Design and clinical evaluation of MIPS – A new perspective on tissue preservation

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Abstract: Tissue preservation surgery has quickly become the gold standard in bone anchored hearing implantation to the benefit of patients around the world. However, the surgical instrumentation was not developed with this surgical technique in mind. At Oticon Medical, we therefore took it upon ourselves to develop surgical components optimized for tissue preservation surgery. The result is the Minimally Invasive Ponto Surgery, or MIPS for short.

MIPS is a surgical technique for implanting the Ponto implants that does not leave any scarring. It is truly minimally invasive because the soft tissue excised exactly matches the shape of the percutaneous abutment. All preparations for the implant installation are done through this circular incision.

This paper describes the tailor-made MIPS surgical components in some detail. The most critical part of any bone anchored surgery is the drilling, and many efforts have been directed at the development and tests of the new drill design. *In vitro* and *in vivo* results related to heat generation, trauma, and quality of the bone bed are presented. As an integral part of the MIPS development, a clinical evaluation across 16 clinics was performed. The surgeons' feedback on the MIPS system is reported here.

In summary, MIPS is a system designed and thoroughly tested to provide the best surgical outcome possible, with the least invasive surgery conceivable. Ninety-four percent of the surgeons who have already tried MIPS would like to continue. For us at Oticon Medical, the most encouraging fact is that 87% of surgeons feel they help their patients better using MIPS compared to their current surgical technique.

Introduction

What would bone anchored surgery look like if it was optimized for tissue preservation? This is the question we asked ourselves at Oticon Medical. Two years later and we have the answer: MIPS – Minimally Invasive Ponto Surgery.

Tissue preservation surgery (Hultcrantz 2009; Hultcrantz 2011; Soo et al. 2009) has fundamentally changed bone anchored hearing surgery. It has shortened and simplified surgery, virtually eliminated the risk for skin necrosis, and most importantly no longer leaves patients with a permanent hairless spot. The long-term results not only show a huge patient benefit in terms of cosmetic outcomes and reduction in numbness around the implant, but also indications of better long-term skin outcomes (Hultcrantz and Lanis 2014; Johansson et al., 2014).

We are convinced that the Ponto abutments with their OptiFit geometry are already optimally designed for tissue preservation (Figure 1). The straight neck and perfect match to the soft tissue lends itself to minimally invasive surgery with results that speak for themselves.

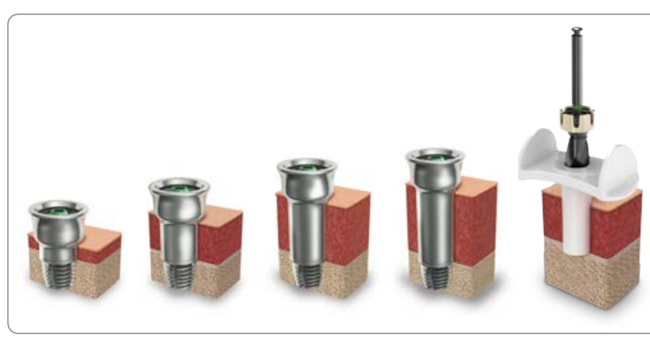

Figure 1. The shape of the Ponto abutments with the OptiFit design naturally lends itself to the MIPS technique. To further reduce trauma during surgery and to improve the outset for healing, the new cannula protects the soft tissue throughout the procedure.

