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ORIGINAL ARTICLE

Pre-fabricated zirconium dioxide implant abutments for single-tooth replacement in the posterior region: success and failure after 3 years of function

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Abstract

Objective. Zirconia implant abutments have gained a much broader clinical use over the past few years. The aim of the present study was to assess the clinical performance of a pre-fabricated zirconium dioxide implant abutment for single-tooth replacement in the posterior region. ***Materials and methods.*** Forty implants of the XiVE® S plus screw type (DENTSPLY Friadent, Mannheim, Germany) were inserted in the posterior region of 24 patients and provided with zirconium dioxide abutments (FRIADENT® CERCON® Abutment, DENTSPLY Friadent). The following parameters were used to document the state of soft tissue: modified plaque index, modified sulcus bleeding index and pocket depth. Mesial and distal bone levels were determined on radiographs during the prosthetic treatment and at the 36-month recall. ***Results.*** Thirty-seven implants could be followed up after 36 months in function. One patient wearing two abutments was lost to follow-up. One abutment exhibited a rotational misfit after 2 years in function. A further abutment showed the same failure at the 36-months recall appointment. In the remaining 36 implants the soft and hard tissue parameters were indicative of a low inflammatory status. Compared to the baseline situation, a partly significant bone apposition could be observed. Chipping of parts of the veneering ceramic was registered in 22% of the remaining implant restorations. ***Conclusions.*** The use of zirconia abutments in this study lead to mainly healthy peri-implant hard and soft tissue conditions but, considering the observed failures after 3 years in function, clinical long-term results should be awaited before recommending full zirconia implant abutments in a posterior indication.

Key Words: *Biomaterials, soft tissue-implant interactions, clinical research, clinical trials, zirconia*

Introduction

Zirconia implant abutments gained a much broader clinical use over the past few years. While aesthetic advantages compared to titanium alloy abutments are indisputable due to the tooth-like colour of all ceramic materials, biological benefits are a matter of scientific debate at the moment [1].

Unquestionable remains the fact that crestal bone stability and healthy soft tissues are considered necessary for the long-term success of implant-supported restorations. Peri-implant tissues are persistently challenged by various hazards. Bacterial plaque [2], loading [3] and prosthetic manipulation [4] are factors that may adversely affect the success of an implant. The soft tissue barrier around dental implants serves as a protective barrier between the oral environment and the underlying peri-implant bone [5]. The abutment material may be of decisive importance for the quality of the attachment that forms between the mucosa and the abutment surface [6]. The structure and function of this barrier tissue have been described previously [5]. High precious alloys, base metals and zirconia or alumina ceramics are available for fabrication of the prosthetic implant abutments [6]. However, currently, there is no evidence to show that zirconium oxide abutments perform better than titanium alloy in maintaining stable peri-implant tissues [7]. Data from animal studies and human histologic studies indicate that zirconium oxide abutments may

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have a more favourable effect on the health of peri-implant soft tissue than titanium alloy abutments [6,8]. Ceramic implant abutments have been mainly used thus far in the aesthetically demanding anterior region of the maxilla [1,9]. Nevertheless, in the meanwhile there is also some clinical data available on the use of zirconia abutments in the posterior region. Clinical and *in vitro* investigations have demonstrated the adequate load-bearing capacity of zirconium dioxide abutments for different implant systems [10,11]. Additionally, clinical trials indicate a low risk of fracture [12,13]. Nevertheless, fracture behaviour of zirconia abutments has been proved to be highly dependent on the geometry of the implant abutment connection [14,15]. Therefore, currently available clinical data on special implant systems and their respective zirconia abutments are not generally transferable to all implant systems. Zirconium dioxide abutments appear to be useful for pre-molar and molar replacement because of their obvious positive impact on the health of peri-implant soft tissue.

The aim of the present prospective study was to assess the clinical performance of a pre-fabricated zirconium dioxide (Y-TZP) implant abutment for single-tooth replacement in the posterior region. This abutment is used in combination together with a screw type implant showing an internal hexagon as connection geometry. Here, the results after 36 months in function are reported. The following hypotheses were investigated: (a) The use of this all-ceramic abutment for the above-mentioned indication is feasible and is not associated with an increased risk of fracture; and (b) the use of the abutment is associated with healthy peri-implant tissue conditions.

