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Key words: bone, ceramic, clinical, dental implants, human, osseointegration, Zirconia

Abstract

Aim: The aim of this clinical trial was to evaluate the safety and efficiency of a one-piece zirconia oral implant after 1 year of function.

Materials and methods: Two centers included 60 subjects in need of implant-supported single-tooth restorations or three-unit bridges. A total of 71 zirconia one-piece implants were placed and immediately restored with a temporary reconstruction for at least 2 months. The final veneered zirconia restorations were then cemented and followed for 6 months and 1 year after insertion of the restorations. At each visit, a clinical evaluation was performed to analyze biological parameters of the implants and the neighboring teeth. A standardized periapical radiograph was taken at implant insertion, at the placement of the restorations and at the 1-year follow-up.

Results: Sixty patients with 71 implants (48 in the mandible, 23 in the maxilla) were included in this study and provided with 11 bridges and 49 crowns. Two patients with three implants (one bridge and one single crown) could not be evaluated. One patient lost his implant 5 weeks after implant insertion. Based on 58 patients, the mean survival rate was 98.3% after one year when the implants of the two patients that did not show up were not counted as lost. The mean marginal bone loss from implant insertion to the 1-year follow-up after the final prosthetic restoration was 0.78 mm with a standard deviation of 0.79 mm. The probing depth around the implants increased from 2.7 mm at insertion of the prosthetic reconstruction to 3.5 mm one year after insertion. The probing depth around the adjacent teeth remained stable at 2.5 mm. At the 1-year recall, the difference was significant. The clinical attachment levels at implants and teeth were not different at the 1-year follow-up with 3.1 mm at tooth and implant sites.

Conclusions: The presently tested one-piece ceramic implant was successful in replacing single tooth and three-unit gaps after one year of function. Further long-term data are necessary to verify these initial findings.

Within the last 40 years, endosseous screw-type implants from commercially pure (cp) titanium have become the material of choice for the fabrication of dental implants. Titanium is frequently applied in many fields of dentistry due to its biocompatibility, high corrosion resistance, and good mechanical characteristics. Cp titanium has been used as implant substrate as well as material for implant abutments for many years [Kasemo & Lausmaa 1988, 1993]. This material proved to be reliable on a middle- and long-term basis in numerous investigations. Current systematic reviews revealed survival rates of cp titanium

implants of 95.2% for single-tooth implants and 93.1% for implants supporting fixed dental prosthesis (FDP) after an observation period of 10 years (Jung et al. 2012; Pjetursson et al. 2012). These results from meta-analysis demonstrate that the implant survival of cp titanium implants is high and the therapy can be considered as safe and predictable.

Nevertheless, there is obviously a general trend in implant dentistry for metal-free solutions. On the patient side, they are informed by more or less scientific reports in the lay press that metals can be considered harmful for the body.

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On the scientific side, there are very few data revealing evidence that titanium might provoke unwelcomed host reactions. In reviewing the medical and dental literature, some investigations showed increased titanium concentrations close to titanium implants and in regional lymph nodes (Weingart et al. 1994; Bianco et al. 1996). In an investigation evaluating tissues from patients who went for a revision of their hip replacements, Lalor et al. (1991) suggested a sensitization to titanium as monoclonal antibody labeling showed macrophages and T lymphocytes in the presence of titanium particles. However, the clinical relevance of these findings is not clear yet.

Regarding the esthetic appearance, it has been reported that the color of the peri-implant soft tissue matched that of the reference tooth in no more than just over one-third of the cases (Furhauser et al. 2005). Hence, the gray color of the titanium implant and/or the abutment, respectively, might pose a problem in the esthetic areas. It has been documented that in cases with a soft tissue thickness of equal to less than 2 mm titanium revealed significantly more soft tissue discoloration compared to all-ceramic materials (Jung et al. 2007).

Based on these possible problems and limitations inherent with titanium implants, the evaluation of tooth-colored ceramic implant materials is of interest. Recently, a ceramic material for oral implants was introduced. Zirconia (zirconium dioxide, ZrO_2) as metal substitute possesses good physical characteristics, like a high flexural strength (900–1200 MPa), hardness (1200 Vickers), and Weibull modulus (10–12) (Piconi et al. 1998). Furthermore, its biocompatibility as dental implant material has been proven in several animal investigations (Akagawa et al. 1993; Kohal et al. 2003). So far, not many clinical studies with the use of zirconia implants are available yet.

The aim of this clinical study was to evaluate the safety and efficacy of a one-piece zirconia oral implant after 1 year of function for single-tooth replacement and three-unit fixed partial dentures.

Materials and methods

Study design

This study was a prospective cohort clinical trial in which subjects were consecutively included according to the inclusion and exclusion criteria. This investigation was carried out in accordance with the Declaration

of Helsinki. All procedures and materials were approved by the local ethical committees (Ethikkommission des Kantons Zürich, Ref. Nr. StV 08/10 and Ethics Committee of the Albert-Ludwigs-University, Freiburg, Germany, Application Number EK-Freiburg 241/08). Informed consent was obtained from all patients prior to the start of the study. The study was conducted as a one-arm clinical trial including two centers: Department of Prosthodontics, University Hospital Freiburg, Germany, and Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Switzerland.

Participants

In this study, 60 patients in need of implant-supported single-tooth restorations or three-unit fixed partial dentures in the upper or lower jaw have been recruited. All patients scheduled have been asked to participate in the investigation in a consecutive order, provided they fulfill the following criteria.

Inclusion criteria

- The subject should be in the age of 20–70 years old.
- The subject should be systemically healthy and have good compliance.
- The subject should be in need of an implant-supported single-tooth restoration.
- The subject should have sufficient bone height and density, that is, an osseous architecture in the implant placement region enough to receive implants of \varnothing 4.0 mm and a sufficient amount of bone for placing implants with a length of at least 8 mm.
- The osseous architecture should be such that it is possible to obtain primary implant stability, that is, final tightening torque of 35–45 Ncm.
- The subject shall have a stable occlusal relationship with no pronounced bruxism.
- The implant sites should be free from infection and/or extraction remnants.

