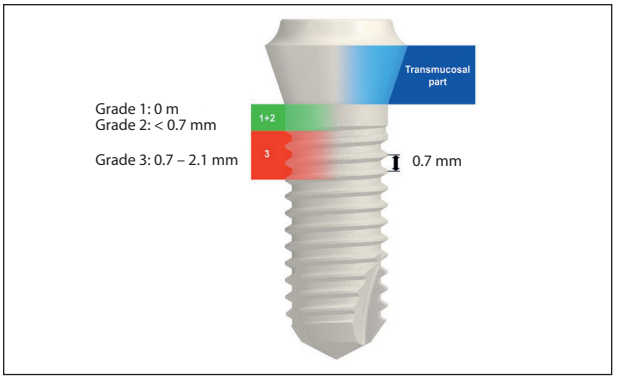

Fig 3 Implant success grades. Grade 1: 0 mm bone loss. Grade 2: up to 0.7 mm of bone loss. Grade 3: Between 0.7 and 2.1 mm of bone loss.

placed with an insertion torque ≤ 35 Ncm. If a higher torque was observed, the implant was removed with the reverse function of the handpiece and a new implant was inserted, achieving the desired torque levels. All threads had to be inserted in the crestal bone. The minimum amount of bone width surrounding the implants was 2 mm. After a transmucosal healing period of 3 months, implants were loaded. Glass fiber posts were provided for every implant, with the glass fibers oriented parallel to the implant long axis. The posts were prepared by the clinician or the laboratory according to prosthetic needs and were fixed with a dual-cure resin cement (RelyX Unicem, 3M ESPE). Due to the implant design and the placement protocol, the prosthetic platform is at the tissue level, and excess cement was visible and easy to remove. The restoration material was mostly zirconia, but in two patients, composite was veneered on a metal frame (a full-arch rehabilitation and a single crown), and one patient received a metal-acrylic bridge. Restorations were cemented with dual-cure resin cement (RelyX Unicem). One patient received an overdenture with PEEK retentive elements on four implants, connected with a zirconia bar.

Radiographic Outcomes: MBL

The implant design (see Fig 3) plans for soft tissue–level placement and includes a threaded rough part (apical), a nonthreaded rough part (middle), and a machined transmucosal part (coronal). The baseline marginal bone level was defined mesially and distally on radiographs at the time of implant placement. Using the implant thread pitch as a reference, MBL was measured under magnification up to the most apical point of peri-implant bone at both interproximal aspects. Initial radiographic measurements were performed on the day of implant insertion until the most recent recall visit (5 to 12 years later). In comparisons of initial and final radiographs, three degrees of MBL were observed: *(1)* no obvious change in marginal bone level; *(2)* remodeling, in which bone loss was observed but did not exceed the first thread (< 0.7 mm) of the implant body; and *(3)* bone loss that exceeded the first but not third thread of the implant body (> 0.7 mm and < 2.1 mm). To scale the radiographic measurements, estimations of radiographic bone loss followed the following formula:

$$\text{MBL} = \frac{0.7*D}{d}\ \text{mm}$$

The thread pitch is 0.7 mm; *D* refers to the bone loss (height) on the radiograph; and *d* refers to the height of thread pitch radiographically. Bone loss was determined only when signs of resorption were observed around the threaded part of the implant.

Clinical Outcomes

Probing was performed in the whole dentition only for the purpose of diagnosing and monitoring periodontitis. Implants were examined at four sites (mesial, distal, buccal, and lingual) with a 15 UNC metallic probe (Hu-Friedy) under light pressure. All pockets > 3 mm were recorded.

Peri-implant mucositis was diagnosed either when bleeding on probing (BOP) occurred or suppuration

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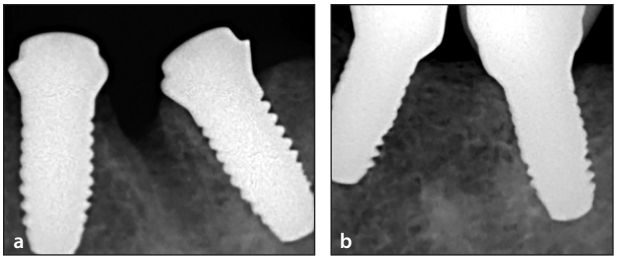

Fig 4 *(a and b)* Radiographic MBL grade I: no bone loss and no clinical disease observed.

