WHITEPAPER
2021

# Oticon Medical
# The MONO procedure

## – functional and clinical aspects of a novel one-step drill system for installation of the Ponto system


ABSTRACT

The percutaneous solution, with direct connection to the bone, and therefore superior transmission of sound, continues to be the preferred hearing implant solution for the majority of patients suffering from conductive or mixed hearing loss, or single sided deafness. Surgical techniques for installing the percutaneous bone anchored hearing system are continuously developing and have become less invasive. Today, the Ponto procedure is one of the least invasive hearing related procedures available. This provides benefits for patients, clinical teams and clinics in terms of excellent clinical outcomes, improved clinical efficiency and reduced costs. The MONO procedure is a new ground-breaking development by Oticon Medical for installation of the Ponto bone anchored hearing system and the world's first one drill step procedure for bone anchored hearing implants. Using a novel, parabolic, drill design the Ponto implant system may now be installed using one single drill step.

Pre-clinical studies were performed to validate the MONO procedure by evaluating the mechanical, thermal and functional aspects of the system. The studies demonstrated a superior cutting performance of the parabolic twist drill design in the MONO drill compared with the currently available drills used in the linear incision and MIPS techniques, enabling the preparation of the full osteotomy in only one short drill step. Importantly, less heat was generated when preparing the osteotomy using the MONO system compared with the existing drill systems, despite the entire bone volume being removed in one sequence, in contrast to the currently available techniques that employ a tree-step drill sequence.

The MONO procedure was evaluated in a controlled market release where 28 surgeons performed 60 MONO procedures. The participants rated the MONO system very positively and considered it to be fast and easy. The majority preferred the MONO procedure over their currently used surgical technique and would continue to use the MONO procedure for their adult cases.

In conclusion, the MONO procedure is the world's first one drill step procedure for bone anchored hearing implants, providing a minimally invasive, safe, streamlined and clinically efficient procedure for installation of the Ponto implant system in adult patients.



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## Introduction

The Ponto System and the bone anchored implant installation procedure has undergone significant improvements since the first introduction of the Ponto implant in 2009. In 2015, Oticon Medical revolutionised the bone anchored procedure with the MIPS procedure – the first and only available minimally invasive bone anchored hearing solution (BAHS) procedure allowing installation of the Ponto system in just a few minutes (Johansson and Holmberg, 2015; Johansson et al., 2017). Recently, a systematic literature review demonstrated an exceptional improvement in patients' quality of life after treatment with the Ponto system, with 98% of the patients reporting an improvement (Lagerkvist et al., 2020). In addition, the review reported excellent implant survival rates (98%), a low incidence of major complications, and it can be expected that minor treatments for adverse skin reactions are required in just one follow-up visit out of 20. These favourable clinical results can be contributed to both the design of the Ponto implants and abutments, as well as to developments in surgical techniques (Johansson, 2018).

Today, MIPS is the most commonly used procedure to install a Ponto implant and its use has resulted in important advantages for the patient compared with previously available surgical techniques. Clinical studies have reported a significantly reduced surgery time, similar or improved soft tissue outcomes, improved cosmetic outcomes and decreased numbness in the area around the abutment (Caspers et al., 2021; Holmes et al., 2021). With MIPS, the patients can benefit from excellent skin outcomes, favourable aesthetic results and fast recovery times with few complications.

*Figure 1*

In addition to providing benefits to the patients, tissue preservation and minimally invasive procedures also enable efficiency for the clinic and its clinical teams. The Ponto procedure is one of the least invasive hearing implant-related surgeries available and can, in most adult cases, be performed under local anaesthetic. For clinics, this may considerably reduce the staffing and the operating room costs associated with a Ponto procedure, shorten the case duration and therefore allow a higher patient throughput (Sardiwalla et al., 2017). Moreover, the Ponto procedure allows for a flexible surgical setting. It can be carried out as an outpatient procedure, outside of the main operating room, leading to a further reduction in surgical time, staffing and running costs (Sardiwalla et al., 2017). Additionally, by relocating to a smaller sterile setting, more patients can get access to the life-changing Ponto treatment and the main operating room may be freed up for other, more complex, surgeries.