Materials and methods

Tested medical device, patient population and surgical/restorative treatment

We tested a pre-fabricated zirconium dioxide (Y-TZP) implant abutment (CERCON® abutment, DENTSPLY Friadent GmbH, Mannheim, Germany), in conjunction with a screw-type implant system with an internal hexagon (XiVE® S plus screw implant, DENTSPLY Friadent GmbH). The abutment is available for implant diameters of 3.8 mm and 4.5 mm, in straight and angulated (15°) design. The abutments are provided in 'neutral' and 'dentin' colours, for gingival heights of 1 mm and 2 mm. The licensed range of indications is limited to the upper and lower anterior teeth.

The recruiting of the patients as well as inclusion criteria and surgical/restorative procedures were described in detail previously [16,17].

In brief, a total of 42 implants were inserted; 40 of these were inserted by the same treating dentist (the author) following a standard two-stage protocol. Two implants had to be removed during the healing phase because of inflammation. All of the remaining implants (24 patients) were osseointegrated without complications. These could be treated with the study devices.

Nearly all abutments had to be individualized in the occlusal aspect and along the chamfer. During this process special care was taken to reduce the wall thickness of the zirconium dioxide ceramic in the cervical region as little as possible. The ceramic was worked on with a turbine (K air plus, Kavo, Biberach, Germany) and diamond grinding tools (Imago Grind, Steco-system-technik GmbH und Co. KG, Hamburg, Germany) under water-cooling.

The crowns were manufactured using a CAD/CAM system (CERCON® smart ceramics, DeguDent, Hanau, Germany). For this purpose, 38 crown frameworks modelled in wax were scanned (CERCON® brain, DeguDent), milled from a sintered zirconium dioxide blank (CERCON® base, DeguDent) and densely sintered at 1350°C (CERCON® heat, DeguDent). Two crown frameworks were constructed after scanning the model situation (CERCON® eye, DeguDent), by the use of a system-specific CAD software (CERCON® art, DeguDent), and then milled. During both types of framework production it was ensured that the thickness of the subsequent veneering ceramic was uniform. The frameworks were veneered using the system-specific veneering ceramic (CERCON® ceram kiss, DeguDent) according to the manufacturer's instructions.

The crowns were required to demonstrate centric contact, but no contact during dynamic occlusion. Any necessary adjustments were made with diamond grinding tools of 46-μm granulation (Gebr. Brasseler GmbH & Co. KG, Lemgo, Germany). Depending on the extent of corrections, either a polishing (Dialite II Polishing Kit, Gebr. Brasseler GmbH & Co. KG) or renewed oven glazing was applied. Cementation of the crowns was carried out using resin-modified glass ionomer cement (GC FujiCEM, GC Corporation, Tokyo, Japan).

The study was performed in accordance with existing laws and regulations, GCP guidelines, and the Declaration of Helsinki. Prior to the start of the trial the study protocol was inspected and approved by the ethics committee of the Medical Society of Saarland (No. 113/15).

Determination of clinical parameters

Modified plaque index (Mombelli) [18]. Analogous to monitoring patients during periodontal treatment, the following two steps were taken to evaluate the effectiveness and efficiency of oral hygiene: (a) a simple stratification was performed between the presence and absence of plaque and (b) any plaque that was

found was graded. Mombelli's classification as detailed below was used for this purpose:

- Grade 0: no plaque;
- Grade 1: plaque was found when the surface was run over with the probe;
- Grade 2: plaque was visible by the naked eye; and
- Grade 3: massive formation of dental calculus and deposits.

A plastic probe (Colorvue PCVUNC12PT, Hu-Friedy, Chicago, IL) was used to peel off the surface of the crown.

Modified sulcus bleeding index (Mombelli) [18]. With the plastic probe inserted ~ 1 mm into the peri-implant epithelium, the sulcus was scratched over its facial and oral surface. The bleeding provoked in this manner could be determined gradually.

- Grade 0: no bleeding;
- Grade 1: isolated points of bleeding;
- Grade 2: the blood forms a confluencing line at the epithelium; and
- Grade 3: massive bleeding/spontaneous bleeding.

Probing depth. The probing depth at the implant was measured at four sites (mesial, vestibular, distal and oral). A calibrated Paro probe (Click-Probe®, KerrHawe, Bioggio, Switzerland) with a perceptible clicking signal and a probing force of 20–25 g was used for this purpose.

Mobility test and percussion sound. Mobility was tested using the Periotest™ procedure (Periotest® S, Medizintechnik Gulden e.K., Modautal, Germany). The centre of the prosthetic crown was selected as the site of percussion. Care was taken to ensure that the measuring rod was placed at right angles to the implant axis. Three measurements were performed at every implant; their mean was determined and registered.

The condition of the implants was assessed by auscultation, based on percussion sound. For this purpose percussion was performed by placing the instrument parallel to the implant axis.

When a bright percussion sound was registered, the implant was considered to be osseointegrated. A dull resonance was interpreted as integration at the level of connective tissue. Implant mobility and percussion sound were determined at the time of prosthetic treatment and at the recall appointment.

Reaction of peri-implant hard tissue. For initial determination of the mesial and distal bone level in relation to the implant shoulder as well as to monitor any degeneration or apposition of bone that may have occurred, we obtained oral dental images by the right-angle technique (7 mA, 60 kV, Heliodent DS, Sirona Dental Systems GmbH, Bensheim, Germany). The necessary standardization was performed by individualizing the film holders with modelling silicone (Optosil P plus, Heraeus Kulzer GmbH, Hanau, Germany). This permitted largely identical spatial arrangement of the film, the object and the tube for obtaining consecutive images and served to minimize incorrect interpretation due to projection. The images were evaluated using the Sidexis neXt Generation software (Sirona Dental Systems GmbH) and programme-specific processing options such as optimization of contrast and brightness as well as inversion. Analogue dental films (Perfection V700 Photo, SEIKO EPSON Corporation, Japan) as well as digital films (Vista Scan, Dürr Dental, Bietigheim-Bissingen, Germany) were scanned during the study.

Based on Gomez-Roman et al.'s [19] report, the implant shoulder served as the reference point. Starting at this point, vertical measurement was performed until there was perceptible contact between implant and bone. The known length of the implant was used to calculate the dimension. If this could not be done, the known length of the inner connection of the abutment was used. Data were obtained at the time of prosthetic treatment and at the yearly recall appointments.

Results

All data were obtained by one clinical investigator (the author). Thirty-seven implant treatments could be followed at the 36-month recall.

One patient treated with two implant restorations did not appear for the recall appointment and was considered as drop-out. One patient exhibited an abutment failure after 2 years of function; a further abutment failure was detected during the 36-months recall. Both failures included a screw loosening and a rotational misfit. The patients themselves were not aware of this rotational misfit. After detecting the failures, the crowns and abutments were removed. Noteworthy is a significant amount of greyish debris inside the implant–abutment connections, which was supposed to be titanium wear (Figure 1). In order to document the failures, impressions were taken from the internal hexagon of an affected implant and from a new implant, which served as control. These were sputtered and inspected using SEM (Quanta 200, FEI, Eindhoven, The Netherlands). Comparing the images from the failed implant with those from the new implant, significant defects in the area of the internal hexagon became evident (Figures 2 and 3).

The remaining patients with 36 implant treatments were satisfied with the restorations. No fractures were found at the abutments. However, in eight out of 36 restorations (22%), fractures were registered within the veneering ceramic. These were relatively

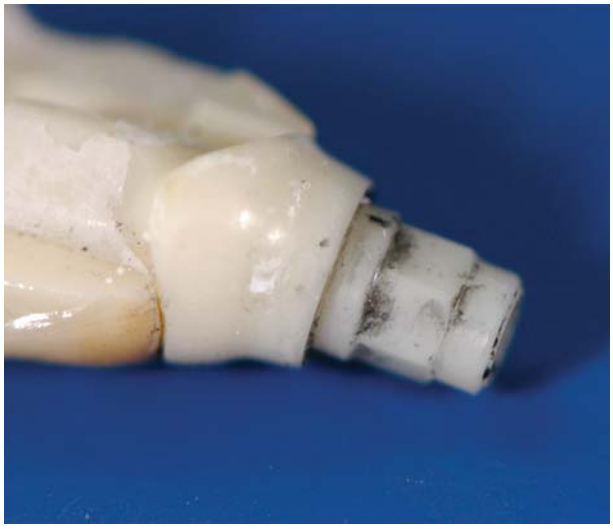

Figure 1. Image of a removed abutment after 2 years in function, which showed a screw loosening and rotational misfit. Residual titanium debris is visible in the area of the internal hexagonal connection geometry.

mild; the patients were satisfied with a polishing instead of replacing the restoration.