Exclusion criteria

If any of the following criteria are applicable, the subject will not be included in the investigation:

- Alcohol or drug abuse as noted in patient records or in patient history.
- Smoking of more than 10 cigarettes per day.
- Health conditions, which do not permit the surgical procedure.

- The subject has infectious disease, heart disease or disease of the circulatory system, metabolic disease, bone metabolism disorders, disturbance of the hematopoietic system, hematological disorders, wound healing disturbances, disorders of the endocrine system (i.e., uncontrolled diabetes), pregnancy, or local contraindications (i.e., tumors and ulcers) for dental surgery as noted in patient records or in patient history.
- The subject is not able to give his/her informed consent to participate.
- The need of bone augmentation before implant installation to obtain a prosthetically correct implantation transversally. However, a minor augmentation procedure (<50% of the buccal implant surface exposed) to cover exposed threads or interproximal/buccal grafting due to deficient sites is not an exclusion criterion.
- Any disorders in the planned implant area such as previous tumors, chronic bone disease, or previous irradiation.
- Severe bruxism or other destructive habits.

Materials

This study investigated a newly developed ZrO_2 dental implant (ceramic.Implant, vita-clinical; VITA Zahnfabrik, Bad Säckingen, Germany). The implant is designed as a single-piece, tapered, cylindrical, and screw-type ceramic implant provided in lengths of 8, 10, 12, and 14 mm and in diameters of 4.0, 4.5, and 5.5 mm. The zirconia material was composed of 93% ZrO_2 , 5% Y_2O_3 , 1.9% HfO_2 , and 0.1% Al_2O_3 by weight, with an average grain size of 0.2 μ m, resulting in a flexure strength of 1500 MPa and a fracture toughness of 7.5 $MPa\sqrt{m}$.

The implants were produced by milling and subsequent hot isostatic pressing. To create a rough endosseous surface, the implants were sandblasted with alumina, etched with 38–40% HF, and finally heat-treated at 1250 °C for 1 h to reduce the monoclinic fraction (Fischer et al. 2015). The process generates a mean average roughness (R_a) of 1.2 μ m.

Interventions

Following pre-treatment examination and information, the patients that gave informed consent have been registered and scheduled for the implant therapy (Fig. 1a,b). Before implant surgery, the patient received antibiotics (2 × 750 mg Clamoxyl® for Zurich; 2 × 300 mg clindamycin for Freiburg) and analgetics (1 × 500 mg Mefenacid in Zurich;

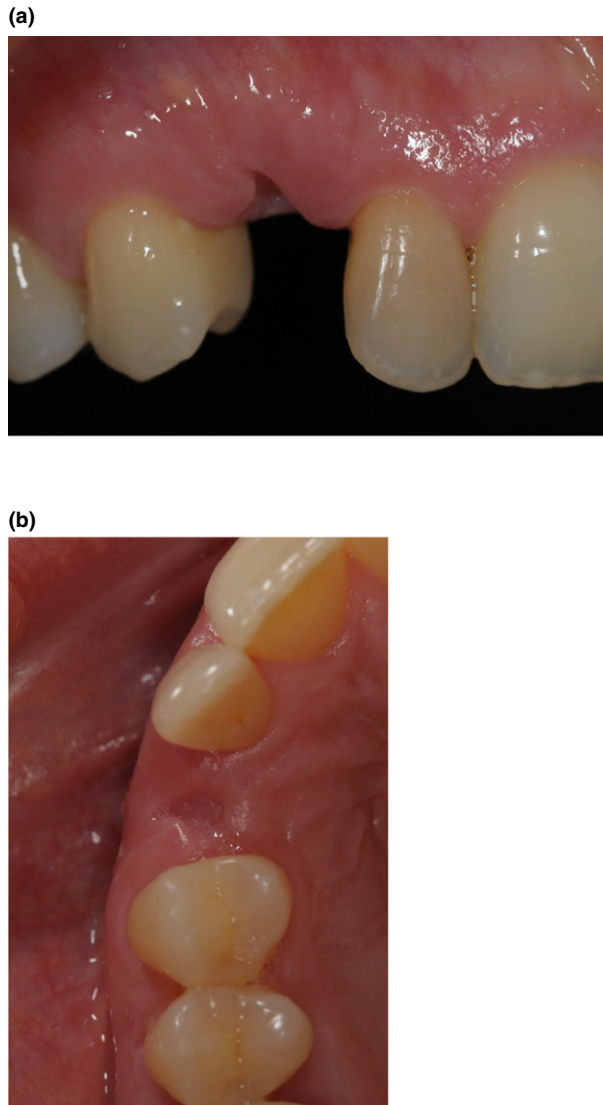


Fig. 1. (a) Preoperative view from the buccal aspect 8 weeks after tooth extraction. (b) Occlusal view revealing a central invagination after tooth extraction.

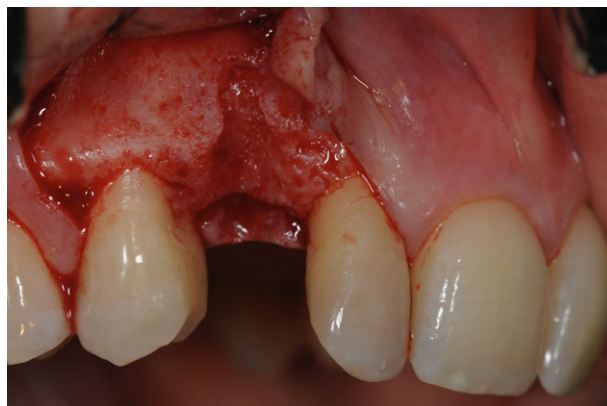


Fig. 2. Buccal view of the bone following mucoperiosteal flap elevation.

1 × 400 mg ibuprofen in Freiburg). Surgery was performed under local anesthesia. The incision was placed at the mid-crest, with releasing incisions if necessary, and a mucoperiosteal flap was raised (Fig. 2). The ceramic one-piece implants were placed

according to the manufacturer's instructions with sufficient primary stability (Fig. 3). In cases with insufficient bone and exposed implant surface, guided bone regeneration procedures were simultaneously performed at implant placement (Fig. 4a,b). These osseous defects were grafted with a natural bone mineral of bovine origin (BioOss® Spongiosa Granules, particle size 0.25–1.0 mm; Geistlich Pharma, Wolhusen, Switzerland) and covered with a standard collagen membrane (BioGide® Membrane, Geistlich Pharma). After implant placement and transmucosal healing, the implants have been immediately temporized with prefabricated provisional reconstruction made of PMMA (Fig. 5a,b). The provisional reconstructions had slight occlusal contacts (shimstock foil of 8 µm thickness could be pulled through), but care was taken to avoid excessive occlusal and lateral loads.