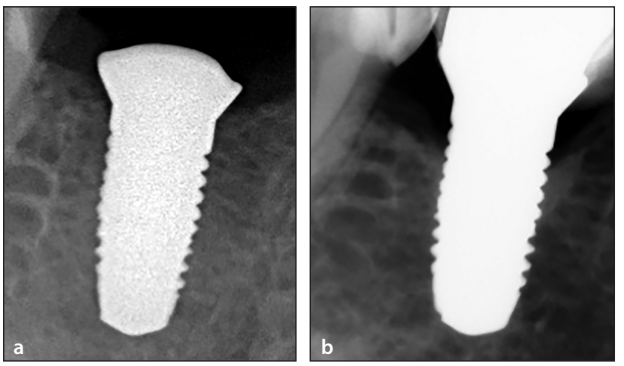

Fig 6 *(a and b)* Radiographic MBL grade III (bone loss): no clinical disease observed, with MBL > 0.7 mm and < 2.1 mm (between the first and third implant threads).

was observed, regardless of whether the probing depth increased. When either finding was combined with a probing depth > 6 mm and > 3 mm of MBL around the rough surface of the implant, peri-implantitis was diagnosed.[18]

Additional Clinical Variables

Oral Hygiene

Oral hygiene was assessed in each patient according to the Simplified Oral Hygiene Index (OHI-S) by Greene and Vermillion[19] and was rated as good (0 or 1), fair (2), or poor (3).

Systemic Diseases and Medication

Various systemic diseases and conditions were recorded, along with the relevant medications. Three patients had hypertension and took appropriate drugs; one patient had a diagnosis of depression and was taking antidepressants; one patient had Down syndrome and was taking antidepressants; one patient had multiple sclerosis and was taking a pyrimidine synthesis inhibitor; and two patients developed cancer during the follow-up period and took immunosuppressants and immune-modifying drugs, including intravenous bisphosphonates for one of them. One patient underwent a heart transplant during the follow-up period and took immunosuppressants and immune-modifying and hypertension drugs.

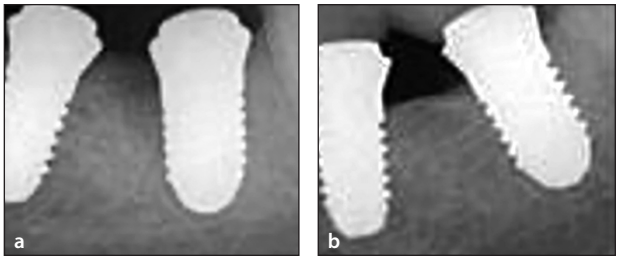

Fig 5 *(a and b)* Radiographic MBL grade II (bone remodeling): no clinical disease observed, with MBL < 0.7 mm (up to the first implant thread).

Smoking Habit

Patients with a smoking habit of up to 30 cigarettes per day were included in the study.

Periodontal Condition and Peri-implant Biotype

Periodontitis was classified according to the Armitage classification[20] and was defined as unstable when bleeding pocket sites > 4 mm were observed. To examine the periodontal biotype, the translucency of the periodontal probe through the gingival margin was observed, and the biotype at each implant site was classified as thick (no probe visible through the gingiva) or thin (probe visible).[21] BOP was recorded at four sites around each implant and was considered present if bleeding occurred within 15 seconds after probing under light pressure.[22]

Grafting Procedures

Various grafting materials were used, as indicated by the clinical parameters and according to patient preference: Algipore (80% tricalcium phosphate, 20% hydroxyapatite; Frios Algipore, Dentsply Sirona), Algoss (50% tricalcium phosphate, 50% hydroxyapatite; AlgOss, MyPlant Dental) and mp3 (corticocancellous bone mixed with 10% collagen gel, porcine allograft; OsteoBiol). No membranes or retentive tacks were used. Plasma rich in growth factors were used in some cases.

Implant Survival and Success and Prosthodontic Complications

To assess implant survival, the preservation of the implant in the cavity was confirmed at the final follow-up examination, and implant success was assessed according to complete fulfillment of two sets of criteria, including those of Buser et al[23]: *(1)* absence of persistent subjective complaints, such as pain, foreign body sensation, or dysesthesia; *(2)* absence of a peri-implant infection with suppuration; *(3)* absence of mobility; *(4)* absence of a continuous radiolucency around the implant; and *(5)* possibility for restoration.

