A wide body implant as alternative for sinuslift or bone grafting.

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ABSTRACT

Purpose: The aim was to evaluate the outcome of a short wide body implant in the atrophic posterior jaw without grafting procedure.

Materials and methods: Patients treated with a tapered wide body implant of 8-9 mm width and 7-9 mm length (Max® implant, Southern Implants®, Irene, South Africa) were recalled to scrutinize implant survival. Preoperative cone beam CT images were analysed to measure bone height in reference to the mandibular canal and sinus floor.

Results: 57 implants were inserted in 18 males and 24 females following a 2-stage procedure and delayed loading. The mean follow-up was 15 months (SD 10, range 1-32), with 63.2% of the implants having at least 1 year and 26.3% having at least 2 years follow-up. 46 implants were inserted in the posterior maxilla and 11 in the mandible. 15 were placed in an extraction socket and 42 in healed bone. 13 implants were supporting a single crown.

2 implants failed, resulting in a survival rate of 96.5%, respectively 90.9% and 97.8% for mandible and maxilla. This was not affected by gender, jaw, immediate or delayed placement, implant diameter and length or the use of a bone substitutes.

The mean preoperative bone height was 7.21 mm in maxilla and 8.76 mm in mandible. In 41 cases, implant length surpassed available bone height.

Conclusions: Despite the compromised bone condition and height, the survival of 96.5% is comparable to normal implants and an alternative for grafting procedures. This is probably related to the enlarged implant surface area and the good primary stability.
INTRODUCTION

Good short and long-term results have been reported with dental implants \(^1,^2,^6\). However, the posterior maxilla and mandible were considered to be “risk” zones due to the higher occlusal forces, inferior bone quality and the often limited amount of bone \(^49,^67\). Additionally, the positioning of the maxillary sinus and the mandibular nerve often limits the available bone height for implant placement.

The first generation, turned titanium implants, were depending on their length to achieve enhanced stability and sufficient bone-to-implant contact. This was not always possible, especially in the posterior jaw and thus short implants were related to an increased failure rate. The wide diameter implant was introduced to increase the available contact surface for osseointegration and enhanced primary stability \(^21,^40,^46\). Unfortunately, the first results were disappointing, reporting failure rates of 9% to 24% within 5 years \(^5,^19,^37,^60\). Later studies, using an improved implant design with modified implant surface and adapted drilling protocol reported less than 5% failures after 5 years \(^4,^10,^12,^42\).

Short implants are defined as being 10 mm or shorter \(^22,^31,^47\). Their advantage lies in the fact that they can be inserted in limited bone height, hereby avoiding sinus lifting, nerve repositioning or onlay grafts. This decreases morbidity and complications linked with these extra surgical procedures, reduce the total treatment time, lowers the costs and improves the patient’s satisfaction \(^47\). However, the initial results when short implants were used were rather disappointing with failure rates of 17% to 25% \(^8,^39,^50,^73\). This was explained by the lower bone quality of the posterior area \(^44\). The introduction of the moderately rough implants increased these survival rates to 95.1% to 100% \(^10,^31,^51\).

The implant used for this study was the Max® implant (Southern Implants®, Irene, South Africa), a wide diameter implant intended for the posterior jaw. Good results have been reported for this implant under various conditions \(^69\). The aim of this study was to evaluate the outcome of short, wide diameter implants in the posterior area as an alternative for bone
grafting or sinus lifting.

MATERIALS AND METHODS

Implant design

The Max® implants are commercially available in 7, 8, 9, or 10 mm width and 7 - 13 mm length, with a 0.8 mm thread pitch (Figure 1). They have an external hex and a moderately rough surface created by sandblasting and chemically conditioned with solvents of a grade 4 commercially pure titanium, with a Sa value of $1.34^{3, 62}$. Due to the wide diameter, there is a platform shifting of 0.25 mm on the horizontal plane and a further 0.35 mm when the 45 degree bevel is included.