Postoperative treatment

The patients were instructed to rinse twice daily with an aqueous solution of 0.2% chlorhexidine and to continue the antibiotic regimen for 5 days (750 mg Clamoxyl®, three times a day for Zurich; 300 mg clindamycin, three times a day for Freiburg). In addition, analgetics (500 mg Mefenacid in Zurich; 400 mg ibuprofen in Freiburg) were prescribed for the next 2 days according to individual needs. Patients were also instructed to refrain from mechanical plaque removal in the area of implantation for 1 week. The sutures were removed 7–10 days following implantation (Fig 6).

Prosthetic insertion and follow-ups

Implants placed in the mandible have been definitively reconstructed 2 months post-surgery, while implants placed in the maxilla have been reconstructed 4 months after implant insertion (Fig. 7). The reconstructions were made of a zirconia framework (VITA In-Ceram YZ fabricated with in-Lab technology from Sirona), which was subsequently veneered (VITA VM9).

The follow-ups have been performed at 6 months and 1 year after placement of the final prosthetic restoration (Fig. 8a,b). At each visit, a clinical evaluation, radiographs, and clinical photographs have been performed. The reconstructions were classified according to the modified United States Public Health Service (USPHS) criteria. The parameters evaluated were the marginal adaptation, chipping of the veneering ceramic, the anatomical shape, and the occlusal wear. However, the reconstructions are not a

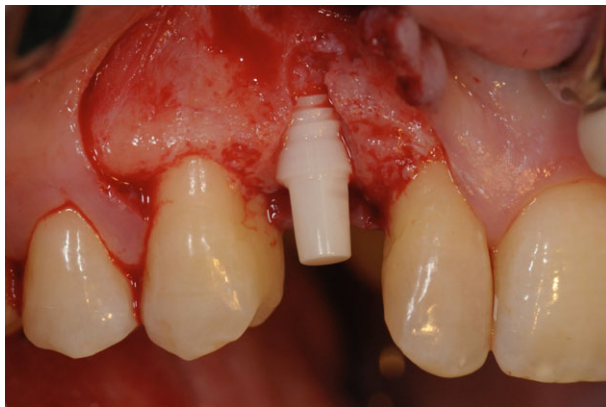


Fig. 3. Zirconia implant placed according to the prosthetic guidelines.

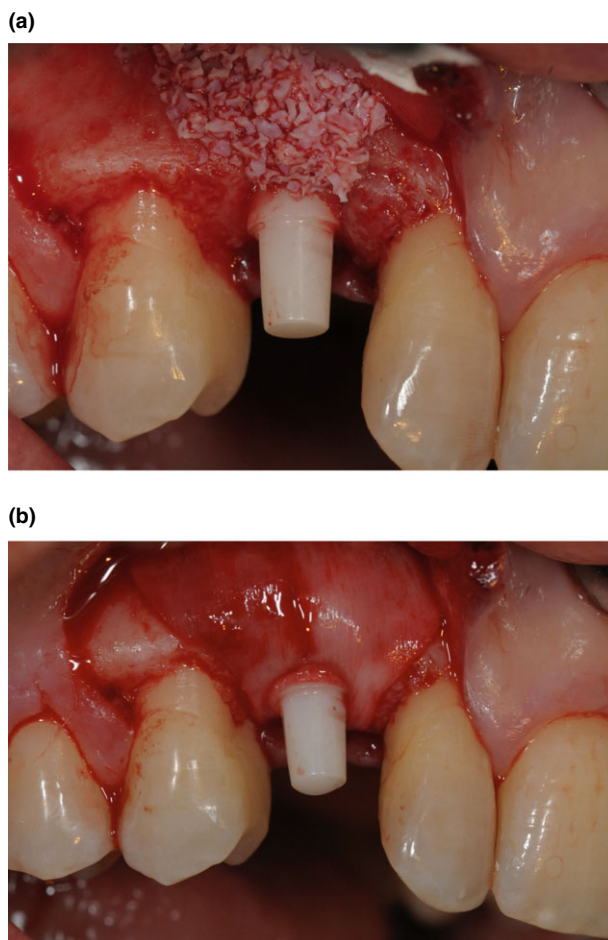


Fig. 4. (a) Bone regeneration using a natural bone mineral. (b) The graft material was covered with a collagen membrane.

topic of this report and will be reported elsewhere.

Analyses

Clinical examination

For the clinical assessment, a variety of peri-implant parameters (plaque control record (O'Leary et al. 1972), bleeding on probing, probing pocket depth, and clinical attach-

ment level, gingival recession) have been recorded at six sites per implant/tooth before treatment, at prosthesis delivery, at 6 and 12 months after insertion of the reconstruction. The same parameters were assessed for the adjacent teeth.

Radiographic examination

Reproducible intra-oral radiographs at the time of implant insertion, prosthesis

insertion, and at the 1-year follow-up visits were taken for evaluation with the help of an acrylic stent around the film holder. These radiographs have been taken with an individual stent and a long-cone parallel technique (Siegenthaler et al. 2007).

Statistical analysis

The statistical evaluation was performed at the Institute of Medical Biometry and Medical Informatics, Freiburg.

Sample size calculation

Using the Power procedure (SAS 9.1.2; SAS Institute Inc., Cary, NC, USA), the conditional probability of obtaining the desired precision was calculated, given that the interval contains the true mean (mean marginal bone resorption after 1, 3, and 5 years). For this, a standard deviation of 0.7 mm (from the literature), a 2-sided interval with a confidence level of 0.95, and a total sample size of 60 probands were assumed. The probability that the half width is ≤ 0.2 is 0.88 (if the half width is ≤ 0.21 , the probability is ≥ 0.96 , and if it is ≤ 0.22 , the probability is ≥ 0.99).

