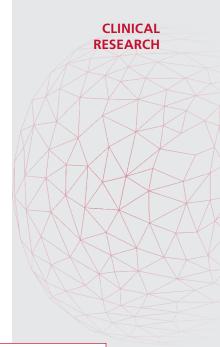
All-Ceramic Zirconium Dioxide Implant Abutments for Single-Tooth Replacement in the Posterior Region: A 5-Year Outcome Report

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Purpose: To assess the clinical performance of a prefabricated all-ceramic zirconium dioxide implant abutment for single-tooth replacement in the posterior region. Materials and Methods: Forty implants (Xive S plus screw type, Dentsply Sirona Implants) were inserted into the posterior region in 24 patients and were provided with zirconium dioxide abutments (Cercon abutment, Dentsply Sirona Implants). The licensed range of indications for these abutments is limited to the maxillary and mandibular anterior teeth. The following parameters were used to document the state of the 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 5-year recall. Results: A total of 34 functioning implants were followed up over a 5-year interval. Two patients wearing three abutments were lost to follow-up. In total, five abutments exhibited a rotational misfit during the observation period, causing significant gingival discoloration and damage to the implants. In the remaining restorations, the soft and hard tissue parameters were indicative of a low inflammatory status. Compared to the baseline situation, partly significant bone apposition could be observed. Conclusion: The observed specific type of failures after 5 years in function for full zirconia posterior implant abutments cannot be recommended, at least not in combination with the implant system used in this study. Int J Prosthodont 2019;32:177–181. doi: 10.11607/lijp.6115

mong other material variants, zirconia implant abutments have gained much broader use over the past few years in different technical specifications as one-piece abutments (made completely from zirconia), two-piece abutments (a zirconia abutment glued to a titanium base providing the connection to the implant), or so-called crown-abutments (directly anatomically veneered zirconia abutments).^{1–3}

Two primary reasons can be formulated for the increasing clinical use of and scientific interest in these ceramic restorative components. While esthetic advantages from the tooth-like color of all ceramic materials (compared to the standard titanium alloy abutments) are indisputable and well documented, the biologic benefits remain a matter of scientific debate currently because of the complex nature of soft tissue/material surface interactions. ^{4–6} Nevertheless, some data emerging from animal studies and human histologic studies have indicated a more favorable effect on the health of peri-implant soft tissues of ceramic abutments than titanium alloy abutments.^{7,8}

Experiments with zirconia abutments and their clinical outcomes have been presented in several publications by different working groups.^{9,10} The evaluated indications have ranged from incisor to molar replacement. The results of the underlying clinical studies have in general been quite promising concerning technical and biologic failure rates. Nevertheless, technical failures have been closely linked with the specific loading situation and far more with the configuration of system-specific

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Submitted September 3, 2018; accepted January 4, 2019. ©2019 by Quintessence Publishing Co Inc. implant-abutment connection geometry, as shown in a number of previously conducted biomechanical investigations. 11–15 Therefore, a general recommendation for one-piece zirconia abutments founded on clinical studies evaluating only a small number of different implant systems seems to incur risks.

The aim of the present prospective study was to assess the clinical performance of a prefabricated zirconium dioxide (Y-TZP) implant abutment for single-tooth replacement in the posterior region. This abutment is used in combination with a screw-type implant providing an internal hexagon as the connection geometry. The following hypotheses were investigated: The use of this all-ceramic abutment for the aforementioned indication is feasible and would not be associated with an increased risk of fracture; and the use of the abutment would be associated with healthy peri-implant tissue

The final results after 5 years in function are reported. The preliminary results from 0.5, 12, and 36 months have been published before. 16–18

MATERIALS AND METHODS

Tested Medical Devices, Patient Population, and Surgical/Restorative Treatment

Prefabricated Y-TZP implant abutments (Cercon abutment, Dentsply Sirona Implants) were tested in conjunction with a screw-type implant system with an internal hexagon (Xive S plus screw implant, Dentsply Sirona Implants). The abutment is available for implant diameters of 3.8 mm and 4.5 mm in both straight and angulated (15 degrees) designs. The abutments are provided in neutral and dentin colors and for gingival heights of 1 mm and 2 mm. The licensed range of indications is limited to the maxillary and mandibular anterior teeth.

The recruitment of a convenience patient sample, as well as inclusion criteria and related surgical/restorative procedures, were described in a previous publication.¹⁶

A total of 42 implants were inserted in a convenience sample of 24 patients; 40 were placed by the author following a standard two-stage protocol. Two implants failed to osseointegrate and had to be removed during the healing phase. All of the remaining implants were successfully osseointegrated.

The crowns were manufactured using a computeraided design/computer-assisted manufacturing (CAD/ CAM) system (Cercon Smart Ceramics, Dentsply Sirona Prosthetics). During framework production, it was ensured that the thickness of the subsequent ceramic veneers was uniform. The frameworks were veneered using system-specific ceramic veneers (Cercon ceram Kiss, Dentsply Sirona Prosthetics) according to the manufacturer's instructions. Cementation of the crowns was performed using resin-modified glass-ionomer cement (GC FujiCEM, GC Corporation).