With the introduction of the MONO procedure, the world's first one step drilling procedure for bone anchored hearing implants, treating patients with BAHS is once again revolutionised. Based on the success with MIPS, the MONO procedure was developed with the aim to further streamline the installation of a Ponto implant. Using the MONO procedure, the complete osteotomy for the implant is prepared in one single drill step, in contrast to the available systems that employ a three-step drill sequence. The osteotomy preparation for osseointegrated implant installations typically employ a stepwise drilling protocol to mitigate the risk of overheating the bone. With the ground-breaking MONO drill and its unique parabolic design (Figure 1) leading to improved cutting performance in comparison with traditional twist drills, bone removal in one single drill step is made possible without overheating the bone. The MONO drill has been extensively evaluated in terms of its mechanical and thermal performance, usability and safety. This whitepaper describes the methods and presents the main results from this extensive preclinical research programme as well as the first clinical experience.

The main conclusions from the experimental studies are:

- The MONO drill has a superior cutting performance compared with the previously available linear incision drills (hereafter referred to as conventional drills) and the MIPS drills. The characteristics and efficiency of the MONO drill permits preparation of the osteotomy in only one drill step
- The drilling sequence should preferably be short and is recommended to last less than 4 seconds
- Less heat is generated when preparing the osteotomy using the MONO system compared with the conventional linear incision system and the MIPS system
- In case of exposed dura, the MONO drill is not more inclined to damage the dura compared with the conventional round burr and MIPS guide drill

## Tailor-made components

Based on clinical feedback and learnings from the MIPS procedure, we concluded that the natural next step was to develop a drilling process reduced to one single step. When drilling just once, the risk of misalignments or angulation between drill steps is avoided, thus reducing the risk of a non-optimal shape of the osteotomy. This was made possible by developing a new type of drill.

The MONO Surgery kit consists of the MONO drill, the Cannula, the Insertion indicator and the Soft healing cap (Figure 2).


*Figure 2: The new tailor-made surgical kit for the MONO procedure containing the MONO drill, the Cannula, the Insertion indicator and the Soft healing cap*

**The MONO drill – Designed for one-step drilling with great outcomes**

With the MONO system, site preparation for BAHS can now, for the first time, be performed using just one single drill step. With its efficient cutting characteristics and low heat generation, the novel MONO drill obviates the need for a stepwise drilling procedure. This is made possible by the unique design of the MONO drill bit where, in contrast to conventional twist drills, the MONO drill has a parabolic cross section. This feature minimises the amount of metal in the drill bit and as a result, the amount of metal in contact with the surrounding bone. Importantly, it also substantially increases the space available for irrigant while at the same time facilitating efficient removal of the hot bone fragment from the osteotomy. Moreover, the parabolic shape allowed for the cutting edges of the drill bit to be designed with increased bone cutting capability compared with conventional twist drills.

**The Cannula – Ensures correct drilling depth while protecting the surrounding soft tissue**

In the MONO procedure, the drilling is performed through the Cannula, analogous to the procedure using the MIPS drills. In addition to acting as soft tissue protection, the Cannula also acts as a stop, preventing drilling deeper than intended. During drilling, the Cannula is filled with irrigation fluid to facilitate sufficient cooling of the bone. Finally, the Cannula guides the direction: the drilling should be performed perpendicular to the skin surface and therefore, the top shoulder of the Cannula should always be kept parallel to the skin surface.

**Insertion indicator – Assists correct installation by helping with alignment of implant and visualization of number of turns**

Due to the punch approach, there is limited visibility when inserting the implant. To compensate for this, the Insertion indicator is used during implant installation. The indicator visualises the number of turns the implant engages in the bone, assuring that the implant is fully inserted at the torque setting chosen. For the MONO procedure, 5 turns of the Insertion indicator indicate that the implant is fully inserted. If the implant engages 4 turns or less, it can be backed out and re-inserted, or careful manual tightening can be performed until the implant reaches 4.5 to 5 turns.

**Soft healing cap – Holds the dressing in place and acts as protective mechanical barrier**

The purpose of the Soft healing cap is to protect the wound during healing. With its soft material and resilient design, the Soft healing cap stays in place and will bend and flip back into position even if displaced. The Soft healing cap has an open interface and patients can use the sound processor at the same time as the healing cap. This is highly beneficial and for the treatment of potential skin complications.

