15-Year Post-Market Clinical Follow-up Study of 1,828 Ceramic (Zirconia) Implants in Humans

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Purpose: To evaluate the 15-year survival rate of zirconia (Y-TZP) implants with a roughened acid-etched surface in a retrospective post-market clinical follow-up (PMCF) study. ***Materials and Methods:*** One-piece ceramic implants (CeraRoot) with a roughened acid-etched surface (ICE) were used. Six different implant shapes/sizes were used in this study. Either a standard or flapless surgical approach was used for implant placement. Simultaneous bone augmentation or sinus elevation was performed when bone height or width was deficient. Definitive zirconia restorations were placed after 2 months or later if the Periotest value was > –3. The implants were followed up for up to 15 years. ***Results:*** A total of 1,828 implants were placed in 771 patients with a mean age of 51.18 years. The overall implant survival rate after 15 years of follow-up was 98.69%. ***Conclusion:*** From this long-term investigation, it can be concluded that CeraRoot ceramic implants showed a 15-year long-term clinical performance with a survival rate of 98.69% under the described protocol, without significant differences between the six implant shapes/sizes. *Int J Oral Maxillofac Implants 2023;38:357–366. doi: 10.11607/jomi.10000*

Keywords: ceramic implant, one-piece, PMCF, zirconia implant, Y-TZP

Ceramic dental implants made out of zirconia are a viable alternative for tooth replacement, though titanium dental implants have been the gold standard since the 1970s. Ceramic implants started to be used in the early 2000s in patients, and since then, the use of this metal-free solution has been growing and becoming more popular. Moreover, the future market trends[1] suggest that the use of ceramic implants is expected to keep growing in the near future.

One of the main advantages of ceramic implants is that they are metal-free. Patients are becoming more concerned about the placement of metals into the body due to potentially harmful long-term effects of the oxidative metal particles accumulating in the surrounding tissues and other parts of the body.[2,3] The more natural look of ceramic implants also offers a potential esthetic advantage.[4] A further argument is that for one-piece ceramic dental implants, the number of additional prosthetic components needed to restore a case can be reduced to zero. In contrast, multiple components and accessories are required to restore a two-piece titanium dental implant; thus, there is a significant reduction of the treatment cost. Finally, the mechanical properties of one-piece ceramic dental implants are comparable to titanium implants and are reported to be safe for everyday use in patients for tooth replacement treatments.[5]

Recent mid-term clinical trials with one-piece ceramic implants from different manufacturers have reported survival rates similar to titanium implants. Bormann et al[6] reported a survival rate of 97.5% after 3 years, and Bethke et al[5] reported a survival rate of 94.3% after 5 years.

The aim of this post-market clinical follow-up (PMCF) study was to provide long-term clinical data for the CeraRoot ceramic dental implant system.

MATERIALS AND METHODS

Patients

This retrospective study included patients aged between 19 and 90 years (mean: 51.18 ± 8.50 years) who were in need of tooth replacement. Patients who smoked more than 10 cigarettes per day, as well as patients with a health condition or disease that might contraindicate oral surgery, including pregnancy and breastfeeding, were excluded from the study. The study was conducted according to the ethical principles for medical research outlined in the 1964 Declaration of Helsinki.

Implants

One-piece ceramic dental implants (CeraRoot) made out of zirconia with an acid-etched roughened surface (ICE) were used in this study.

Six different implant shapes/sizes (Fig 1) were used for different indications. Each type of implant was

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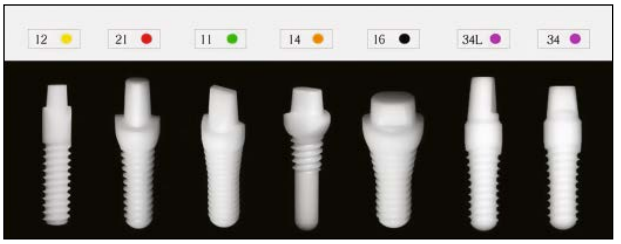

Fig 1 Six CeraRoot implant models for different indications.

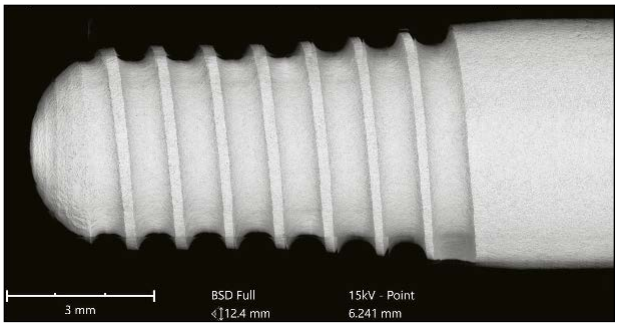

Fig 2 SEM image of CeraRoot 34 implant (intrabony and transmucosal part).

anatomically designed to simulate the emergence profile of the natural dentition to improve the prosthetic restoration. These one-piece implants had three distinct parts: *(1)* the endosseous part, with threads; *(2)* the transmucosal part; and *(3)* the abutment part, for the seating and cementation of the prosthetic restoration.