Excellent soft tissue tolerability has been reported both for installation with soft tissue reduction (Foghsgaard and Caye-Thomasen 2014; Nelissen et al. 2015), as well as with tissue preservation techniques (Gordon and Coelho 2015; Hultcrantz 2015; Singam et al. 2014). One of the early adopters of tissue preservation techniques went so far as to say they are now predominantly using Ponto abutments, "the shape of which seems ideally suited for soft-tissue preservation" (Singam et al. 2014). The titanium surface of the Ponto abutment remains the clinically proven solution for tissue preservation surgery, with long-term follow up data and robust biomechanical properties (Johansson et al., 2014; Holmberg et al., 2015). The wide Ponto implant has been shown to have high initial stability, and increasing stability reported over time (Foghsgaard and Caye-Thomasen 2014; Hultcrantz 2015; Nelissen et al. 2015) with 100% implant survival in those studies. The high primary and secondary stability is a prerequisite to supporting the longer abutments needed for successful outcomes with tissue preservation surgery. The Ponto abutment family now comes in four different lengths: 6, 9, 12 and 14 mm supporting a skin thickness of up to 12 mm. For MIPS procedures the 9 mm and 12 mm abutments will be the most common lengths.

It is probably no coincidence that all studies on minimally invasive punch techniques without soft tissue reduction (sometimes known as punch-only surgery) used Ponto implants and abutments (Gordon and Coelho 2015; Wilson and Kim 2013; Goldman et al., 2013). The straight shape of the Ponto abutments matches the incision created by the biopsy punch, which avoids both dead space and tension in the soft tissue (Figure 1). To further improve the results of tissue preservation surgery we decided to focus on the surgical procedure and the instruments themselves. As a company we are in a unique position to optimize both procedure and implant, as well as the interaction between the two.

The development of MIPS has taken more than two years and involved some of the world's leading bone anchored implant surgeons. The first animal studies were performed in late 2013, and the very first MIPS procedures in humans were performed in May 2014. These patients have remained satisfied Ponto users. Throughout the development process, we have created and tested a large number of prototypes in order to optimize the surgical components. More than 100 Ponto systems have been installed using the MIPS technique during this period, making MIPS probably the most well-documented product introduction in the world of bone anchored hearing implants. This is clear testimony to the scientific and evidence-based approach that is an integral part of Oticon Medical.

MIPS step-by-step

The basic steps of the MIPS technique are the same as for any other bone anchored surgery. However, MIPS is only designed for single-stage surgery. That means MIPS is primarily recommended for adult patients with normal bone thickness and where no complications are anticipated. For a detailed description of how to perform MIPS, please refer to the Addendum to the Surgical Manual including MIPS (M52188) and the MIPS Surgical Quick Guide (M52358).