Data collecting and patient selection

All patients were consecutively treated in the past with at least one short Max® implant (7 to 9 mm) by one maxillofacial surgeon (AT). Patients were encouraged to participate in the study and asked to attend a clinical examination by an independent multidisciplinary team of researchers of the University of Ghent, Belgium. All patients were personally contacted to be invited for a clinical examination. Thus, patients were included depending on their availability at the time of the clinical examination by the visiting research team. This study was approved by the Ethical Comité of the University Hospital Ghent, Belgium, and was in accordance with the Consort statement on clinical research design and the Helsinki statement on medical protocols and ethics.

Implant data were collected from patient files and clinical examination. Parameters were time of placement, time of loading, 1 or 2 stage surgery, additional usage of a grafting material, implant position and implant dimensions, type of prosthetic reconstruction and gender. Delayed placement was defined as “implant placement at least 6 months after tooth extraction”. Pre-operative cone beam CT’s (I-Cat, Imaging Sciences, Hatfield, PA, USA)
were analyzed and the available bone height was measured. In the maxilla, the distance from the bone crest to the sinus floor was measured and in the mandible, the distance from the crest to the mandibular nerve.

Statistics were done using PASW v18. Fisher’s Exact Test was used to compare implant survival between groups. The level of significance was set at $P = 0.05$.

RESULTS

Up to the time of examination, 94 implants corresponding to the selection criteria had been installed in 84 patients. In total 3 implants had failed, resulting in an overall survival rate of 96.8%.

In total, 42 patients (18 males and 24 females), representing 57 implants, presented themselves for detailed clinical examination. Mean age was 59 years (SD 13, range 28-84). The mean follow-up time was 15 months (SD 10, range 1-32), with 63.2% of the implants having at least 1 year follow-up and 26.3% having at least 2 years follow-up. 46 implants were inserted in the posterior maxilla and 11 in the mandible (Figure 2). 15 were immediate placements in an extraction socket and 42 in healed bone. All implants were placed with a 2 stage procedure and delayed loaded after 3 to 6 months. Implant dimensions are depicted in Table 1. A bone substitute was used around 13 implants (22.8%), of which 3 extraction cases. 13 implants were supporting a single crown (22.8%), 35 a fixed partial prosthesis (61.4%), 7 a fixed full prosthesis (12.3%) and 2 a full removable prosthesis (3.5%).

2 out of 57 implants failed, resulting in an overall survival rate of 96.5%, respectively 90.9% and 97.8% for mandible and maxilla. The survival rate was not affected by gender ($P = 0.499$), jaw ($0.352$), immediate or healed bone ($P = 1.000$), implant diameter ($P = 1.000$), implant length ($P = 0.119$), the use of a bone substitute (Cerasorb®, Curasan AG, Kleinostheim, Germany) ($P = 1.000$) or the type of prosthetic reconstruction ($P = 0.220$).
(Table 2). Additionally, there was no significant difference in failure rate between the splinted (2.3%) and non-splinted (7.7%) implants (P=0.351).

In the maxilla the mean preoperative bone height was 7.21 mm (SD 1.78, range 4.30 – 12.13) for a mean implant length of 8.39 mm (SD 0.93, range 7.00 – 9.00). In the mandible 8.76 mm (SD 1.98, range 7.00 – 12.74) bone height was available for a mean 7.91 mm (SD 1.04, range 7.00 – 9.00) implant length.

In 41 cases (71.9%), the implant length surpassed the available bone height. 39 were in the maxilla and 2 in the mandible. 13 implants had a length of 7 mm, while 28 had a length of 9 mm (Figure 3).