Figure 2 shows the scanning electron microscopy (SEM) images of the CeraRoot 34 implant model at the transmucosal (nonthreaded) and the intrabony (threaded) parts. Much higher magnifications reveal the roughness derived by the acid-etching process at the transmucosal region (Fig 3a: ×500; Fig 3b: ×2,500) and the threaded region (Figure 4a: ×500; Fig 4b: ×2,500)

Treatment

All patients received relevant information about zirconia implants and the possible alternatives, and written informed consent was obtained.

Radiographic 2D and 3D images were obtained preoperatively, as well as intraoral scans (CEREC IOS) that were used to virtually design surgical guides to help determine the best implant type and 3D position for each situation using Planmeca Romexis software. The guides were either 3D printed (Formlabs 2) or CAD/CAM milled (Zirkonzahn M2) for cases done before 2015.

In most cases, the implants were placed immediately after tooth extraction (1,166 implants, 63.79%) or transmucosally using a flapless technique. When the soft tissue and bone conditions were not favorable, then standard procedures for implant placement were used. If the implants were placed immediately after tooth extraction, no incisions, flaps, or sutures were necessary. The implant sites were examined for bone fenestrations or dehiscences after site preparation. When small fenestrations were detected, bone graft was placed through the osteotomy to fill the fenestration; however, in cases where large fenestrations or dehiscences were observed, a flap was raised, and a bone regenerative procedure was performed in the same intervention just before implant placement. Regenerative procedures were carried out simultaneously with implant placement in all sites with insufficient horizontal or vertical crestal bone (874 implants, 47.81%) with either autogenous, demineralized freeze-dried bovine bone, platelet-rich plasma (PRP) , or a combination of materials. However, large defects were augmented before implant placement, and implants were thus also placed in a two-stage approach (662 implants, 36.21%).

The standard drill sequence was: first, initial bur; second, twist drills; and finally, a countersink. Radiographs (2D or 3D) were obtained immediately after surgery to verify implant positions. Periotest[6] values were recorded on the day of surgery and every month for at least 2 months and until the readings were ≤ –3 , after which the implant was restored. The first choice for immediate provisional restorations was always a vacuum-formed stent with composite veneer inside the missing tooth because it served as both a provisional restoration and as a protective stent to avoid mastication forces on the implant that could induce micromobility and further implant loss. Moreover, the simplicity of it and the fact that the implant was easily visible and accessible for clinical inspection during the healing period were also of major importance. However, when the implants were placed in full-arch rehabilitations, a fixed temporary resin restoration was placed with permanent cement (FujiCEM [GC America] prior to 2016 or SpeedCEM [Ivoclar] after 2016) to avoid the temporary decementation and mobility that could induce implant failure.

In the posterior maxilla, all patients with insufficient bone height (≤ 8 mm) received a sinus graft elevation at the time of implant placement. If the residual crestal bone height was < 5 mm, then the implants were placed in a second stage after a sinus elevation.

All patients received strict oral hygiene maintenance instructions, which included the use of an electric brush (Oral-B iO, Braun) and water flosser (Waterpik) using hypochlorous acid (HOCl; HomeGuard by Ecowell) instead of regular water to help reduce biofilm formation.[7–9] For optimal performance, the pH was 5 to 6, and the active chlorine concentration of HOCl was 50 ppm for healthy patients, 100 ppm for patients with a history of periodontal disease, and 200 ppm in the cases with active suppuration, smokers, and patients with health conditions that made them more prone to infections, such as diabetes mellitus. The patients were instructed to eat and chew with the protective vacuum stent during

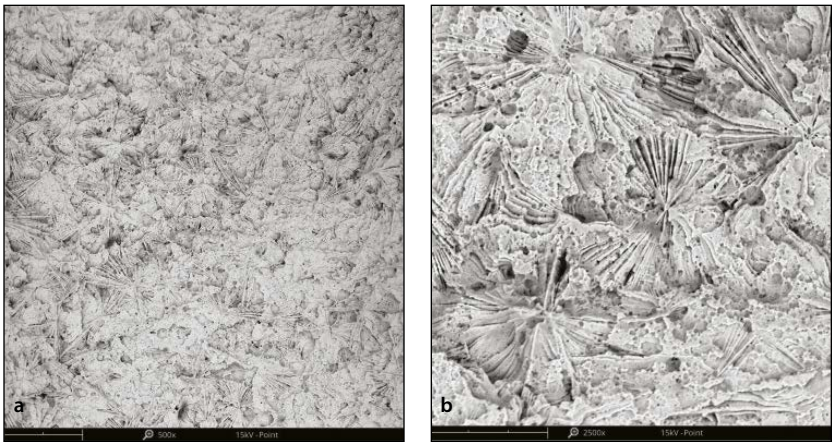

Fig 3a SEM ×500 magnification of the transmucosal area.