Modified plaque index (Mombelli) and modified sulcus bleeding index (Mombelli)

Determination of mPI revealed no plaque in 83%. The mean mPI was 0.3 (SD = 0.7), while the mean mSBI was 0.5 (SD = 0.8) (Table I).

Probing depth

Probing depths at the four sites of measurement ranged between 1–6 mm; the maximum depths were on average 2.3 mm at the mesial sites of measurement. The overall probing depths remained at a low level (see Table II).

Mobility test and percussion

During axial percussion, a bright sound was registered at all restorations. Periotest values revealed, on average,

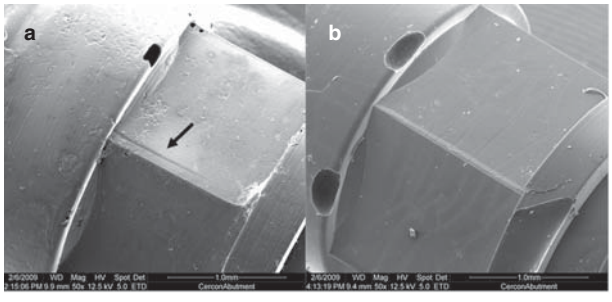

Figure 2. Gold-sputtered silicone impressions of the internal connection geometries from the implant which has supported the failed zirconia abutment from Figure 1 (A) and from a new implant (B) in the SEM. Note that there is a marked irregularity detectable (arrow) in the affected implant.

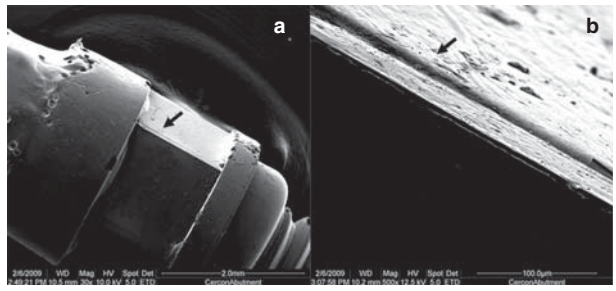

Figure 3. The same impression as in Figure 1A depicted in another viewing angle as overview (A) and close-up (B). A 'step' is clearly visible, which represents the edge of a defect of the connection geometry of the affected implant resulting from wear, presumably caused by rotational movement of the zirconia abutment.

less abutment mobility in the mandible than in the maxilla. While the mean values in the mandible remained at the same level (baseline = −4.0, SD = 1.5; 36 months = −4.0, SD = 1.7) during the first 36 months of function, a decline of −1.2 (SD = 2.7) to −1.6 (SD = 3.7) was registered in the maxilla.

Reaction of peri-implant hard tissue

Figures 4 and 5 and Table III summarize the values registered at the mesial and distal bone levels at the time of prosthetic treatment and after 36 months of functioning for the remaining 36 restorations. On average, lower values of proximal bone degeneration were registered at the mandible than at the maxilla. Mean values were higher at the distal sites of measurement than at the mesial sites of measurement. In general, bone defects in the mandible were reduced by 0.4 mm during the 36-month period of function. In contrast, the distal sites of measurement in the maxilla revealed a mild degree of additional bone degeneration by ~ 0.2 mm, while the mesial sites remained stable.

Discussion

Standard implant abutments were previously made of titanium alloy. Noteworthy features of these abutments are their soft tissue tolerability and favourable mechanical properties [6,20]. Ceramic abutments were introduced in order to facilitate aesthetic implant

Table I. Modified plaque index and modified sulcus bleeding index at 36 months in function.

	mPI 36 months, *n*	mSBI 36 months, *n*
Grade 0	30	16
Grade 1	3	10
Grade 2	2	10
Grade 3	1	—
n (total)	36	36
Mean	0.3 (SD = 0.7)	0.5 (SD = 0.8)

Table II. Probing depths at the mesial, distal, vestibular and oral sites of measurement after 36 months of implant use.

