A Pilot Study of Small-Diameter One-Piece Ceramic Implants Placed in Anterior Regions: Clinical and Esthetic Outcomes at 1-Year Follow-up

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Purpose: The aim of this study was to evaluate the clinical, esthetic, and patient-reported outcomes of one-piece zirconia implants placed in incisal areas using digital surgical templates after 1 year of follow-up. Materials and Methods: Patients who had lost an anterior tooth received a 3.3-mm-diameter zirconia implant placed by computer-guided surgery. Implant survival and soft tissue conditions were assessed periodically 1 week, 3 months, 6 months, and 1 year after loading. Standardized radiographs were taken at definitive prosthesis insertion and 1 year postloading to evaluate peri-implant bone loss. Additionally, theesthetic outcomes and patient-reported outcomes were also investigated. Results: Twenty zirconia implants were placed in 20 patients with no implants lost, resulting in 100% survival rates. A minor change in the mean marginal bone level (0.14 ± 0.87 mm) was found between definitive prosthetic loading and 12 months later. Peri-implant soft tissue remained stable throughout the observation period. The mean Pink Esthetic Score and White Esthetic Score were 12.05 and 8.60, respectively, while the mean Gingival Papilla Index scores were 93.3 ± 7.8, 95.1 ± 5.3, 93.6 ± 7.6, and 94.5 ± 6.2 mm, respectively. Conclusion: For the 1-year results, 3.3-mm-diameter one-piece ceramic implants placed by computer-guided surgery showed favorable clinical performances with no failure when used for single-tooth replacement in anterior regions. Int J Oral Maxillofac Implants 2020;35:965–973. doi: 10.11607/jomi.8308

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Dental implant therapy has been shown to improve the oral comfort and oral health–related quality of life (OHRQoL) of patients. In particular, for anterior tooth replacement, an improvement in OHRQoL has been observed both in terms of esthetics and function in patients who had lost at least one tooth in the frontal area.

Dental implants have generally been made of titanium or its biomedical alloys due to their good mechanical properties, high corrosion resistance, and excellent biocompatibility. Previous clinical studies showed implant survival rates of more than 95% for a sand-blasted and acid-etched (SLA) surface with a follow-up period of at least 10 years. However, controversy still exists regarding titanium corrosion products and their allergic reactions. A new study has demonstrated that titanium particles can induce an inflammatory response, resulting in bone loss; and that, in susceptible patients, titanium can induce hypersensitivity, potentially leading to implant failure. Additionally, one major drawback of titanium implants is the esthetic compromise due to their gray color. The discoloration, as a metal shadow, may be visible through the peri-implant mucosa, especially when a missing anterior tooth is replaced in a patient with a thin gingival biotype or high smile line. Several studies with spectrophotometric analyses have documented that a ceramic material shows less discoloration through the gingival margin compared with titanium.

Recently, the growth of esthetic demands has prompted the use of ceramic as an alternative material for dental implants. Yttria-stabilized zirconia (yttria tetragonal zirconia polycrystal [Y-TZP]) was proposed for the fabrication of ceramic dental implants due to its superior biomechanical properties. Preclinical research has shown comparable osseointegration for zirconia...
and titanium implants, particularly after surface roughening. Apart from their color, zirconia implants appear to offer other advantages, including reduced in vitro bacterial biofilm formation and fewer inflammatory cells, thereby improving the soft tissue around dental implants and reducing the risk of peri-implantitis. A recent systematic review has indicated favorable clinical outcomes for zirconia implants, with 98.3% survival rates after 1-year follow-up.

Tooth replacement in anterior regions is a major challenge for most clinicians due to the physical structure, which is often found with thin ridge width and limited interdental space. In order to obtain a successful esthetic outcome and to stabilize peri-implant tissue, small-diameter implants (< 3.5 mm) seem to be a predictable option in the incisal areas. The 3.3-mm-diameter zirconia implants used in this study are highly capable of withstanding mechanical loading forces in the anterior regions. However, limited clinical data are available concerning the outcomes of zirconia dental implants with diameters of less than 4 mm.

The objectives of the present study were to evaluate the clinical performance, including success rates, marginal bone loss, and peri-implant soft tissue status, of one-piece 3.3-mm-diameter zirconia dental implants placed in esthetically demanding areas utilizing a digital surgical template after 1 year. Esthetic outcomes and patient satisfaction were also investigated.