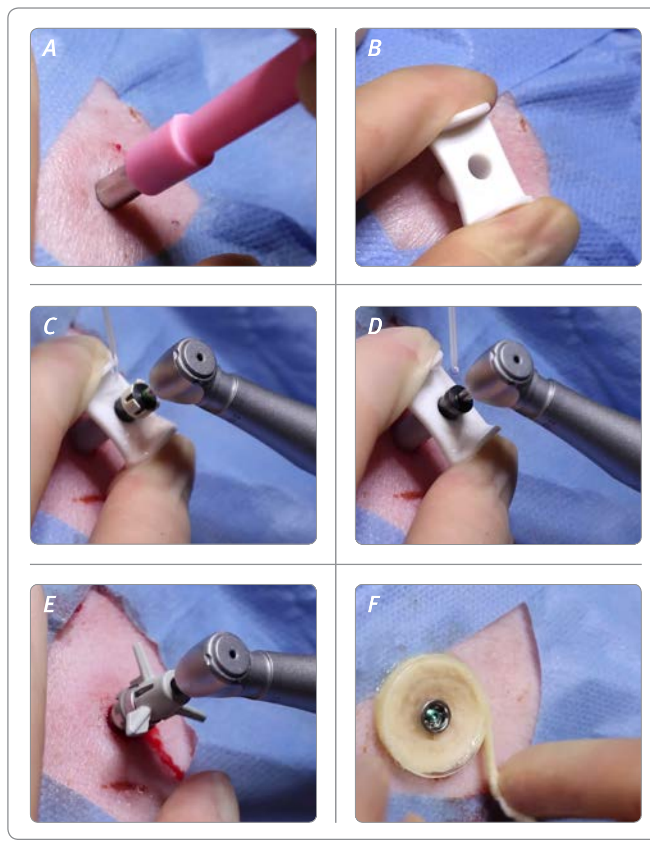

Figure 2. The MIPS technique step-by-step

The main steps of the MIPS technique are outlined in Figure 2. The implant position is chosen in the same way as in any bone anchored implant surgery. Abutment length is determined based on the skin thickness in the natural state before local injections. An incision is then made using a 5 mm biopsy punch (Figure 2A). The raspatorium side of the double-ended dissector is used to ensure that all soft tissue and periosteum are removed at and around the surgical site. The cannula is then inserted (Figure 2B). The cannula must always remain in place during all drilling. To facilitate cooling and avoid heat-induced trauma, the cannula is filled with saline solution ahead of the subsequent drilling steps, and a generous amount of saline is used during and after drilling. Guide drilling is performed through the cannula with the new cannula guide drill (Figure 2C). As with current techniques, the cannula guide drill has a spacer that is removed if the bone thickness allows a 4 mm long implant. The appropriate cannula widening drill (for a 3 or 4 mm Ponto implant) is then used to widen the hole (Figure 2D). Any remaining bone fragments are removed by generous flushing, and the implant is prepared for installation. The cannula is then removed. Implant installation is performed through the circular incision, and as with any technique with a pre-set torque setting of between 40 and 50 Ncm for normal adult bone quality (Figure 2E). A newly developed insertion indicator can be used to count the number of turns the implant engages in the bone. This gives an assurance that the implant is fully inserted. Finally, a soft healing cap is attached to the abutment and a suitable dressing applied (Figure 2F). Aftercare is handled in the same way as for any other tissue preservation surgery.

Tailor-made surgical components

The guiding star throughout the development of MIPS has been to create a method that limits the surgical trauma as much as possible. Both the surgical trauma and the biomaterial itself will influence the healing process after installation of any implant or prosthesis in the body (Anderson 2001, Suskà et al. 2008). Hence, minimizing the intervention during implantation of the device is logical and gives the best possible starting point for a long-term successful implant.

The cannula

An integral part of reducing potential soft tissue trauma is the cannula (Figure 3). All drilling is performed through the cannula. In this way, the drills never touch the soft tissue. In addition to soft tissue protection, the cannula was designed to have multiple functions. It acts as a stop for the drills, and prevents drilling deeper than intended. MIPS must therefore always be performed through the cannula. By having a slightly larger diameter than the circular incision, the cannula can help reduce bleedings in the soft tissue. The cannula also holds cooling fluid to facilitate sufficient cooling of the bone while drilling. Finally, the cannula guides the direction. The goal is to install the implant (and therefore to drill) in a direction that is perfectly perpendicular to the skin surface. For this reason, the top shoulder of the cannula should always be kept parallel to the skin surface.

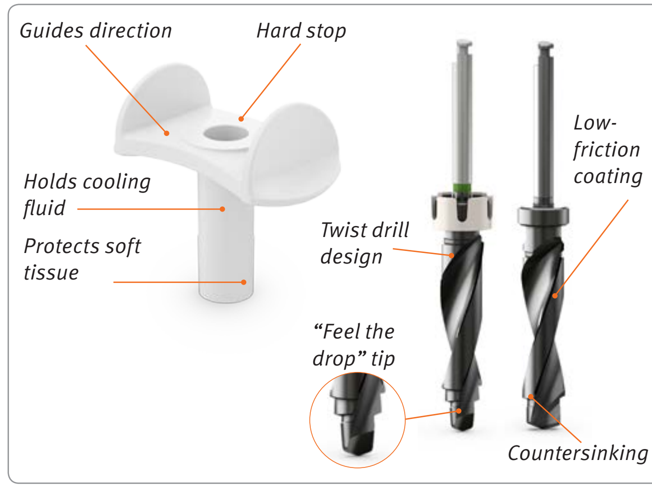

Figure 3. The MIPS surgical components: Cannula, cannula guide drill and cannula widening drill

