Different implant designs are used for single-tooth replacement. One of these designs is an implant with a tapered body. Compared with parallel-walled implant bodies, tapered implants have the alleged clinical benefits of, for example, less risk of apical bone fenestrations due to bony undercuts, which are commonly seen in the maxillary alveolar processes, and a higher primary implant stability is claimed when a comparison is made with parallel-walled implants.

When the alveolus is left to heal without bone preservative measures after a tooth is extracted, the buccal bone wall is subject to progressive physiologic resorption. The resorption pattern can lead to a deficient labial bone wall and can compromise proper soft tissue support. To prevent this “physiologic collapse,” the technique of alveolar ridge preservation has been proposed, either with or without immediate implant placement. It has been demonstrated that if implant treatment does become an option at a later date, guided bone regeneration is needed to augment the deficient labial bone wall, and this successfully enhances the contour of soft and hard tissues.

Different brands of tapered implants are available. The results of placing these implants in the esthetic
region are good regarding survival, peri-implant bone level stability, and esthetic outcome, in nonpreserved as well as in preserved sites.\textsuperscript{11–13} In 2015, a new line of bone level tapered implants was launched (Straumann Bone Level Tapered implant, Institut Straumann). This implant system is equipped with the successful characteristics established by previous studies,\textsuperscript{14,15} such as a sandblasted, large-grit, acid-etched surface and platform switching with a conical implant-abutment connection, but it also has a tapered body, which means it is more applicable for challenging anatomical sites and for enhanced primary stability in soft bone.

Currently, limited studies have been published on this bone level tapered implant system.\textsuperscript{16–18} Of these, only one describes placement specifically in the anterior maxilla. However, the study has a follow-up of only 6 months and does not describe implant stability, esthetics, or patient-reported outcomes.\textsuperscript{16} Therefore, a full-scale assessment on the performance of the bone level tapered implant system in healed sites in the maxillary esthetic region using the newly launched bone level tapered implant system was to assess the clinical, radiographic, and esthetic performance and patient-reported outcomes of implant treatment in healed sites in the maxillary esthetic region using the newly launched bone level tapered implant system.

**MATERIALS AND METHODS**

**Study Design**

The study is a prospective clinical case series with 30 participants. Recruitment and inclusion of participants in need of single-implant treatment was carried out at the Department of Oral and Maxillofacial Surgery, of the University Medical Center Groningen (UMCG), the Netherlands, from January 2016 until December 2017. The Medical Ethics committee of the UMCG approved the protocol (METc 2015.517). The protocol was placed in a trial register (Trial ID: NL8755). All participants signed informed consent prior to treatment. The construction of the article followed the guidelines for cohort studies (STROBE).\textsuperscript{19}

**Participants**

The inclusion criteria were as follows:

- The site to be treated was in the anterior region of the maxilla (central or lateral incisors, canines, or first premolars).
- A single-tooth diastema (healed unassisted for at least 3 months) with sufficient bone volume for implant placement.
- Natural teeth neighboring the implant site.
- Minimum age is 18 years.
- Capable of understanding the treatment and giving informed consent.

The exclusion criteria were as follows:

- Periodontal disease in rest of the dentition.
- Smoking.
- Former radiotherapy in the region of the implant site.
- Former use of bisphosphonates.

**Surgical Phase**

Patients took antibiotics starting 1 day before treatment (amoxicillin 500 mg for 7 days, three times daily, or clindamycin 300 mg for 7 days, four times daily). Although it has been acknowledged that implant placement in healed sites probably does not require antibiotic therapy, it was expected that a substantial number of patients would need local bone augmentation because of limited thickness of the buccal bone wall. For this reason, antibiotics were prescribed for all included patients. Surgery in the study was performed by one surgeon (G.M.R.). A midcrestal incision was made. The position of the implant was dictated by a surgical template. A bone level tapered implant (Bone Level Tapered Implant, SLActive, Roxolid, $\Omega$ 3.3 mm and 4.1 mm, Institut Straumann) was placed. The depth of the implant was 3 mm apically from the gingival margin of the future crown. The reason for this was to take full advantage of the biologic width to design abutments with a natural emergence profile. Next to this, the implants were placed somewhat palatally from the center of the former tooth root to have at least 2 mm of buccal bone thickness, whether or not it was reached with an additional bone augmentation procedure. When the labial bone wall thickness after placing the implant was < 2 mm, a bone augmentation procedure was performed with a 1:1 mixture of xenogenic bone (Cerabone, Bôtiss Biomaterials) and autologous bone chips (collected during implant bed preparation). A collagen membrane (Jason membrane, Bôtiss Biomaterials), secured with interrupted sutures (5-0 ethilon, Johnson & Johnson Gateway), was used to cover the augmentation material. A removable partial denture (RPD) was provided to wear until the day of abutment connection.