The second set of criteria used is a modification of those by Kohal et al.[24] Success was categorized as grade I (no bone loss) when neither clinical disease nor

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Table 1 Patient Demographics

Characteristic	n (%)*
Total	39 (100%)
Age, y	
Mean (SD)	58.5 (12.7)
Median (Min, Max)	59.0 (29.0, 81.0)
Gender	
Female	22 (56.4%)
Male	17 (43.6%)
Smoking habit	
No	33 (84.6%)
Yes	6 (15.4%)
Length of observation, mo	
Mean (SD)	74.6 (21.4)
Median (Min, Max)	67.0 (54.0, 136.0)
Total implants per patient, n	
Mean (SD)	2.36 (1.2)
Median (Min, Max)	3.00 (1.0, 6.0)
Systemic disease	
No	30 (76.9%)
Yes	9 (23.1%)
Systemic medication	
No	29 (74.4%)
Yes	10 (25.6%)
Thin biotype	
No	24 (61.5%)
Yes	15 (38.5%)
Hygiene level	
Poor	8 (20.5%)
Good	16 (41.0%)
Fair	15 (38.5%)
Presence of periodontitis	
No	32 (82.1%)
Yes	7 (17.9%)
Presence of peri-implant mucositis	
No	36 (92.3%)
Yes	3 (7.7%)

*Data presented as n (%) unless otherwise specified.

obvious MBL was observed; grade II (bone remodeling) when no clinical disease was observed and MBL was < 0.7 mm (reaching but not exceeding the upper part of the first implant thread); and grade III (bone loss) when no clinical disease was observed and MBL was > 0.7 mm and < 2.1 mm (between one and three threads). Figures 4 to 6 show examples of each grade. Potential prosthodontic complications to be recorded included chipping of veneering material, crown loosening or decementation, and crown and bridge fractures.

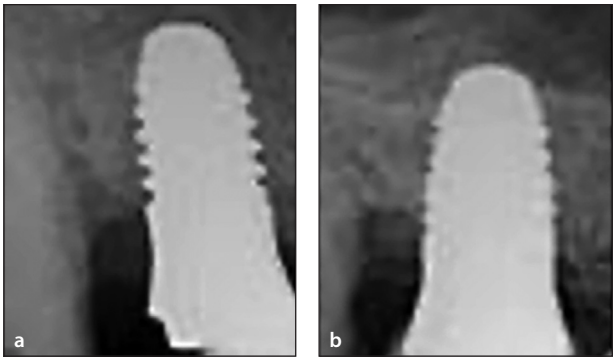

Fig 7 *(a and b)* One patient showed peri-implant bone loss adjacent to a relapsing periodontal lesion at the 60-month follow-up.

Statistical Methods

The mean values for patient demographics, patient characteristics, and implant characteristics were calculated. In addition, the mean observation period, extent of edentulism, total number of implants per patient, and other variables were measured. Implant success and survival rates were calculated using the percentage of implants that met the corresponding criteria at the final clinical examination. The numbers of sites where radiographic images indicated remodeling, MBL, bone stability, and bone gain were calculated according to the presence of adjacent teeth and the degree of implant submergence.

To explore the potential association between radiographically evident MBL and risk factors, multinomial regression models were constructed. Smoking, oral hygiene level, BOP, follow-up period, frequency/count of recall visits per patient, degree of implant submergence, and gingival biotype were examined as explanatory factors for MBL on mesial and distal aspects separately.

RESULTS

In all, 39 received a total of 91 implants and were monitored for up to 12 years. For various reasons, the frequency of review assessments varied from twice per year to twice in a total of 7 years. In 36 patients (82 implants), peri-implant tissues appeared healthy during the follow-up period of 5 to 12 years. Of these, 15 patients (38.5%) with a total of 34 implants (37.4%) exhibited thin biotypes (Tables 1 and 2). Three patients (9 implants) had peri-implant mucositis, of whom 2 had poor oral hygiene (OHI-S scores of 3), and 2 of these patients (8 implants) showed no bone loss. One of the implants in a patient with peri-implant mucositis was next to a tooth that

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Table 2 Implant Characteristics, Surgical Approach, and Biologic Outcomes

