Osseointegrated Hearing Implant Surgery with Soft Tissue Preservation Using the Cochlear™ DermaLock™ (BA400) Abutment

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Abstract

Introduction: Recently, a novel hydroxyapatite-coated concave bone-anchored hearing device abutment was introduced, the first designed specifically to improve outcomes in soft tissue preservation osseointegrated hearing implant surgery. We sought to evaluate our early experience with this abutment.

Methods: The first 30 consecutive patients undergoing osseointegrated hearing implant surgery using the Cochlear™ DermaLock™ (BA400) abutment at our institution (February-September 2013) were studied. Follow-up was for a minimum of six months. The following data were collected: operative duration; wound healing; post-operative complications, chiefly soft tissue reactions graded by Holger’s classification; post-intervention patient-perceived health-related quality-of-life, as assessed by the Glasgow Benefit Inventory (GBI).

Results: The mean operating time was 16 minutes (range 9–22 minutes). Favourable and rapid wound healing was observed in all cases. Three patients (10%) reported transient periautment paraesthesia. Four patients (13.3%) suffered adverse soft tissue reactions, all of which were successfully managed conservatively, and graded as follows: Holger’s grade 1 (n=2), 2 (n=1), and 3 (n=1). Respective overall, general health, social support, and physical health GBI mean scores were +38 (95% confidence interval [CI]: 31.45), +51 (95% CI: 42.60), +19 (95% CI: 8.30), and +8 (95% CI: -1.17).

Conclusions: Our preliminary clinical and patient-reported outcomes support soft tissue preservation surgery, and indicate that the technology on which the Cochlear™ DermaLock™ (BA400) abutment is based may enhance soft tissue outcomes in this context. We recommend further appraisal of this approach on a larger scale with more extensive follow-up.

Introduction

Recently, several authors have proposed contemporary soft tissue preservation techniques for osseointegrated hearing implant surgery. All such reports, however, have utilised traditionally shaped titanium-based implant systems.

In 2012, the Cochlear™ introduced the DermaLock™ (BA400) abutment (figure 1), the first designed specifically for soft tissue preservation surgery. We present our early experience with this abutment with corresponding patient-reported outcomes.

Figure 1: The DermaLock™ abutment features a pronounced concavity on its lower section and is coated with a layer of hydroxyapatite, both unique design characteristics which facilitate tight integration between abutment and surrounding soft tissues to prevent adverse soft tissue reactions.

Methods

This was a prospective study of the first 30 consecutive patients implanted using the DermaLock™ (BA400) abutment at our institution (February-September 2013).

Intra-operatively, soft tissue thickness was measured to guide selection of abutment length. Subsequently, a 2-3cm linear incision was made to gain access and extended to a small cruciate incision around the designated implant site (figure 2). No dermal reduction was undertaken and thereafter implant insertion was performed in a standard fashion.

Figure 2: Intra-operative appearances pre- and post-closure

Post-operatively, patients were followed for a minimum of six months and any complications recorded. Time to loading of the sound processor was also noted. Four months after loading patients were asked to complete the Glasgow Benefit Inventory (GBI) by means of postal survey.

Figure 3: Typical post-operative appearances at 1 week (A) and 8 weeks (B and C) following implantation

Results & Discussion

Mean patient age was 61 years (range 23-91 years) and mean follow-up eight months (range 6-13 months). Mean operating time was 16 minutes (range 9-22 minutes). The distribution of abutment lengths used was as follows: 6mm (n=5), 8mm (n=8), 10mm (n=10), 12mm (n=7). Post-operatively, rapid and favourable wound healing was observed in all cases, with no noticeable defect and minimal hair loss (figure 3).

Table 1: Soft tissue outcomes in our patient group as graded by Holger’s classification.

<table>
<thead>
<tr>
<th>Holger’s Grade</th>
<th>Characteristics</th>
<th>Number of Patients (%)</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>No reaction</td>
<td>26 (86.7)</td>
</tr>
<tr>
<td>1</td>
<td>Redness, slight swelling</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>2</td>
<td>Redness, moistness, moderate swelling</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>3</td>
<td>Redness, moistness, moderate swelling, granulations</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>4</td>
<td>Overt signs of infection requiring implant removal</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Respective general health, social support, and physical health GBI mean subscale scores were +51 (95% CI: 42.60), +19 (95% CI: 8.30), and +8 (95% CI: -1.17). The overall score is depicted in table 2 and compared with previous studies reporting GBI scores with traditional surgical techniques.

Table 2: Overall GBI compared with those reported for traditional soft tissue reduction techniques.

<table>
<thead>
<tr>
<th></th>
<th>Current Study</th>
<th>Arunachalam et al8</th>
<th>McLaren et al9</th>
<th>Gillet et al8</th>
</tr>
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<tbody>
<tr>
<td>Overall GBI Score</td>
<td>+38 (31.45)</td>
<td>+31 (22.41)</td>
<td>+33 (25.42)</td>
<td>+32 (20.55)</td>
</tr>
<tr>
<td>Number in Study</td>
<td>30</td>
<td>60</td>
<td>94</td>
<td>59</td>
</tr>
<tr>
<td>Response Rate</td>
<td>87%</td>
<td>85%</td>
<td>73%</td>
<td>69%</td>
</tr>
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</table>

Conclusions

• Our preliminary findings support soft tissue preservation surgery and indicate that the technology on which the DermaLock™ abutment is based may indeed translate favourably into clinical practice, possibly improving soft tissue outcomes in this context.

• We have also demonstrated that patient-reported quality-of-life may be enhanced when using a soft tissue preservation approach.

References: