The introduction of the Cochlear™ Baha® BI300 Implant and DermaLock™ Abutment (BA400) have significantly improved clinical practices and the patient experience with bone conduction hearing implants. First introduced in 2010, the BI300 Implant is now used by over 50,000 patients worldwide. Of these patients, more than 24,000 have also received the DermaLock Abutment since its introduction in 2013. These two products have been studied and discussed in over 40 publications in peer-reviewed journals; and their performance has been proven through numerous investigations, including large-scale, prospective, randomised, controlled clinical studies with as many as five years of follow-up. The BI300 Implant is now the most tested and evaluated implant in bone conduction hearing since the original Brånemark implant introduced in 1977.

The recent and upcoming publication of three ground-breaking studies provides a unique time to take a step back and evaluate global clinical experiences with the BI300 Implant and the DermaLock Abutment. This paper will review the rapid innovation of bone conduction hearing implants over the last several years. It will begin by looking at the BI300 Implant, the first bone conduction hearing implant with a modified, roughened surface. Next, it will look into the only abutment specifically designed for soft tissue preservation surgery. Both sections will begin by examining the scientific principles that lead to the conception of these devices. Then, they will summarise the clinical evidence put forth by researchers worldwide and the impact each technology has had on patient outcomes. The summation will reveal a commitment to transforming both novel and well-proven ideas into industry-shifting and life-changing products built on a foundation of extensive and systematic research. These new solutions have made a significant impact on clinical and patient experiences across the globe.

The BI300 Implant

Optimised for stability and stronger osseointegration.

With the development of the BI300 Implant, clinically-proven, state-of-the-art technology from the dental implant industry was brought to bone conduction hearing implants for the first time. Using this technology, the entire implant was re-designed for patients with hearing loss. Though numerous design changes were made, there were three critical success factors:

1. A wide implant – The larger diameter (4.5 compared to 3.75 mm) improves the anchorage in the bone at the time of insertion. The primary stability is a critically important prerequisite for avoiding micro-mobility during early healing. Preventing micro-mobility supports uninterrupted osseointegration while simultaneously allowing the sound processor to be attached to the implant.

2. A moderately rough implant surface – Over the last three decades scientists have been working on improving the osseointegration properties of titanium implants. This research has primarily been focused on using various techniques to roughen the traditional, smooth, as-machined titanium surface. The implant surfaces that have resulted from this work all feature topographical modifications at a micrometre and nanometre scale. These improvements are all designed to achieve the same goal: enhancing osseointegration (faster and stronger) by promoting bone formation in intimate contact with the implant surface. The overwhelming success of these surfaces lead them to become the industry standard for load-bearing dental implants.

Today, the BI300 Implant incorporates the clinically successful titanium dioxide blasted TiOblast™ surface (Dentsply, Mölndal, Sweden) on the entire intraosseous portion of the implant. The completely roughened surface of the BI300 Implant ensures that the entire bone-to-implant interface benefits from the enhanced osseointegration properties of the TiOblast technology (Figure 2). The TiOblast surface has an impressive clinical track-record with
An industry leading 25 years of clinical use⁴, including more than six years of use in bone conduction hearing implants. Its osseointegration properties have been researched through numerous clinical and pre-clinical investigations⁵,⁶. An optimised drilling protocol – Significant effort was spent on optimising drills, surgical instruments and the surgical protocol for the BI300 implant. Minimising the surgical trauma was one of the cornerstones in the original work by Prof. Per-Ingvar Brånemark. He stressed the importance of using sharp disposable instruments and generous cooling during drilling to ensure good osseointegration⁶. In addition to redesigned widening drills, the development of a more efficient, conically-shaped guide drill was an important improvement to further reduce the risk of generating excessive heat during drilling.

Pre-clinical research – Enhanced osseointegration

The excellent osseointegration and biomechanical properties of the BI300 implant have been demonstrated in pre-clinical animal investigations⁸,⁹. As early as five days after implantation, the TiOblast surface was covered by osteoblasts. This indicates early formation of bone directly on the surface resulting in osseointegration by contact osteogenesis, or osteoconduction. This pattern was not seen on the previous generation smooth, as-machined, titanium implant, the osseointegration process around as-machined implants relies on bone growth originating from the osteotomy, i.e. distance osteogenesis (Figure 3). Distance osteogenesis is a slower and less efficient osseointegration process. Early osseointegration is key in reducing the risk of implant failure during the initial post-surgery period when the bone, triggered by surgical trauma, is undergoing remodeling and relaxation. This is a critical time for implant survival as it could overlap with processor loading times. The faster and stronger osseointegration seen with the TiOblast surface, along with the improved implant geometry of the BI300 implant, resulted in an increase in stability of over 100% in biomechanical removal torque tests (when compared to as-machined implants - Figure 4).