Probing depth	Mesial (*n*)	Distal (*n*)	Vestibular (*n*)	Oral (*n*)
1 mm	9	10	15	14
2 mm	12	10	11	15
3 mm	10	10	6	5
4 mm	1	2	1	—
5 mm	1	—	1	—
6 mm	1	2	—	—
n (total)	34	34	34	34
Mean	2.3 mm	2.1 mm	1.9 mm	1.7 mm

treatment in the anterior teeth. In cases of thin mucosa, Jung et al. [21,22] proved that an all-ceramic restoration material is subject to significantly less discolouration than titanium.

Independent of aesthetic aspects, the use of all-ceramic implant abutments may also provide functional benefits. Animal experiments have yielded contradictory data concerning peri-implant soft tissue health when using titanium or zirconium oxide as abutment material. In a canine model, Welander et al. [5] showed much less inflammatory infiltrates in the epithelium of peri-implant mucosa around ZrO_2 abutments compared to titanium abutments. In monkeys, Kohal et al. [23] found no evidence of a difference in the behaviour of peri-implant tissue around ZrO_2 and titanium. However, a human histology study performed by Degidi et al. [8] indicates that zirconium oxide used as abutment material in humans causes less inflammatory soft tissue infiltration than titanium alloy after a 6-month healing phase. Whether this observation was derived from the fact that the abutment material or its surface topography provides more favourable attachment properties for the surrounding connective tissue and the epithelium has not been conclusively established. Possibly, less inflammatory reactions are not merely an expression of better insulation through the soft tissue but are also due to the proven lesser accumulation of bacteria on ceramic surfaces [24,25].

In the last years the number of reported clinical trials on the use of zirconia all-ceramic abutments has enlarged but has already to be mentioned as limited. For the all-ceramic restoration of implants placed in the anterior region, promising results were published by Ekfeldt et al. [26], who reported a low incidence of zirconia abutment fractures (1%) used in conjunction with different implant systems. Recently, 5-years data of zirconia abutments installed in a posterior indication connected to an implant system with an external hexagonal implant–abutment connection were published from Zembic et al. [27]. The authors recorded no abutment fractures and similar peri-implant soft and hard tissue response compared to titanium alloy abutments, which served as control. Similar results were obtained from Lops et al. [28], who followed posterior single crown restorations with 38 zirconia and 47 titanium abutments on implants with a morse taper connection geometry over a period of 5 years. Here the authors observed no abutment fractures, but retention screw loosening on one zirconia and one titanium abutment each. Our study exhibited no abutment fractures as well as the previously mentioned studies; nevertheless, there occurred two cases of screw loosening and resulting rotational misfit. The more comprehensive investigation of the internal connection geometry of an affected implant revealed a marked defect of the internal hexagon. We assume

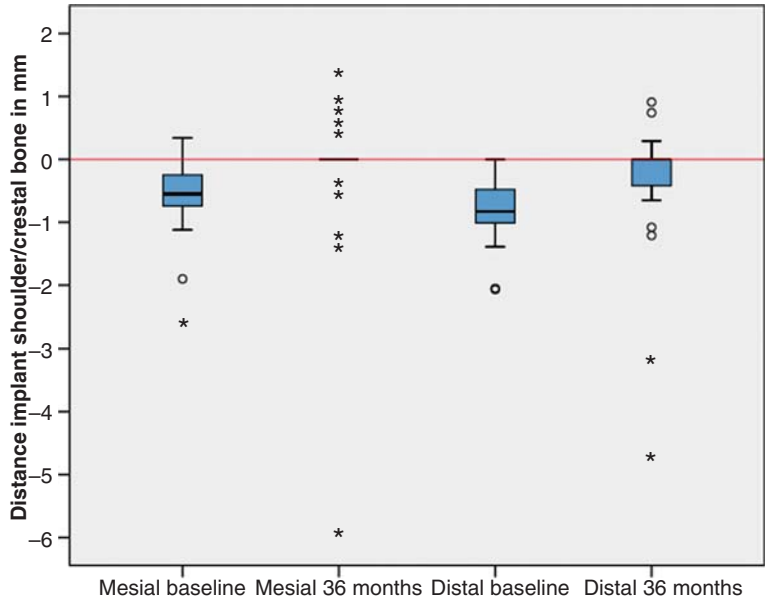

Figure 4. Measured distances between the implant shoulder and crestal bone for implants at the mesial and distal site of measurement in the mandible at the time of prosthetic treatment (baseline) and the 36-month recall.

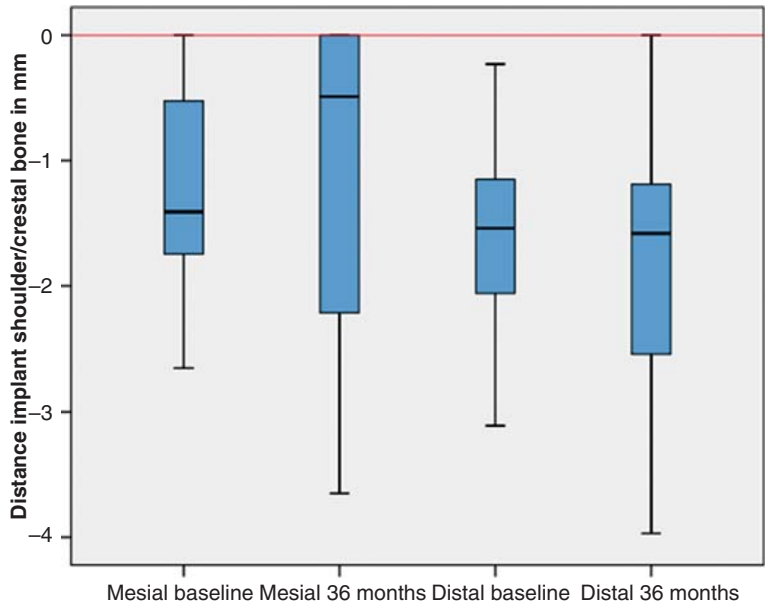

Figure 5. Measured distances between the implant shoulder and crestal bone for implants at the mesial and distal site of measurement in the maxilla at the time of prosthetic treatment (baseline) and the 36-month recall.

the quite different material properties of zirconia and pure titanium to be crucial for pronounced wear in the interface zone once rotational misfit and mobility occurs in the course of a screw loosening incident. Furthermore, it should not be excluded that screw loosening maybe is not the trigger but the result of material wear due to an unavoidable micro-movement between abutment and implant connection geometry. The occurrence of such a complication leads not only to a re-restoration in case of a definitively cemented superstructure, but bears the additional potential hazard of frequently occurring technical complications as a result of an increased rotational mobility. Increased wear between zirconia abutments and titanium implants is a problem which dental practitioners and researchers became more aware of recently, resulting in two publications, which simulated this phenomenon in experimental laboratory settings using two different types of connection geometries [29,30].

Notably, in the present investigation we registered on average a tendency towards bone apposition between the time of prosthetic treatment and the 36-month recall. This was unexpected when considering other published studies [31,32] and might be an indication of good cervical insulation by the peri-implant soft tissue which, based on the determined clinical parameters, was in a largely non-inflamed state. In this respect, we would like to address the probing of the pocket depths, which was performed in this study as part of the annually carried out recall evaluations. This procedure may be discussed critically as a routine measure as it is difficult to interpret the outcome. It has to be considered that, compared to periodontal attachment, peri-implant soft tissue provides less resistance against the penetrating tip of the probe. This could lead to higher values for the measured pocket depth and, even more importantly, to a lower grade of reproducibility [33]. Therefore, we decided to use a force calibrated

Table III. Measured distances between the implant shoulder and crestal bone for implants in the mandible and the maxilla at the time of prosthetic treatment (baseline) and the 36-month recall.

	n	Minimum	Maximum	Mean	SD
Bone level mesial, mandible, baseline	29	−2.60	0.34	−0.58	0.60
Bone level mesial, mandible 36 months	29	−5.94	1.39	−0.16	1.24
Bone level mesial, maxilla, baseline	7	−2.65	0.00	−1.23	0.97
Bone level mesial, maxilla, 36 months	7	−3.65	0.00	−1.22	1.52
Bone level distal, mandible, baseline	29	−2.07	0.00	−0.80	0.54
Bone level distal, mandible, 36 months	29	−4.73	0.91	−0.41	1.09
Bone level distal, maxilla, baseline	7	−3.11	−0.23	−1.61	0.93
Bone level distal, maxilla, 36 months	7	−3.97	−0.00	−1.86	1.34

probe for the reason of a better standardization. In our eyes, it seemed to be valuable to have the information from this measurement, because the oral and buccal aspects of the attachment could not be evaluated based on the two-dimensional radiographs [34].

