Cochlear™ Baha® BI300 Implant & DermaLock™ Abutment

Breakthroughs in Bone Conduction Hearing Implants

HOW INDUSTRY-LEADING INNOVATION HAS TRANSFORMED CLINICAL AND PATIENT EXPERIENCES

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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[1-3]. 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[4]. The overwhelming success of these surfaces lead them to become the industry standard for load-bearing dental implants.

Figure 1. *BI300 Implant and DermaLock Abutment*

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 use[5,6], including more than six years of use in bone conduction hearing implants. Its osseointegration properties have been researched through numerous clinical and pre-clinical investigations[5,6,8,9].

(3) **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 osseointegration[7]. 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 investigations[8,9]. 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 remodelling 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).

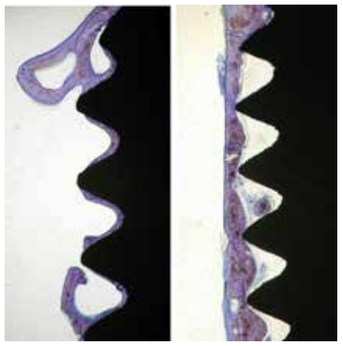

Figure 3. *The histological image on the right depicts distance osteogenesis with an as-machined titanium implant. The image on the left shows the more efficient process of contact osteogenesis with the TiOblast surface.[10]*

Figure 2. *Illustration of BI300 Implant threads immediately after insertion and during early osseointegration. The inserted histological light micrograph from an animal investigation shows how new bone forms and grows along the TiOblast surface (adapted from Gottlow et al. 2010[8]).*

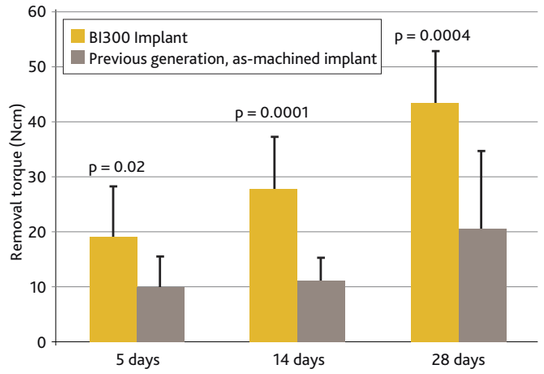

Figure 4. *The enhanced implant design and osseointegration properties of the BI300 Implant led to a significant increase in removal torque compared to the previous generation, smooth, as-machined, titanium implant in an extensive animal investigation. Adapted from Sennerby et al. 2010[9].*

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)[11,12].

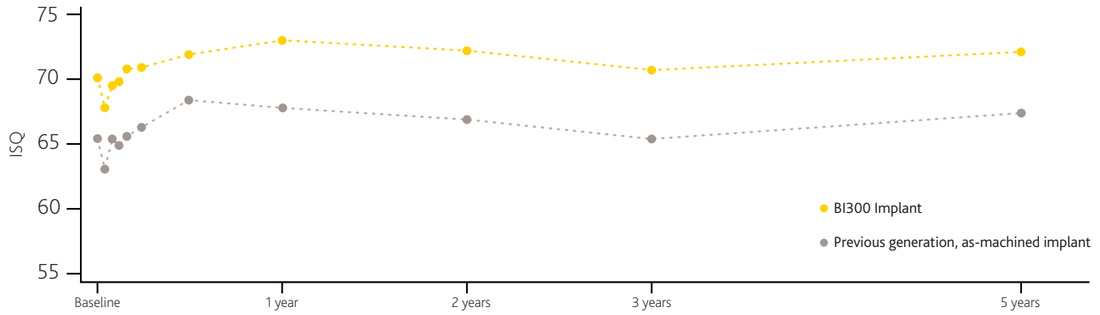

Figure 5. *Implant stability quotient (ISQ) measurements during five years of follow-up show higher stability at the time of insertion and at every point in time for the BI300 Implant compared to the previous generation , as-machined implant. Mean ISQ values after five years remain higher than at insertion[11,12].*