Primary objective

The expected mean marginal bone resorption after 1 year and the 95% confidence intervals were estimated in a linear mixed model. Missing values were dealt with as follows: The estimator and confidence interval at 1 year were derived from the data of all patients in whom the implant has not failed until year 1. The estimator and confidence interval were reported together with the number and percentage of patients in whom the implant has failed up to year 1. No adjustments for multiple calculations of 95% confidence intervals were made.

Secondary objectives

Successful implant rates, surviving implant rates, and cumulative implant failure rates were calculated from the date of implantation, using life-table analysis, Kaplan–Meier (product limit) methods. Patients in whom the event of interest was not observed were censored at the date of their last follow-up visit.

For the comparison of the clinical dichotomous variables (plaque control record, bleeding on probing) between the tooth and implant group, the McNemar test was performed. For the clinical continuous variables, probing depth, clinical attachment level and recession, the Wilcoxon signed-rank test was applied. The level of significance was set to 0.05.

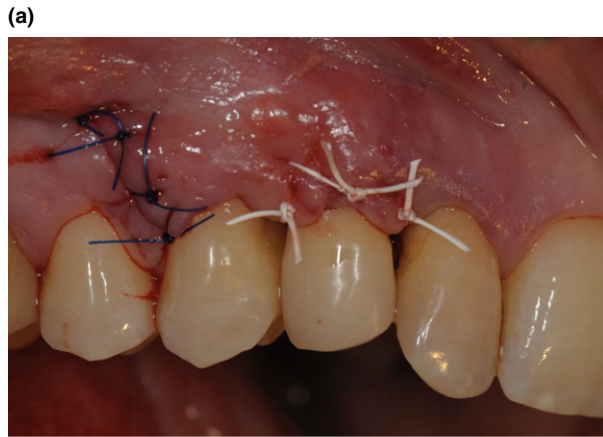


Fig 5. (a) Immediately after implant placement a temporary crown has been inserted and the mucosa adapted around the provisional crown. (b) Occlusal view of the temporary crown without occlusal contact points.



Fig. 6. At the time of suture removal 10 days after implant insertion, the healing was uneventful.

Results

Patient demographics and implant characteristics

Sixty-three patients received pretreatment examination in both centers and have signed

the informed consent. Three patients had to be withdrawn from the analysis. One of these patients did not receive an implant due to insufficient bone volume for implant placement. In two other patients, one of the inclusion criteria had been violated by placing

more than one single-tooth implant within the same patient. Nevertheless, these two patients with a total of five implants have been followed up for at least 3 years but were not included within the statistical analysis.

Hence, a total of 60 patients (30 female and 30 male) with 71 implants (48 in the mandible, 23 in the maxilla) were finally analyzed in this study. At the time of implant insertion, a variety of implant diameters ranging from 4.0 to 5.5 mm and different implant lengths from 8 to 14 mm have been placed (Table 1). The distribution of the implants according to the location in the jaws is displayed in Table 2. Six implants in the mandible and five implants in the maxilla received a bone regeneration procedure simultaneously with the implant placement.

The mean time period from implant surgery to the insertion of the final prosthesis was 5.9 months (SD ± 4.4 months) in the mandible and 6.4 months (SD ± 2.8 months) in the maxilla.

At prosthetic delivery, a total of 11 fixed partial dentures and 48 crowns have been provided to a total of 59 patients. One patient lost his implant 5 weeks after implant insertion. The implant had to be removed before delivery of the restoration due to early loss of osseointegration and resulting mobility.

Analysis of primary endpoint

Radiographic analyses

The mean marginal bone loss from implant insertion to the 1-year follow-up after the final prosthetic restoration was 0.78 mm with a standard deviation of 0.79 mm.

A linear mixed model was fitted, where within-subject dependencies (i.e., two implants within one patient) were taken into account. The response variable was defined as the difference of the mean marginal bone resorption after one year and the corresponding value taken at implantation.

As in one patient (1.4%) the implant had failed (one implant of the 71 implants), the mean marginal bone resorption was investigated in the remaining 70 implants only.

In the analysis, we adjusted for the mean marginal bone level at implantation, center, jaw, single tooth/bridge, implant diameter, and implant length. Implant diameter and implant length are categorical variables; hence, the model estimates the difference of a category to the baseline category.

The estimator for “bone level at implantation” (Table 3) indicated that a change of bone level at implantation of 1 mm leads to



Fig. 7. Four months after implant insertion the Zirconia crown has been cemented.

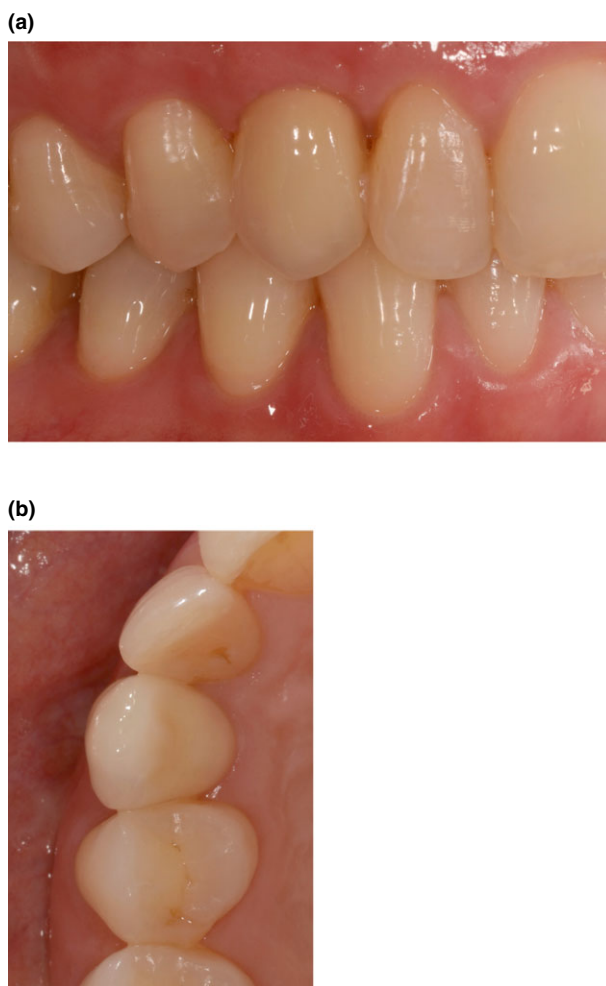


Fig. 8. (a) Buccal view of final reconstruction 1 year after crown insertion. (b) Occlusal view of cemented all-ceramic reconstruction 1 year after loading.

