Latest clinical results of the Cochlear™ Baha® DermaLock™ Abutment

Cochlear Baha DermaLock technology is the result of seven years of research to develop an abutment specifically designed for soft tissue preservation. Following extensive pre-clinical and clinical activities, the new abutment and surgical technique were introduced for clinical practice in 2012. The DermaLock Abutment is the only abutment cleared for soft tissue preservation surgery, and it has been successfully implanted in more than 1,500 patients with good clinical outcomes being reported by several teams worldwide.

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Titanium abutment required soft tissue reduction

In the past, titanium has been the material of choice for different types of bone-anchored implants due to good mechanical properties and proven tissue-friendliness; however, despite its unique osseointegration properties, titanium does not provide a stable junction with soft tissues. Through clinical experiences gathered during the first series of bone conduction implant surgeries, Tjellström concluded that extensive soft tissue reduction was required to guarantee long-term stability of the soft tissues around the percutaneous titanium abutment. In short, he found that meticulous removal of subepidermal tissues reduced the risk of soft tissue reactions, which was critical to success. Since then, advances in biomaterial research have shown that with careful material selection and bespoke surface characteristics, interactions between skin-penetrating devices and surrounding tissues can be achieved. During the past few decades, modern materials have positively affected treatment outcomes in various biomedical percutaneous applications, such as external fixators, as well as in endosseous applications, including the TiOblast surface on Baha implants.

Research supports soft tissue preservation

The aim of the development of the DermaLock technology was to design an abutment that provides a stable interface with the surrounding epidermal and dermal tissues without surgical removal of soft tissues. A goal is to prevent abutment and soft tissue is the key to ensuring longevity of the device by limiting epidermal migration, which has been described as the principal failure mode of percutaneous implants. With DermaLock technology, the goal was to achieve clinical outcomes that are “as good as—or better than—traditional treatment, while providing the patient with the obvious cosmetic and surgical benefits of soft tissue preservation. The DermaLock technology is the culmination of several years of extensive laboratory work, in vitro testing animal research and clinical investigation to identify an abutment material and design that provides the desired soft tissue stability while not having to excise viable subepidermal tissue. The final design selection was based on results from an animal investigation where the hydroxyapatite-coated concave design outperformed three other material/design configurations in terms of soft tissue integration.

Improved integration with DermaLock Abutment

Recently, data was presented from another, more extensive, animal investigation comparing the integration of the DermaLock Abutment and the conventional titanium abutment when placed without surgical removal of subepidermal tissues. The study confirmed that the surface of the DermaLock Abutment creates intimate contact with the dermal tissue, thus effectively suppressing migration of the overlying epidermis. The titanium surface, on the other hand, showed only weak adherence between the dermal tissues and abutment surface; the adherence was not strong enough to hinder significant downward epidermal migration, resulting in pronounced pocket formation. Even after only four weeks, statistically significantly more epidermal downgrowth and pocket formation was recorded for the titanium abutment.

Good soft tissue attachment and limited pocket formation are desirable in order to obtain a barrier and effective peripheral immunological defense against microorganisms to maintain a healthy implant site long-term. The mode of action of hydroxyapatite in tissue integration has been investigated by many authors. It is believed that the ability of important proteins to specifically bind to hydroxyapatite in an orientation that favors subsequent cell attachment explains—Read more at www.cochlear.com/clinicalreview.
Good clinical outcomes reported

The DermaLock Abutment and associated soft tissue preservation technique has been clinically used since August 2012, and more than 1,500 patients worldwide have now been successfully treated using this technology. Clinical experiences were recently reported by several teams at The 4th International Symposium on Bone-Conduction Hearing and Craniofacial Osseointegration in Newcastle, United Kingdom, and at The 11th European Symposium on Pediatric Cochlear Implantation in Istanbul, Turkey.

Overall positive experiences were reported by all research teams. The presented data showed soft tissue outcomes on par with what has been reported for traditional bone conduction implant surgery and significant improvements in terms of aesthetic outcomes, post-operative numbness and ease of surgery. Data from 276 patients gathered as part of a global post-market clinical follow-up (up to 9 months) from 85 clinics in 18 countries showed that 91.5% of patients had a Holgers grade 0-1 (normal skin to slight redness) and no patient had a Holgers grade 4 (infection requiring abutment removal) at the last reported visit. Soft tissue thickening was reported in 5.3% of the patients. Additional data presented from several case series performed as part of, or outside, the controlled market release, as well as results from an extended controlled market release on 190 subjects in the USA (Holgers grade 0-1 in 94% of patients at 3 months), showed outcomes in line with the global experience. It should be noted that, as patients are more likely to attend check-ups in case of complications there may be a risk that patients seeking treatment are over-represented in the statistics, since the controlled market clinical evaluation did not include post-defined post-operative visits and follow-up from patients not requiring treatment is sometimes incomplete.

While the recommended protocol for DermaLock surgery advocates a straightforward incision slightly offset to the implant site, good outcomes were also reported using alternative surgical incisions including punch-only techniques. Irrespective of technique used, the importance of minimizing tension at the abutment-to-tissue interface to obtain good integration was emphasized. A reduction in total surgery time compared to traditional bone conduction implant surgery was consistently reported, and most authors reported faster healing, less post-operative problems and less visits needed.

Post-operative inflammation and soft tissue swelling were reported by some presenters, sometimes indicating corticosteroid treatment or a change to a longer antibiotic. This observation stresses the need for careful pre-operative soft tissue measurement and adequate abutment selection, opting for a longer abutment in borderline cases. Four different abutment lengths have been developed to suit the different soft tissue thicknesses.

A certain degree of transient swelling may be seen in a few patients as part of the natural response of the soft tissue — now with viable structures preserved — to the surgical trauma and to the implanted material. The host tissue is expected to initially respond more actively to hydroxyapatite compared to a titanium surface as a result of direct tissue-to-surface interactions, stimulated by the characteristics of the hydroxyapatite surface, leading to the establishment of firm soft tissue integration. Early generation biomaterials, like the smooth titanium surface, were chosen for their inertness, and hence elicit minimal biological response and allow tissues to passively adapt to — rather than create an active bond with — the device surface. While a passive surface is adequate for certain medical device applications, other situations require that the material should specifically react with the tissues rather than be ignored by them. Hydroxyapatite, as opposed to titanium, has been shown to provide the tight adherence with the surrounding soft tissues that is believed to be crucial for maintaining a healthy implant site long-term.

In comparison to outcomes with conventional titanium surfaces, the recently presented pre-clinical and clinical data shows that the hydroxyapatite-coated DermaLock Abutment and associated soft tissue preservation technique provides a superior treatment with good clinical outcomes and significantly improved aesthetics for the Baha patient. Cochlear continues to closely monitor clinical experiences with the DermaLock technology.

References

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