Clinical research – Proven long-term stability and early access to sound

With six years of use in daily clinical practice and numerous clinical investigations published in peer-reviewed scientific journals, the safety and efficacy of the BI300 Implant is remarkably well-documented and proven. Throughout a prospective, randomised, controlled, multi-centre clinical investigation with an industry-first five-year follow-up time, the BI300 Implant outperformed the previous generation, as-machined implant in numerous aspects, including implant stability (Figure 5)⁷⁻¹².

The investigation, which began in 2009, took place in four hospitals across Europe and included 77 adult subjects. Only two BI300 Implants were lost during the investigation— one early failure due to non-osseointegration and one late loss four years after implantation. The excellent cumulative survival rate of 96% after five years demonstrates the ability of the implant to withstand the rigours and forces of daily life. Of crucial clinical significance – and shown for the first time – the implant stability did not demonstrate signs of gradual reduction at long-term follow-up and remained higher after five years than at the time of insertion.

The excellent implant stability and high survival rates with the BI300 Implant have been further demonstrated in a large series of clinical investigations by independent researchers. The superior primary stability and faster osseointegration made it possible to safely reduce the time between implant surgery and the moment of loading the implant with the sound processor. With the previous generation implant, the recommendation was to allow a minimum of three months of unloaded healing. With the development of the BI300 Implant, Cochlear worked alongside the clinical community to thoroughly investigate the safety and efficacy of lowering the recommended loading time to six weeks⁴. Once six weeks was established as safe, Cochlear again worked with clinicians to lower the loading time to three weeks and then again down to two weeks. Two weeks is the recommended loading time today*. As of this writing, several authors have reported excellent survival rates with loading times down to one-to-three weeks post surgery in both adult and paediatric patients with the BI300 Implant⁷⁻¹⁰. The survival rates reported from these studies are high and range between 97% and 100% in adults, and between 93% and 100% in children with follow-up times between four months and one year (Figure 6). The data suggests that the sound processor can be loaded on the implant shortly after

### Table of Recommended Loading Times

<table>
<thead>
<tr>
<th>Study</th>
<th>Loading Time</th>
<th>Population</th>
<th>Implant Survival</th>
<th>F-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hegedius et al. Otol Neurosurg. 2015;36:e51-7.</td>
<td>47 2 weeks</td>
<td>Adult</td>
<td>100%</td>
<td>1 Y</td>
</tr>
<tr>
<td>Neilsson et al. Otol Neurosurg. 2015 [E-pub].</td>
<td>30 3 weeks</td>
<td>Adult</td>
<td>97%</td>
<td>3 Y</td>
</tr>
<tr>
<td>D’Emilia et al. Otolaryngol Head Neck Surg. 2012;145:973-83</td>
<td>12 3 weeks</td>
<td>Adult+Paed</td>
<td>100%</td>
<td>1 Y</td>
</tr>
<tr>
<td>Wajen et al. Am J Otolaryngol. 2015;36:195-9</td>
<td>20 3 weeks</td>
<td>Adult</td>
<td>100%</td>
<td>1 Y</td>
</tr>
<tr>
<td>Wilke et al. Otolaryngol Head Neck Surg. 2014;151:1014-9</td>
<td>30 2½–9 weeks</td>
<td>Adult</td>
<td>100%</td>
<td>6-13 M</td>
</tr>
<tr>
<td>McLarnon et al. Otol Neurosurg. 2012;33(9):1578-82</td>
<td>88 4 weeks</td>
<td>Adult</td>
<td>100%</td>
<td>4 M</td>
</tr>
<tr>
<td>Iseri et al. J Laryngol Otol. 2015;129:32-7.</td>
<td>16 4 weeks</td>
<td>Adult+Paed</td>
<td>94%</td>
<td>12-16 M</td>
</tr>
<tr>
<td>Neilsson et al. Otol Neurosurg. 2014;35:1486-97</td>
<td>52 1–5 weeks</td>
<td>Adult</td>
<td>98%</td>
<td>3 Y</td>
</tr>
<tr>
<td>Mierzwinski et al. Otol Neurosurg. 2015;36:2209-15</td>
<td>24 2–14 weeks</td>
<td>Paed.</td>
<td>100%</td>
<td>3 M post loading</td>
</tr>
</tbody>
</table>

*The recommended loading time for adults in the U.S. and Canada is 3 months.
loading protocols are quite common in the dental industry today and are used to stabilize implants and reduce the incidence of peri-implantitis. These protocols are designed to maintain the integrity of the surrounding tissue and prevent complications such as infection or migration.