Fig 3b SEM ×2,500 magnification of the transmucosal area.

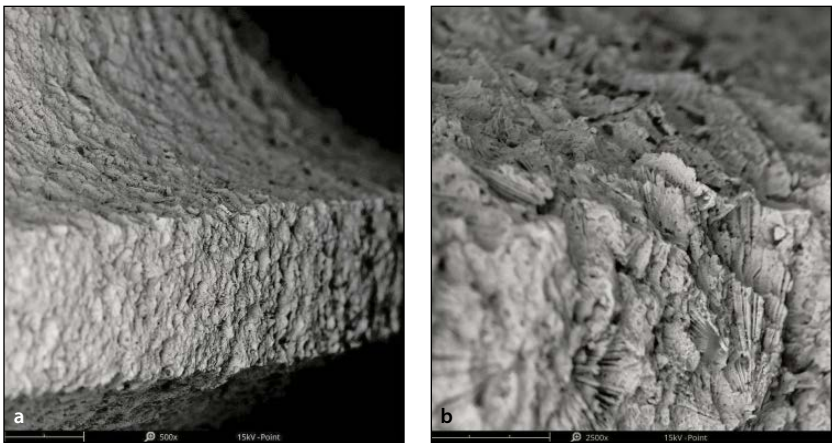

Fig 4a SEM ×500 magnification of threaded area.

Fig 4b SEM ×2,500 magnification of threaded area.

the first 2 months. The patients were seen 15 days postsurgery for follow-up and suture removal if needed. Implants were checked for hygiene maintenance, pain, and Periotest once a month, and dental hygiene was performed whenever necessary to maintain a clean and healthy mucosa. After the 2-month period, if the Periotest result was ≤ –3, the case was considered ready to be finished, and digital impressions with IOS were made to produce the zirconia definitive restoration that was inserted 2 to 3 months postsurgery. The cases with > –3 Periotest values were further allowed to heal until the values were ≤ –3. This was especially important for the simultaneous grafted sites and the cases with poor initial stability and Periotest > 0.

CAD/CAM-produced definitive zirconia restorations were created for all the implants included in the study. The single-unit restorations were left in slight infraocclusion to compensate for the elasticity of the periodontal ligament of the neighboring natural teeth. Contacts during lateral excursions were also avoided.

The final cementation was done with a composite cement (FujiCEM [GC America] prior to 2016 or SpeedCEM [Ivoclar] after 2016).

After delivery of the definitive restoration, the patients were followed up after 1, 3, 6, and 12 months and up to 15 years. Periodic 2D and 3D radiographs were obtained regularly during checkups.

An implant was designated as surviving if it was present with no mobility, no pain, no persistent peri-implant mucositis, and no implant fracture. An implant was designated as successful if it survived and in addition showed no persistent peri-implant bone loss.

Figures 5 to 11 demonstrate examples of the treatments performed in the patients of this study, including full-mouth rehabilitation on teeth and implants (Figs 5 and 9), immediate single-unit implant placement with simultaneous bone grafting (Fig 6), two immediate contiguous central incisors (Figs 7 and 10), and finally, two full-mouth rehabilitations solely on implants (Figs 8 and 11).

Statistical Methods

Kaplan-Meier was used to calculate survival probabilities of the different CeraRoot implant types. To compare the survival probabilities of the different implant types, the log-rank test was used. The null hypothesis (H0) was that there would be no difference in survival