The cannula drills

When installing implants in cortical bone, the drilling protocol and drills must be designed to prevent excessive heating of the bone during drilling. With a minimally invasive approach, the cooling of the bone during drilling is potentially impaired compared to a traditional procedure in which the incision gives direct access to the bone surface while drilling and irrigating. Considerable attention was therefore paid to optimizing the drill design for MIPS. The result is the completely redesigned cannula guide drill and cannula widening drills (Figure 3). The most apparent difference is the new twist drill design. Twist drills are inherently more efficient, and the wide helical flutes of the drills both transport the hot bone fragments upwards, and allow cooling fluid to reach the bone. To further reduce heat generation, the drills were given a low-friction coating.

In a MIPS procedure, tactility plays a much bigger role than in an open surgery where all steps can be visually guided and confirmed. In light of this, the cannula drills were designed to give tactile guidance. The soft tissue above the temporal bone is mobile, and therefore the cannula can move during surgery. With the innovative design of the drill tip of the cannula guide drill, there is always a space for the subsequent drill to fall into (Figure 4). We call this "feel the drop". This gives the surgeon very clear tactile feedback that the drill steps are being performed at the exact same location. Therefore, it is important to always use the drill tip to identify the previously drilled hole before starting to drill.

The novel cannula drills are significantly more efficient than the classic drills. They generate less heat and also alter the feeling when using the drills as they require less force.

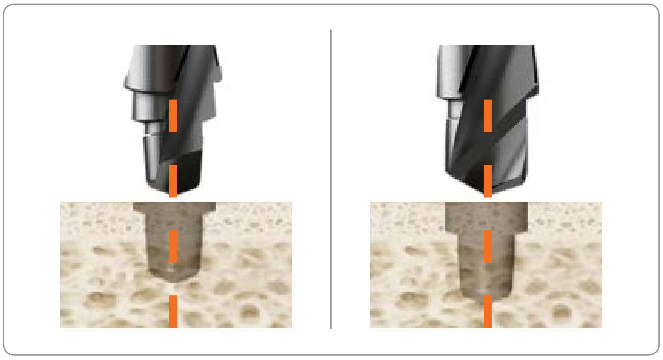

Figure 4. The drill tip of the cannula guide drill was designed to create tactile feedback to ensure perfect alignment. The drill hole after drilling with the cannula guide drill with spacer in place (left panel), and after drilling without the spacer (right panel). The cannula widening drill falls into the guide drill hole.

Insertion indicator

In MIPS, the incision is not much larger than the abutment itself. Consequently, there is limited visibility while inserting the implant. To compensate for this, the newly developed insertion indicator can be used during implant installation (Figure 5). The indicator is used to visualize the number of turns the implant engages in the bone. This gives an assurance that the implant is fully inserted at the torque setting chosen.

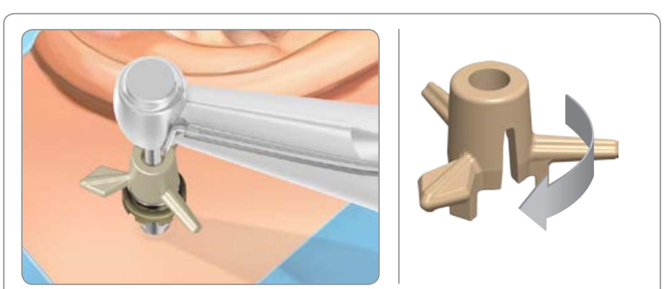

Figure 5. The insertion indicator is attached to the abutment inserter and helps guide implant installation.

Soft healing cap

Tissue preservation has changed many of the fundamental assumptions of bone anchored surgery. In skin thinning surgery, the key function of the healing cap was to create adequate pressure against the skin. Too little pressure resulted in hematoma and possible skin overgrowth, whereas too much pressure potentially led to skin necrosis. In tissue preservation surgery the situation is quite different, and to match the changes in surgical techniques we have created the soft healing cap (Figure 6).

