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Two-piece zirconia implants in the posterior mandible and maxilla: A cohort study with a follow-up period of 9 years

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Abstract

Objectives: Long-term follow-up observations of zirconia implants are rare. This study aimed at evaluating the clinical performance of two-piece zirconia implants in the posterior jaws over 9 years.

Materials and Methods: Sixty partially edentulous patients were treated with two-piece zirconia implants. In eight no primary stability could be achieved. Fifty-two patients received the final restoration (i.e., cemented fibreglass abutments and all-ceramic crowns). After 2 years, 2 implants failed and 4 dropouts were recorded. The remaining 46 patients with one target implant each were recalled at 9 years. Besides implant survival, clinical parameters at the implant level (plaque index–PI, bleeding on probing–BOP, probing depth–PD, mucosal recession–MR) were recorded and compared with previously collected data. Mechanical and technical complications were assessed.

Results: Thirty patients responded. The mean observation period was of 111.1 ± 2.2 months. One implant was lost. Data recorded from the remaining 29 implants were analysed. PI values increased overtime. Mean BOP and PD remained unchanged during follow-up. No additional cases of peri-implantitis were recorded over the 10 diagnosed during the first 2 years of follow-up. No significant changes in mean MR values were detected over time, with 65% of the all included implants exhibiting no recession at 9 years and all the others, but one, a maximum MR of 1 mm. Three technical and 6 mechanical complications occurred in 7 patients between 2- and 9-years (6.9% and 20.7%, respectively, at patient level).

Conclusion: Within the limitations of the present study, a high survival rate was registered. Albeit frequent mechanical and technical complications, two-piece zirconia implants could represent a valid solution for the replacement of single teeth in the posterior jaws.

KEYWORDS
clinical study, implant survival, zirconia implants

Frank Schwarz and Jürgen Becker contributed equally to this work.

1 | INTRODUCTION

Zirconia dental implants are regarded as a valid alternative to the commonly used titanium implants, owing to their high biocompatibility, favourable soft-tissue response, as well as tooth-like colour (Roehling et al., 2018). The spread of ceramic implants is projected to increase in the next decade (Kohal & Dennison, 2020; Sanz et al., 2019). This tendency can be ascribed to the current high levels of aesthetic expectation, as well as to the growing demands for metal-free solutions, at least among the European population (Cionca et al., 2017; Sanz et al., 2019).

Advancements in dental implant manufacturing have paved the way for the consolidation of high-strength ceramic materials in implant dentistry (Roehling et al., 2018). The first generation of ceramic implants was made of alumina (Al_2O_3). However, they are no longer available on the market due to their poor mechanical properties leading to a high rate of fracture at the implant neck (Cionca et al., 2017; Depprich et al., 2014). Since the beginning of the 90s, zirconia (ZrO_2) has been establishing itself as the material of choice for ceramic implants.

Zirconia is of particular interest for its excellent optical properties when used for transmucosal components (Bressan et al., 2011; Kniha et al., 2019; Kohal & Dennison, 2020). Aesthetic problems can be associated with the greyish shimmering of the titanium, which is not always masked by the surrounding soft tissues, especially in presence of a thin biotype (Jung et al., 2007; van Brakel et al., 2011). The transmucosal components play also a crucial role in the prevention of implant failure, as plaque accumulation and a weak mucosal seal around the implants may likely contribute to the onset of peri-implant diseases (Schwarz et al., 2018). Beside the noticeably enhanced appearance of the peri-implant tissues, zirconia surfaces have been demonstrated to be advantageous in terms of resistance to bacterial adhesion and colonization (Al-Radha et al., 2012; Rimondini et al., 2002; Scarano et al., 2004). Furthermore, it has been suggested that zirconia resulted in a stronger mucosal barrier at the soft-tissue implant interface (Kohal et al., 2004; Lee et al., 2019; Liñares et al., 2016; Welander et al., 2008).

Despite their favourable biological and aesthetic characteristics, the osseointegration of zirconia implants largely depends on the surface topography. Moderately rough surface-modified zirconia implants exhibited higher osteointegration properties than untreated ones, as well as similar or better outcomes compared to titanium implants (Depprich et al., 2008; Ding et al., 2020; Hafezeqoran & Koodaryan, 2017; Hempel et al., 2010; Kubasiewicz-Ross et al., 2018).

Among zirconia-based materials, yttria-stabilized tetragonal zirconia polycrystal (Y-TZP) has become quite popular for load-bearing applications, due to its ability to withstand occlusal loads (Roehling et al., 2018). It has to be noted that initial concerns regarding the fracture resistance of complex zirconia structures determined the development of implant systems characterized by a one-piece design. These implants are known to possess limited restorative flexibility and might be exposed to undesired immediate loading due to their conformation (Cionca et al., 2017; Payer et al., 2013; Pieralli et al., 2017). More recently two-piece zirconia implants were introduced in the commerce, thus overcoming the inherent limitations of one-piece implants. However, the late development of two-piece zirconia solutions reflects in the scarce information on their medium- and long-term clinical outcomes (Cionca et al., 2017; Pieralli et al., 2017; Roehling et al., 2018).