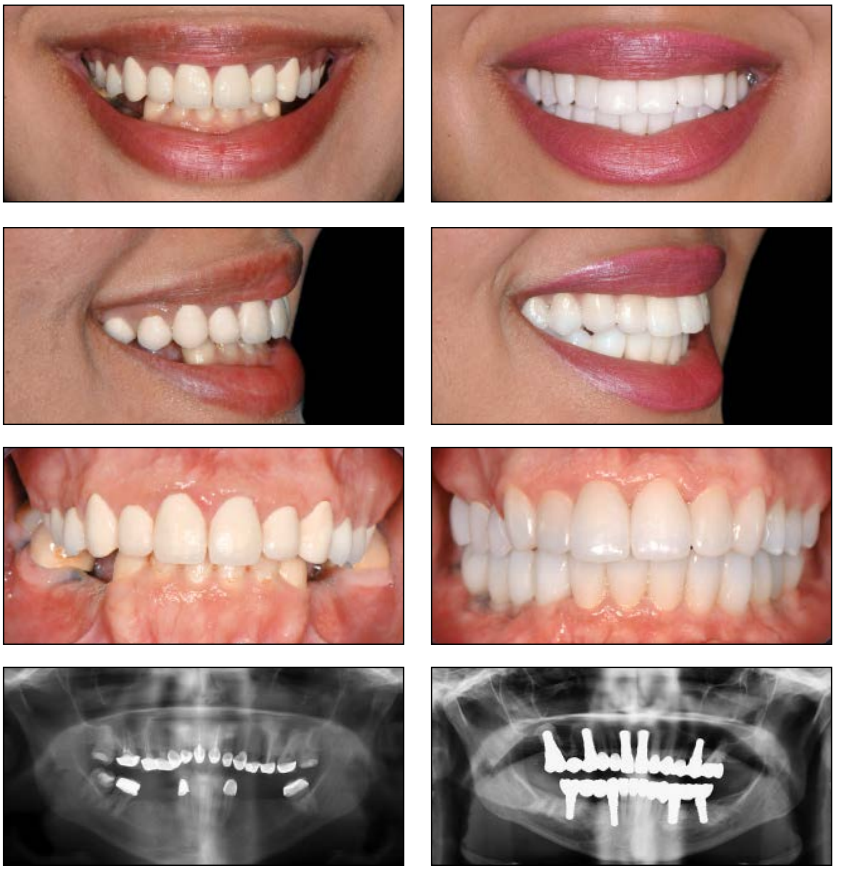

Fig 5 Full-mouth rehabilitation combining CeraRoot dental implants and natural dentition with zirconia crowns and prostheses. Preoperative images are shown on the left, and 7-year postoperative images are shown on the right.

between the different CeraRoot types. The alternative hypothesis (H1) was that there would be a difference in implant survival rates between the CeraRoot types. *P* values < .05 were considered significant.

RESULTS

A total of 771 patients (women [60.05%] and men [39.95%]) received a total of 1,828 implants. The mean follow-up period was 8.87 ± 2.94 years (Table 1). A total of 335 implants (19.42%) were placed in the anterior maxilla, 47 (2.57%) in the anterior mandible, 809 (44.26%) in the posterior maxilla, and 617 (33.75%) in the posterior mandible; 1,166 implants (63.79%) were placed immediately after extraction, and 662 (36.21%) were placed in a two-stage or delayed approach.

A total of 300 implants (16.41%) were placed in smokers (who smoked < 10 cigarettes/day), and 874 (47.81%) were placed in combination with bone grafting procedures. Patients received between 1 and 8 implants, with 381 patients (49.42%) receiving 1 implant (Table 2). Table 3 represents the distribution of implants placed and lost by FDI tooth number. The distribution of implants and their survival by implant type are illustrated in Table 4.

As far as prosthetics, 925 implants (50.6%) received a single crown, and 903 (49.40%) were part of a multiunit prosthesis.

Within the limits of this study, the overall 15-year survival rate of the 1,828 implants was 98.69%. The survival rates by implant shape/size were: CeraRoot16, 98.1%; CeraRoot11, 99.0%; CeraRoot14, 98.5%; CeraRoot 21, 99.5%; CeraRoot34, 99.2%; and CeraRoot12, 100%. These differences were not statistically significant between the six implant types.

A total of 24 implants (1.31%) failed, 5 (20.83%) of which were lost in smokers (0.27% of the total), 10 (41.67%) of which were lost in grafted sites (0.55% of the total), 1 (4.17%) of which was fractured (0.05% of the total) after infection and bone loss of two-thirds of the implant, 12 (50%) of which failed to integrate (0.66% of the total), and 9 (37.50%) of which were lost after infection (0.49% of the total). In addition to the lost implants, 9 implants (0.49%) developed peri-implant mucositis as a complication with bone loss up to the second thread