## A novel parabolic drill system that enables a one-step drill procedure

For bone anchored implants, careful preparation of the osteotomy is essential to allow for a successful osseointegration (Johansson et al., 2019b). Therefore, the MONO drill and the drilling procedure have been subjected to extensive investigations to establish the procedure. In this section, the results from the mechanical, thermal and functional evaluations are presented. A more detailed description of these experimental studies are reported elsewhere (Johansson et al., 2021; Strijbos et al., 2021).

**The MONO drill has superior cutting capability**

The intention of the unique parabolic drill design is to allow the generation of the final osteotomy for a 4 mm Ponto implant in one drill step. The cutting properties of the MONO drill have been determined by measuring the torque and force while drilling in artificial bone and compared with the results for the conventional drills for linear incision (round burr and countersink) and the MIPS drills. In addition, the influence of the feed rate (the rate at which the drill is moved into the bone, i.e. a high feed rate results in a short drilling sequence) on the drilling force and torque was studied.

Drilling in artificial bone (Sawbones, 50 PCF) was performed with a constant rotational speed of 2,000 rpm and at three different feed rates (0.5, 1 and 2.0 mm/sec, corresponding to a drilling time of 9.5, 4.8 and 2.4 seconds, respectively) while measuring the force and the torque. Using the data obtained, the energy needed to generate the osteotomy was calculated. For comparison, the conventional drill bits (round burr and countersink) and the MIPS drills were also subjected to artificial bone while measuring the force and torque, however

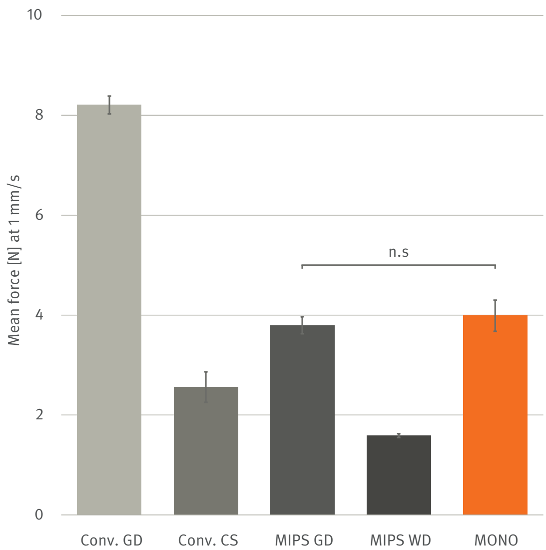



*Figure 3: Mean force when drilling in artificial bone using the drills of the conventional, MIPS and MONO system at a feed rate of 1.0 mm/sec. Statistically significant difference between all drills except MIPS Guide drill versus MONO. GD=Guide drill, CS=Countersink, WD=Widening drill. p<0.05 Independent T-test.*

only at a feed rate of 1 mm/sec.
The magnitude of force needed to feed the drill bit through the substrate is directly related to the tactile feedback the surgeon will feel when moving the drill bit into the bone during a drilling sequence. When drilling in artificial bone at a feed rate of 1 mm/sec, the force using the MONO drill was equal to the MIPS Guide drill but lower compared with the conventional round burr (Figure 3). This is a demonstration of the cutting efficiency of the MONO drill design since the volume of bone removed using the MONO drill is approximately twice that removed with guide drills in the conventional and MIPS systems.

For the MONO drill, both the force and torque increased significantly with feed rate. In contrast, the energy needed to create the osteotomy was significantly reduced with increasing feed rate (Figure 4A). Importantly, this energy is used for cutting the bone and is subsequently almost fully transformed into thermal energy distributed to the drill bit, bone fragments and the surrounding bone. The energy needed to generate the osteotomy at a fast feed rate (1 and 2 mm/sec) was less than a third of what was needed using a slow feed rate (0.5 mm/sec), suggesting that the drilling sequence should be fast and preferably last less than 4 seconds (Figure 4A). In comparison, the total energy needed to generate the osteotomy using the conventional linear incision technique and the MIPS system is significantly higher than using MONO, demonstrating the cutting efficiency of the MONO drill design (Figure 4B).