This study was performed in accordance with existing laws and regulations, Good Clinical Practice 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).

Informed consent was obtained from all individual participants included in the study.

Determination of Clinical Parameters

Modified Plague Index¹⁹. Analogous to the monitoring of patients during periodontal treatment, the following two steps were undertaken to evaluate the effectiveness and efficiency of oral hygiene: (1) a simple stratification was performed between the presence and absence of plague; and (2) any plague that was found was graded. Mombelli's classification¹⁹ was used for this purpose: Grade 0 = no plague; Grade 1 = plaque was found when the surface was traced with the probe; Grade 2 = plague was visible to the naked eye; and Grade 3 = massive formation of dental calculus and deposits.

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

Modified Sulcus Bleeding Index¹⁹. With the plastic probe inserted approximately 1 mm into the periimplant epithelium, the sulcus was scratched over its facial and oral surfaces. The bleeding provoked in this manner could be determined gradually: Grade 0 = nobleeding; 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) with a perceptible clicking signal and a probing force of 20 to 25 g was used for this purpose.

Reaction of Peri-implant Hard Tissue. For initial determination of the mesial and distal bone levels relative to the implant shoulder, as well as to monitor any degeneration or apposition of bone that might have occurred, oral dental images were obtained using the right-angle technique (7 mA, 60 kV, Heliodent DS, Sirona Dental Systems). The necessary standardization was performed by individualizing the film holders with modeling silicone (Optosil P plus, Heraeus Kulzer), which allowed for largely identical spatial arrangement of the film, the object, and the tube to obtain consecutive images and served to minimize incorrect interpretation due to projection. The images were evaluated using the Sidexis neXt Generation software (Dentsply Sirona Dental Systems) and program-specific processing options, such as optimization of contrast and brightness, as well as inversion. Analog dental films (Perfection V700 Photo, SEIKO EPSON) and digital films (Vista Scan, Dürr Dental) were scanned during the study.

Based on the report of Gómez-Román et al, the implant shoulder served as the reference point. Starting at this point, vertical measurement was performed until there was perceptible contact between the implant and bone.²⁰ The known length of the implant was used to calculate the dimensions. If this process could not be performed, 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 of the data were obtained by one clinical investigator (the author), and the 34 implants were re-assessed at the 5-year recall.

One patient treated with two implant restorations did not appear for the 2-year recall appointment, and another patient stopped participating after the 4-year recall. Both were considered drop-outs. One patient exhibited an abutment failure after 2 years in function, and a further abutment failure in another patient was detected at the 3-year recall. At the 5-year recall, three further abutment failures became evident. All of these failures included 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 was a significant amount of grayish debris inside the implant-abutment connections, which was supposed to be titanium wear. To document the failures, impressions were taken from the internal hexagons of the affected implants and from the new implants, which served as controls. These implants were sputter coated with gold and inspected using scanning electron microscopy (SEM) (Quanta 200, FEI). Comparing the images of implant-abutment connections from the failed restorations to those of the new implants, significant defects in the area of the









Fig 1 (a-c) Peri-implant soft tissues surrounding three abutment failures showing a massive grayish discoloration. (d) Severe and proceeding discoloration observed in another patient with no evident screw loosening, which might be a signifier of forthcoming failure.

Modified Plaque Index (mPI) and Modified Sulcus Bleeding Index (mSBI) at 5 Years of Function

mPI	No. of implants	mSBI	No. of implants
Grade 0	25	Grade 0	21
Grade 1	4	Grade 1	9
Grade 2	0	Grade 2	1
Grade 3	2	Grade 3	0
Total no.	31	Total no.	31
Mean (SD) index score	0.3 (0.8)		0.4 (0.6)

Determination of mPI revealed no plaque in 81% of the restorations. SD = standard deviation.

Table 2 Probing Depths (PD) at the Mesial, Distal, Vestibular, and Oral Sites of Measurement After 5 Years of Function

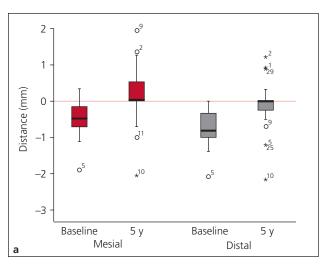
Probing depth (mm)	Mesial no. of implants	Distal no. of implants	Vestibular no. of implants	Oral no. of implants
1	13	7	13	9
2	9	11	11	15
3	4	7	-	4
4	1	2	3	_
5	1	-	-	-
6	_	_	1	_
Mean PD (mm)	1.9	2.1	1.9	1.8

internal hexagon became evident. Detailed photographic documentation of these failures and the resulting damage at the implant-abutment connections were presented in the report on the 3-year results.¹⁸

Examining the three abutment failures noted during the 5-year recall, it is remarkable that the peri-implant soft tissues showed massive grayish discoloration (Figs 1a through 1c). In another patient with no evident screw loosening, severe and proceeding discoloration could also be observed, which might be a signifier of forthcoming failure (Fig 1d).

