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Randomized Controlled Clinical Trial of All-Ceramic Single Tooth Implant Reconstructions Using Modified Zirconia Abutments: Radiographic and Prosthetic Results at 1 Year of Loading

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ABSTRACT

Purpose: This study aims to test whether or not veneering of the submucosal part of zirconia abutments with pink dental ceramic affects radiographic and technical outcomes of implant-supported single crowns (ISSC).

Materials and Methods: Single tooth implants were randomly restored with either pink-veneered zirconia abutments (test; \(n = 10\)) or non-veneered zirconia abutments (control group; \(n = 10\)) and all-ceramic crowns. At baseline (crown insertion), and 6- and 12-month radiographic and technical evaluations were performed including standardized x-rays and modified United States Public Health Service criteria (technical). Survival and complication rates were assessed for implants and restorations. Robust linear mixed model analysis was performed to investigate the effect of group and time-point on radiographic outcomes.

Results: At 1 year, the survival rate for implants was 100% and 95% for ISSC. Most of the implants were placed subcrestally. Therefore, mean marginal bone levels decreased in both groups between implant insertion and baseline (\(p < .05\)), but then remained stable up to 1 year (test: 0.15 mm ± 0.42 mm; control 0.23 mm ± 0.63 mm) (\(p > .005\)). At 6 months, one minor chipping occurred in the test group. At 1 year, three crowns (control) exhibited occlusal roughness. In addition, one abutment fracture occurred (test). The differences between test and control group were not statistically significantly different for any of the evaluated outcome measures (\(p > .05\)).

Conclusions: Veneering of the submucosal part of zirconia abutments did not affect biological and technical outcomes of ISSCs. Technical complications of the reconstructions, however, were frequent, resulting in a rate of 75% of the crowns being complication free.

KEY WORDS: ceramic abutments, crowns, dental abutments, dental implants, titanium abutments, zirconia

INTRODUCTION

Implant-borne single crowns have become a valid alternative to conventional fixed dental prostheses with high survival and success rates reported in clinical studies and systematic reviews.1–3 Traditionally, from a material point of view, metal abutments and porcelain-fused to metal crowns are considered the gold standard.2 Whereas clinical studies revealed excellent survival rates for this type of reconstruction,4–6 limitations apply mainly in terms of...
esthetic aspects. It has been reported that metal abutments can lead to a grayish discoloration of the mucosa, thereby limiting the esthetic outcome.\(^7,8\) In order to enhance the esthetic results of single-tooth implant reconstructions, a number of all-ceramic materials have been introduced. Of those, the high strength ceramic zirconia is mainly used today. Zirconia abutments and frameworks meet current clinical standards with respect to strength\(^9\) and render survival rates comparable with titanium in longer term clinical studies.\(^10,11\)

However, even zirconia might not be esthetically ideal as implant abutment or reconstruction material. Zirconia has a high light reflectance index and a low translucency and, due to this, the ceramic appears brightly white even in very low dimensions.\(^12\) Recent studies have shown that even zirconia led to a discoloration of thin peri-implant mucosa in comparison with the gingiva of the contralateral neighboring teeth.\(^2,10,13,14\) The white zirconia abutments caused too bright and pale soft tissues. The ideal color of the submucosal part of implant abutments or restorations was found to be either pink or light orange.\(^15\)

Hence, a modification of the bright white color of the zirconia seems desirable for esthetic improvement. Modifications may include generalized tinting/coloring of the zirconia blanks used for the fabrication of abutments or frameworks, or individual application of colored veneering ceramic to the fabricated white zirconia abutments. The latter option using a veneering ceramic appears to be more promising from an esthetic point of view, as the veneering may be done individually according to the desires of each clinical situation. The esthetic benefit of the veneering of the submucosal part of zirconia abutments with fluorescent light orange veneering ceramic was recently demonstrated in one clinical study.\(^16\)

It has to be considered, though, that the application of veneering ceramic to the submucosal part of abutments or reconstructions may have a biologic consequence.