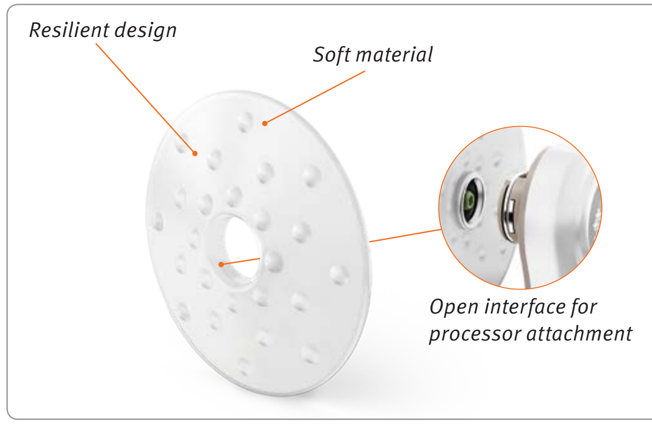

Figure 6. The soft healing cap with its open interface allows the sound processor to be attached. Fitting of the Ponto system is based on the individual patient evaluation, at the earliest 2 weeks (in Europe, CE countries) or 3 months (in USA) after surgery.

With its soft material and resilient design the soft healing cap stays in place during the critical healing period. Instead of being easily displaced, for example from a light blow or during movement while sleeping, it will bend and flip back in position. Additionally, the soft healing cap is the first ever healing cap with an open interface. Patients can use the sound processor at the same time as the healing cap (Figure 6). This is highly beneficial both for surgical aftercare and for treatment of potential skin complications.

The soft healing cap has been thoroughly investigated in a clinical trial where the use of the sound processor started already at the surgical follow-up visit. Preliminary data shows good healing and implant success (Dupont Hougard et al., 2015).

Pre-clinical investigations of the MIPS technique

For successful installation of bone anchored implants, the result of the drilling procedure is essential. There are three obvious requirements: securing the quality of the bone-to-implant interface; preventing heat-induced trauma to the tissue and cells (including the bone cells and their progenitors) surrounding the implant site; and finally, ensuring that the drills are as atraumatic as possible to the dura in case the skull is penetrated.

The cannula drills were designed to meet these requirements. In fact, the quality of the drilled hole is much better with the more efficient twist drill design. Figure 7 shows the uneven edge after the classic drilling protocol using the Ponto drill system (left panel). This can be compared to the clean cut edge created by the cannula drills (right panel).

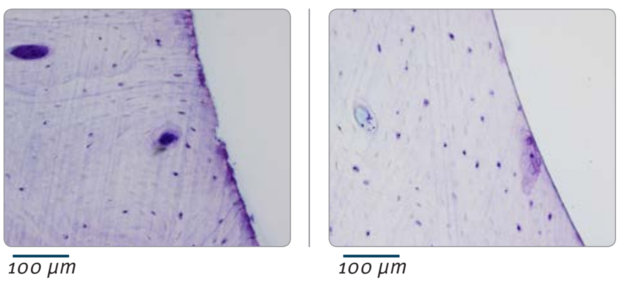

Figure 7. Histological slides of drill sites from bovine compact bone (tibia) using the classic drill system (left panel) compared to the cannula drills (right panel). An uneven edge with micro-fractures was present with the classic Ponto drills. In comparison, the MIPS drilling protocol provided a clean cut edge of the bone.

Temperature investigations
The classic drill system is clinically proven, with thousands of implant installations successfully completed. The MIPS drilling protocol was evaluated *in vitro* with respect to heat generation by measuring the temperature in hard artificial bone and comparing it with the temperature generated by the classic drill system. The temperature was measured by a thermocouple positioned 0.5 mm from the periphery of the drill tract of the final drill (Jeong et al. 2014). To simulate the clinical condition as much as possible, the drilling protocols described in the surgical manual were followed. In the classic protocol, cooling fluid was able to flow directly onto the artificial bone. In the MIPS system, a layer of artificial skin was added to the bone and cooling was applied through the cannula.