a change of -0.393 mm in the response variable, that is, the difference between mean marginal bone resorption at 1 year and at implantation decreases by 0.393. The estimated difference in the mean marginal bone resorption (1 year to implantation) was about a value of 0.221 mm larger for Zurich than

for Freiburg, about 0.181 mm smaller for the upper jaw than for the lower jaw and 0.08 mm smaller for a bridge than for a single tooth. For an implant diameter of 4.5 and 5.5 mm, the differences in mean marginal bone resorption were 0.034 and 0.148 units larger than for diameter 4.0 mm, respec-

tively. For an implant length of 10 and 14 mm, the differences in mean marginal bone resorption were 0.160 and 0.292 units smaller and for an implant length of 12 mm about 0.010 units larger than for length 8 mm, respectively.

None of the prognostic factors had a significant influence on the difference in mean marginal bone resorption, except for the baseline value of mean marginal bone resorption ($P = 0.005$). Yet, this factor was only considered because adjustment for the baseline value was required in change from baseline analyses according to the EMA guidance “points to consider on adjustment for baseline covariates” (European Agency for the Evaluation of Medical Products, CPMP/EWP/2863/99).

For the two patients, who have not been treated according to the protocol (violating one inclusion criterion), the mean marginal bone loss from implant insertion to the 3 and 4 years follow-up amounted to 0.7 mm. One of these implants revealed a fracture of the abutment component after the unsuccessful try to remove the crown because of a cementation mistake. No further complication occurred to these implants.

Analysis of secondary endpoint

As mentioned before, in one patient an implant had to be removed 5 weeks after implant insertion. Furthermore, one year after delivery of the prostheses, two patients with three implants (one bridge and one single crown) could not be reevaluated. One of the patients was abroad at the time point of the 1-year recall and the second patient moved away and could not be contacted anymore.

In Table 4, the rates and 95% confidence intervals for successful implants and prostheses, surviving implants, and implant failures at the date of prosthetic delivery and 1-year follow-up are presented.

Based on 58 patients with 67 implants, the mean survival rate was 98.6% after one year of function when the two patients that did not show up for evaluation were not counted as lost.

Clinical measurements

Peri-implant soft tissue conditions

For the plaque control record (Table 5), the frequencies of plaque around implants and teeth were 21.4% vs. 52.4% at the time point of crown and fixed partial denture insertion (month 0: $P < 0.0001$). This value increased until month 12 (1-year follow-up) to 38.8% for

Table 1. Numbers of implants according to implant diameter and implant length by jaw

| Jaw | Implant diameter (in mm) | No. of implants | Implant length (in mm) | No. of implants |
|----------------------|--------------------------|-----------------|------------------------|-----------------|
| Mandible | 4.0 | 15 | 8 | 6 |
| | 4.5 | 21 | 10 | 31 |
| | 5.5 | 12 | 12 | 11 |
| | | | 14 | 0 |
| Total | | 48 | | 48 |
| Maxilla | 4.0 | 11 | 8 | 6 |
| | 4.5 | 11 | 10 | 8 |
| | 5.5 | 1 | 12 | 8 |
| | | | 14 | 1 |
| Total | | 23 | | 23 |
| Mandible and Maxilla | 4.0 | 26 | 8 | 12 |
| | 4.5 | 32 | 10 | 39 |
| | 5.5 | 13 | 12 | 19 |
| | | | 14 | 1 |
| Total | | 71 | | 71 |

implants and 80.3% for teeth ($P < 0.0001$). The increase in the plaque frequency in both groups was significant ($P = 0.0007$ for implants and $P = 0.0025$ for teeth).

The mean probing depth (PD) (Table 6) at the time point of installation of the restorations was 2.7 mm at implant sites and 2.5 mm at the adjacent teeth ($P = 0.1110$). After 12 months (1-year follow-up), the PD increased significantly in the implant group to 3.5 mm ($P < 0.0001$), whereas PD decreased slightly at tooth sites (2.4 mm; $P = 0.0459$). The difference at month 12 between implants and teeth was statistically significant ($P < 0.0001$).

The clinical attachment level (CAL) (Table 7) around the implants at prosthetic reconstruction was 2.8 and 3.1 mm at the teeth ($P = 0.0115$). At the 1-year follow-up, the CAL increased at implant sites (3.1 mm; $P = 0.2167$) and remained stable (3.1 mm; $P = 0.3074$) around the teeth. CAL was not statistically significant different at 12 months between implants and teeth ($P = 0.9427$).

Bleeding on probing (BOP) (Table 8) was not different between the implants and teeth at the installation of the crowns and bridges (38.6% vs. 38.1%; $P = 1.0000$). At the 1-year follow-up, the BOP increased in the implant group to 89.6% ($P = 0.0008$) and to 52.5% in the tooth group ($P = 0.5831$). After one year, the BOP was significantly higher around implants than around teeth ($P < 0.0001$).

Gingival recession (Table 9) at baseline (installation of prostheses) was 0.7 mm at implants and 1.2 mm at tooth sites ($P < 0.0001$). The gingival recession remained stable at implants and teeth with 0.7 mm ($P = 0.6187$) and 1.2 mm ($P = 0.9680$).

Discussion

In the present prospective multicenter clinical trial, 71 implants were inserted in 60 healthy subjects. The size of this investigation is rather large when compared to other prospective investigations. In a recent clinical study, 20 patients with 20 implants have been evaluated over a two-year period (Payer et al. 2013). In a subsequent randomized controlled clinical trial with a two-piece implant system, the same authors treated 22 patients with 31 implants (Payer et al. 2014). Cannizzaro et al. included 40 patients with 40 implants in their multicenter clinical trial (Cannizzaro et al. 2010). In 2013, Kohal et al. presented a prospective cohort investigation, where 28 patients received 56 implants for the reconstruction of three-unit bridges (Kohal et al. 2013). The largest prospective investigation assessed a total of 65 patients receiving 65 implants (Kohal et al. 2012). The largest patient group treated with zirconia implants was presented in a retrospective investigation, where 378 patients were treated with 831 implants with five different

implant designs and three different surface treatment modalities (Oliva et al. 2010).