A previous prospective cohort study investigated the clinical performances of two-piece zirconia implants restored with cemented fibreglass abutments and all-ceramic single crowns in the posterior jaws (Becker et al., 2017). Despite 8 target implants out of 60 were lost due to the absence of primary stability and did not receive the final restoration, the short-term results on the remaining 52 were promising, with a cumulative survival rate of 95.8% (excluding early implant failures prior to loading), improved soft-tissue conditions and rare mechanical and technical complications over a period of 25 ± 5.8 months (Becker et al., 2017). The aim of the present study was to retrospectively evaluate the long-term clinical outcomes in the aforementioned patient cohort after a period of 9 years.

2 | MATERIALS AND METHODS

This study was designed as a single-centre cohort study. Patients received a detailed description of the procedure and gave their written informed consent to the treatment. The study was conducted in accordance with revised principles stated in the Helsinki Declaration and ethics approval for the follow-up assessments was obtained from the Ethics Committee of the Heinrich Heine University of Düsseldorf, Germany (Prot. Number 3712/2021). The study was reported in accordance to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting observational studies (von Elm et al., 2014).

2.1 | Patient population and study design

The original population consisted of 60 partially edentulous patients in need for at least one single-tooth implant-supported fixed prosthesis in the premolar/molar regions of either the maxilla or the mandible. Details of the treatment protocol were reported previously (Becker et al., 2017). In brief, 60 patients received, between November 2011 and April 2012, two-piece, screw-type zirconia implants (Patent™, Zircon Medical, Altendorf, Switzerland—former ZV3, Zircon Vision GmbH, Wolfratshausen, Germany) with individualized heights of the transmucosal aspect (Figure 1). The implants had diameters of 4.5 and 5.0 mm and were used in three different lengths, that is 9, 11 or 13 mm. In case of multiple implant placements in the same patient, the most anterior site was considered as target as decided a priori in the original protocol. An insufficient primary implant stability could be achieved in eight cases (early implant failure prior to loading); therefore, only 52 patients out of 60 were restored with all-ceramic single crowns cemented on fibreglass

FIGURE 1 Schematic cross-section of the 2-piece zirconia implant, highlighting the three components, that is the ceramic implant, the cemented fibreglass abutment (light green) and the all-ceramic crown.

abutments using a conventional loading protocol. At 2-year follow-up, 2 target implants failed and 4 dropouts were recorded. The remaining 46 patients with one target implant each were recalled for the 9-year follow-up examination.

Inclusion criteria were as follows:

The Subjects were included in the study if they present all of the following conditions: (1) Successful implant placement in the initial study (Becker et al., 2017), (2) final restoration and (3) written informed consent.

The subjects were not included in the study if they present one of the following conditions: (1) occurrence of newly diagnosed diseases interfering with implant success, (2) history of a trauma to the implant site, (3) pregnant or lactating women, (4) participation in a clinical study interfering with the objective of this follow-up observation, (5) unregular maintenance care.

2.2 | Surgical procedure and prosthetic rehabilitation

All the surgeries were carried out under local anaesthesia by three experienced and previously calibrated oral surgeons. In brief, after the elevation of a mucoperiosteal flap, implant site preparation was performed under copious irrigation following the manufacturer's guidelines. Good primary stability, defined as absence of clinical implant mobility, had to be achieved and each customized implant had to be positioned as preoperatively planned, in a way so that the limit between the transmucosal and intrabony part of the implant coincided with the lingual bone crest. Implant diameter and length were selected based on the individual clinical and radiological situation. Simultaneous grafting of buccal dehiscence-type defects with deproteinized bovine bone mineral particles (Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland) and resorbable collagen membranes (Bio-Gide®, Geistlich Pharma AG) as well as transcrestal sinus lift were performed, if required. In cases of sinus lift using lateral window approach, implants were inserted after 4–6 months from grafting (Bio-Oss®, Bio-Gide®). One-stage implant placement was used in all cases with transmucosal healing and without any provisional restoration. Implant loading was accomplished after approximately 12 and 10 weeks in the maxilla and in the mandible, respectively. Fibreglass abutments were cemented using a dual-cure resin cement and a self-adhesive primer (Panavia F2.0, Kuraray Europe GmbH, Hattersheim am Main, Germany). Then, conventional impressions using a monophase technique were taken with polyether material (Impregum, 3M Deutschland GmbH, Neuss, Germany) and monolithic all-ceramic single crowns (IPS e.max, Ivoclar Vivadent GmbH, Ellwangen, Germany) were fixed using the same cement.

2.3 | Supportive therapy

Individualized supportive care program included professional cleaning, local pocket irrigation using chlorhexidine and patients' motivation. Patients were recalled, depending on their individual needs, in the first two years from the therapy. Thereafter, the patients were under regular maintenance care either at the Department or at the referring dentist according to individual needs.

2.4 | Clinical examinations

At the baseline (i.e., crown delivery), and after 2 and 9 years, the following clinical parameters were recorded for each of the available target implants as described previously (Becker et al., 2017): (1) plaque index (PI), (2) bleeding on probing (BOP), (3) probing depth (PD) and (4) mucosal recession (MR) measured taking as fixed