Taken together, these results demonstrate the superior cutting capability of the MONO drill compared with the conventional round burr and countersink drill as well as the MIPS drills. These characteristics and the efficiency of the MONO drill permit preparation of the osteotomy for a 4 mm Ponto implant to be executed in only one drill step. Moreover, it is also demonstrated that the drilling sequence should preferably be short (less than 4 seconds is recommended).

**The MONO system limits heat transfer to the peri-implant bone**

Excessive heat generation during drilling may result in bone injury such as thermal necrosis, which can result in delayed healing or potentially a lack of osseointegration. To mitigate this risk, a gradual augmentation of the osteotomy using a multi-step drilling protocol is

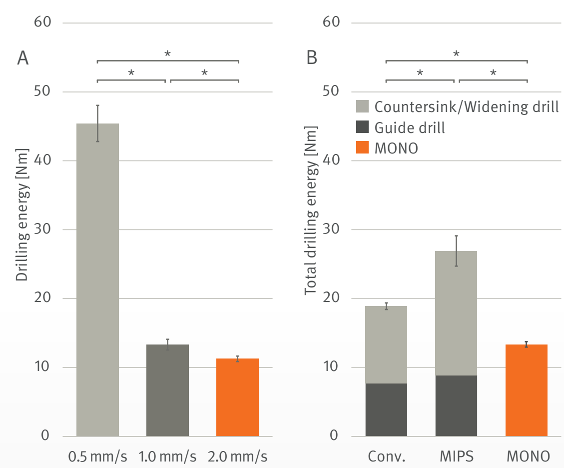



*Figure 4: (A) Drilling energy required to generate the osteotomy using MONO at a feed rate of 0.5, 1.0 and 2.0 mm/sec. (B) The total drilling energy needed to generate the osteotomy using the conventional drills (guide drill and countersink), MIPS (guide drill and widening drill) and MONO at a feed rate of 1 mm/sec. Asterisk indicate statistical significance, p<0.05 Independent T-test.*

typically employed. With a minimally invasive, guided approach, such as MIPS and MONO, the cooling of the bone during drilling is potentially impaired compared with an open procedure where the incision allows direct access to the drilling site. This was already considered during the development of the MIPS procedure, resulting in the innovative twist drill design of the two MIPS drills used together with the Cannula (Johansson et al., 2019a; Johansson et al., 2019b).

To ensure that the temperature in the peri-implant bone is maintained within biological limits, the MONO drilling protocol was evaluated *in vitro* with respect to heat generation. The temperature was determined using the methodology previously described (Johansson et al., 2019b). In brief, the heat generation was determined by measuring the temperature increase using four thermocouples positioned 0.5 mm from the periphery of the drill tract of the final drill hole while drilling in artificial bone (Sawbones, PCF 50). The MONO drill system was compared with the heat generated by the conventional system and the MIPS system when drilling was performed according to the recommended protocol (in terms of generous irrigation and recommended feed rate). To investigate the robustness of the different systems, the temperature increase was determined when deviating from recommended protocol (reduction in irrigation and prolonged drilling sequence with the drill left idling after reaching final depth).

When adhering to the standard protocol, the MONO drill system generated a temperature increase of 1.4±0.4 °C compared with 2.4±1.9 °C and 2.3±0.7 °C for the conventional and MIPS systems, respectively, with statistical significance reached between the MONO and MIPS drills (Figure 5A). These levels are well below the threshold for thermal induced tissue damage. When deviating from the protocol, subjecting the system to reduced irrigation and allowing the drill to spin a few seconds after reaching the stop, the temperature increase for the conventional and MIPS system was 16.9±8.8 °C and 12.8±0.7 °C, respectively (Figure 5B). Strikingly, the MONO system was less sensitive towards deviating from the protocol with a mean maximum temperature increase still below 5 °C (4.7±1.0 °C), which was statistically significantly lower compared with the other two systems (Figure 5B).

In conclusion, the MONO system generated equal or less heat in the peri-implant bone than the currently available drill systems, both under standard and impaired conditions. Importantly, the MONO system was shown to be less sensitive to deviations from the recommended drilling procedure as demonstrated by a lower degree of heat generation when irrigation is impaired and the drilling sequence is prolonged. The test also points to the importance of following the instructions and carefully applying adequate cooling irrespective drill systems.