When rating the outcome of hard and soft tissue measurements, it has to be considered that some patients received more than one restoration, which means that the tissue response on some restorations was determined by the integrative ability of one individual. This has to be mentioned as a limitation of the study set-up.

The relatively high chipping rate of veneering ceramic after just 36 months is also worthy of note. Published data concerning implant-borne all-ceramic restorations is scarce. In their investigation of all-ceramic implant-borne restorations, Glauser et al. [12] registered no chipping. However, the authors did not use ZrO_2-based restorations for integration, but crowns with a framework made of lithium disilicate ceramic. Furthermore, with the exception of a few restorations in the pre-molar region, the majority of the treatments were performed on the anterior teeth. Thus, the clinical loading situation cannot be reliably compared with that in the present study. For the use of tooth-borne ZrO_2-based bridges in the posterior teeth, clinical trials show different results concerning the frequency of veneer defects. Chipping rates of 0–13% have been reported for observation periods of 3 years [35–38]. A clinical trial conducted by Sailer et al. [39] reports a chipping rate of ~ 15% over an observation period of 5 years. In contrast, Molin and Karlsson [40] registered no chipping defects for the same time period and emphasized the importance of the anatomical support of the veneer provided by the frame.

Brägger et al. [41] reported significantly more frequent chipping for implant-borne metal-supported bridges than for tooth-borne restorations. In a meta-analysis, Jung et al. [42] showed that chipping may generally be expected in 4.5% of implant-borne single-tooth restorations after a functioning period of 5 years. The authors conclude that the risk of technical complications is significantly higher in cases of all-ceramic crowns than for metal-supported restorations. Clinical data concerning treatment with ZrO_2-based implant-borne restorations is scarce in the current published scientific literature. However, Larsson et al. [43] report a very high chipping rate of ~ 50% for implant-borne ZrO_2 bridges in the posterior region during a 1-year observation period. Thus, one may possibly anticipate a greater risk of chipping for implant-borne ZrO_2-based restorations. This assumption was recently well supported by a comparative clinical study on implant-borne single crown restorations conducted by Schwarz et al. [44]. The authors found a statistically significant higher incident of superficial chipping of veneering porcelain in zirconia-based restorations compared to metal-ceramic restorations after a mean functional period of 2 years. Differences compared to tooth-borne restorations might be due to the loss of periodontal receptors and the higher threshold for sensitivity to pressure as a consequence thereof [45].

The superstructures were not in the focus of this study. Nevertheless, with view on the observed technical complications of the veneered zirconia-based restorations we would like to mention all-ceramic material alternatives like lithium-disilicate or the recently developed highly translucent zirconia ceramics which both enable for the fabrication of full-contour crowns without the high susceptibility for fractures of layering ceramics.

It should be considered that the period of function described in the present report is short. Nevertheless, the applied zirconia abutments are not licensed for the use in the posterior region. This fact justifies short intervals for reevaluation and let seem the reported short-terms results to be interesting for the readership.

In conclusion, the hypotheses of the study could be confirmed after an observation period of 36 months. Under largely healthy and non-inflammatory peri-implant conditions in hard and soft tissue, no fractures were noted in the all-ceramic abutments. However, chipping of the crown veneer occurred in 22% of cases as well as a screw loosening with resulting rotational misfit in two patients. These events must be critically monitored during the further course of the study. Longer functional periods of the superstructures will have to be awaited before final clinical recommendations can be issued on the use of CERCON® abutments in the posterior region. Nevertheless, the occurring failures seem to justify the information of the profession about the current status of this clinical study. Final results will be reported after the completion of 5 years of observation.

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