reference point the crown margin, as each customized implant had been designed and manufactured in a way that the implant neck and subsequently the crown margin were located in an epimucosal position. At the 9-year follow-up, a dichotomous plaque index was used (O'Leary et al., 1972); therefore, the PI values (Löe, 1967) from previous examinations were modified accordingly, considering 0 as absence of plaque and values from 1 to 3 as presence of plaque. All measurements were performed at six aspects per implant: mesiobuccal (mb), midbuccal (b), distobuccal (db), mesiooral (mo), midoral (o) and distooral (do). All the measurements were performed by two investigators in the first two years, while two other investigators (N.R. and G.J.) collected the data at the 9-year follow-up. All examiners initially underwent a standard calibration procedure as required for clinical routine examinations in the authors' Department. This included double measurements of the assessed clinical parameters, which were commonly performed within a 5-minute interval in three patients and accepted when repeated measurements were similar at >95% level. Implant mobility (i.e., loss of osseointegration) was also recorded by manual palpation. According to the German Röntgenverordnung based on 97/43/EURATOM directive and the Strahlenschutzgesetz based on the 103/2013 Euratom directive, two-dimensional radiographs for the assessment of marginal bone level changes at 9 years were not routinely justified. This included suspected cases of peri-implant mucositis, as defined by Renvert et al. (2018), where the radiographic assessment would have not changed the therapeutic approach. Consequently, radiographs were taken if clinically justified (e.g., in presence of both BOP e PPD ≥ 6 mm or mechanical/technical complications).

2.5 | Survival and complications

Implant survival was considered as the presence of the implant in situ at the 9-year follow-up examination. Technical and mechanical complications occurred during the follow-up period were recorded. Technical complications comprised all the events affecting the cemented crown (according to the definition of Heitz-Mayfield et al., 2014) as well as the decementation of the fibreglass abutment. Mechanical complications were considered all the events affecting the integrity of the implant or of the abutment. Biological complications considered the presence of peri-implantitis at the target implant, as defined by Berglundh et al. (2018) (i.e., presence of bleeding and/or suppuration on gentle probing, probing depths of ≥6 mm and bone levels ≥3 mm apical of the most coronal portion of the intraosseous part of the implant) or of mucositis (Renvert et al., 2018).

2.6 | Statistical analysis

The statistical analysis was performed using R (R Core Team, 2021) and SPSS (IBM Corp., Armonk, NY, USA). Each included patient contributed with one target implant and was, therefore, considered as the statistical unit. Descriptive statistics were also performed for recorded clinical parameters (i.e., PI, BOP, PD and MR). Dummy regression was performed to assess association of mean rounded BOP values with mean PD values. For each clinical parameter, values were compared at the patient level among the different time points (i.e., baseline and the follow-ups at 2 and 9 years) using the Friedmann test. In case of significance, the Wilcoxon signed rank test was utilized as post-hoc test. To assess differences in clinical parameters at 2 years between patients who dropped out before the 9-year follow-up and those who did not, a Mann–Whitney *U* test was utilized. Kruskal-Wallis test was used to assess differences in mean BOP at 9-year follow-up among patients treated for peri-implantitis, mucositis or who did not receive any treatment. A Mann–Whitney-*U* test was used to assess differences between patients who were treated for peri-implantitis and those who were not. The results were found significant at $p < .05$. The *p*-values were adjusted using the Bonferroni method.

TABLE 1 Patient demographics and implant site characteristics after 2- and 9-year follow-up

Variables	2-year follow-up	9-year follow-up
Patient number (*n*)	48	30
Female	31	19
Male	17	11
Age (years at implant placement)	47.6 ± 13.4	49 ± 12.8
Observation period (months)	25.5 ± 5.8	111.1 ± 2.2
Patient with multiple implant sites	15	10
Patients with 1/2/3 implants	33/10/5	10/6/4
Patients treated by surgeon 1/2/3	7/29/12	7/16/7
Target implant sites	48	30
Location maxilla	13	10
Location mandible	35	20
Target implant sites with augmentation	19	11
Simultaneous grafting of a dehiscence-type defect	12	7
Internal sinus floor elevation	6	3
External sinus floor elevation	1	1

Note: Data are presented as frequency or as mean ± SD.

3 | RESULTS

Thirty patients out of the 46 eligible ones were available for the 9-year follow-up assessment. All the patients responding to the 9-year follow-up recall met the inclusion criteria. Demographic data and implant site characteristics are summarized in Table 1. Among the 16 patients lost to the 9-year follow-up, one patient moved to another state, another one unfortunately died, while the remaining 14 patients were not reachable. For all the investigated clinical variables, there was no significant difference at two years between the

subjects that reached the 9 years follow-up and the group of subjects that dropped out after the 2 years of follow-up (i.e., PI, $p = .565$; BOP, $p = .506$; PD, $p = .639$; MR, $p = .548$). Between 2 and 9 years, all the included patients were under regular professional maintenance regimen either at the Department (10%) or at the referring dentist (90%). The mean follow-up period was 111.1 ± 2.2 months from the time of implant placement. Among the included patients, one target implant 5 mm in diameter and 11 mm in length positioned in the lower molar in a female patient failed after 110 months from implant placement (Figure 2). Therefore, data recorded from the remaining 29 target implants were included in the statistical analysis.

3.1 | Clinical measurements and biological complications

The clinical parameters (i.e., PI, BOP, PD and MR) at patient level at different time points (i.e., baseline and the follow-ups at 2 and 9 years) are reported in Table 2 and Figure 3. The *p*-values adjusted using Bonferroni method are presented in Table 3 for all the investigated *post-hoc* comparisons, if the Friedman test was significant. The Friedmann test failed to find any significant difference among BOP ($p = .555$) and MR ($p = .077$) values; therefore, *post-hoc* comparison was not performed for these clinical parameters.