**Prosthetic Phase**

The implants were uncovered 3 months after insertion, with the use of a soft tissue punch technique. The dental laboratory manufactured a screw-retained provisional crown, which avoided centric and eccentric contact with the antagonist teeth. The provisional crown consisted of a titanium stock abutment and a CAD/CAM designed acrylic resin crown, which was placed the
same day and torque to 25 Ncm. Three months thereafter, a definitive porcelain-fused-to-zirconia crown was manufactured. The crown was either cemented onto an individualized zirconium abutment with a platform-switched, internal conical connection (zirconium CARES abutment, Institut Straumann), or it was designed to be screw-retained with a titanium base (Variobase for single crowns AS, Institut Straumann). In both cases, the screws were tightened to the implant with a torque of 35 Ncm. For screw-retained restorations, the inclination of the implant is crucial. In the beginning of the study, therefore, definitive restorations were cement-retained with a separate zirconia abutment and a porcelain-veneered core. During the study, angulated screw channels became available with the possibility of having any restoration screw-retained with porcelain-veneered zirconia abutments. At placement of both the provisional and the definitive restoration, oral hygiene instructions were given. All prosthetic procedures were carried out by the same prosthodontist (H.J.A.M.).

Evaluation
Outcomes were assessed 1 month after placement of the definitive crown (T1) and 12 months after placement of the definitive crown (T12) by the same observer (C.M.M.). Next to this, patient satisfaction was scored prior to implant placement (Tpre) and 12 months after placement of the definitive crown.

Outcome Measures
Outcome measures were as follows:

- Survival of the implant.
- Peri-implant bone level, measured on standard periapical radiographs.20
- Measurement of labial bone wall thickness at implant placement and decision if additional augmentation was needed in case thickness was < 2 mm.21
- Implant stability quotient (ISQ), measured with the Osstell mentor device (Integration Diagnostics).22,23 ISQ was measured at implant placement and at placement of the definitive crown.
- Probing depth by using a periodontal Click-Probe (KerrHawe Dental Corporation).
- Modified Plaque Index,24 modified Sulcus Bleeding Index,24 Gingival Index,25 and Papilla Index.26
- Esthetic parameters were assessed with the modified pink and white esthetic scores (PES-WES).27
- Midbuccal gingiva and papilla change,28 analyzed on color photographs.
- Patient-reported outcomes were assessed with a questionnaire,29 and overall satisfaction was measured on a visual analog scale (VAS).

• Any complications during the treatment and evaluation period were recorded.

Statistical Analysis
Statistical analysis was performed to gain insight into the data of clinical, radiographic, and esthetic outcome scores and difference in patient satisfaction between the preoperative situation and 1 year after definitive restoration placement. Normality checking was done using QQ-plots and the Shapiro-Wilk test. The Wilcoxon signed-rank test was used to analyze ordinal and not normally distributed continuous data to test any significance between time intervals. A paired t test was used to analyze the normally distributed data. Categorical data were analyzed with the McNemar test. A P value of .05 was considered to indicate statistical significance. A Bonferroni correction was performed to correct for multiple testing.

RESULTS
Thirty patients participated in the study. Population characteristics are depicted in Table 1. All participants could be followed during the entire follow-up period.

Implant Stability
The median ISQ value at implant placement was 73 (68;76 interquartile range; min 46, max 81) and had increased significantly to 79 (77;81 interquartile range; min 73, max 85) on the day the definitive restoration was placed (Table 2).

Buccal Bone Thickness
Although there was sufficient bone volume in all cases to place the implants with adequate primary stability (manually torqued with a ratchet to at least 35 Ncm), the bone thickness in 23 of the 30 cases was < 2 mm buccally from the implant. These cases received additional augmentation. One patient lost granules of the augmentation material 2 weeks after implant placement, but no further treatment was needed. All the wounds healed uneventfully.

Table 1 Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. of participants</th>
<th>Mean age, mean ± SD, y (range)</th>
<th>Male/female ratio</th>
<th>Implant location (I1/I2/C/P1)</th>
<th>Implant length 10/12/14 mm</th>
<th>Implant diameter 3.3/4.1 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of participants</td>
<td>30</td>
<td>38 ± 16 (18–75)</td>
<td>15/15</td>
<td>15/11/2/2</td>
<td>3/25/2</td>
<td>11/19</td>
</tr>
</tbody>
</table>

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Implant Survival Rate
All implants remained functional during the follow-up, with a 100% implant survival rate (Table 2).