**DISCUSSION**

The current study is based on a cohort of 42 clinically examined patients out of a total group of 84 consecutively treated patients. This selection was not biased, but relied on the availability of the patients during the time of visit of the external examiners. The study by Hermann et al.\(^{34}\) indicates that with this approach, even a 50% drop-out, does not alter the outcome. Hence, the outcome of the cohort can be considered representative for the whole population. With a 96.5% survival rate, the outcome of the Max implant is comparable with other studies using a similar treatment protocol, reporting survival rates of 73.8% to 100% \(^{4, 5, 19, 28, 30, 42, 45, 48, 60, 65}\). However, some of these include turned implants, which may be responsible for some of the lower results. Although only a limited number of 15 implants were followed for over 2 years, implant failure occurred only during the first months after surgery, suggesting a stable condition over time.

Although some authors reported better results in the maxilla compared to the mandible \(^{19, 30, 37, 57}\), this was not observed in the current study. The wide diameter of the implants allowed good primary stability when placed in molar extraction sites. In this study, no difference was found between immediate and delayed placement, which confirms earlier reports in the
Immediate placement can be a predictable procedure if primary stability is achieved.

Neither implant length nor diameter had any effect on implant survival. This confirms the conclusion of an extensive review, which found no correlation between implant length or diameter, and implant failure. Although all implants were shorter than 10 mm, the 96.5% survival rate is still better than most other short-implant studies reporting survival of 79.7% to 100%.

This is possibly due to the wide diameter, which increases the contact surface. However, to be clinically relevant and honest, one should compare the outcome of short/wide implants with those implants placed in combination with sinus graft or nerve transposition. Implant survival rates in combination with sinus graft range between 84% and 100%.

Although some studies report results comparable to short implants, one should not forget the additional costs and time that goes with sinus grafting.

In the current study, the available bone height was very limited. 41 implants exceeded the available bone height in length, which means that these perforated the sinus floor or were positioned above the crest. As can be seen in Table 3, the contact surface is still large when the implant is placed 2 mm above the crest or 3 mm above the sinus floor. The Max implant largely surpasses the contact surface of standard implants. A standard diameter implant (Ø3.75mm) with a length of 7 or 13 mm has a maximal contact surface of 95.3 and 193.1 mm² respectively.

Gabbert et al. reported no difference when implants were placed in normal bone or when implants were placed in limited bone height, without the use of a graft material. In 30% of the cases, additional bone formation was observed by lifting the membrane alone without the use of a bone substitute. Although it was not the aim of the study to perform cone beam evaluations for reasons of radiation protection rules, some images were available. On those images, bone formation around the apex of the implant when the membrane was lifted was likely to have occurred. (Figure 4). The interpretation of
these cone beam images remains, however, questionable and further long-term research seems mandatory in order to sustain this conclusion.

The results of the cross sectional study revealed that implants were often inserted in bone with limited width. Often the available crest was smaller than the used implant diameter. Consequently, the implant was not always completely surrounded by bone and some threads were exposed supracrestally. Whether this affects the peri-implant health in the long term remains to be investigated. In the meantime, it seems advisable to introduce a diameter 7 mm implant of the same design to overcome the vast majority of these cases and to facilitate inclusion of patients.

CONCLUSION

Despite the compromised bone condition and height, the survival of 96.5% is comparable to normal implants and a good alternative for grafting procedures. This is probably related to the enlarged implant surface area, the good primary stability, the moderately rough surface and the bicortical anchorage obtained in the maxilla due to lifting of the sinus floor membrane. However, more long-term survival studies on a larger patient cohort are necessary to sustain this treatment protocol.
Figure 1: Image of the Max implant
Figure 2: Overview of implant positions