The majority of the patients (82.8%) presented no plaque around the target implants at the baseline. Mean PI values obtained in the early phase increased over time. Mean PI values at both 2 and 9 years were significantly higher compared to those recorded at baseline. Although the descriptive analysis indicates an increase in PI between 2 and 9 years (Figure 3a), no statistically significant difference was detected.

At 9-year follow-up, 16 (55%) out of 29 target implants included for the analysis presented a BOP of 0%. A maximum of two bleeding sites was detected in all the remaining cases, except for two target implants presenting BOP+ in 3 out of 6 sites. No significant differences in mean BOP values were evidenced between the three time points (Figure 3b). Before the 2-year follow-up, among the included 29 target implants, 10 implants diagnosed with peri-implant mucositis received mechanical debridement and local antiseptic therapy with chlorhexidine digluconate. Whilst, 10 implants diagnosed with peri-implantitis were treated with Er:YAG laser therapy, as described elsewhere (Schwarz et al., 2015). Kruskal-Wallis test revealed no significant differences in mean BOP at 9 years between the implants previously treated for peri-implantitis, the ones treated for peri-implant mucositis and the remaining 9 implants ($p = .456$). Similarly, no differences were observed between the group treated for peri-implantitis and all the others ($p = .845$).

The highest PD value registered at 9-year follow-up was of 6 mm in two patients, which was recorded in only one site per target implant. In these patients, the x-ray confirmed a bone level <3 mm. According to the given definition (Berglundh et al., 2018), no peri-implantitis was diagnosed. However, at 9 years signs of inflammation (i.e., BOP+) at the target implant were observed in 13 out of 29 patients with survived target implants (44.8%).

As shown in Figure 3c, an increase in mean PD values was observed during the first two years after loading, whereas the values remained constant from 2- to 9-year follow-up. Significant differences in mean PD values were found between the baseline and both 2 and 9 years. The worst PD value per time point at each target implant is reported in Figure 4, showing similar outcomes at 2 and 9 years.

A graphical overview of the correlation at 9-year follow-up of the site-specific PD values and the concomitant presence or absence of BOP at the same sites is provided in Figure 5. Furthermore, dummy regression revealed that mean rounded BOP values of 50%, which was the highest value reported at 9-year follow-up and occurred just in two patients, were significantly associated with an increase of 0.94 mm in PD values.

At 9-year follow-up, the mean MR values were below 1 mm for all the included target implants (Figure 3d). A recession of 1 mm at least at one site was recorded around only 10 out of 29 target implants. Among these, only one patient presented an exposure of 2 mm of the transgingival portion of the implant, specifically on the lingual aspect. Details on worst MR values are reported in Figure 6. No significant differences in MR values could be detected between different time points, confirming the stability of the results overtime.

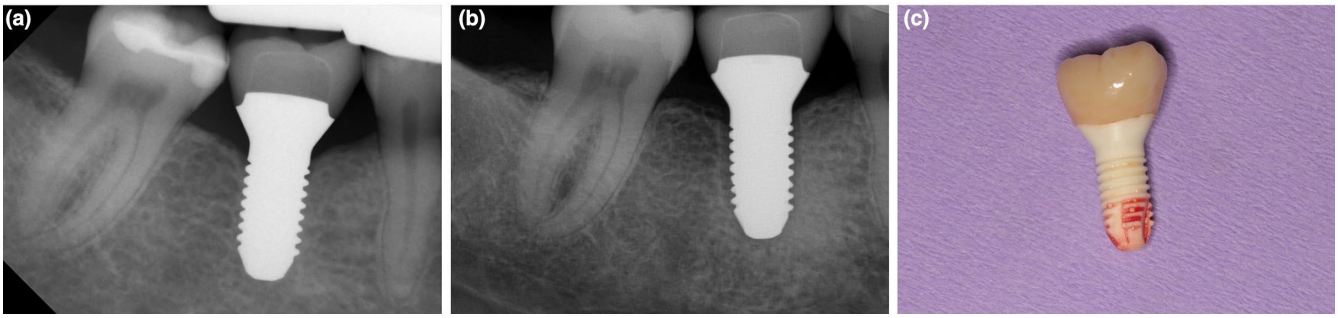

FIGURE 2 Case of implant failure between 2- and 9-year follow-up. (a) Intraoral radiograph at 6 months after crown fitting confirming implant osseointegrarion; (b) intraoral radiograph at 110 months after implant placement showing the characteristic peri-implant radiolucency; (c) removed implant. The absence of an adequate contact point after the replacement of the restoration at tooth 37 might have played a role in implant failure.

Overall, clinically, an improvement of soft-tissue conditions was observed. A representative case of creeping attachment leading to a full coverage of the initial buccal mucosal recession at the target implant (46) and at the two neighbouring ceramic implants is shown in Figure 7.

3.2 | Mechanical and technical complications

Between the 2-year and 9-year follow-up, three technical complications occurred in two patients (6.9% at patient level). These included one abutment decementation and one case of crown fracture followed by the loosening of the new crown. These complications were observed after a mean time of 43.7 months (SD 36.6) from the initial loading or from the new crown fitting.

TABLE 2 Clinical parameters (mean and SD) at the target implant, that is baseline and the follow-ups at 2 and 9 years

	Baseline		24 months		9 years	
Index	Mean	SD	Mean	SD	Mean	SD
PI	0.09	0.26	0.26	0.27	0.33	0.28
BOP (%)	22.4	29.4	14.7	17.1	12.9	15.8
PD (mm)	1.9	0.8	3.2	0.5	3.0	0.6
MR (mm)	0.2	0.4	0.1	0.1	0.1	0.2

Note: $n = 29$ target implants within the 30 patients included in the current study (1 implant failed).

Six mechanical complications, consisting in the fracture of the fibreglass abutment, were registered in six patients (20.7%). One of those was detected in the patient who had previously experienced two complications at crown level. Mechanical complications were successfully resolved with the removal of the fractured abutment and the delivery of a new crown. Mechanical complications occurred after a mean observation time of 53.7 months (SD 22.9) from the initial loading or from the new crown fitting.

4 | DISCUSSION

Thirty patients with one target implant each responded to the 9-year recall invitation. Among them, only one implant was lost. Albeit, no case of peri-implantitis was diagnosed. Mean PI values tended to increase between 2- and 9-year follow-up, while mean BOP and PD values remained stable over the same observation time. Approximately two third of the implants included in the analysis exhibited no mucosal recession (19 out of 29 target implants) and all the remaining implants but one presented a maximum MR value of 1 mm, confirming the healthy conditions of the peri-implant soft tissues. Contrary to our previous examination, a high rate of technical and mechanical complications was registered. Nevertheless, they were all resolved with the replacement of the prosthetic components and none of them affected the integrity of the implants.

As emerges from a systematic review evaluating the clinical performances of zirconia implants (Roehling et al., 2018), the broad

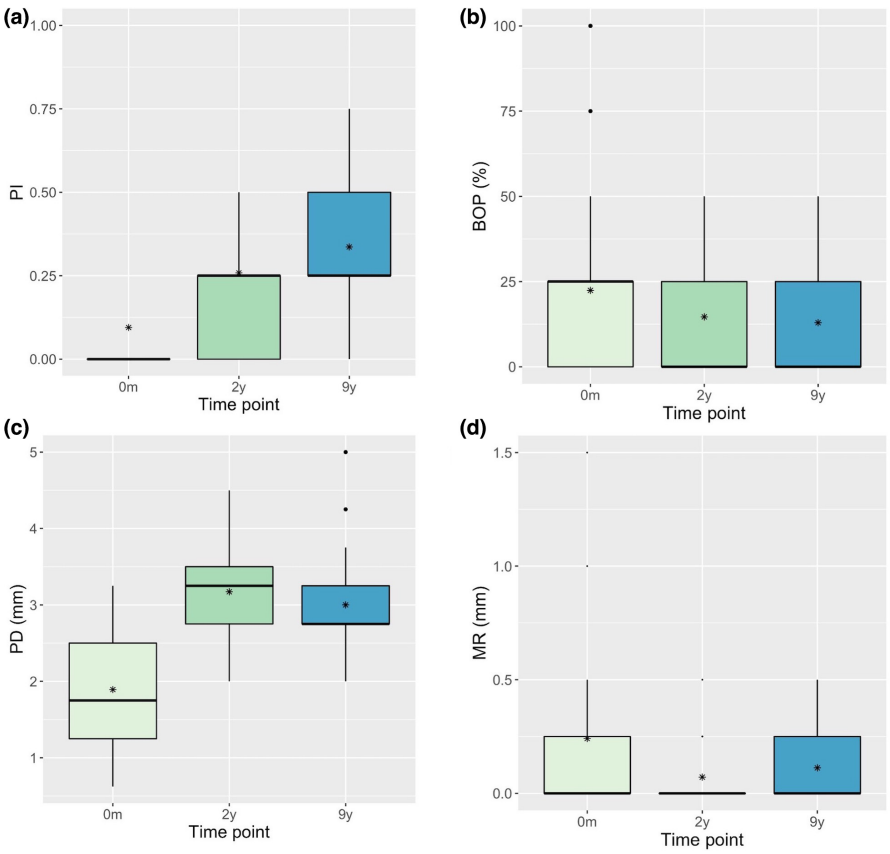

FIGURE 3 Boxplot representations at different time points (i.e., baseline and the follow-ups at 2 and 9 years) of PI (a), BOP (b), PD (c) and MR (d) recorded at the 29 target implants considered for analysis at the 9-year follow-up. Mean value is reported as follows (✳).

TABLE 3 Clinical parameters

Grouping variable	Comparator 1	Comparator 2	*p*-value
PI	Baseline	2 years	.026*
	Baseline	9 years	.001**
	2 years	9 years	.881
PD	Baseline	2 years	.000***
	Baseline	9 years	.001**
	2 years	9 years	.345

Note: The Friedmann test was performed for each investigated clinical parameter (i.e., PI, BOP, PD and MR) to compare the values at the patient level among the different time points (i.e., baseline and the follow-ups at 2 and 9 years). In case of significance, a post-hoc Wilcoxon signed rank test with Bonferroni *p*-value adjustment was utilized. The adjusted *p*-values from the post-hoc test are reported.
*$p < .05$; **$p < .01$; ***$p < .001$.