Figure 8 demonstrates the average maximum temperature increase in artificial bone. Each data point gives the average of ten measurements of the maximum temperature increase. For comparison, drilling was also performed without any cooling (leftmost measurements). The measurements demonstrate the efficiency of the MIPS drilling system, with its twist drill design and low-friction coating. The temperature generated with this system is lower than the classic system when no cooling is applied. However, the results from these bench experiments also clearly illustrate the need for proper cooling regardless of drilling protocol.

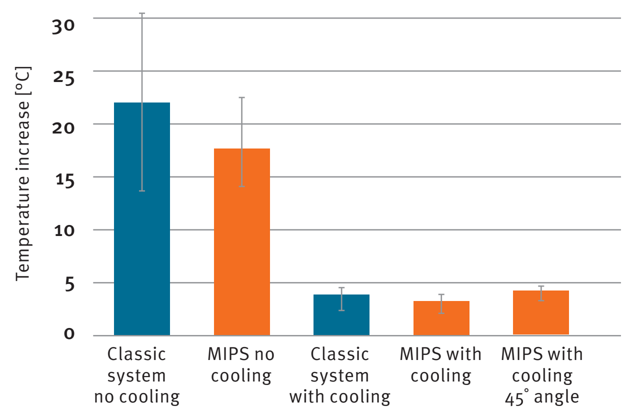

Figure 8. Average maximum temperature increase during drilling with the classic and MIPS drilling protocols, measured 0.5 mm from the drill tract in artificial bone. The two leftmost bars show the temperature increase without any cooling (Johansson et al., in preparation).

The rightmost measurements of Figure 8 show the maximum temperature increase when cooling is performed according to the surgical manual. The effect of cooling is quite striking, with the temperature increase reaching only 3-4°C. In this case, a third condition was added where the cannula was used at a 45° angle to simulate different patient positions on the operating table. The maximum temperature increase is similar between MIPS and the clinically proven system, with no significant differences between systems.

In conclusion, these *in vitro* tests of the MIPS drilling protocol demonstrate that the end result after drilling is an excellent starting point for successful osseointegration of the implant. The cannula drills allow sufficient cooling. Importantly, the tests also underscore the importance of following the instructions and carefully applying adequate cooling, both with MIPS as well as in a linear incision technique using the classic drill system.

Test of drill tips
Temporal bone quality and bone thickness vary individually, resulting in a risk of penetrating the bone during drilling. We therefore carried out *in vivo* experiments comparing the invasiveness of the MIPS drilling system with the classic Ponto drilling system on the dura in a porcine model.

A large 12 mm defect was carefully created to give access to the dura. Drilling was performed at different depths (1, 2, 3 and

4 mm) beneath the inner bone surface, i.e. depressing the dura by different amounts. Each drilling sequence lasted 5 seconds at the bottom position. In a clinical setting, the 4 mm test condition would correspond to drilling for 5 seconds in a 0.5 mm thick temporal bone with the guide drill without the spacer. Hence, this is to be considered a worst-case scenario that will never happen if surgical instructions are followed. An example can be seen in Figure 9. Damage to the dura was visible only after the 4 mm step (white arrow). However, the dura was not penetrated, neither with the classic nor the MIPS system, in any of the test conditions. No difference between the two drill systems could be detected, and it was concluded that the MIPS system is equal to the classic system regarding this important safety aspect.

Figure 9. Dura in a porcine model after drilling for 5 seconds with the drill tip positioned 4 mm beneath the inferior bone surface. Drilling was performed at the position of the white arrow with the cannula guide drill. Impression on the dura could be seen, however there was no penetration of the dura.