After one year, one implant was lost five weeks after implantation in the present investigation, resulting in a 98.6% survival rate after 1 year. The survival rate of implants in other investigations dealing with zirconia implants was from 98.2% (Kohal et al. 2013) and 95.4% (Kohal et al. 2013) to 87.5% (Cannizzaro et al. 2010) all after one year. In the investigations of Kohal et al., one paper was dealing with single crowns (Kohal et al. 2012) and one with 3-unit bridges (Kohal et al. 2013). In both investigations, the one-piece implants were immediately temporized after insertion. A guided bone regeneration procedure to augment small dehiscence type defects was not a contraindication and performed in about 45% of the implants. Cannizzaro et al. (2010) presented the results of 40 immediately provisionalized single-tooth implants. The authors used autogenous bone or bone substitute for filling gaps between the implant and the alveolar socket wall. Four of the five failed implants in their investigation were immediately placed after tooth extraction. The authors performed a *post hoc* analysis to evaluate a possible association between immediate post-extractive implants and increased risk of failure. The association was statistically significant as 40% of the immediate post-extractive implants failed vs. 3% of the implants placed in healed bone. The authors noted that all failures occurred with operators who were less experienced with one-piece zirconia implants.

Payer et al. reported on two-year survival rates of 95% for one-piece zirconia implants and 93.3% for two-piece zirconia implants, respectively (Payer et al. 2013, 2014). In their earlier investigation on one-piece implants, Payer et al. (2013) treated 20 single-tooth implants similar to the present investigation, namely performed an immediate temporization with all-ceramic crowns. However, patients in need for bone augmentation and for immediate implant placement were excluded. A minimum torque of 30 Ncm was a prerequisite for immediate provisional restoration. One implant of 20 was lost 4 months after placement giving the 95%

Table 2. The distribution of the implants according to the location in the jaws

| | | | | | | | | | | | | | | |
|--------------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Tooth number FDI | 17 | 16 | 15 | 14 | 13 | 12 | 11 | 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| No. of implants maxilla | 1 | 1 | 4 | 5 | 1 | 0 | 1 | 0 | 0 | 0 | 2 | 5 | 3 | 0 |
| No. of implants mandible | 4 | 11 | 4 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 7 | 13 | 6 |
| Tooth number FDI | 47 | 46 | 45 | 44 | 43 | 42 | 41 | 31 | 32 | 33 | 34 | 35 | 36 | 37 |

FDI: nomenclature according to the Federation Dentaire Internationale (World Dental Federation).

Table 3. Analysis adjusted for the mean marginal bone resorption at implantation, center, jaw, single tooth/bridge, implant diameter, and implant length

| Variable | Estimator | 95% CI | P-value |
|--------------------------------------|-----------|------------------|---------|
| Bone resorption at implantation | -0.393 | (-0.666, -0.120) | 0.005 |
| Center | 0.221 | (-0.095, 0.536) | 0.171 |
| Jaw | -0.181 | (-0.500, 0.138) | 0.266 |
| Single tooth/bridge | -0.080 | (-0.509, 0.349) | 0.715 |
| Implant diameter 4.5 relative to 4.0 | 0.034 | (-0.237, 0.305) | 0.740 |
| Implant diameter 5.5 relative to 4.0 | 0.148 | (-0.243, 0.539) | 0.506 |
| Implant length 10 relative to 8 | -0.160 | (-0.479, 0.158) | |
| Implant length 12 relative to 8 | 0.010 | (-0.349, 0.401) | |
| Implant length 14 relative to 8 | -0.292 | (-1.349, 0.766) | |

Table 4. Rates in % and 95% confidence intervals for successful implants and prostheses, surviving implants, and implant failures

| | Prosthetic delivery | 1-year follow-up |
|-----------------------|---------------------|-------------------|
| Successful implant | 98.6 [92.4, 99.9] | 98.6 [92.4, 99.9] |
| Successful prosthesis | 98.3 [91.1, 99.9] | 98.3 [91.1, 99.9] |
| Surviving implant | Not observed | Not observed |
| Implant failure | 1.41 [0.03, 7.60] | 1.41 [0.03, 7.60] |

Table 5. Comparison of the plaque frequency at implants and adjacent teeth

| Plaque in % | Implants | Teeth | McNemar test |
|--------------|------------------------|------------------------|--------------|
| 0 month | 21.4 | 52.4 | $P < 0.0001$ |
| 6 months | 39.1 | 71 | $P < 0.0001$ |
| 12 months | 38.8 | 80.3 | $P < 0.0001$ |
| McNemar test | 0 vs. 12; $P = 0.0007$ | 0 vs. 12; $P = 0.0025$ | |

0 vs. 12 = comparison between insertion of the restorations (0) and the 1-year follow-up (12).

survival/success rate. In the second investigation, Payer et al. (2014) evaluated 16 two-piece single-tooth implants that were placed in a submerged fashion. After a healing period of 4 (lower jaw) and 6 (upper jaw) months, the second-stage surgery was performed. One of the 16 implants was lost 8 months after restoration leading to “only” 93.3% survival rates.

During a mean follow-up of 3.4 years, Oliva et al. reported an overall survival rate of 95% (Oliva et al. 2010). These authors

were using five different implant designs with three different surfaces. Furthermore, simultaneous bone augmentation and sinus elevation was performed when necessary. Their first choice of “immediate restoring” the implants was vacuum stents which served as protective mean. Some implants (16.5%) in the esthetic zone received cemented provisional restorations. Forty-two of the 831 implants failed in the investigation from Oliva et al. (2010): Twenty-nine implants were lost in smokers, eight lost implants were combined with grafts, and nine failed implants were placed with simultaneous sinus lifts. The implants in the investigation of Oliva et al. (2010) were placed for the replacement of a single missing tooth and for the fixed restoration of partially and fully edentulous jaws.

Similar to the present investigation, in four further studies, the implants received a temporary restoration immediately after insertion (Cannizzaro et al. 2010; Kohal et al. 2012, 2013; Borgonovo et al. 2013; Payer et al.