Characteristic	n (%)
Total	91 (100%)
Implant diameter	
4.1 mm	5 (5.5%)
4.5 mm	43 (47.3%)
4.7 mm	3 (3.3%)
5 mm	35 (38.5%)
5.3 mm	5 (5.5%)
Implant length	
9 mm	15 (16.5%)
10 mm	2 (2.2%)
11 mm	68 (74.7%)
13 mm	6 (6.6%)
Bone grafting before/during implant placement	
No	78 (85.7%)
Yes	13 (14.3%)
Bone grafting materials used	
Fluorohydroxyapatite (Frios Algipore)	3 (3.3%)
Hydroxyapatite (Algioss)	2 (2.2%)
Allograft mixed with collagen gel (mp3)	3 (3.3%)
PRGF	2 (2.2%)
PRGF w/ allograft	3 (3.3%)
No grafting	78 (85.7%)
Immediate placement	
No	77 (84.6%)
Yes	14 (15.4%)
Immediate loading	
No	88 (96.7%)
Yes	3 (3.3%)
Sinus elevation	
I (transcrestal)	
No	89 (97.8%)
Yes	2 (2.2%)
II (lateral window)	
No	85 (93.4%)
Yes	6 (6.6%)
Peri-implant mucositis	
No	82 (90.1%)
Yes	9 (9.9%)
Thin biotype	
No	57 (62.6%)
Yes	34 (37.4%)

PRGF = plasma rich in growth factors.

Fig 8 Gingival tissue adaptation from *(a and b)* baseline to *(c and d)* the 84-month follow-up.

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Table 3 Incidence of Mesial MBL According to Local Clinical Conditions

	Mesial position of the top of the rough, nonthreaded part				
	No adjacent tooth		Adjacent tooth		
	Implant at crest level	Deep placement	Implant at crest level	Deep placement	Total
Bone loss cases	1 (16.7%)	0 (0%)	5 (83.3%)	0 (0%)	6 (100%)
No bone loss cases	22 (44%)	2 (4%)	23 (46%)	3 (6%)	50 (100%)
Bone remodeling cases	7 (20%)	8 (22.9%)	4 (11.4%)	16 (45.7%)	35 (100%)
Total	30 (33%)	10 (11%)	32 (35.2%)	19 (20.9%)	91 (100%)

$\chi^2 = 39.612$; df = 6; Cramér's V = 0.467; $P = .000$[a]
Data are presented as n (%). Cramér's V interpretation shows a strong association between the variables.
[a]Fisher exact test.

Table 4 Incidence of Distal MBL According to Local Clinical Conditions

	Distal position of the top of the rough, nonthreaded part				
	No adjacent tooth		Adjacent tooth		
	Implant at crest level	Deep placement	Implant at crest level	Deep placement	Total
Bone gain cases	0 (0%)	0 (0%)	1 (100%)	0 (0%)	1 (100%)
Bone loss cases	2 (40.0%)	1 (20.0%)	2 (40.0%)	0 (0%)	5 (100%)
No bone loss cases	46 (76.7%)	0 (0%)	13 (21.7%)	1 (1.7%)	60 (100%)
Bone remodeling cases	5 (20.8%)	11 (37.5%)	4 (8.3%)	5 (33.3%)	25 (100%)
Total	53 (58.2%)	12 (11%)	20 (19.8%)	6 (11%)	91 (100%)

$\chi^2 = 54.158$; df = 9; Cramér's V = 0.445; $P = .000$[a]
Data are presented as n (%). Cramér's V interpretation shows a strong association between the variables.
[a]Fisher exact test.

Table 5 Profile of the 6 Patients Presenting with Advanced MBL Around Implants

Patient no.	Systemic disease	Stable periodontitis and other oral pathology	MBL	Mucositis	Follow-up
1	Multiple sclerosis	History of periodontitis	Mesial: 0.7 mm Distal: 1.29 mm	No	11 y
2	Depression	History of periodontitis	Mesial: 0.7 mm Distal: 1.65 mm	No	6.5 y
3	Cancer (bisphosphonates)	History of periodontitis	Mesial: 0.84 mm Distal: 0.7 mm	No	9.8 y
4	None identified	Developed a periodontal pocket > 6 mm on adjacent tooth	Mesial: 1.4 mm Distal: 0 mm	Yes	5 y
5	None identified	None identified	Mesial: 1.24 mm Distal: 0.93 mm	No	5 y
6	None identified	Caries and abscess on adjacent tooth	Mesial: 0.84 mm Distal: 1.12 mm	No	5 y

showed relapsing periodontal disease. This was the only implant with BOP and a 4-mm pocket next to the tooth (Fig 7). No deepened pockets were found at the other examination points for this implant nor at any of the other implants. However, some soft tissue creeping was observed (Fig 8).