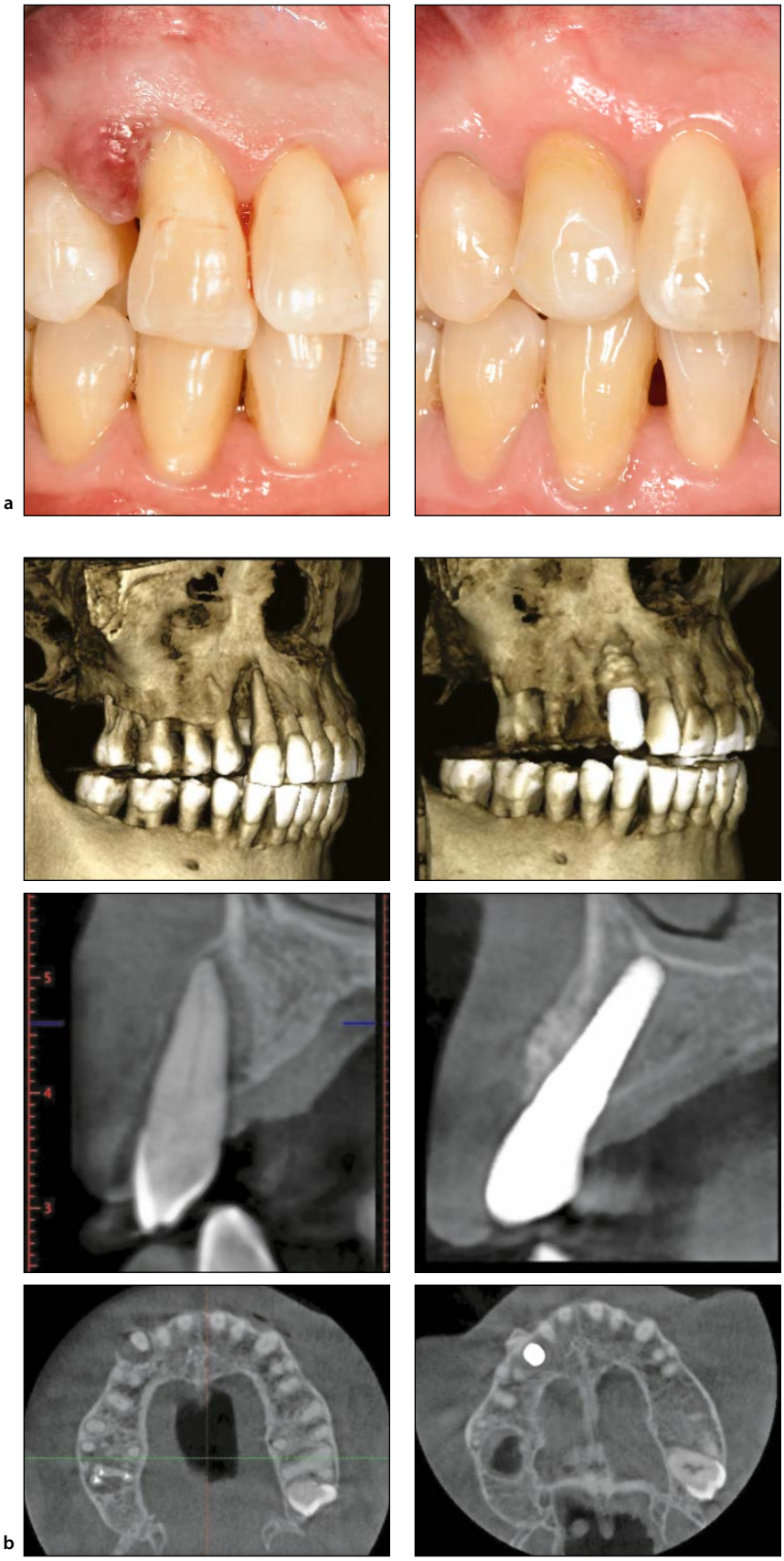

Fig 6 Immediate implant placement in the maxillary canine region with bone grafting. *(a)* Preoperative *(left)* and 7-year postoperative *(right)* intraoral images. *(b)* Preoperative *(left)* and 8-year postoperative *(right)* 3D and 2D radiographs.

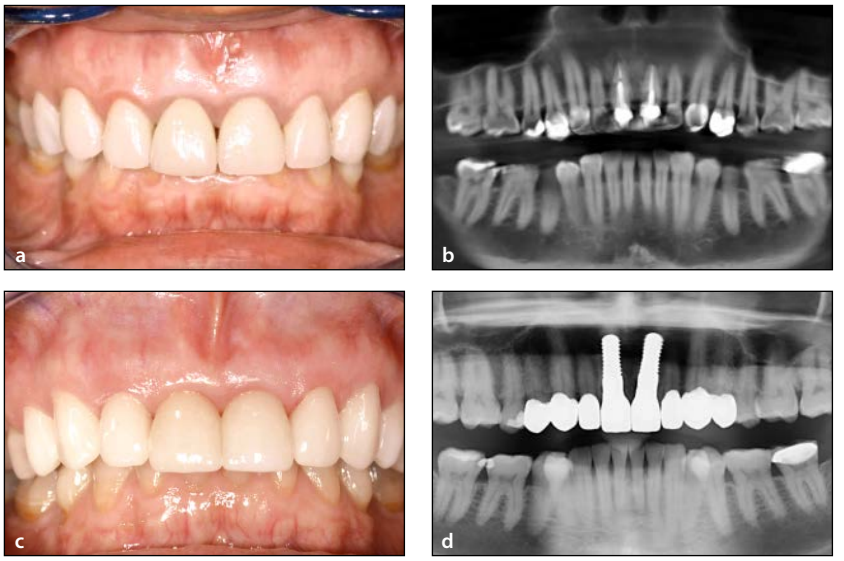

Fig 7 Two maxillary central incisors replaced with CeraRoot34 implants. *(a and b)* Preoperative and *(c and d)* 6 years postoperative.