Peri-implant Bone Level Change
Figure 1 shows the radiographic changes from before the treatment to 12 months after definitive crown placement. Peri-implant bone level changes are depicted in Table 2. The mean marginal bone level changed significantly in the first 7 months after implant placement. Thereafter, only little, nonsignificant change occurred. Peri-implant bone level changes were not normally distributed, so it is appropriate to note the medians and IQR, but to give more insight into the actual change, the bone level changes are also depicted as mean ± SD.

Clinical Parameters
The Bleeding Index, Gingival Index, and mean probing depth scores from the 12-month evaluation are depicted in Table 3. Between T1 and T12, there were no significant differences.

Fig 1 Bone level during the course of treatment: (a) before implant placement; (b) immediately after implant placement; (c) 1 month after definitive crown placement; (d) 12 months after definitive crown placement.

Table 2 Survival Rate (%), Implant Stability Quotient, and Bone Level Change from Time of Implant Placement to 12 Months After Definitive Crown Placement (in mm, n = 30)

<table>
<thead>
<tr>
<th></th>
<th>At implant placement</th>
<th>At definitive crown placement</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant stability (ISQ)</td>
<td>73 (68;76 IQR)</td>
<td>79 (77;81 IQR)</td>
<td>&lt; .00</td>
</tr>
<tr>
<td>Bone level change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesial</td>
<td>−0.48 ± 1.13</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>−0.55 ± 0.98</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Mean of mesial+distal</td>
<td>−0.53 ± 1.02</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Survival rate at T12</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Wilcoxon signed-rank test.
**The threshold for significance is P < .017 due to the Bonferroni correction.
T0 = time of implant placement; T1 = 1 month after definitive crown placement; T12 = 12 months after definitive crown placement (18 months after implant placement); IQR = interquartile range.

Table 3 Clinical Parameters at 12 Months After Definitive Crown Placement (n = 30)

<table>
<thead>
<tr>
<th>Pocket probing depth (mm), median (IQR)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesial</td>
<td>4.0 (3.0;5.0)</td>
</tr>
<tr>
<td>Midbuccal</td>
<td>3.0 (2.0;4.0)</td>
</tr>
<tr>
<td>Distal</td>
<td>4.0 (3.0;5.0)</td>
</tr>
<tr>
<td>Palatinal</td>
<td>3.0 (2.0;3.0)</td>
</tr>
<tr>
<td>Mean of all sites</td>
<td>3.4 (2.8;3.9)</td>
</tr>
</tbody>
</table>

| Gingival Index (median, IQR) | 0 (0;0) |
| Bleeding score (median, IQR) | 1 (0;1) |
crown placement. The change in midbuccal mucosa height between T1 and T12 was –0.14 ± 0.40 mm. There was an overall gain in papilla height: +0.05 ± 0.60 mm mesially and +0.06 ± 0.53 mm distally. There was not a significant difference in midbuccal mucosa level and in papilla height between 1 month (T1) and 12 months (T12) after placement of the definitive crown.

Patient Satisfaction
At baseline, which was before implant treatment, 25 patients rated their satisfaction with the RPD as 53.0 ± 23.5. There was a significant increase after implant therapy to a mean score of 90.1 ± 6.5 at the T12 follow-up (Table 5). Five participants did not wear any prosthetic construction at baseline and could not answer the questionnaire. They were therefore excluded from this part of the analysis.

Complications
Mobility of the provisional crown occurred in four patients, all of them 2 weeks after placement. The screws were retightened without any further complications. One patient had suffered extensive marginal bone loss during the 3 months with the provisional crown. The crown was removed, and the peri-implant region was surgically explored and chemically cleaned using 35% phosphoric acid gel.30 The area was augmented with a mixture of autologous bone from the tuberosity region and deproteinized bovine bone mineral (Bio-Oss, Geistlich) and covered with a collagen membrane (Bio-Gide, Geistlich); after 4 months, an implant was placed and left to heal submerged for 4 months. A new restoration was manufactured after uncovering the implant. At the T12 follow-up, this implant had a peri-implant bone level at the neck of the implant and healthy peri-implant soft tissues.