In terms of radiographic bone loss, 85 of the 91 implants showed no MBL or only slight remodeling that did not exceed the upper part of the first implant thread (< 0.7 mm; success grades I and II). Tables 3 and 4 show MBL according to the level of implant insertion at mesial and distal sites.

Six implants showed bone loss farther than the upper part of the first implant thread (> 0.7 mm; success grade III); the maximum bone loss extended up to 1.67 mm and not beyond the third thread (2.1 mm). With this

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moderate MBL, all implants remained clinically successful (no BOP or pocket depth > 4 mm). Implants with MBL grade III are described in Table 5.

For 32 implants, the mesial aspects of the rough endosseous portion was at the crestal level and was adjacent to teeth. For 30 implants, the mesial aspects were at the crestal level and were not adjacent to teeth. For 29 implants, the mesial aspects were placed deep, and only 19 were adjacent to teeth. MBL was observed in only 6 mesial sites, of which 5 were next to a tooth and none had deep placement. Bone remodeling was more prevalent near implants whose mesial sites were adjacent to teeth and for which a submerged insertion was deemed appropriate (16 [45.7%] of the 35 sites with remodeling).

For 71 implants, the distal sites of the rough endosseous part were at the crestal level. For 20 implants, the distal sites had deep placement. In all, 63 distal sites were not adjacent to teeth (Table 4). One distal site seemed to exhibit slight bone gain, and 5 exhibited bone loss. Of these 5 distal sites with bone loss, 2 were next to teeth and 3 were adjacent to an edentulous area; 1 was placed deep. Bone remodeling was found in a total of 25 sites and was more prevalent with deep placement but comparable for sites adjacent or not adjacent to teeth.

All 91 implants survived, and none were removed during the follow-up period. The rate of success was 100% according to Buser et al's[23] criteria, and success was also 100% according to the adjusted Kohal et al[24] criteria, presenting mainly with implant success grades I and II.

Using multinomial regression models with one dependent variable and one independent variable for each, various factors were assessed for associations. Implant position in the oral cavity, smoking habit, oral hygiene, and follow-up period did not seem to affect the development of MBL at mesial or distal sites. Thin biotype only showed a statistically insignificant trend with bone loss on both mesial and distal aspects.

DISCUSSION

Zirconia implants have been evaluated in in vitro, preclinical, and clinical studies.[25–28] However, clinical evidence on the long-term biologic, biomechanical, and prosthodontic performance of zirconia implants is insufficient.[29,30]

In this study, the data on biologic and prosthetic complications were collected over 5 to 12 years. Three patients with a total of 9 implants did not attend scheduled recalls, comply with maintenance therapy, or practice adequate hygiene, and they showed signs of peri-implant mucositis. One of these implants was located next to a tooth with relapsing periodontitis.

MBL (up to the third thread; < 2.1 mm) tended to occur at mesial sites adjacent to teeth when the implant had a deep placement (Table 3), whereas this was not clearly seen at distal sites (Table 4). Bone remodeling was more prevalent in implants with deep placement, regardless of the presence of adjacent teeth (Tables 3 and 4), which corresponded to the biologic width around implants.[31] Further, implant position in the oral cavity, smoking habit, oral hygiene, follow-up period, and frequency/count of recall visits per patient seemed to have no substantial effect on bone remodeling (MBL up the first implant thread) or the development of further bone loss (up to the third thread). The small sample size and consequently low number of observations per group, vertical placement, and presence of adjacent teeth may explain the insignificant trends that were observed.

Peri-implant mucositis and peri-implantitis around titanium implants are common. The prevalence of peri-implant mucositis is 43% to 47% at the patient level and 29% at the implant level, whereas the prevalence of peri-implantitis is approximately 20% to 22% at the implant level and 9% at the patient level.[4,32] These numbers are substantially increased, along with peri-implant infection severity, with full-arch restorations.[33] In the present study, the prevalence of peri-implant mucositis was relatively lower at both the patient level (7.7%) and the implant level (10.0%). Derks et al[34] reported an odds ratio of 15 for peri-implantitis in patients with four or more implants. However, in the present study, the number of implants per patient did not affect the findings. No peri-implantitis was recorded. These findings are in line with previous clinical studies on one-piece zirconia implants.[35]