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 weeks[13]. 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 Implant[14-20]. 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

STUDY	N	LOADING	POPULATION	IMPLANT SURVIVAL	F-UP
McLarnon et al. *Int J Peidatr Otorhinolaryngol. 2014;78:641-4.*	30	1–6 weeks	Paed.	93%	4 M
Høgsbro et al. *Otol Neurotol. 2015;36:e51-7.*	47	2 weeks	Adult	100%	1 Y
Nelissen et al. *Otol Neurotol. 2015 [E-pub].*	30	3 weeks	Adult	97%	3 Y
D'Eredità et al. *Otolaryngol Head Neck Surg. 2012;146:979-83.*	12	3 weeks	Adult + Paed.	100%	1 Y
Wazen et al. *Am J Otolaryngol. 2015;36:195-9.*	20	3 weeks	Adult	100%	1 Y
Wilkie et al. *Otolaryngol Head Neck Surg. 2014;151:1014-9*	30	2½–9 weeks	Adult	100%	6-13 M
McLarnon et al. *Otol Neurotol. 2012;33(9):1578-82.*	88	4 weeks	Adult	100%	4 M
Iseri et al. *J Laryngol Otol. 2015;129:32-7.*	16	4 weeks	Adult + Paed.	94%	12-16 M
Nelissen et al. *Otol Neurotol. 2014;35:1486-91.*	52	≥ 6 weeks	Adult	96%	3 Y
Mierzwiński et al. *Otol Neurotol. 2015;36:1209-15.*	24	2–14 weeks	Paed.	100%	3 M post loading

Figure 6. *Selected publications from clinical studies using different loading times all show excellent implant survival rates with the BI300 Implant. These publications represent the 10 shortest loading times reported in peer reviewed journals.*

**The recommended loading time for adults in the U.S. and Canada is 3 months.*

surgery as long as clinical stability is achieved at insertion. Immediate loading protocols are quite common in the dental industry today[21] and it is of significant benefit to the patient to safely have access to hearing as soon as possible. While not cleared by regulatory agencies today, hopefully, additional collaboration between Cochlear and independent surgeons and researchers will reveal the safety and efficacy of even earlier loading protocols. Given this, in the future it may be possible to load the implant as soon as the day of surgery with the current BI300 Implant.

BI300 Implant – Platform for the future

The BI300 Implant design was first developed to provide anchorage in the bone for skin-penetrating abutments, not only for the Baha sound processor, but also for retention of craniofacial prostheses (Cochlear Vistafix® System). Furthermore, the BI300 Implant was built for the future. It was built to support future transcutaneous systems, as well as increased abutment lengths (3 mm to 14 mm), which could theoretically be subject to higher forces via the lever arm effect.

Building on the proven clinical outcomes and high survival rates of the BI300 Implant in the Baha Connect System, it was clear that the BI300 Implant would serve as an excellent foundation for the magnetic coupling of the Baha Attract System. With the ability to use the BI300 Implant as the foundation of both systems came the possibility of choosing between an abutment or magnetic connection to the sound processor. This provided surgeons with the unparalleled option of adapting the system to a patient's individual needs, both at the time of implantation and over the lifetime of the implant. Since its launch in 2013, the success of the BI300 Implant in the transcutaneous application has been reported by several authors. After eight thousand Baha Attract System implantations (March 2016), zero implant failures have been reported in the literature[22-26] or in Cochlear's own post market surveillance. Furthermore, there have been numerous successful surgical transitions between the percutaneous and transcutaneous systems on the same BI300 Implant[27,28]. Looking forward, the clinically proven stability and long-term survival of the BI300 Implant make it the ideal osseointegrated foundation for future generations of bone conduction systems.

DermaLock technology

An abutment surface designed for soft tissue preservation.