The remaining patients with 31 implants were satisfied with the restorations. No fractures were found at the abutments.

Results for modified Plaque Index, modified Sulcus Bleeding Index, and probing depth are reported in Tables 1 and 2. The mean mesial and distal



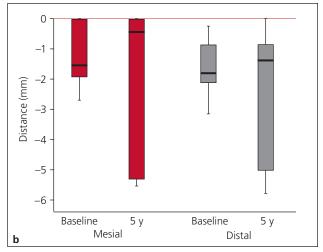


Fig 2 Measured distances between the implant shoulder and crestal bone at the mesial and distal sites of measurement at the time of prosthetic treatment (baseline) and at the 5-year recall in the (a) mandible and (b) maxilla.

Table 3 Measured Distances (mm) Between the Implant Shoulder and Crestal Bone in the Mandible and Maxilla at the Time of Prosthetic Treatment (Baseline) and the 5-Year Recall

	No. of implants	Minimum	Maximum	Mean	SD	
Bone level mesial						
Mandible Baseline 5 y	25 25	-1.90 -2.05	0.34 1.93	-0.48 0.17	0.49 0.80	
Maxilla Baseline 5 y	6 6	-2.65 -5.49	0.00	-1.23 -1.93	1.06 2.69	
Bone level dist	al					
Mandible Baseline 5 y	25 25	-2.07 -2.15	0.00 1.20	-0.74 -0.12	0.52 0.68	
Maxilla Baseline 5 y	6 6	-3.11 -5.73	-0.23 -0.00	-1.64 -2.37	1.02 2.38	

SD = standard deviation.

marginal bone level values registered at the time of prosthetic treatment and after 5 years of function for the remaining 31 restorations are summarized in Fig 2 and Table 3. On average, lower values of proximal bone change were registered in the mandible than in the maxilla. In general, bone defects in the mandible were reduced by approximately 0.6 mm over the 5-year period of function. In contrast, the measurements in the maxilla revealed a certain degree of additional bone reduction of approximately 0.7 mm.

DISCUSSION

The experimental setting and rationale for the conduct of this study have been discussed thoroughly in previously published interim reports. 16-18 Therefore, to avoid repetition, the focus here will be on the final results.

The evaluation of the collected data on the periimplant tissue status confirmed the outcomes of prior 1and 3-year recall examinations. 17,18 Regarding soft tissue parameters alone, in general, healthy conditions could be recorded. Hard tissue parameters revealed stable bone levels around the implants, and in the mandible, remarkable bone gain could be observed. The documented tissue reactions were in accordance with findings reported by other working groups investigating the clinical performance of all-ceramic zirconia abutments for different indications.²¹

However, the major observation in the present study was the large number of an unexpected type of technical complication. No fractures occurred, which confirmed the outcomes of similar investigations, 9,10 but screw loosening and subsequent damage to the internal implant-abutment connection were not reported in these investigations, which used other implant systems with different connection geometries. More precisely, these differences seem to determine the potential for specific types of technical complications. The influence of different implant-abutment connection geometries on fracture behavior was shown by the present working group in an in vitro investigation indicating that the connection type applied in the present clinical study was less prone to fracture events than conical connection geometries. 12 Screw loosening and rotational misfit of zirconia abutments under functional load were evaluated by Stimmelmayr et al and by Klotz et al regarding the example of two different connection geometries.^{22,23} In the corresponding publications, the subsequently occurring damage at the implants and the creation of titanium debris were also reported. It is assumed that the guite different material properties of zirconia and pure titanium are crucial for pronounced wear in the interface zone once rotational misfit and mobility occur in the course of a

screw loosening incident. Furthermore, it should not be excluded that screw loosening is perhaps not the trigger but the result of material wear due to unavoidable micromovement between abutments and the implant connection geometry. To the understanding of the present authors, this type of failure is even more consequential than fractures concerning clinical success. First, the occurrence of such a complication not only leads to re-restoration in cases of definitively cemented superstructures, but also bears the additional potential hazard of frequently occurring technical complications as a result of an increased rotational mobility. Second, esthetics will be compromised by the migration of titanium particles into the surrounding soft tissue with subsequent dark discoloration, which was impressively evident in the present observations. This finding is especially an issue in patients treated with zirconia abutments for esthetic reasons. Third, biologic effects and the possible harmfulness of titanium particles released into the surrounding soft and hard tissues are currently the subject of scientific evaluation and debate.²⁴

CONCLUSIONS

The study hypothesis was not confirmed over the 5-year observation period. Registered indices indicated largely healthy and noninflammatory peri-implant conditions in hard and soft tissues, but in view of the partly significant discoloration presumably resulting from released titanium particles, the second hypothesis was rejected. No fractures were noted in the all-ceramic abutments. Therefore, the first hypothesis could be accepted. However, screw loosening with resulting rotational misfit in five patients must be mentioned, given the severe potential harm to the medical device, as well as to the surrounding tissues. While not tested in a comparative study, it appears that use of one-piece posterior zirconia implant abutments cannot be recommended, at least not in combination with the implant system used in this study.

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