2013). This is in contrast to other clinical reports where the implants were sheltered from forces in the oral cavity during the period of integration (Blaschke & Volz 2006; Oliva et al. 2010). The survival results for the implants did not differ between these investigations (irrespective of the loading protocol) with the exception of one clinical trial (Cannizzaro et al. 2010). In the latter investigation, it is reported that four of the five failures occurred with implants that have been placed into extraction sockets and which were immediately temporized. Similarly, a higher failure rate of immediately restored implants that have been placed immediately after tooth extraction was found in a study using titanium two-piece implants (Chaushu et al. 2001). In that study, the survival of immediately placed and immediately restored implants was 82% and the survival of non-immediately placed and immediately restored implants was 100%. It might be speculated that the higher failure rate of zirconia implants is not attributed to the zirconia implant material *per se* but more likely to the fact that immediate implant placement has been combined with immediate loading.

The results obtained from the present and other clinical investigations may lead to the assumption that immediate provisional restoration of one-piece implants placed in healed bone and their immediate exposure to oral forces was not a hazard for implant survival in the short-term period (Kohal et al. 2012, 2013; Borgonovo et al. 2013; Payer et al. 2013).

Besides the survival rate, the peri-implant bone remodeling/alteration/loss is of interest to rate an implant system as successful. The consensus report of session IV of the Proceedings of the 1st European Workshop on Periodontology suggested that a marginal bone loss of <1.5 mm during the first year after functional loading and of 0.2 mm annually thereafter can be regarded as a successful treatment outcome (Albrektsson & Isidor 1993). The amount of bone loss for the presented implant system from implant insertion to 1 year after implant loading was 0.78 mm in average. The time interval for the bone loss analysis was therefore longer as the one that was set as a base for the success criterion in the above-mentioned proceedings (from prosthesis insertion to 1 year). Also, other clinical zirconia implant investigations reported on the alteration of the peri-implant bone. In an investigation with 13 patients, a bone loss of 1.38 mm 6 months after implant insertion was reported (Borgonovo et al. 2013). One year after loading, Cannizzaro

Table 6. Comparison of the probing depth around implants and adjacent teeth. The four implant/tooth sites (mesial, buccal, distal, and lingual) were averaged (SD = Standard deviation)

| Probing depth in mm | Implants Mean ± SD (Median) | Teeth Mean ± SD (Median) | Signed-rank test |
|---------------------|-----------------------------------|--------------------------------|------------------|
| 0 month | 2.7 ± 0.6 (3) | 2.5 ± 0.4 (2.5) | $P = 0.1110$ |
| 6 months | 3.2 ± 0.6 (3.25) | 2.5 ± 0.5 (2.5) | $P < 0.0001$ |
| 12 months | 3.5 ± 0.7 (3.5) | 2.4 ± 0.5 (2.5) | $P < 0.0001$ |
| Signed-rank test | 0 vs. 12; $P = 0.0000$ | 0 vs. 12; $P = 0.0459$ | |

0 vs. 12 = comparison between insertion of the restorations (0) and the 1-year follow-up (12).

Table 7. Comparison of the clinical attachment level around implants and adjacent teeth. The four implant/tooth sites (mesial, buccal, distal, lingual) were averaged (SD = Standard deviation)

| Clinical attachment level in mm | Implants Mean ± SD (Median) | Teeth Mean ± SD (Median) | Signed-rank test |
|--|-----------------------------------|--------------------------------|-------------------|
| 0 month | 2.8 ± 0.7 (3) | 3.1 ± 0.9 (3) | <i>P</i> = 0.0115 |
| 6 months | 2.9 ± 1 (3) | 3.1 ± 0.9 (3) | <i>P</i> = 0.3206 |
| 12 months | 3.1 ± 0.9 (3) | 3.1 ± 0.9 (3) | <i>P</i> = 0.9427 |
| Signed-rank test | 0 vs 12; <i>P</i> = 0.2167 | 0 vs 12; <i>P</i> = 0.3074 | |
| 0 vs. 12 = comparison between insertion of the restorations (0) and the 1-year follow-up (12). | | | |

Table 8. Comparison of the bleeding on probing frequency at implants and adjacent teeth

| Bleeding on probing in % | Implants | Teeth | McNemar test |
|--|-----------------------------|-----------------------------|-------------------|
| 0 month | 38.6 | 38.1 | <i>P</i> = 1.0000 |
| 6 months | 68.1 | 48.4 | <i>P</i> = 0.0106 |
| 12 months | 89.6 | 52.5 | <i>P</i> < 0.0001 |
| McNemar test | 0 vs. 12; <i>P</i> = 0.0008 | 0 vs. 12; <i>P</i> = 0.5831 | |
| 0 vs. 12 = comparison between insertion of the restorations (0) and the 1-year follow-up (12). | | | |

Table 9. Comparison of the gingival recessions at buccal implant and adjacent teeth sites (SD = Standard deviation)

| Gingival recession in mm | Implants Mean ± SD (Median) | Teeth Mean ± SD (Median) | Signed-rank test |
|--|-----------------------------------|--------------------------------|-------------------|
| 0 month | 0.7 ± 0.3 (0.75) | 1.2 ± 0.8 (0.875) | <i>P</i> < 0.0001 |
| 6 months | 0.7 ± 0.5 (0.75) | 1.2 ± 0.8 (0.875) | <i>P</i> < 0.0001 |
| 12 months | 0.7 ± 0.2 (0.75) | 1.2 ± 0.7 (1) | <i>P</i> < 0.0001 |
| Signed-rank test | 0 vs. 12; <i>P</i> = 0.6187 | 0 vs. 12; <i>P</i> = 0.9680 | |
| 0 vs. 12 = comparison between insertion of the restorations (0) and the 1-year follow-up (12). | | | |

et al. observed a bone loss of 0.7–0.9 mm for the implants placed with different loading protocols (Cannizzaro et al. 2010). An additional clinical study reported on bone loss in a similar range of 1 mm after one year of implant placement (Payer et al. 2013). However, a higher bone loss with 1.31 mm and 1.95 mm around one-piece zirconia implants was reported by Kohal et al. (Kohal et al. 2012, 2013) with high frequencies of bone loss of ≥2 mm. A possible explanation for the increased bone loss reported in the latter two investigations might be the unique porous surface structure of these particular one-piece ceramic implants (Fig. 9).