Preclinical data revealed that zirconia and titanium used as abutment material demonstrated the highest biocompatibility and the least inflammatory reaction.\(^17,18\) An enhanced inflammatory reaction was observed, however, when gold abutments and veneered metal abutments were used.\(^18\)

The effect of submucosally applied veneering ceramic on radiographic and technical outcome measures is unknown today. Hence, the aim of the present study was to test whether or not veneering of the submucosal part of zirconia abutments influences radiographic and technical outcomes of single tooth implants.

**MATERIAL AND METHODS**

**Study Design/Subjects**

This study was designed as a pilot randomized controlled clinical trial at the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich. Following approval by the local ethical committee (KEK-ZH Nr. 2010-0041/5), 20 patients were consecutively recruited, having received 20 dental implants (OsseoSpeed, ASTRA TECH Implant System, DENTSPLY Implants, Mölndal, Sweden) in the anterior area of the maxilla or the mandible (incisors, canines, or premolars). The following inclusion/exclusion criteria were applied: successfully osseointegrated implants,\(^19\) no systemic disease, good oral hygiene, smokers and nonsmokers, and no signs of bruxism. All implants were to be restored with single tooth reconstructions using customized zirconia abutments (ATLANTIS Abutments shade 00, DENTSPLY Implants) and all-ceramic crowns (emax®, Ivoclar Vivadent, Schaan, Finland). At the time of the final impression (Figure 1A), patients were randomly allocated to either the test (white zirconia abutment with a pink veneered submucosal part) (Figure 2, A and B) or the control group (white zirconia abutment) (Figure 1, B and C) using a computer-generated randomization list.

**Prosthetic Protocol and Treatment Modalities**

The prosthetic protocol has already been described in detail in a previous publication.\(^20\) In brief, customized zirconia abutments were fabricated. In the test group, the submucosal part of the zirconia abutments was veneered with pink-shaded ceramic (Creation ZI G2, Klema, Meiningen, Austria) (Figure 2B). The same pink shade of the veneering ceramic was used for all patients. This pink shade was determined to match the mean color of human gingiva best in a previously performed unpublished pilot study. The thickness of the ceramic layer was standardized to 0.5 mm at the level of the abutment – crown marginal shoulder and decreased continuously towards the implant shoulder. In the control group, no modifications were applied to the white zirconia abutments (Figure 1C). The abutment shoulder height was positioned to be circumferentially
Figure 1 Control group A, Emergence profile at the time of the final impression. B, Try-in of the zirconia abutment. C, Final abutment. D, Baseline examination: all-ceramic crown 21. E, 1-year follow-up.

Figure 2 Test group A, Try-in of the zirconia abutment. B, Final abutment and final all-ceramic crown 24. C, Baseline examination: all-ceramic crown 24. D, 1-year follow-up.
1 mm below the mucosal margin. Subsequently, all ceramic crowns (Emax, Ivoclar Vivadent, Schaan, Finland) were manufactured. The abutments were fixed with a torque of 20 Ncm and the crowns cemented using a resin cement (Panavia 21®, Kuraray Medical Inc., Okayama, Japan).

Clinical Examinations and Outcomes Measures
All patients were recalled for a baseline examination (7 to 10 days after crown insertion) (Figures 1D and 2C) and at 6 and 12 months of loading (Figures 1E and 2D). At these visits, the following parameters were assessed:

Radiographic Examination. Standardized x-rays were taken at implant sites using a paralleling technique with Rinn holders and analogue films (Kodak Ektaspeed Plus, Eastman Kodak and Co., Rochester, NY, USA) at the days of implant placement, at baseline, at 6, and at 12 months. All x-rays were digitalized, and the marginal bone level was calculated at a 10× to 15× magnification using an open-source software (Image J; National Institutes of Health, Bethesda, MD, USA). The distance between the implant shoulder and the bone crest was measured at the mesial and distal aspect of the implants to the nearest 0.1 mm (distance implant shoulder to bone = DIB). The flat top of the implant shoulder and the pitch distance between two implant threads served as reference points for standardization purposes. Marginal bone level changes over time were then calculated between implant placement (IP), baseline, 6 months (6M), and 12 months (12M).