### Table 4 Evaluation of the Ethetic Outcome at T12 (PES-WES) and Mucosa-Level Change from T1 to T12 (n = 30)

<table>
<thead>
<tr>
<th>Esthetic evaluation at T12</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PES median (IQR)</td>
<td>6 (4.7)</td>
<td></td>
</tr>
<tr>
<td>WES median (IQR)</td>
<td>8 (7.25)</td>
<td></td>
</tr>
<tr>
<td>Mucosa level change from T1 to T12 (mm; mean ± SD)</td>
<td></td>
<td>P</td>
</tr>
<tr>
<td>Midbuccal mucosa</td>
<td>–0.14 ± 0.40</td>
<td>.07</td>
</tr>
<tr>
<td>Mesial papilla</td>
<td>+0.05 ± 0.60</td>
<td>.69</td>
</tr>
</tbody>
</table>

*Paired t test.

### Table 5 Patient Satisfaction Rated on a 0–100 VAS Scale and Further Clarified in a Questionnaire

<table>
<thead>
<tr>
<th>Questionnaire % in agreement</th>
<th>Tpre (n = 25a)</th>
<th>T12 (n = 30)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall patient satisfaction, VAS scale (mean ± SD)</td>
<td>53.0 ± 23.5</td>
<td>90.1 ± 6.5</td>
<td>&lt; .05b</td>
</tr>
<tr>
<td>Questionnaire % in agreement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Well-being</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of shame</td>
<td>32.0</td>
<td>0.0</td>
<td>.008c</td>
</tr>
<tr>
<td>Decreased self-confidence</td>
<td>16.0</td>
<td>3.3</td>
<td>.25c</td>
</tr>
<tr>
<td>Aware of prosthesis visibility</td>
<td>24.0</td>
<td>3.3</td>
<td>.063c</td>
</tr>
<tr>
<td>Function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evade eating with affected zone</td>
<td>60.0</td>
<td>10.0</td>
<td>.000c</td>
</tr>
<tr>
<td>Decreased chewing ability</td>
<td>52.0</td>
<td>0.0</td>
<td>.000c</td>
</tr>
<tr>
<td>Influences speech</td>
<td>32.0</td>
<td>3.3</td>
<td>.016c</td>
</tr>
<tr>
<td>Influences taste</td>
<td>28.0</td>
<td>0.0</td>
<td>.016c</td>
</tr>
<tr>
<td>Esthetics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfied with shape of the RPD/crown</td>
<td>48.0</td>
<td>100</td>
<td>.000c</td>
</tr>
<tr>
<td>Satisfied with color of the RPD/crown</td>
<td>68.0</td>
<td>93.3</td>
<td>.016c</td>
</tr>
<tr>
<td>Satisfied with shape of the mucosa</td>
<td>60.0</td>
<td>86.7</td>
<td>.016c</td>
</tr>
<tr>
<td>Satisfied with color of the mucosa</td>
<td>44.0</td>
<td>86.7</td>
<td>.006c</td>
</tr>
</tbody>
</table>

*Tpre = time prior to implant placement; T12 = 12 months after definitive crown placement. Significance levels between Tpre and T12. aFive participants did not wear the RPD and therefore did not answer the questionnaire. These participants were left out of the statistical analysis. bPaired t test. cMcNemar test.

Fig 2 Soft tissue changes: (a) before implant placement (patient had worn a RPD prior to treatment); (b) 1 month after definitive crown placement; (c) 12 months after definitive crown placement.
DISCUSSION

The results of this prospective clinical case series of single bone level tapered implants, placed in unassisted healed sites in the esthetic region, 1 year after definitive crown placement, regarding all outcomes, were favorable.

Comparison of the outcomes of the present study with others that used the same bone level tapered implant in healed sites is limited to two studies: Levine et al.17 and Pariente et al.18 They used the implant mainly in the posterior region and with different treatment protocols than the present study. Both studies also reported high survival rates (98%) and stable marginal bone levels (0.3 ± 0.46 mm17 and 0.35 ± 0.23 mm18) after 1 to 2 years. Because studies using the same implant brand in the esthetic region are missing, studies with other implant systems, but with a tapered design, can best be used for comparison. De Bruyckere et al.31 and Cosyn et al.13 used another tapered implant system (NobelActive, Nobel Biocare) and reported the same range of bone loss as Levine et al.17 and Pariente et al.18 1 year after implant placement (−0.42 ± 0.36 mm13 and −0.48 ± 0.4 mm31). Also, Zuiderveld et al.32 used another tapered implant system (NobelReplace CC, Nobel Biocare) and recorded bone level changes of +0.06 ± 0.5 mm mesially and −0.01 ± 0.4 mm distally in the time from definitive crown placement to 12 months thereafter. The results of the present study are in the same range as the mentioned studies, and the bone level changes are comparable with the peri-implant bone level changes of the other tapered implants in the esthetic region, including very little bone loss after the first year in function.