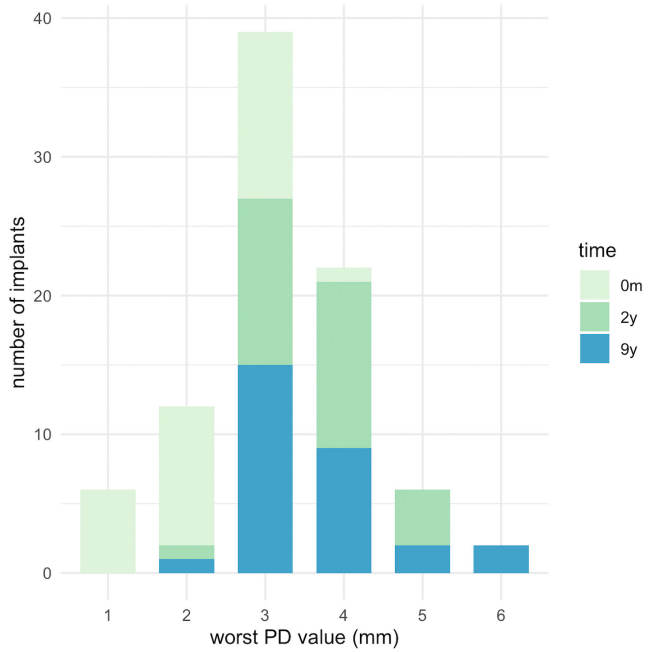

FIGURE 4 Bar chart reporting worst PD value at each target implant at different time points (i.e., baseline and the follow-ups at 2 and 9 years).

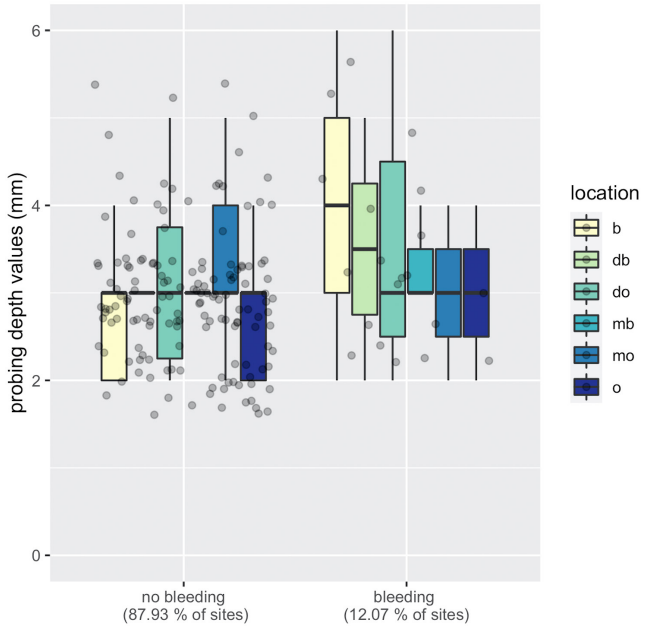

FIGURE 5 Boxplot illustrating site-specific PD values (i.e., b, db, do, mb, mo, o) recorded at the 29 target implants at 9-year follow-up based on the concomitant presence or absence of site-specific BOP.

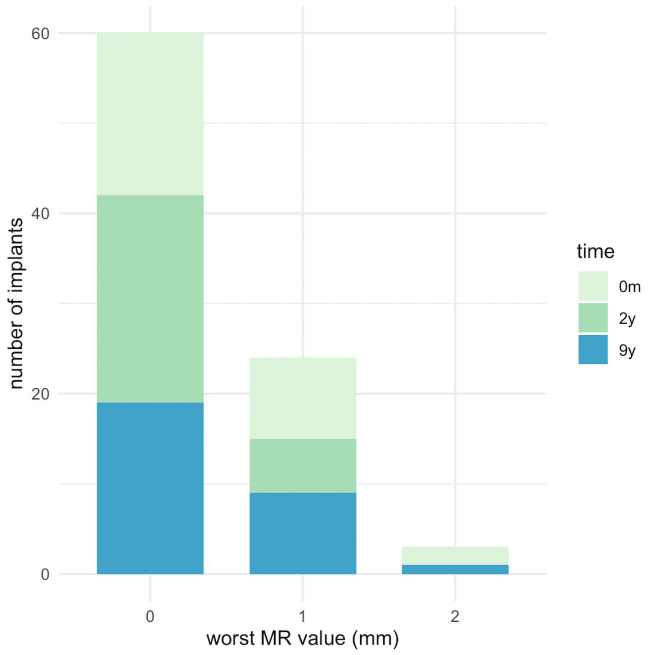

FIGURE 6 Bar chart reporting worst MR value at each target implant at different time points (i.e., baseline and the follow-ups at 2 and 9 years).

majority of the included studies were conducted on one-piece zirconia implants, and only 4 out of 18 on two-piece implants (Becker et al., 2017; Brüll et al., 2014; Cionca et al., 2015; Payer et al., 2015). Interestingly, only two studies investigated commercially available implants (Becker et al., 2017; Brüll et al., 2014). The first one consisted in the previous study of our group (Becker et al., 2017), in which two-piece zirconia implants restored with fibreglass abutments and all-ceramic single crowns revealed a high survival rate of 95.8% at a mean survival time of 32.9 months. The data were in line with results obtained in the other study utilizing the same commercially available implant system, reporting on an overall survival rate of approximately 96% after 3 years (Brüll et al., 2014). However, it has to be noted that both two-piece and one-piece implants were included in that retrospective analysis. Moreover, implants were provided either with single- or multi-unit fixed restorations and outcomes where not stratified for implant and prosthesis type. The implant loss documented in the current study has to be added to

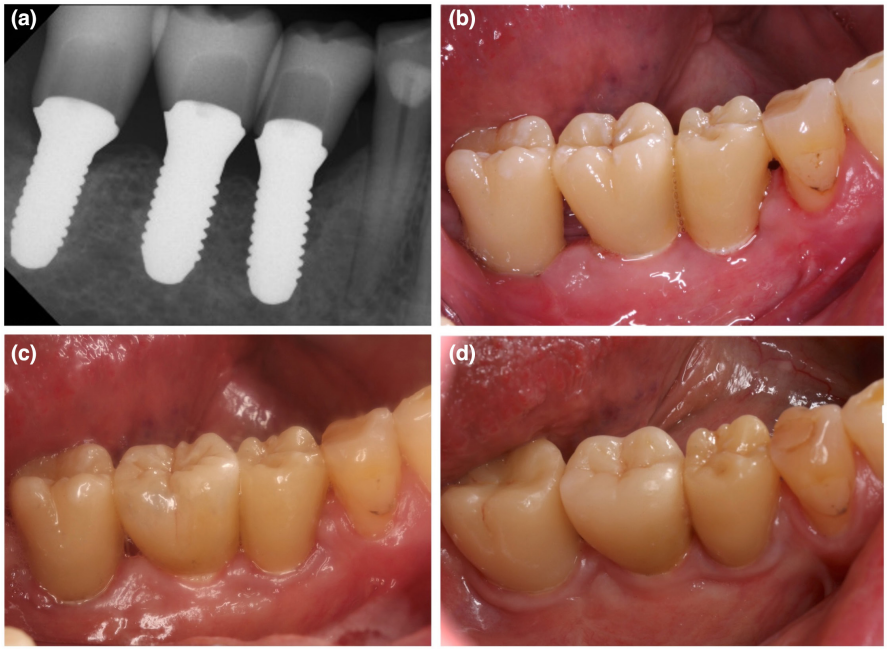

FIGURE 7 Representative case of long-term follow-up patient. (a) Intraoral radiograph and (b) clinical photo taken at crown fitting. Clinical images 2 years (c) and 9 years (d) after implantation, confirming the improvement and the long-term stability of peri-implant soft-tissue health.

the two previously reported failures (Becker et al., 2017). However, the pool of patients here included represents only a subgroup of the original group of participants, hence no cumulative survival rate can be calculated.

Plaque was detected around the majority of the target implants (22 out of 29). Despite no significant difference in mean PI was detected between 2- and 9-years, values tended to increase over-time. By contrast, in Koller et al. PI values significantly decreased between 30 and 80 months of loading of two-piece zirconia implants supporting single-unit crowns (Koller et al., 2020). Adequate daily at-home implant care as well as regular attendance to maintenance recall programs are considered fundamental for the long-term success of implant treatments (Brunello et al., 2020; Heitz-Mayfield & Mombelli, 2014; Roccuzzo et al., 2010; Schwarz et al., 2021). The decision to follow supportive care programs outside the clinic at the referring dentist was left to the patients after two years of follow-up. However, despite the impact of the quality and frequency of supportive maintenance care provided could not be assessed, since the plaque scores were relatively low at the final visit, the maintenance protocols are likely not to have confounded the results.

As regards mean BOP values, in our previous investigation they significantly increased over the first 12 months, while a significant decrease was found at 24 months (Becker et al., 2017). The favourable outcome was ascribed to the effective non-surgical treatments performed between the two time points for the management of peri-implant diseases (Schwarz et al., 2015). Thereafter, BOP at the available target implants remained almost unvaried, with mean values of 14.7% (SD 17.1) and 12.9% (SD 15.8) at 2 and 9 years of follow-up, respectively. Interestingly, no statistical difference was detected in mean BOP values at 9 years between target implants previously treated for peri-implantitis with laser and the remaining implants. The opposite trend was encountered in the prospective study of Koller et al. (2020), where zirconia implants were associated with a significantly higher BOP score at 80 than at 30 months from crown fitting, with mean BOP value of 16.43% (SD 6.16) at the latest time point. Whereas, six years after loading, the modified Sulcus Bleeding Index (mBI) (Mombelli et al., 1987) values at the surviving implants were equal to 28.5% and 3% for mBI>0 and mBI>1, respectively (Cionca et al., 2021).

Among the 30 included implants, one failed. Localized PD values of 6 mm were detected only in two patients in a singular point per target implant. However, this clinical observation was not accompanied by interproximal bone loss as compared to the time of crown fitting. A higher number of sites with PD values higher than 5 mm was documented in another prospective study on two-piece zirconia implants, reaching 7.5% of sites (17 out of 222) at 6 years after loading (Cionca et al., 2021). It has to be noted that in the current study the mean PD values were found to set around 3 mm after two years of follow-up and subsequently remained constant.

As regards soft-tissue healing, median MR values of 0 mm at all time points and localized MR of maximum 1 mm (except for a 2 mm recession) in approximately 35% of the target implants included at the 9-year examination were recorded. The present data supports previous findings observed both in pre-clinical and clinical studies (Becker et al., 2017; Kohal et al., 2004; Lee et al., 2019; Liñares et al., 2016; Welander et al., 2008).