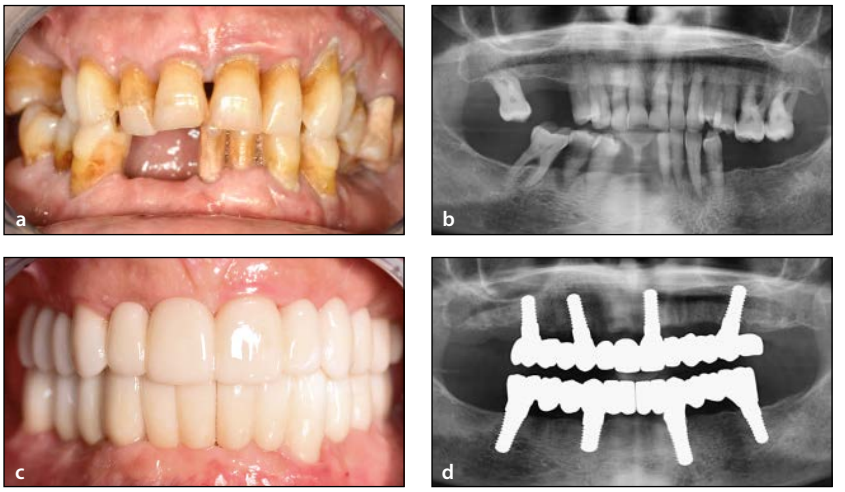

Fig 8 Full-mouth rehabilitation with immediate loading of temporary teeth. *(a and b)* Preoperative and *(c and d)* 3 years postoperative.

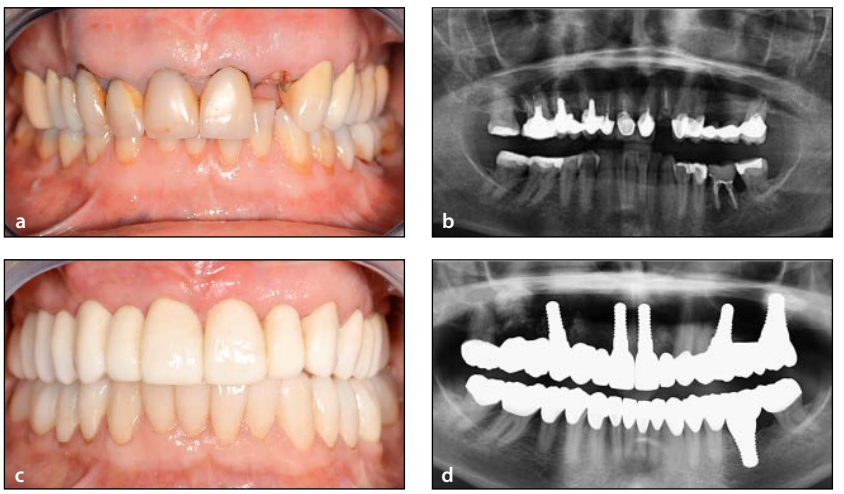

Fig 9 Full-mouth rehabilitation combining CeraRoot dental implants and natural dentition with zirconia crowns and prostheses. *(a and b)* Preoperative and *(c and d)* 6 years postoperative.

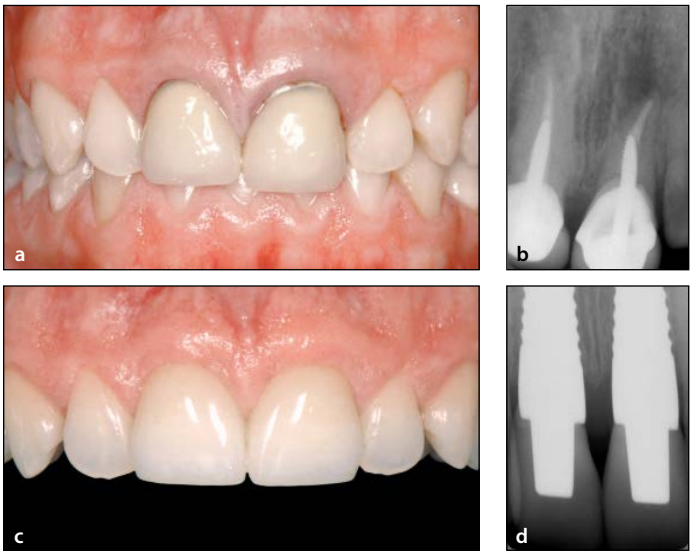

Fig 10 *(a)* Two failing central incisors with root canals. *(b)* Preoperative radiograph confirming root fractures. *(c and d)* Immediate upper central incisors at 15 years follow-up.