**MATERIALS AND METHODS**

All the study materials and methods were approved by the Institutional Review Board of the Faculty of Dentistry/Faculty of Pharmacy, Mahidol University (COA no. MU-DT/PY-IRB 2016/018.1803) and complied with international guidelines for human research protection. Patients who presented at the Implant Center, Faculty of Dentistry, Mahidol University, between May 2016 and May 2017 and who met the eligibility criteria were recruited. In total, 20 patients who had lost one of their anterior teeth (central or lateral incisor) in the maxilla or mandible were included in the study. Patients were excluded if the following criteria applied: general contraindications for oral surgery; pregnancy; heavy smoking, ie, more than 10 cigarettes per day; active periodontitis; inadequate posterior occlusal support; a history or signs of parafunctional habits, including clenching and bruxism; inadequate peri-implant architecture; and the need for extensive hard and/or soft tissue augmentation (simultaneous bone augmentation with implant insertion was accepted).

**Surgical Procedures**

All enrolled participants underwent cone beam computed tomography (CBCT, 3D Accuitomo 170, J. Morita) prior to the implant surgery. The radiographic data from the CBCT with a radiopaque marker for the future prosthesis and the surface scan of a study cast were superimposed in the coDiagnostiX planning software (Dental Wings) to locate the 3D implant position, ie, minimum of 1.5 to 2 mm from the adjacent teeth, 1 mm palatal to the ideal point of emergence, and 2 mm apical to the midfacial gingival margin of the implant restoration. The surgical template was then fabricated for each patient.

The surgery was done under local anesthesia. After flap elevation, the implant site was prepared using the Straumann Guided Surgery instruments for a one-piece ceramic implant (Straumann PURE Ceramic Implants, Institut Straumann), and the surgical protocol was strictly followed from the first to the final drilling. Next, the one-piece ceramic implant was manually inserted with a handpiece insertion torque of 30 Ncm. In some cases where the bone volume was deficient, the contour augmentation could be done simultaneously by the guided bone regeneration technique with xenograft (Geistlich Bio-Oss, Geistlich Pharma North America) and collagen membrane (Geistlich Bio-Gide, Geistlich Pharma North America). To fabricate the immediate provisional crown, the plastic provisional cap from the manufacturer had been seated on the implant abutment before the prepared shell crown was relined in place using a self-curing acrylic material. After shaping and polishing, the provisional restoration was cemented on the implant abutment with zinc phosphate cement. Excess cement was completely removed, and centric and eccentric occlusal contacts were then removed to avoid any excessive forces on the implant.

**Prosthetic Procedures**

Three months after implant placement, a final impression was taken at abutment level using an impression cap. Polyether was used as the impression material, and the crowns were made of either lithium disilicate or zirconia. On the day of prosthesis insertion, the restoration was checked for color, contact, contour, and marginal adaptation. The occlusion was adjusted to achieve light centric contact and no eccentric contact. All-ceramic crowns were cemented to the implant abutment using self-adhesive resin cement (RelyX U200, 3M ESPE).

**Follow-up Protocols**

Each patient attended follow-up visits at 1 week, 3 months, 6 months, and 12 months after prosthesis insertion by one of the authors. The following were
assessed during these visits: implant survival and success, marginal bone loss, peri-implant soft tissue status, esthetic outcomes, and patient perception.

Implant survival was defined as implant existence in the mouth at the time of examination. Implant success was defined as the absence of implant-related complications over the entire observation period. In this study, the success of the implant was strictly evaluated at 12 months after prosthesis insertion according to the following success criteria of Buser et al: absence of recurrent peri-implant infection with suppuration; absence of persistent subjective complaints, such as pain, foreign body discomfort, and/or dysesthesia; absence of continuous radiolucency around the implant; and absence of any detectable implant mobility.

Crestal bone level data were obtained from periapical radiographs recorded at two time points: on the day of prosthesis insertion as baseline and 12 months after insertion. The individual biting jig, custom-made from GC pattern resin (GC Corporation), was used with an anterior periapical film holder (Hanshin) during radiograph recording to ensure identical positioning of the radiographic sites. The mesial and distal bone levels of the implants were measured from the implant shoulder to the first bone-to-implant contact using a PACS software ruler tool (PACS by HNMiracle, version 1.0.0.0), as shown in Fig 1. The bone levels at different time points were compared. Additionally, the vertical distances between the contact point and the peak of crestal bone were measured on the radiograph.