It is stated that tapered implants have good primary stability due to the self-tapping property combined with underdrilling during osteotomy. Therefore, implant stability was analyzed by measuring the ISQ. ISQ was not measured by Levine et al.17 or Pariente et al.18 Torroella-Saura et al.33 and Morii et al.34 compared ISQ values of tapered implants with cylindrical implants. Although different implant brands were used, mainly in the molar and mandibular region, they noted mean ISQ values at implant placement of 72.9 ± 2.533 and 60.2 ± 12.434 for the tapered implants, which were higher compared with cylindrical implants. The ISQ of the present study at implant placement was 73 (68;76 interquartile range), indicating high implant stability,35 and is comparable to the values measured with other implant brands and in the posterior mandibular region by Torroella-Saura et al.33 and Morii et al.34 In addition to knowing this, Pariente et al.18 did describe the mean insertion torque value as 34 ± 5.3 Ncm. This can be classified as good primary stability,36 even though the majority of the implants were placed in poor type III or IV bone. At the time the study protocol was drafted, only little was known about the bone level tapered implant, especially in the anterior zone, so it was decided to be careful when subjecting the study participants to immediate loading without knowing beforehand what the implant stability would be. Knowing that this implant scores high on both ISQ and insertion torque values might help in considering immediate loading in future patients.

One of the inclusion criteria for the participants was the presence of sufficient bone for implant placement. Despite this, the thickness of the buccal bone wall was insufficient (< 2 mm) in 23 cases and had to be augmented. The need for additional augmentation was also seen in other studies with unassisted healed sites in the esthetic region. In the study by Zuiderveld et al.32 90% of the cases needed a bone augmentation procedure. Compared with a study with cylindrical implants in the maxillary esthetic region, Boardman et al.37 reported that 90% of the healed site cases needed an additional bone augmentation procedure at implant placement. These percentages are very much alike, leaving the question if a tapered implant design diminishes the need for additional bone augmentation unanswered. A thin bone wall (< 2 mm) labial to the implant tends to be more susceptible to resorption, leading to poor soft tissue support, which might lead to esthetic failure as a consequence.38,39

The esthetic outcome in the present study was satisfactory, with an acceptable median PES score of 6 (4;7 interquartile range)27 and small changes to the midbuccal mucosa (−0.14 ± 0.40 mm) and papillae (+0.05 ± 0.60 mm) after removal of the tooth and flap surgery in combination with a local bone augmentation procedure. Comparison of the PES value with a study in which immediate implant placement was used in the maxillary esthetic region reveals that this is slightly higher, with a mean value of 6.8 ± 1.5.40 An explanation could be the flapless surgery in case of immediate implant placement. There was not a significant difference in midbuccal mucosa level and in papilla height between the first month (T1) and 12 months (T2) after definitive crown placement, meaning that soft tissues are stable in the first year after definitive restoration placement. The mucosa changes of both the midbuccal gingiva and the papillae are within the range of those previously found by other authors,13,31,32 who also presented minor changes in the soft tissues, indicating that the bone level tapered implant is comparable to the other, more or less equally shaped, implants and accompanied with stable marginal bone levels, as well as, or maybe because of, stable peri-implant soft tissues after 1 year. The overall patient satisfaction score in the present study resembles those
mentioned by Zuiderveld et al\textsuperscript{32} and Lowy et al\textsuperscript{41}; the participants were more satisfied with the end result than the professional observers. Perhaps this is because the patients pre-treatment situation is still fresh in their minds, and they express satisfaction as oral well-being, function, and esthetics in comparison to the pre-treatment situation, whereas the professionals use an index and might be more critical about the smaller defects than the participants.\textsuperscript{42} However, both are consistent in liking the whites better than the pinks, as can be seen in comparing the answers to the questionnaire with the PES and WES outcomes.

Although the overall results of this study were good, two major limitations need to be mentioned and addressed in future research. First, the study did not compare the performance of a tapered implant to the performance of a cylindrical implant, preferably from the same brand, by means of a randomized controlled trial. Comparisons were made with other studies addressing a tapered implant design. Second, although acknowledging the importance of the facial bone thickness, the buccal bone thickness was not measured by means of CBCT to monitor the original bone, the augmented bone, and its stability over time.

**CONCLUSIONS**

Within the limitations of this study, it can be concluded from a 1-year follow-up that treatment with the bone level tapered implant system resulted in good implant stability, healthy peri-implant hard and soft tissues, satisfying esthetics, and good patient-reported outcomes.

**ACKNOWLEDGMENTS**

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**REFERENCES**