BI300 Implant – Platform for the future

The BI300 Implant was designed to improve the healing and stability of implants by using a combination of modern materials and advanced surgical techniques. This design was intended to reduce the healing time and minimize the risk of complications. The BI300 Implant was chosen as the foundation of both systems because it provides a stable platform for the future.

Hydroxyapatite – Natural soft tissue interface

In order to maintain a healthy, long-term, percutaneous skin penetration, the BI300 Implant was designed to ensure that the surrounding tissue was protected and maintained. This was achieved through the use of hydroxyapatite-coated DermaLock Abutments. These abutments were designed to provide a barrier between the implant and the surrounding tissue, preventing the entry of foreign materials and bacteria.

Clinical Research – Proven soft tissue integration

Results from two in vivo animal investigations showed that the hydroxyapatite-coated abutments established stable adhesion with the surrounding tissue and reduced complications such as infection and migration. The dermal and all-titanium abutments, along with their surrounding tissues, were retrieved from patients and analyzed using a series of advanced imaging techniques. The hydroxyapatite coating on the DermaLock Abutment was shown to be capable of integrating with the surrounding tissue, providing a stable platform for the future.

Clinical investigations – Proven patient benefits

The above-mentioned investigations confirmed that soft tissue integration with full-thickness skin can be achieved with the DermaLock Abutment. This was the key goal when developing a bespoke abutment for soft tissue preservation surgery. The clinical requirement of such a system was that the new treatment (DermaLock Abutment with soft tissue preservation) would result in as good - or better - soft tissue outcomes than with the traditional, standard treatment (BA300 Abutment with soft tissue reduction). Performing a large-scale, prospective, multi-centre, randomised, controlled clinical investigation with a head-to-head comparison of the two treatments was the only way to scientifically verify if the new treatment met this goal. In 2013, Cochlear initiated the largest ever study of its kind to evaluate bone conduction hearing implants. This study was conducted in over 100 patients in five countries and has recently reached its one-year primary evaluation time point.

The one-year data from this unique clinical investigation showed that the DermaLock Abutment combined with soft tissue preservation surgery is a safe and effective treatment with clear advantages compared to the traditional treatment with soft tissue reduction. The results demonstrated a reduced number of medical events of interest, and several significant patient advantages, while maintaining a low incidence of major skin reactions.

DermaLock technology

An abutment surface designed for soft tissue preservation

The DermaLock technology was designed to mimic the body’s natural soft tissue interaction with the implant. This was achieved through the use of hydroxyapatite coating on the DermaLock Abutment. The DermaLock Abutment was shown to provide a barrier between the implant and the surrounding tissue, preventing the entry of foreign materials and bacteria.
overgrowth, pain, or numbness during the first year compared to the traditional treatment (13%) (Figure 9).

In combination with the DermaLock Abutment, alternative surgical incisions are also being used by surgeons worldwide with good results. These include placing the implant in line with a small incision, as well as placing the implant through only a biopsy punch hole. Based on clinical experience, the implant site, regardless of the type of incision or the shape of the incision used, adhering to certain principles promotes soft tissue integration and good outcomes. These principles are all centred around respecting the soft tissue and its own ability to heal undisturbed around the abutment. They can be summarised in three main points: (1) minimal use of cautery, (2) a close, tension-free fit between the abutment and surrounding skin (e.g. concentric location of the punch hole), (3) minimal pressure on the skin during healing (e.g. use of very thin, non-adherent dressing underneath the healing cap).

Conclusions

Cochlear has always been committed to helping people hear through developing and introducing innovative technology, including pioneering the first commercial bone conduction hearing implant back in 1970. The sophistication and clinical success of bone conduction hearing implants has rapidly accelerated in recent years. With the introduction of the first bone conduction hearing implant with a roughened surface in 2010, Cochlear initiated this contemporary evolution of bone conduction hearing implants. The enhanced osseointegration of the Baha 3000 implant has led to a massive reduction in loading time (including US and Canada due to regulatory guidelines), and early loading protocols continue to be pushed shorter and shorter to the point that research is being conducted on the possibility of loading the processor on the day of surgery. The legacy of innovation continued with the introduction of the hydroxyapatite coated DermaLock Abutment, developed specifically for soft tissue preservation surgery. Soft tissue preservation surgery has since lead to numerous patient benefits, including a significant reduction in surgery time, improved post-operative sensitivity and significantly improved cosmetic results. This evolution of technology has been – and continues to be – backed up with extensive pre-clinical and clinical long-term, prospective research.

The summation of all of these technological changes has transformed bone conduction hearing implant surgery to the point where today it barely resembles the procedure and outcomes of just a few years ago.

References