Technical Examination. Technical aspects were evaluated at 6 and 12 months according to modified USPHS (United States Public Health Service) criteria.21

In brief, the abutments and reconstructions were examined for catastrophic fracture, chipping of the veneering ceramic, abutment screw fracture, abutment screw loosening, occlusal roughness at the veneering ceramic, and decementation of the reconstructions.

All parameters were rated alpha (A) in case of no problem, bravo (B) in case of minor extent of the complication, charlie (C) if the complication was major, and delta (D) if the abutment and/or reconstruction had to be removed due to the complication.

Esthetic Examination. The esthetic outcome measures assessed at baseline were mucosal color by means of spectrophotometric measurements, and measurements of papilla height and papilla index.22 The latter parameters (papilla height and papilla index) were also assessed at 6 and 12 months.

Baseline biological and esthetic outcomes have already been reported in a previous publication.20 In the present manuscript, the radiographic and the technical outcomes observed between baseline and 6 and 12 months are reported.

Statistical Analysis
All data were analyzed descriptively calculating mean values and standard deviations. A robust linear mixed effects model by robustification of scoring equations using Design Adaptive Scale approach23,24 was used to analyze the radiographic outcomes (statistical software R, R Foundation for Statistical Computing, Vienna, Austria). Robust statistical methods provide accurate p-values even if some assumptions (e.g. normal distribution) are violated.25 The mean marginal bone level was used as the dependent variable, and group (white zirconia abutment and pink zirconia abutment) and time-point (implant time-point, baseline, 6 months and 1 year) as fixed factors and participants as a random factor were entered into the model. The Kenward-Roger approximation was used to perform F-tests and to estimate p-values for each factor and their interaction in the mixed model.26 If the factor time-point was significant in the model, additional post hoc Wilcoxon signed-rank tests were performed, and Bonferroni corrections of the p-values were applied. Significance levels were set to p < .05.

RESULTS
The mean age of the patients (13 men; 7 women) at baseline was 46 ± 15 years with a range of 21 to 69 years. The 10 implants in the test group replaced two incisors (maxilla = 1, mandible = 1) and eight premolars (maxilla = 6, mandible = 2), whereas the 10 implants in the control group replaced eight incisors (maxilla = 7, mandible = 1) and two premolars (maxilla = 2). All 20 implants (OsseoSpeed S 3.5 or 4.0; length 6 to 15 mm) osseointegrated successfully, and all crowns could be inserted as planned. No biological complications were observed at baseline. The mean time of follow-up for the 6-month examination was 7.7 months, whereas for the 12-month examination it was 14.8 months.
Radiographic Outcomes

Box-plots representing marginal bone levels at all time-points are displayed in Figure 3 (test and control separately) and Figure 4 (combined data for test and control group). The time-point had a significant effect on marginal bone level \( (F_{3,49.9} = 33.9, p < .0001) \). The mean distance between the implant shoulder and the bone crest at implant insertion (MBL impl) was 1.27 mm (standard deviation = ± 0.96 mm) in the control and 1.04 mm (±0.99 mm) in the test group (Figure 3). The mean bone level at baseline (MBL B) amounted to 0.18 mm ± 0.52 mm (control) and −0.06 mm ± 0.62 mm (test). This decrease in marginal bone level between implant insertion and baseline was statistically significant in both groups \( (p < .05) \). Between baseline and 6- and 12-months (MBL control: 0.20 mm ± 0.49 mm; 0.23 mm ± 0.63 mm; MBL test: −0.05 mm ± 0.40 mm; −0.15 mm ± 0.42 mm), the marginal bone levels remained stable in both groups \( (p > .005; \text{Bonferroni corrected}) \). No statistically significant differences were observed between the two groups at any time-point (factor group: \( F_{1,16.3} = 2.02, p > .05 \)).

Technical Outcomes

All data are displayed in Tables 1 and 2. At the 6-month recall, a minor chipping (B) was observed at one crown in the test group; no chipping of the veneering ceramic happened in the control group (Table 1). At the 1-year follow-up, three crowns in the control group exhibited occlusal roughness. The rate of minor chippings (B) at 1 year was therefore 5% (including all crowns). Crown loosening occurred on one implant in the test group between 6 and 12 months (Table 2). An access hole was drilled through the cemented crown and the abutment/crown retightened. Four weeks later, the crown was loose again, and upon inspection presented a fractured abutment. The fracture had happened in the internal part of the implant-abutment connection. A new abutment and crown was fabricated and inserted. The rate for abutment fractures was therefore 5% (including all crowns) at the 1-year follow-up. Other than mentioned, no more failures and complications occurred, and all other crowns were rated “A” according to the USPHS criteria at the 6- and 12-month follow-up.

The overall number of crowns being complication free was 75% at 1 year.

DISCUSSION

The present study revealed i) that veneering of the submucosal part of zirconia abutments did not affect biological and technical outcomes of single tooth implant crowns; ii) a 100% implant survival rate; iii) a minimal bone loss between baseline (insertion of final reconstruction) and 1 year of functional loading; iv) a relatively high technical complication rate with only 75% of crowns rated as complication free.

The survival rate of dental implants supporting single crowns is high, as reported in a recent systematic review with an estimated mean 5-year survival rate of 97.2% (95% confidence interval [CI]: 96.3–97.9%) and 10-year survival rate of 95.2% (95% CI: 91.8–97.2%). In the present study, no implant failures occurred, rendering a 100% survival rate at 1 year of functional loading. Yet, the present observation period is rather short. Based on the above-mentioned systematic review,
implant failures after loading occurred with an estimated annual failure rate of 0.29 (95% CI: 0.17–0.47) over 5 years.2

The marginal bone levels in the present study were assessed firstly at implant placement and subsequently at abutment/crown insertion up to 1 year of loading. The marginal bone exhibited the highest levels at implant placement indicating that most implants were placed below the bone crest. This is common in clinical situations in the esthetic zone in order to leave room for the emergence profile of the reconstruction. In addition, this is often typical for the use of platform-switched implants, at which the prosthetic diameter is even smaller at the implant-abutment connection zone than the one of the implants themselves. The present study, however, showed that this marginal bone level decreased over time due to bone resorption. One might speculate that the bone above the implant shoulder was not supported by the implant, that is, no load was transferred to this bone, thereby leading to bone resorption, predominantly following implant placement. The greatest decrease in marginal bone levels occurred between implant insertion and baseline. This is in agreement with previously published clinical data and preclinical data.27,28 Data from preclinical and clinical studies demonstrated that following the insertion of dental implants, a biological integration reaction starts, ending with the establishment of the biologic width.28–31 This biologic reaction of the peri-implant soft tissues is considered to be physiological and not inflammatory related and specific for each implant design.32 Hence, under healthy conditions, the marginal bone levels ought to be stable. At 1 year of loading, the marginal bone levels in the present both groups were slightly apical (control) or coronal (test) to the implant shoulder. Similar stable marginal bone levels at 1 year of loading were reported earlier for this implant system.33,34

The rate of technical complications, however, was high during the present short-term observation. Technical problems at the 1-year follow-up affected 25% of the crowns (or five out of 20 crowns). This included complications such as minor chipping, occlusal roughness, and loss of retention due to a framework fracture. In general, technical complications are frequently reported for fixed reconstruction on dental implants. In a systematic review on single-tooth implant-borne reconstructions, the cumulative 5-year complication rate for technical issues reached 0.4% (abutment screw