The rounded, all-titanium BA300 Abutment was introduced in 2010. It replaced the previous generation conically shaped abutment. The aim of this rounded abutment was to reduce soft tissue complications while still using the traditional surgical technique with soft tissue reduction. The abutment shape was a translation of findings in dental literature, which suggested that a concave shape at the apical portion of the abutment reduces soft tissue mobility and may improve the clinical outcome[29]. A prospective, randomised, controlled clinical investigation confirmed that adverse soft tissue reactions were kept at a lower level with the rounded BA300 Abutment compared to the preceding abutment design throughout a five-year follow-up period[11,12]. While improvements were made with the BA300 Abutment, the inherent clinical drawbacks of the soft tissue reduction technique remained. These drawbacks include localised baldness, numbness, pain, soft tissue thickening/overgrowth, reduced healing capacity of the skin and surgical complexity.

Beginning in 2008, Cochlear initiated an extensive research project with the goal of developing a completely new tissue-friendly abutment that would make it possible to perform surgery without having to remove viable soft tissue. The aim was to develop a safe and reproducible minimally invasive surgical procedure that would preserve the natural appearance, blood flow and healing capacity of the skin. The ultimate goal was to achieve clinical outcomes as good as – or better than – the traditional treatment, while providing the patient with the obvious cosmetic and surgical benefits of soft tissue preservation.

Good adherence between the abutment and soft tissue is the key to ensuring the longevity of a skin-penetrating device. This bond limits epidermal migration, which has been described as the principal failure mode of percutaneous implants[30,31]. Deep epidermal pockets around the abutment can serve as reservoirs for bacteria. Although titanium is the material of choice for osseointegrating applications, it does not provide a stable junction with soft tissue[32,33]. Through his early clinical experiences, Dr. Anders Tjellström concluded that soft tissue stability and acceptable soft tissue complication rates around titanium abutments could only be achieved if the subepidermal tissues were meticulously removed[34]. This gave rise to the soft tissue reduction technique that became the gold standard for decades.

Hydroxyapatite – Natural soft tissue interface

In order to maintain a healthy, long term, percutaneous skin penetration when surgically preserving full thickness soft tissue, it was assumed that an abutment would need to establish a natural union with the surrounding skin (i.e. soft tissue integration). Following several years of extensive pre-clinical investigations[35-37], hydroxyapatite proved capable of integrating with soft tissue. Based on this extensive research, it was determined that hydroxyapatite would feature in Cochlear's next generation abutments (Figure 7). The introduction of a hydroxyapatite coating on the DermaLock Abutment was a new application of an already-proven technology from adjacent implant fields[38-41]. Hydroxyapatite – $Ca_{10}(PO_4)_6(OH)_2$ – is a naturally occurring mineral in the human body and the main constituent of teeth. Teeth maintain lifelong soft tissue integration as well as an effective immune system in a bacteriologically demanding environment. The specific mode of action of hydroxyapatite in tissue integration has been investigated by many authors. It is believed that the ability of certain proteins to specifically bind to hydroxyapatite in an orientation that favours subsequent cell attachment[42] explains – at least partly – its unique properties as a biomaterial.

Figure 7. *The DermaLock Abutment attempts to mimic the body's natural skin penetration in teeth. The coating is made of hydroxyapatite, which is also a major constituent of teeth.*

Clinical Research – Proven soft tissue integration

Results from two in vivo animal investigations[36,37] showed that the hydroxyapatite-coated abutments established tight adherence with full-thickness soft tissue with zero or minimal epidermal migration along the abutment surface (hence minimal pocket formation). On the other hand, the same investigations showed that all-titanium abutments resulted in the formation of deep epidermal pockets and a lack of adherence between the soft tissue and the titanium surface. The macroscopic design of the hydroxyapatite-coated DermaLock Abutment is built on research from the dental field that suggests a concave shape contributes to stabilising the soft tissue by increasing the available surface for tissue contact and creating a void space where a blood clot can form and new tissue regeneration can occur[29]. The specific shape is derived from one of the animal investigations where different combinations of abutment designs and surfaces were compared[37]. The presence of blood inside the concavity and in intimate contact with the hydroxyapatite-coating was seen histologically with the new abutment design shortly after surgery in the animal investigation[37].