Peri-implant soft tissue was examined at five time points: on the day of prosthesis insertion and 1 week, 3 months, 6 months, and 12 months after prosthesis insertion. A periodontal probe (Hu-Friedy) was used to measure the probing pocket depth at six surfaces: mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual. The angulation of probing conformed with the shape of the restoration beneath the gingiva. The results were reported to the nearest millimeter on the probing scale. Furthermore, plaque accumulation and bleeding on probing were investigated and stated to be present or absent.

The intraoral photographs were taken at 1 week and 12 months after prosthesis insertion. The photographs were taken at right angles to the central incisor in the maxilla or mandible and covered the canines from right to left. Three esthetic indices were used in this study: the Pink Esthetic Score (PES), White Esthetic Score (WES), and Gingival Papilla Index (GPI) according to Jemt’s Classification (1997). The esthetic analyses were performed by a dental implant specialist who was familiar with all the indices and had not been involved in the treatment of any patients. The examiner performed each esthetic evaluation twice on different days to reduce bias and ensure optimum reproducibility.

Patient perception was assessed after 1 year of prosthesis insertion. The open-ended questionnaires on the overall treatment procedures, speech, masticatory function, and esthetics were printed out and given to the patients. The patients were instructed to answer the questions according to their own perception on the 10-cm line of the visual analog scale (VAS), a line labeled with the worst experience at one end and the best experience at the other end. This scale was used to convert a subjective experience into a numeric score.

Statistical Analysis
The survival and success rates for the one-piece zirconia implant were calculated and presented as percentages. After testing for normal distribution, the pretreatment to posttreatment changes in crestal bone level were compared using the nonparametric Wilcoxon signed rank test for related samples per implant. The changes in probing pocket depth and the presence of plaque and bleeding on probing during the observation periods (1 week, 3 months, 6 months, and 1 year after prosthesis loading) were estimated by repeated-measures analysis of variance (ANOVA). The PES, WES, and GPI scores at the 1-week postloading and 1-year postloading follow-up visits were compared with the paired t test after testing for normal distribution. The adjusted P values are reported at the significance level α = .05. All calculations were carried out using SPSS 21 (IBM).

RESULTS
At the day of implant surgery, 20 zirconia dental implants achieved more than 30 Ncm of insertion torque; therefore, immediate provisional crowns were placed with no occlusal contact. All implants were restored with ceramic crowns as definitive restorations after 3
months. The patient demographics are described in Table 1. No patients dropped out during the 1-year follow-up periods. All 20 implants were functioning normally at the last follow-up visit, resulting in a 100% survival rate. When considered according to the criteria of Buser et al, the success rate for the one-piece zirconia dental implants in this study was 100% after 1 year of function. No complications arose during the surgical or prosthetic procedures.

The crestal bone levels were measured digitally from the periapical radiographs twice: on the day of prosthesis insertion as baseline and at the 1-year follow-up visit (Figs 2 and 3). The mean values for marginal bone levels are shown in Table 2. At the 1-year follow-up, the change in mesial bone levels was 0.14 ± 0.98 mm, while the change in distal bone levels was 0.14 ± 0.85 mm. Ten of the 20 implants (50%) showed a slight bone gain after 1 year, while eight implants (40%) showed a marginal bone loss of less than 1 mm, one implant (5%) lost 1 to 3 mm of bone, and one implant (5%) lost more than 3 mm of bone. The statistical analysis exploring the change in marginal bone levels revealed no significant differences between the marginal bone levels at baseline and at the 1-year follow-up (Wilcoxon signed rank test; \( P = .823 \)).

The results of the soft tissue examination, including the probing pocket depth and the presence of plaque and bleeding on probing, are presented in Table 3. No statistically significant differences in the mean probing depth were found between any of the visit intervals (repeated-measures ANOVA; \( P = .161 \)). The percentages for the presence of plaque and bleeding on probing are presented in Table 4. No plaque was detected on any of the zirconia implants at any point during soft tissue examination. The highest percentage for sulcus bleeding was found at the first follow-up, ie, 39.16%, dropping to 16.66% at 3 months, 17.50% at 6 months, and 16.66% at 12 months. This decrease in bleeding on probing was statistically significant (\( P < .001 \)). No fistulas and no cases of gingival discoloration were detected.
The overall esthetic results are shown in Table 4. Figure 4 shows the intraoral images of the cases at the 1-year follow-up visit. The mean PES of 11.25 ± 1.16 was observed at 1 week and had improved at the 1-year follow-up visit to 12.05 ± 1.09. This difference was statistically significant (paired $t$ test; $P < .05$). Figure 5 shows the PES for each parameter. With respect to WES, the mean value observed for all included patients showed similar results between the first follow-up at 1 week (8.50 ± 1.23) and the follow-up after 1 year of loading (8.60 ± 1.18) with no statistically significant difference (paired $t$ test; $P > .05$). The WES scores and corresponding variables are shown in Fig 6. The mean GPI scores at the 1-week follow-up were 1.40 ± 0.68 for the mesial aspect and 1.65 ± 0.87 for the distal aspect. According to the results at the 1-year follow-up,
the mean GPI scores were 1.55 ± 0.82 and 1.65 ± 0.93, respectively, at the mesial and distal papilla. No statistically significant difference was found (paired t test; P > .05) between the two time points.