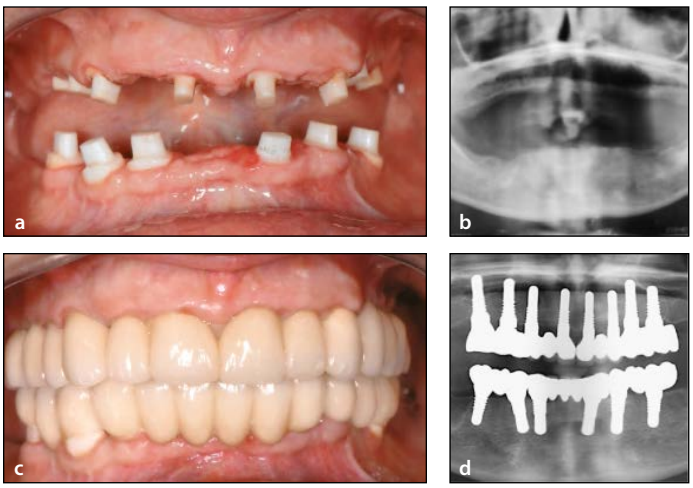

Fig 11 *(a)* Ceramic implants 3 months after implantation. *(b)* Preoperative radiograph of edentulous patient. *(c and d)* Full mouth rehabilitation at 15 years follow up.

Table 1 Number of Implants Per Years of Follow-up

Follow-up years	No.	%
15	124	6.78
14	226	12.36
13	160	8.75
12	105	5.74
11	141	7.71
10	151	8.26
9	138	7.55
8	142	7.77
7	82	4.49
6	53	2.90
5	120	6.56
4	91	4.98
3	86	4.70
2	115	6.29
1	66	3.61
0	28	1.53
Total	1,828	100.00
Mean		8.87 ± 2.94

Table 2 Number of Implants Placed Per Patient

Implants placed per patient	No. of patients	%
1	381	49.42
2	166	21.53
3	64	8.30
4	61	7.91
5	31	4.02
6	22	2.85
7	23	2.98
> 8	23	2.98
Total		100

or further of the implant, resulting in an overall success rate of 98.19%. Two implants (8.33%) failed in the anterior maxilla, 12 (50.00%) in the posterior maxilla, 1 (4.17%) in the anterior mandible, and 9 (37.50%) in the posterior mandible. Table 4 represents the distribution of failed implants among the different groups.

DISCUSSION

The osseointegration of ceramic zirconia implants is currently accepted, as it has been demonstrated in various animal models[11] as well as in the clinical practice with patients.[12,13]

The long-term chemical and physical stability of ceramic compared to metals makes it a very interesting alternative to titanium implants for overcoming biocorrosion[10] and its potential effects on the human body. Moreover, the market trend forecast studies and patient preference seem to be shifting into a more "organic," "green," and "metal-free" lifestyle, which also applies to dental implant materials.[1]

The present publication represents the longest follow-up publication on ceramic dental implants in humans. The CeraRoot implant system with its acid-etched ICE surface has been available since 2005 and has remained unchanged since its introduction. It therefore represents the ceramic dental implant with the longest follow-up clinical data available on the market today.

The results of this 15-year retrospective study, giving an overall 98.69% survival rate, are in line with

Table 3 Distribution of Implants Placed and Lost Per Tooth Number, Quadrant and Anterior/Posterior

	Placed implants			Failed/lost implants		
FDI tooth no.	No.	Anterior, n (%)	Posterior, n (%)	No.	Anterior, n (%)	Posterior, n (%)
Maxilla		355 (19.42)	809 (44.26)		2 (8.33)	12 (50.00)
11	84			1		
12	33			0		
13	57			1		
14	139			1		
15	96			1		
16	157			0		
17	25			1		
21	96			0		
22	41			0		
23	44			0		
24	109			3		
25	115			2		
26	143			2		
27	24			2		
28	1			0		
Mandible		47 (2.57)	617 (33.75)		1 (4.17)	9 (37.50)
31	1			0		
35	53			1		
36	177			2		
37	40			1		
41	2			0		
42	8			0		
43	10			0		
44	36			0		
45	62			1		
46	173			2		
47	45			2		
Total	1,828	402 (21.99)	1,426 (78.01)	24 (1.31)	3 (12.50)	21 (87.50)

Table 4 Implants Placed, Survived, and Lost Per Model

Implant model	Placed (%)	Survived (%)	Lost (%)
14	667 (36.49)	657 (98.50)	10 (1.50)
16	462 (25.27)	453 (98.05)	9 (1.95)
11	209 (11.43)	207 (99.04)	2 (0.96)
21	192 (10.50)	191 (99.48)	1 (0.52)
34 + 34L	248 (13.57)	246 (99.19)	2 (0.81)
12	50 (2.74)	50 (100.00)	0 (0.00)
Total	1,828 (100.00)	1,804 (98.69)	24 (1.31)

other recent clinical studies performed with different ceramic one-piece implant systems. Bormann et al[6] (2018) reported a 97.5% survival rate after 3 years with the monotype pure Straumann implant. In a similar way, Bethke et al[5] reported a 94.3% survival rate after 5 years of follow-up with the one-piece Metoxit implant (ATZ).