The unique property of the DermaLock Abutment to achieve soft tissue integration has now also been confirmed clinically. In a clinical study from Maastricht University Medical Center (The Netherlands), DermaLock and all-titanium abutments, along with their surrounding tissues, were retrieved from patients and analysed using a series of advanced imaging techniques[43]. Distinct differences were seen between the two types of abutments, both in terms of tissue adherence and the appearance of the surrounding tissues. Histological light microscopy analyses of the surrounding skin layers showed the presence of viable cells facing, and in intimate proximity to, the DermaLock Abutment, suggesting adherence between the two (Figure 8). The tight adherence between the abutment and surrounding skin minimises the risk for pocket formation and therefore impedes bacterial access. The presence of viable cells in contact with the surface also allows the body's natural immune system to access the area, which is a prerequisite long-term soft tissue health. In the same study, the all-titanium abutment showed the presence of cornified skin layers (undergoing shedding) facing the abutment surface. This demonstrated an absence of soft tissue integration. The cornified skin layer acts as a barrier for the immunological cells, denying them access to the abutment surface.

Electron micrographs of the clinically retrieved DermaLock Abutment showed that the hydroxyapatite coating was fully covered with viable tissue that closely adhered to the surface. In contrast, no viable tissue was present on the all-titanium abutment. It was instead covered with non-viable skin-remnants and biofilm. No evidence of biofilm was found on the retrieved DermaLock Abutment. The establishment of soft tissue integration has been described as a race between the host's skin and bacterial growth[44,45]; in the absence of integration, the bacteria are most likely to win the race and inhabit the implant surface. Hence, the presence of biofilm on all-titanium abutments is not surprising.

Clinical investigations – Proven patient benefits

The above-mentioned investigations all 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 as – 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[46]. It is being conducted across seven sites in four European countries. The study includes 106 patients who were randomised to receive either treatment. A wide range of clinical parameters are being evaluated in the investigation including – but not limited to – soft tissue reactions (Holgers score, soft tissue swelling), numbness, pain, aesthetic outcomes, subjective benefit and adverse events. The study will run over a total of three years 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 clinical 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 (Holgers grade 2–4) with the DermaLock treatment. Specific key findings are as follows:

1. Twice as many subjects who received the DermaLock treatment (29%) did not show any significant infection/inflammation,

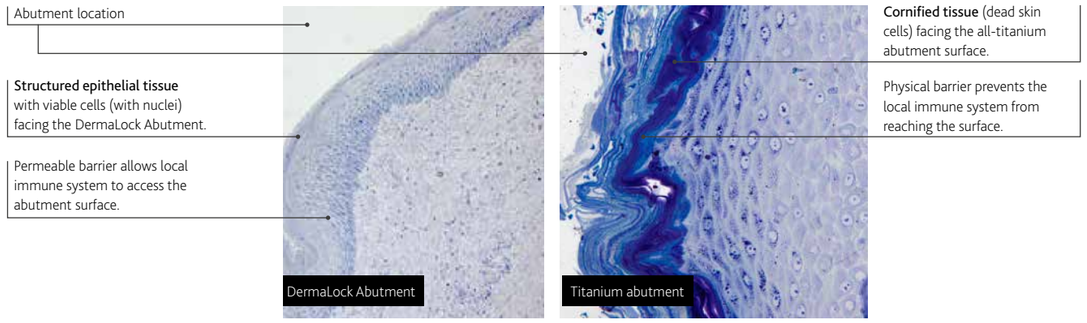

Figure 8. *Histologic evaluation of the skin retrieved from a DermaLock and a titanium abutment. The skin directly surrounding the titanium abutment shows extensive stratified keratinisation and cornification. The skin directly surrounding the DermaLock Abutment shows viable stratified layers of epithelial cells; no keratinisation or shedding is present. Adapted from van Hoof et al. 2015[42].*