The results of the presented zirconia oral implant investigations – with the exception of the latter two – indicate that the implant systems show minor bone resorption in the short to mid-term. The presently evaluated zirconia implant system with a bone loss of approximately 0.78 mm from implant insertion to the

evaluation one year after prosthesis insertion can be considered as successful after one year.

The bone remodeling result of the present investigation is furthermore not different to (historical) titanium implant data. A study with a comparable investigational design on immediately loaded two-piece titanium implants presented a mean marginal bone loss of 0.7 mm during the first year in function (Östman et al. 2008). In other, comparable titanium implant studies, the mean crestal bone loss after 12 months was 1.05 mm (Siddiqui et al. 2008) and 1.1 mm (Van de Velde et al. 2010), 0.83 mm after 24 months (Crespi et al. 2012), and 0.4 mm after 36 months (De Bruyn et al. 2013). Bone loss around implants with a submerged healing from implant insertion until 12–18 months after insertion was recently reported to be of 1.11–1.25 mm (Basseti et al. 2014) and of 0.54–0.88 mm (Kadkhodazadeh et al. 2013) for two-piece titanium implants.

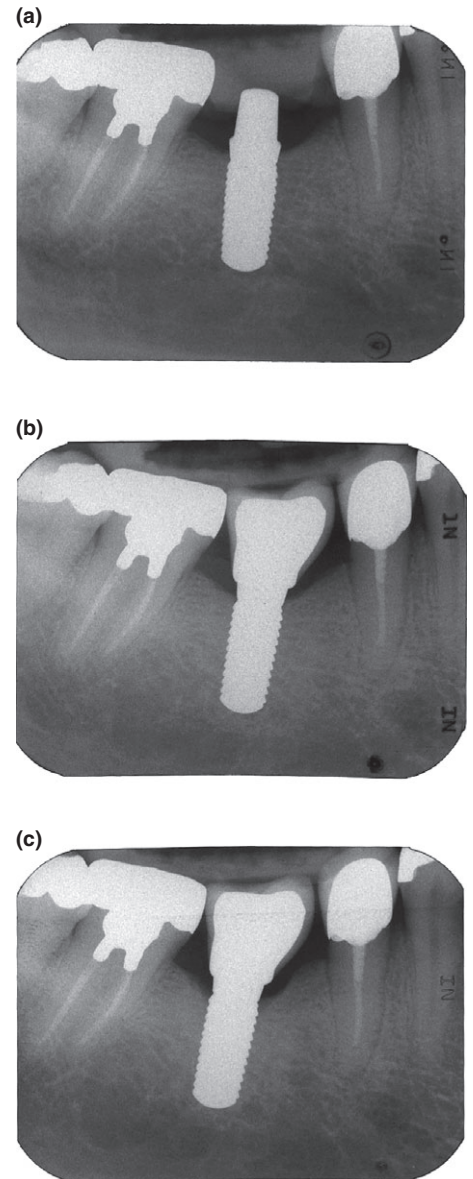


Fig. 9. Periapical radiographs at different timepoints. (a) Implant insertion. (b) Insertion of the final crown. (c) One year after loading.

The clinical parameter “plaque control record” in the present investigation revealed that there were more teeth having plaque compared to implants. The plaque record increased around teeth and implants over the 12 months from crown/ fixed partial denture installation to the 1-year follow-up. The increase around teeth was, however, more prominent than around implants. The reason for the increase in number of implants and teeth having plaque is due to the fact that the patients obviously reduced their effort in cleaning the implants and teeth. From implant insertion until the installation of the prosthetic reconstructions, the patients were seen frequently for evaluation of the wound

healing process, performing the impressions and finally rendering the restorations. At every visit, the implants and teeth were cleaned and the patients motivated to keep up their oral hygiene. From restoration placement until the 1-year follow-up, only the 6-month follow-up was in between to clean implants and teeth. The patients, apparently, could not continue with performing an optimal oral hygiene on their own over a longer time period without remotivation/reinstruction (Axelsson et al. 2004).

The probing depths were significantly higher at implants (3.2 mm; 3.5 mm) than at teeth (2.5 mm; 2.4 mm) for the 6- and 12-month reevaluation. However, higher probing depths around implants have been shown to be a normal observation (Ericsson & Lindhe 1993; Schou et al. 2002). Cutrim et al. presented probing depths of 3.3–3.4 mm at implants vs. 2.37–2.44 mm at teeth after 1 year (Cutrim et al. 2011). The difference was – as in the present investigation – statistically significant. In addition, Wolleb et al. showed a mean probing depth of 3.7 mm around implants and 2.4 mm around teeth

after a follow-up of 5 years. This difference is comparable to the difference found in the present investigation (Wolleb et al. 2012). A possible explanation for the increased probing depth around implants might be that the implant shoulder has been placed further submucosal resulting in a deeper pocket around the implants, especially in the approximal areas.

The frequency of bleeding on probing around implants increased over time and was significantly higher at the 1-year recall compared to the bleeding on probing frequency at tooth sites. This seems also to be a common finding (Chang et al. 1999; Weber et al. 2000).

There was no increase in gingival recession from the placement of the reconstruction until the 1-year follow-up. According to the literature, a recession of approximately 1 mm can be expected after abutment connection at two-piece implants and 3 months after implant placement of one-piece implants (Small & Tarnow 2000). Other authors reported that “one year after prosthesis insertion, the soft tissue shrinkage on the buccal

side of the implant crown was 0.6 mm on average” (Bengazi et al. 1996; Grunder 2000).

Summarizing the results of the clinical evaluation of the soft tissues around implants and teeth, it can be stated that the peri-implant soft tissue conditions are in a state of health after the 1-year follow-up.

In conclusion, the presented zirconia implant system showed survival and success results similar to traditional two-piece titanium implants after one year. Also, the soft tissue results were comparable to those of two-piece titanium implants. The presented zirconia implant system seems to fulfill the success criteria that have been proposed for titanium implants (Albrektsson & Isidor 1993). However, long-term data have to support the positive results that the implant system achieved after one year.

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