After having placed 1,828 CeraRoot ceramic implants and followed them for up to 15 years with a 98.69% survival rate, the authors have updated their initial surgical and prosthetic protocol published in 2010[14] (Table 5). The updated protocol includes critical factors to minimize the risk of implant failure that

Table 5 Updated Protocol (V.20) and Recommendations for the CeraRoot Implant System

Patient selection
Indications:
• Good oral and general health
• Single- or multiple-unit and full-arch restorations
• Correct occlusion
• Immediate implantation
• Transmucosal implantation
• Immediate temporary provisionalization for full-arch restorations
Contraindications:
• Health conditions that affect the capacity of the immune system to avoid oral infections
• Smoking more than 5 cigarettes/day
• Malocclusion or parafunctions
• Active periodontitis
• Significant bone defects should be grafted prior to implantation surgery.
• Immediate loading on single-unit restorations.
Preoperative planning
• Meticulous initial examination with a multidisciplinary approach
• Preoperative IOS scan, photographs, 2D and 3D radiographs
• Surgical guide
• Planning a two-stage procedure if large horizontal or vertical regeneration is needed
• Vacuum-formed protective stent to use 24/7 for 2 months to avoid chewing forces on the implant
• No smoking 15 days before and after surgery
• Sinuses with < 8 mm of residual bone should be treated in a two-stage approach
Surgery
• Hygiene control
• Use of a surgical guide for correct 3D positioning of the implants
• Follow CeraRoot surgical drilling instructions
• Immediate implants are viable provided that *(1)* there are no active infections with suppuration and *(2)* there is sufficient bone to achieve primary stability
• 2D and 3D radiographs to control implant position
• PRP is recommended fbefore immediate implant placement. Add biomaterial if there is a > 2-mm gap between the bone and implant
• Antibiotics are recommended for open-flap procedures, grafted sites with biomaterials, patients with a history of periodontitis, smokers, and patients with health conditions
• Periotest the implants
Provisional restorations
• The first choice is always the vacuum-formed protective stent, where the missing tooth can be shaded with composite
• Avoid immediate fixed temporary restorations for single-unit cases
• Full arch PMMA CAD/CAM temporary restorations can be placed with permanent cement to avoid decementation and micromovement during healing that could affect osseointegration
Healing period
• No smoking for at least 15 days postoperation
• Control hygiene every 1 month
• Periotest at 1 and 2 months postoperatively
• Make sure the protective stent is used to avoid masticatory forces on the implant
• After 2 months, if the Periotest is < –3, the case is ready to be restored with the final crown
• Immediately loaded full-arch provisional restorations should be left 4 months before delivering the definitive restoration
• Significant regeneration procedures should be allowed to heal at least 6 months before definitive restoration and until Periotest is < –3.
Definitive restoration
• Zirconia restorations with full anatomical contour are recommended to avoid porcelain chipping
• For single-unit anterior implants, high translucency zirconia is recommended
Maintenance
• Professional maintenance every 6 months
• Nightguard for bruxers to avoid overstressing the implants and restorations

include protecting the implant during the healing phase as the most important factor.

The use of Periotest has been described[6] as a critical tool to evaluate the osseointegration process of ceramic implants through objective assessment of implant stability. This is particularly important in immediate extraction and regenerated sites that may need more time for healing. Clinical examination and radiography have proven insufficient to evaluate the actual maturation of bone and osseointegration.

In the present study, the use of HOCl as a chemical adjunctive[7] to the mechanical hygiene control performed with the toothbrush and waterjet has been well accepted by patients because it has no taste or smell, and it can be produced at home with a simple kit. In the patients with a history of periodontal disease, HOCl was used as a disinfectant irrigating solution for professional hygiene in combination with ultrasound scalers and air polishing systems.

CONCLUSIONS

The one-piece CeraRoot acid-etched (ICE surface) ceramic implant showed 15-year long-term clinical performance with a survival rate of 98.69% and an overall success rate of 98.19%, under the described protocol. There were no significant differences between the six implant shapes/sizes of the CeraRoot implant system. Of the failures that occurred, 50% were in the maxillary posterior arch.

The results show that the benefits of this treatment modality outweigh the inherent perceived risks. Moreover, the survival of these ceramic implants rivals the survival of two-piece metal alloy implants, which are considered the gold standard, and thus, these implants can be considered a well-established technology.

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