The survival rate of the implant system used herein (100%) is comparable with that of titanium implants. In a recent systematic review of eight clinical studies on survival and complications as secondary outcome measures for zirconia implants, Spitznagel et al[36] showed survival rates of 94% to 100% for the first year, 94% to 100% for the first 5 years, and 88% to 00% for the first 10 years. These findings were consistent with those of other systematic reviews: The rate of survival after 1 year varied between 92% and 98.3%[8,15,27,37]; after 2 years, it was 97.2%[8]; and after 1 to 7 years, it was 95%.[37] A cohort clinical study with a 9-year follow-up of the implant system used herein reported results that are similar to the present findings.[38]

For commercially available zirconia implants (follow-up of 12 to 61.20 months), technical complications (1.6%), implant fractures (0.2%), and biologic complications (4.2%) have been reported.[8] According to meta-analyses, the 1- and 2-year survival rates were 98.3%

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(95% CI: 97.0% to 99.6%) and 97.2% (95% CI: 94.7% to 99.7%), respectively, and the mean 1-year MBL was 0.7 mm (95% CI: 0.4 to 1.0 mm).[8]

Initial drawbacks to osseointegration with zirconia implants could be solved with various surface modifications, such as roughening, surface activation, and coating.[39] In a study of miniature pigs, among the techniques aiming to increase hydrophilicity, acid-etching (but not alkaline-etching) of sandblasted zirconia implants caused more bone-to-implant contact than sandblasting alone. A miniature pig study on the implant system used by Glauser and Schupbach[40] reported > 70% bone-to-implant contact after 4 weeks of healing following immediate postextraction placement. Contact osteogenesis was observed along the implant surface.The high levels of survival and success with current commercially available systems may suggest that poor osseointegration may no longer be a drawback to the implant material.

Nonetheless, factors that may increase the risk of fractures (such as implant design, surface treatment, implant diameter, and distribution of occlusal loads) do exist and need to be carefully and separately assessed with each system before clinical use.[41] The interpretation of the current literature on zirconia implant systems with different designs and physical properties and commercial availability seems to be inconclusive.[8,27,37]

The mechanical properties of the present implant system are as follows: *(1)* four-point bending strength of 1,200 MPa; *(2)* Young modulus of 205 GPa; *(3)* hardness of 13 GPa; and *(4)* a chemical composition (mass percentage) that is ≥ 99% $ZrO_2 + HfO_2 + Y_2O_3$, ≤ 0.5% Al_2O_3, and ≤ 0.5% other oxides. With these properties, a rather pure yttria-stabilized, non-hipped zirconia implant is produced, and comparison of this system with other aluminum-reinforced and hipped implants, with an aluminum percentage up to 25% of the mass, may not yield accurate results. In fact, the manufacturing process of zirconia implants varies considerably and affects the physical properties of different systems. With the system that was used in the present study, all manufacturing steps were completed before sintering, and the implants were milled from a presintered blank. Consequently, the surface created on the transmucosal part is machined and smooth (roughness average: 1.2 µm), the surface on the endosseous part of the implant is rough (roughness average: 5.7 µm), and microcracks or flaws are sealed in the shrinking process during sintering.

Other studies[40,42–44] have shown that the smooth transmucosal part favors soft tissue adaptation, and this can also be seen in the present study (Fig 8). Herein, results were stable over an observation period of up to 12 years. However, there were various limitations; first and foremost are the lack of protocol registration with a scientific database, the large variability of the treated areas by including different sites in the dentition, the variability associated with different bone deficiencies (severity/morphology), and the variability in the type of implant-supported restorations. Nonetheless, prospective clinical studies like the present one can provide valuable data, inform clinical practice, and influence the design of future studies.[45]

Strengths of the present study include the prospective design, data collection from two independent private clinics, inclusion of patients with different medical profiles (which could increase generalizability), and the long-term follow-up (5 to 12 years). This study is among the few longitudinal clinical studies on two-piece zirconia implants whose findings must be confirmed in prospective controlled trials.

CONCLUSIONS

The results of this prospective study document high survival rates and a seemingly low prevalence of biologic and prosthetic complications for this two-piece zirconia implant system over an observation period of up to 12 years. Further prospective clinical trials, ideally with a randomized design, are warranted to confirm these findings.

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Author contributions were as follows: S.K.: study conception, data collection, manuscript drafting; D.V.: data interpretation, manuscript drafting; M.P.: data interpretation, manuscript drafting; H.F.: study conception, data collection; G.A.: data analyses, data interpretation, manuscript drafting.

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