![Bar chart showing implant positions with counts for each position. The chart has a bar for each implant position from 15 to 47, with varying heights indicating the count for each position.]
Figure 3: Boxplot representing the pre-operative available bone height and actual implant length for the maxilla and mandible.
Figure 4: Cone Beam CT image, pre- and 1 year post-operatively with the restoration in place. The sinuslift elevation has stimulated apical bone appositioning. On the other hand, buccal bone loss is visible because the original bone width was limited and the implant was obviously not completely surrounded with bone.
<table>
<thead>
<tr>
<th>Implant length</th>
<th>Implant diameter</th>
<th>8,0 mm</th>
<th>9,0 mm</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>7,0 mm</td>
<td></td>
<td>19</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>9,0 mm</td>
<td></td>
<td>30</td>
<td>7</td>
<td>37</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>49</strong></td>
<td><strong>8</strong></td>
<td><strong>57</strong></td>
</tr>
</tbody>
</table>
Table 2: The different variables with their corresponding implant number, implant survival and P-value

<table>
<thead>
<tr>
<th>Variable</th>
<th># Implants</th>
<th>Survival</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>25</td>
<td>100 %</td>
<td>0.499</td>
</tr>
<tr>
<td>Female</td>
<td>32</td>
<td>93.8 %</td>
<td></td>
</tr>
<tr>
<td><strong>Jaw</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxilla</td>
<td>46</td>
<td>97.8 %</td>
<td>0.352</td>
</tr>
<tr>
<td>Mandible</td>
<td>11</td>
<td>90.9 %</td>
<td></td>
</tr>
<tr>
<td><strong>Implant length</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 mm</td>
<td>20</td>
<td>90.0 %</td>
<td>0.119</td>
</tr>
<tr>
<td>9 mm</td>
<td>37</td>
<td>100 %</td>
<td></td>
</tr>
<tr>
<td><strong>Implant diameter</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 mm</td>
<td>49</td>
<td>95.9 %</td>
<td>1.000</td>
</tr>
<tr>
<td>9 mm</td>
<td>8</td>
<td>100 %</td>
<td></td>
</tr>
<tr>
<td><strong>Time of placement</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate</td>
<td>15</td>
<td>100 %</td>
<td>1.000</td>
</tr>
<tr>
<td>Delayed</td>
<td>42</td>
<td>95.2 %</td>
<td></td>
</tr>
<tr>
<td><strong>Bone substitute</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13</td>
<td>100 %</td>
<td>1.000</td>
</tr>
<tr>
<td>No</td>
<td>44</td>
<td>95.5 %</td>
<td></td>
</tr>
<tr>
<td><strong>Type of prosthetic reconstruction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single crown</td>
<td>13</td>
<td>92.3 %</td>
<td>0.220</td>
</tr>
<tr>
<td>Fixed partial prosthesis</td>
<td>35</td>
<td>100 %</td>
<td></td>
</tr>
<tr>
<td>Fixed full prosthesis</td>
<td>7</td>
<td>85.7 %</td>
<td></td>
</tr>
<tr>
<td>Full removable prosthesis</td>
<td>2</td>
<td>100 %</td>
<td></td>
</tr>
</tbody>
</table>
Table 3: Available contact surface for osseointegration when the implant is fully in the bone, 2 mm above the crest or 3 mm into the sinus.

<table>
<thead>
<tr>
<th>Implant</th>
<th>Fully in bone (mm²)</th>
<th>2mm supra crestal (mm²)</th>
<th>3mm apically lifting sinusfloor (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAX-8-7</td>
<td>224,4</td>
<td>151,5</td>
<td>150,0</td>
</tr>
<tr>
<td>MAX-8-9</td>
<td>282,5</td>
<td>208,4</td>
<td>218,4</td>
</tr>
<tr>
<td>MAX-9-7</td>
<td>258,4</td>
<td>172,3</td>
<td>174,4</td>
</tr>
<tr>
<td>MAX-9-9</td>
<td>326,7</td>
<td>313,1</td>
<td>249,4</td>
</tr>
</tbody>
</table>


46. Misch CE. Implant design considerations for the posterior regions of the mouth. *Implant Dent* 1999; **8**: 376-386.
73. Wyatt CC, Zarb GA. Treatment outcomes of patients with implant-supported fixed partial prostheses. *Int J Oral Maxillofac Implants* 1998; **13**: 204-211.