Figure 4 Box-plots representing median and interquartile range of marginal bone levels (mm) for all implants over time. Positive values represent marginal bone levels located more coronal than implant shoulder, whereas negative values indicate marginal bone levels located more apical than implant shoulder (bone loss). Circles indicate outliers. Numbers on top of the circles represent respective study subject number.
<table>
<thead>
<tr>
<th></th>
<th>Alpha (A)</th>
<th>Bravo (B)</th>
<th>Charlie (C)</th>
<th>Delta (D)</th>
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<tbody>
<tr>
<td></td>
<td>Fracture of framework</td>
<td>Fracture of veneering ceramic</td>
<td>Occlusal roughness</td>
<td>Loss of retention</td>
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<td></td>
<td>Test</td>
<td>Control</td>
<td>Test</td>
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<td>10</td>
</tr>
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<tr>
<td>No fracture</td>
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<td>100%</td>
<td>100%</td>
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<tr>
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<td>0%</td>
<td>0%</td>
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<tr>
<td>Major chipping, up to framework</td>
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<tr>
<td>No roughness</td>
<td>10%</td>
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<td>Slight roughness, $\varnothing&lt;2\text{ mm}$</td>
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<td>Obvious roughness, $\varnothing&gt;2\text{ mm}$</td>
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<tr>
<td>Reconstruction needs to be replaced</td>
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$n = \text{number of patients.}$
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<th>Charlie (C)</th>
<th>Delta (D)</th>
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<tbody>
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<td>Minor chipping, polishable</td>
<td>Major chipping, up to framework</td>
<td>Fracture = loss of reconstruction</td>
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<td><strong>Fracture of veneering ceramic</strong></td>
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<td>Obvious roughness, $\varnothing &gt; 2$ mm</td>
<td>Reconstruction needs to be replaced</td>
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<td>Abutment (loosening)</td>
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<td><strong>Loss of retention</strong></td>
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$n = \text{number of patients.}$
fracture), 8.8% (screw loosening), 4.1% (loss of retention), 3.5% (ceramic chipping) and 1.3% (framework fracture).\(^2\) One has to bear in mind that most of the clinical studies that provided more detailed data on the reconstruction material (26 studies) for this specific systematic review reported on porcelain-fused to metal (PFM) crowns. Only a limited number of studies contributed with outcomes of all-ceramic implant-borne reconstructions. From a statistical point of view, no significant differences between PFM and all-ceramic crowns were calculated, yet this result needs to be judged cautiously due to the low number of included all-ceramic crowns (10% and 211 all-ceramic crowns compared with 76% and 1572 PFM crowns). Still, data on all-ceramic implant-supported single crowns (ISSC) demonstrated, however, that these reconstructions present survival rates comparable with the PFM crowns.\(^11,35–37\)

In the present study, one out of the 20 one-piece internally connected zirconia abutments fractured during the first year of loading. The abutment fractured at the internal part of the implant-abutment connection. From a technical point of view, the type of connection between the abutment and the dental implant may play a crucial role.\(^38\) In a series of in vitro studies, the strength of different types of zirconia (test) and titanium (control) abutments was tested. It was shown that zirconia abutments in general exhibit less strength than titanium abutments.\(^39–42\) It was further demonstrated that the strength of zirconia abutments/reconstructions is influenced by the implant-abutment connection. One-piece internally connected zirconia abutments demonstrated lower strength (bending moments) compared with other types of connections.\(^40\)

Clinical documentation on one-piece internally connected ceramic abutments is scarce, and the translation of the laboratory findings into clinical reality is difficult.

The data currently provided for internally connected zirconia abutments show similar biological outcomes, better color match, better esthetics on the soft tissue level, but higher frequency of marginal discrepancy compared with metal abutments.\(^10,14,43\) Still, most of the positive clinical outcomes published so far on zirconia abutments were observed for all-ceramic reconstructions on dental implants with an external hexagon.\(^11,35\)

Only long-term randomized controlled clinical trials provide the necessary evidence to either reject or support a certain type of reconstruction or material for the clinical use. The present randomized controlled clinical trial showed positive radiographic outcomes of the ceramic single implant reconstructions on the pink veneered and un-veneered zirconia abutments with no differences between the two types. Yet, although occurring similarly in the test and control groups, the number of technical complications was rather high considering the short preliminary observation period.

**CONCLUSION**

The present clinical study revealed veneering of the submucosal part of zirconia abutments did not affect biological and technical outcomes of single tooth implant crowns. Overall, a high implant survival rate and minimal marginal bone loss between the insertion of the final reconstruction and the 1-year follow-up. Technical complications of the reconstructions, however, were frequently observed. The overall rate of crowns being complication free was only 75%.

**ACKNOWLEDGEMENTS AND CONFLICT OF INTEREST**

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