In our short-term evaluation (Becker et al., 2017), only one mechanical complication was registered, consisting in the fracture of the fibreglass abutment in a patient that did not attend the 9-year recall visit. Among the subgroup of target implants here included, the majority of the complications occurred at the abutment level. In details, the abutment was found decemented in one case, whilst the fracture of the fibreglass abutment was observed six times. Although it can be hardly proven in vivo, in some cases abutment fractures might chronologically follow their loosening. Hence, it can be speculated that the correct cementation of the abutment represents a critical

step for the long-term success of the restorations. In a retrospective study utilizing the same implant system (Brüll et al., 2014), no loss of abutment retention or integrity was reported over an observation time up to 3 years.

In other studies, zirconia abutments were connected by adhesive luting to the zirconia implants, to support cemented single-unit all-ceramic restorations (Cionca et al., 2015, 2021; Koller et al., 2020; Payer et al., 2015). In the prospective study of Cionca et al., only two abutment-related complications were reported in the short term (Cionca et al., 2015). Nevertheless, at the 6-year follow-up evaluation numerous mechanical and technical complications were registered among the 24 included patients with a total of 39 implants, in particular 6 abutment fractures and 6 cases of loss of retention at the abutment-crown complexes. In a randomized clinical trial, aside from the failed implants (2 out of 16 in the zirconia group), any mechanical or technical were reported. However, the authors emphasised the challenges related to the cementation of the abutment (Koller et al., 2020).

As this phase is deemed to be highly sensitive, it would be interesting to investigate if there is any correlation between the experience of the prosthodontist and the final outcomes. Similarly, the morphology of the abutment, the abutment material, the type of cement, the cementation technique (e.g. use of the rubber dam), as well as the implant design (i.e., bone level or tissue level) might have an effect on the abutment-implant connection.

Active matrix-metalloproteinase-8 (aMMP-8) in the peri-implant crevicular fluid (PICF) is considered an important biomarker for the onset and progression of peri-implant diseases (Ghassib et al., 2019; Ramseier et al., 2016; Wohlfahrt et al., 2014). The authors recognize the importance of assessing aMM8 levels in the PICF for research purposes. However, contrary to our previous investigation, it was decided not to collect PICF samples at the 9-year follow-up visit, because its quantification would have not modified the treatment of peri-implant diseases if detected by means of clinical and radiological examinations.

Study limitations included the relative high rate of dropouts. Nonetheless, the reason why the patients were lost to follow-up was reported and statistical analyses accounted for them (Tonetti & Palmer, 2012). Further, when data are missing not at random (i.e. dropouts are related to unobserved information or to outcome variables) they could lead to considerable bias in the results (Fewtrell et al., 2008; Kristman et al., 2004; Touloumi et al., 2002). However, there was no significant difference after 2 years of follow-up in terms of clinical variables considered (i.e., PI, BOP, PD and MR) between the participants that reached the final investigation and the 16 dropouts. Therefore, the cohort of patients included at 9 years should truthfully represent the original one in terms of compliance and clinical conditions. Other limitations of the present study include the absence of a control group and the retrospective design of the study and the lack of longitudinal assessment of interproximal radiographic bone level, due to the strict compliance with the current national legislation. As clinical parameters (BOP and PD) can be considered predictors of disease progression (Berglundh et al., 2021; Carcuac et al., 2017; Karlsson et al., 2019), the sole presence of BOP+ in absence of PD values ≥6 mm was not considered sufficient for taking x-rays. Indeed, in these circumstances the therapeutic approach would have been in the first place non-surgical no matter what.

Furthermore, it is worth noting that nowadays zirconia implants are mainly used in the front areas for aesthetic purposes; however, this material might represent a valid alternative to titanium implants also in the posterior jaws. Hence, on one side our study design with implants exclusively positioned in the posterior areas might be considered as a limitation, on the other side this makes it particularly suitable to evaluate the behaviour of two-piece zirconia implants when subjected to higher loading.

In recent studies utilizing either one- or two-piece zirconia implants, participants generally reported good satisfaction (Cionca et al., 2021; Kohal et al., 2020). This aspect could be further investigated in future studies, to longitudinally assess patients' satisfaction about the treatment and related effects on their quality of life.

Finally, it has been demonstrated that the type of abutment substrate (i.e., titanium vs. zirconia) could have a relevant impact on the microbial adhesion and colonization (de Freitas et al., 2021; de Oliveira Silva et al., 2020). It would be interesting to characterize changes overtime in individual microbiological profile associated to two-piece zirconia implants restored with cemented fibreglass abutments and all-ceramic crowns. The impact of microbiota on the clinical outcomes could also be assessed.

In conclusions, within the limitations of the present retrospective cohort study, an overall stability of the results was registered between 2 and 9 years of follow-up. Two-piece zirconia implants supporting single-unit crowns could represent a valid solution for the rehabilitation of the posterior edentulous jaws. Despite the occurrence of several mechanical and technical complications, they were all successfully solved by replacing the prosthetic components.

AUTHOR CONTRIBUTIONS

Giulia Brunello: Data curation (equal); formal analysis (supporting); writing – original draft (lead); writing – review and editing (equal). **Nicole Rauch:** Data curation (equal); investigation (equal); writing – original draft (supporting); writing – review and editing (equal). **Kathrin Becker:** Formal analysis (lead); writing – original draft (supporting); writing – review and editing (equal). **Ahmad Hakimi:** Investigation (equal); writing – review and editing (equal). **Frank Schwarz:** Supervision (equal); writing – review and editing (equal). **Jürgen Becker:** Conceptualization (equal); project administration (equal); supervision (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest related to this study.

DATA AVAILABILITY STATEMENT

Data will be provided upon reasonable request.

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