At the 1-year follow-up, the patients were asked to rate their feeling on a 10-cm horizontal line (VAS scores). Table 5 presents the mean percentages for the overall process, speech function, masticatory function, and esthetics, which were 93.3%, 95.1%, 93.6%, and 94.5%, respectively. The individual scores ranged from 79.3% to 100.0%. Five patients expressed the most satisfaction, with the maximum score of 100% for all parameters. Two patients gave the lowest scores (7.7 and 7.8 out of 10) for the overall process. These patients reported postoperative pain and swelling after the surgery.

Table 5 Patient Perceptions of Overall Process, Speech Function, Masticatory Function, and Esthetics (% calculated from VAS)

<table>
<thead>
<tr>
<th>Evaluated topic</th>
<th>Mean VAS ± SD (%)</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall process</td>
<td>93.3 ± 7.8</td>
<td>77</td>
<td>100</td>
</tr>
<tr>
<td>Speech function</td>
<td>95.1 ± 5.3</td>
<td>83</td>
<td>100</td>
</tr>
<tr>
<td>Masticatory function</td>
<td>93.6 ± 7.6</td>
<td>71</td>
<td>100</td>
</tr>
<tr>
<td>Esthetics</td>
<td>94.5 ± 6.2</td>
<td>79</td>
<td>100</td>
</tr>
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DISCUSSION

This investigation demonstrated a favorable result of 100% survival; ie, no zirconia dental implants were lost during the 1-year observation period. The result corresponded with that for a study using the same one-piece zirconia implant placed in healed sites, which also demonstrated no implant failure (100% survival) during the first year of function. A systematic review revealed survival rates for commercially available zirconia implants ranging from 93.3% to 100% for mean follow-up periods between 12 and 61 months. When compared with the survival rates for titanium implants, the 3.3-mm one-piece zirconia implants used in this research showed a comparable outcome.

Due to the lack of homogeneity in the dental literature, there are no definitive criteria for evaluating the success of dental implant treatments. In this study, the frequently accepted criteria of Buser et al were used to estimate the success rate for the zirconia implants. All 20 implants exhibited desirable clinical outcomes, with an absence of implant mobility, peri-implant radiolucency, persistent pain, dysesthesia, or any infection. Therefore, the success rate in this investigation was 100%. The result compared favorably with the previous clinical data for both titanium and zirconia dental implants based on the same success criteria. Recent studies on zirconia implants have shown 1-year success rates ranging from 95% to 98%. Additionally, a large multicenter study with similarly designed titanium implants reported a success rate of 96% after 1 year.

In the present study, the mean marginal bone level change between definitive prosthetic loading and 12-month follow-up was 0.14 mm. A previous study using the same one-piece zirconia implants observed a bone level change of 0.25 mm at the 1-year post-loading visit. On the other hand, compared with the previous clinical data from a systematic review, which reported a marginal bone level change of 0.79 mm after 12 months, this study seems to show more favorable results. However, the heterogeneity of the studies included in systematic reviews is a primary concern here, as many factors affect the alteration in the marginal bone level around dental implants, including the implant design, surface topography, and follow-up periods.

In the present study, immediate temporization was performed without incisal contacts. The result for the mean crestal bone loss compared well with that in the studies with identical implants but delayed temporization and was also in agreement with a previous meta-analysis that indicated no significant difference in marginal bone level changes based on the temporization mode. A simultaneous guided bone regeneration procedure was not a contraindication in this study. As reported for previous studies, bone augmentation procedures during implant placement did not have any significant effect on the changes in marginal bone levels. Fourteen of the 20 implant sites in the present investigation underwent bone augmentation during the implant surgery and demonstrated acceptable outcomes with no excessive bone loss after 1 year.