Clinical experiences

A new surgical technique is a big step, and it is the surgeons and patients who ultimately decide if MIPS represents progress or not. Therefore, an evaluation of the MIPS technique was performed in 15 centers in six countries. Data recorded included intra-operative and post-operative complications, surgical time, skin healing after surgery and Holgers scores. At the end of the evaluation, a questionnaire was used to investigate surgeons' subjective experiences with the technique. All surgeons who used MIPS were asked their opinion (n=21, response rate 87%).

The full clinical results will be published elsewhere (Holmberg et al., in preparation). In short, 77 MIPS procedures were performed. The results showed excellent healing and cosmetic outcomes. Intra-operative complications were rare, but as with any new surgical technique there is a learning curve.

So, what did the surgeons say about their experience with MIPS? Ninety-four percent answered 'yes' to the question "Are you likely to continue to use the MIPS procedure" (Figure 10). As a company that prides itself on always putting patients first, this was highly positive. However, it was even more encouraging to find that more than 85% of the surgeons felt they helped their patients in a better way using MIPS. It can be noted that 90% of the surgeons who participated in the evaluation already used tissue preservation techniques prior to trying MIPS. This is really the best sign we can get that MIPS indeed takes tissue preservation to a new level.

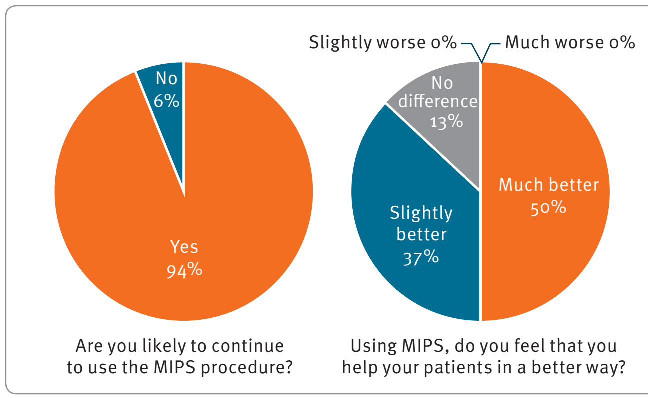

Figure 10. Overall feedback on the MIPS technique by all surgeons who participated in the MIPS evaluation.

Why this clear preference? Figure 11 shows how the surgeons rate MIPS compared to their current technique. Healing time and patient satisfaction stand out with around 50% of participating surgeons stating MIPS as much better than their current technique. When rating ease of surgery, the picture becomes more diversified. More than 75% of surgeons rate MIPS as easier, but several also find it slightly more difficult than a technique with an open incision. Indeed, MIPS looks deceptively easy, but it requires full attention and surgical experience. In a MIPS procedure, visibility is reduced, and the MIPS instruments are therefore designed with a focus on enhancing tactility. This requires a process of adjustment, and when asked how many MIPS procedures it took to be comfortable with the

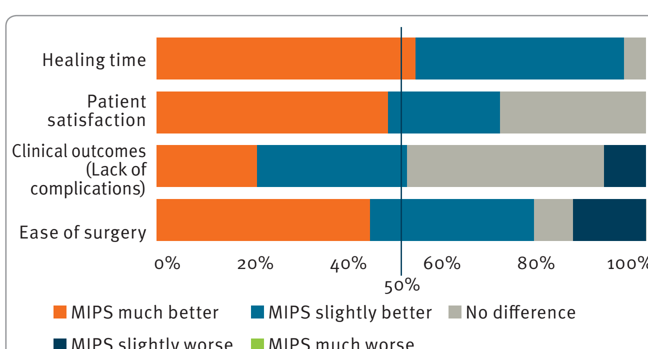

Figure 11. Ratings comparing the MIPS technique to the technique the surgeons currently use. 90% of the participants used tissue preservation, a majority with a linear incision method described by Hultcrantz, as their reference.

new technique, more than 50% reported that it took at least 1-2 surgeries (Figure 12). Adequate training and careful surgery is critical for long-term success.