overgrowth, pain, or numbness during the first year compared to the traditional treatment (13%) (Figure 9).
2. Patients who received the DermaLock treatment demonstrated many distinct advantages, including statistically significantly reduced surgery time (15 versus 25 minutes on average), reduced numbness, faster wound healing, less neuropathic pain, improved aesthetic outcomes and less abutment changes due to skin overgrowth.
3. There was no statistically significant difference in Holgers scores between the two treatments during the first year. There was a tendency towards more initial swelling with the DermaLock treatment. This is not surprising, and is a sign of healthy, fully functional tissue, as it indicates that the preserved full-thickness skin maintains its natural ability to swell and heal in response to the surgical trauma. Also of note, a slight thinning of the peri-abutment skin was seen over time with the DermaLock treatment. The opposite trend was seen with the traditional treatment. It showed a tendency for skin thickening over time.

Other independent authors have also reported good clinical outcomes with the DermaLock Abutment and soft tissue preservation surgery[15,47]. These independent investigations confirmed many of the clinically beneficial outcomes of soft tissue preservation surgery combined with the DermaLock Abutment, including reduced surgery time, reduced healing time, improved cosmetic outcomes and reduced pain. Moreover, these authors indicated that the Holgers scores for the DermaLock Abutment were favourable compared to previous all-titanium abutments with soft tissue reduction surgery.

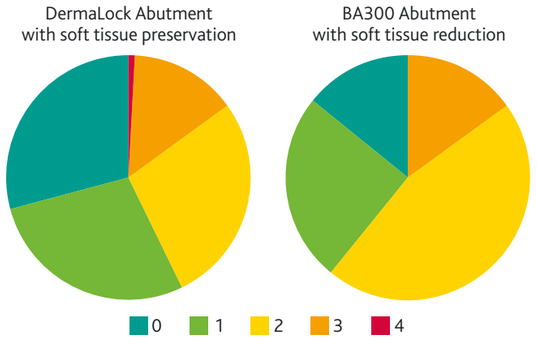

Figure 9. *Distribution of patients presenting 0, 1, 2, 3 or 4 types of complications (inflammation/infection, soft tissue thickening, pain and/or numbness) at some point during the first year post-surgery. Of note, more than twice as many patients receiving the DermaLock Abutment had zero events, and more than half of the recipients of the DermaLock Abutment had 0 or 1 event[46].*

Surgical technique – Options to meet different needs

The DermaLock Abutment and associated surgical technique are designed to interfere as little as possible with soft tissue in an effort to preserve the tissue's natural ability to heal and prevent infection. Cochlear's recommended surgical procedure for soft tissue preservation surgery with the DermaLock Abutment involves making a short, linear incision lateral to the implant site to allow good access, visibility and irrigation. A punched hole through the skin at the implant location allows tight adherence between the skin and the abutment. The time to perform surgery is very short with surgical times down to seven minutes (from first incision to final suture) reported in clinical investigations[46].

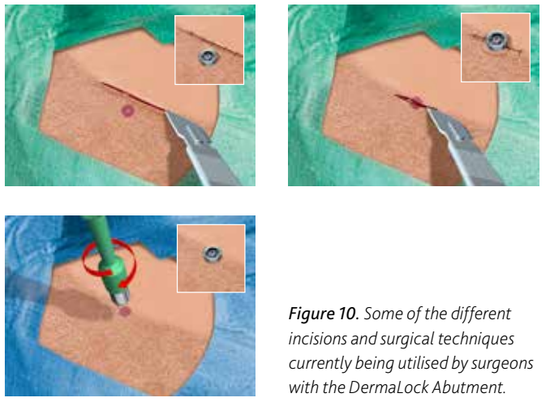

Figure 10. *Some of the different incisions and surgical techniques currently being utilised by surgeons with the DermaLock Abutment.*

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[15,48]. Based on clinical experience, and supported by the literature, regardless of the type or 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).

Conclusion

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 the 1970's. The sophistication and maturity 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 BI300 Implant has led to a massive reduction in loading time [excluding 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 sensibility 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.

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