Nineteen implants had a peri-implant crestal bone loss of less than 1.5 mm, and bone gain even occurred in some cases. Only one implant displayed more than 2 mm of crestal bone resorption. The cause for this excessive bone loss may be due to loosening of the provisional crown during healing periods and required re-cementation of the provisional restoration. Removing excess cement during a re-cementation visit might have disturbed the healing process and caused excessive bone loss.

The assessment of soft tissue status was important in diagnosing of peri-implant disease. A physiologic pocket depth around the dental implant is difficult to define, as the range can vary considerably from 1.6 to 7.0 mm. However, it has been recommended that, in general, peri-implant pocket depths should not exceed 5 mm. In the present study, there was a positive trend in the probing depth measured in each period. The mean value fell from 2.93 mm at the first follow-up visit to 2.70 mm at the last follow-up after 1 year. No implants showed a probing depth of more than 5 mm. The prognosis for peri-implant soft tissue health was evaluated by the presence of bleeding on probing, which decreased significantly from 39.16% at 1 week to 16.66% at 3 months after prosthetic delivery and remained almost stable after 1 year. Additionally, no plaque accumulation occurred on any implant surfaces since the first follow-up. These findings support the previous in vitro studies of bacterial biofilm formation on zirconia material, which describe significant reductions in biofilm formation and the accumulation of inflammatory cells associated with zirconia compared with titanium. In clinical research, several studies have reported similar results indicating a decrease in the Bleeding Index and Plaque Index during the follow-up period. The present results emphasize the biocompatibility of zirconia, which is reassuring regarding the use of zirconia dental implants in areas with delicate soft tissue, such as anterior areas.

Thanks to the white color and biocompatibility of the Y-TZP zirconia material, the use of one-piece zirconia dental implants could be advantageous in the aesthetic areas. The mean PES in this study increased significantly, from 8/14 at 1 week after loading to 12.05 at the 1-year follow-up. When the threshold for clinical acceptance was set at 8/14, every single case demonstrated acceptable esthetics. The improvement in peri-implant
soft tissue conditions was seen for all seven variables, with the exception of soft tissue margin level. At the 1-year follow-up, all patients obtained the maximum score for soft tissue color. The result was supported by several studies indicating that the peri-implant mucosa around the zirconia abutments produces a better color match with the mucosa around natural teeth than titanium or gold-hued titanium abutments.\textsuperscript{11,41,42} No statistically significant difference was found in the WES between the 1-week and 1-year follow-ups. When the threshold of clinical acceptability was set at 6,\textsuperscript{26} none of the 20 single implants was regarded as anesthetic failure. The WES result was clearly more favorable than the data documented for titanium implant-supported all-ceramic crowns utilizing Ti-design abutments, which demonstrated a WES score of 7.0 after 1 year.\textsuperscript{43} This may result from the esthetic advantage of the ivory-colored abutment of the one-piece zirconia implant. Several in vitro and in vivo studies have also demonstrated that a zirconia abutment provides a more satisfactory restoration shade than a titanium abutment.\textsuperscript{44,45}

Since the abutment on one-piece zirconia implants should not be modified during definitive prosthesis fabrication, careful prosthetic-driven implant planning is necessary. Computer planning software and guided surgery were used in this study. None of the implants in this study were modified for definitive prosthesis insertion. Therefore, when placing one-piece zirconia implants, computer-guided surgery was recommended.

At the 1-year follow-up, the patients were provided with the VAS assessment, which was their assessment of the esthetic results. All patients found the results to be quite satisfactory. No adverse effects of major consequence were seen in the study.

**CONCLUSIONS**

This preliminary clinical investigation showed high survival and success rates of 100% after 12 months of function. No technical complications or cases of implant fracture occurred during the follow-up periods. The hard and soft tissues surrounding the implants exhibited favorable results, except for one case that presented with excessive marginal bone loss (> 3 mm). However, there were no associated signs of peri-implant disease. No plaque was observed in any of the patients. From the esthetic standpoint, every single implant demonstrated good, clinically acceptable results, especially regarding the PES, which significantly improved over time. In addition, the mean VAS indicated a high level of patient satisfaction, with a score of more than 90% for all questions. Therefore, one-piece ceramic implants with a small diameter of 3.3 mm seemed to be effective when used for single-tooth replacement in anterior regions.

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