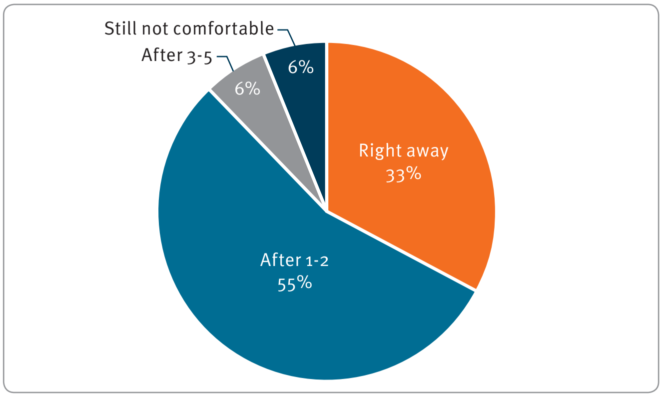

Figure 12. Reponses to the question "After how many MIPS cases did you feel confident/comfortable with the technique and instruments?"

However, the outcomes are well worth this effort, as the feedback from surgeons above shows. The patient results also speak for themselves. Figure 13 shows the one-week results for the first four MIPS patients in a large randomized controlled trial investigating the outcomes of the MIPS technique (Calon et al., 2015). Without cherry picking, these are the one-week post-operative result you can expect.

Figure 13. Patient pictures 7 days post-surgery (Calon et al., 2015). The pictures were kindly provided by the team at Maastricht UMC+.

Conclusion

We believe that the Minimally Invasive Ponto Surgery, MIPS, creates an optimal starting point for a long-term successful percutaneous implant. The percutaneous solution, with the direct connection to the bone and therefore efficient sound transfer, continues to be the best possible bone anchored hearing solution for a majority of patients. In short, we feel we have created a better way to the optimal hearing experience. The minimally invasive approach of MIPS is made possible by a complete new set of tailor-made surgical components. An extensive pre-clinical and clinical research program has validated the instruments and the technique. Among the surgeons that have installed Ponto implants using MIPS, more than 85% report that with MIPS they help their patients in a better way than previously. This means that MIPS is indeed providing a truly new perspective on tissue preservation.

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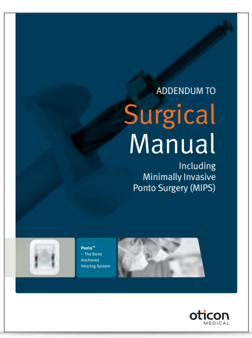
Scan this code to watch a demonstration video on how to perform the Minimally Invasive Ponto Surgery.

Tailor-made surgical components

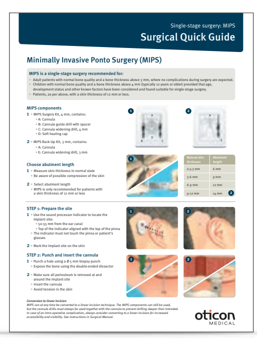
MIPS Surgery Kit, 4 mm

MIPS Back-Up Kit, 3 mm

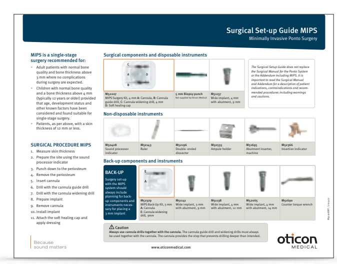
Surgical materials



Addendum Surgical Manual including MIPS



MIPS Surgical Quick Guide



Surgical Set-up Guide MIPS

Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. As a member of one of the world's largest groups of hearing healthcare companies, we share a close link with Oticon and direct access to the latest advancements in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we ensure that every solution we create is designed with user needs in mind. We share an unwavering commitment to provide innovative solutions and support that enhance quality of life for people wherever life may take them. Because we know how much sound matters.

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