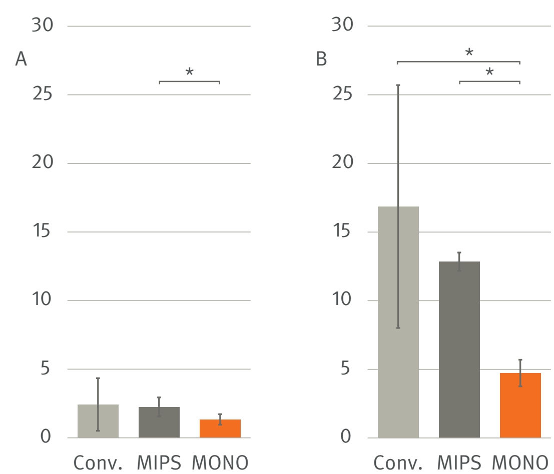



*Figure 5: Graphs showing the mean maximum temperature increase for the conventional, MIPS and MONO drill systems. (A) Mean maximum temperature increase during drilling when adhering to the standard protocol (B) Mean maximum temperature increase during drilling when deviating from the standard protocol with imparied irrigation and a prolonged drilling sequence. Asterisk indicate statistical significance, p<0.05, 1-way ANOVA.*

### *Ex vivo* evaluation of dura response to the MONO drill

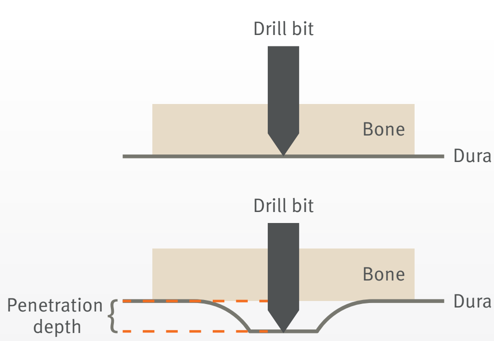
The majority of adult patients are implanted with a 4 mm implant requiring an osteotomy of 5 or 4.9 mm depth using the linear incision or MIPS, respectively (Lagerkvist et al., 2020). Using CT scan data, the average bone thickness in adult patients at the BAHS implant position has been shown to be 6.90 ± 2.27 mm (Baker et al., 2017). Another study, also using CT scans, reported an average bone thickness between 6.17 and 7.41 mm for subjects over 10 years (Kim et al., 2020). Importantly, the study confirmed that 95% of adults had a bone thickness exceeding 5 mm. Hence, for adults with normal anatomy, it is reasonable to assume a sufficient bone thickness of at least 5 mm. In some cases, however, there may be reasons to expect thin bone. If the patient has been subjected to previous surgeries at the implant site or if the patient has craniofacial or auricular anomalies, then there is a higher likelihood that the bone thickness is below 5 mm.

Penetration of the mastoid bone and subsequent dura exposure is a known event during BAHS surgery occurring in approximately 6% of the surgeries and it is more commonly seen in paediatric cases (Lagerkvist et al 2020). There is, however, no indication that this results in an increased complication rate. Furthermore, penetration of the mastoid bone, followed by a penetration of the dura with resulting CSF leak, is reported in the literature with a frequency of 0.3% of cases (Lagerkvist et al 2020).

In the MONO procedure, drilling for a 4 mm implant is performed in one step down to a depth of 4.75 mm. This contrasts with the linear incision and MIPS procedures where an initial penetration to 4 mm is made using the respective guide drills with the spacer attached. As part of the MONO development, an *ex vivo* study was performed to qualitatively and quantitatively evaluate dura response to drill trauma using the MONO drill in comparison with the linear incision round burr and the MIPS guide drill (Strijbos et al., 2021). The aim of the study was to evaluate the risk of penetrating the dura if the mastoid bone was penetrated. Fresh, frozen, human cadaver temporal bone was subjected to the three drills (round burr, MIPS Guide drill and MONO) by penetrating beyond the base of the bone to different depths (penetration depth 1, 2, 3 and 4 mm) (Figure 6A). Ten drillings per depth and drill type was performed in the ten temporal bones according to a randomisation scheme resulting in a total of 160 sites. The sites were independently evaluated by four investigators using a microscope (Zeiss OPMI pico Surgical Microscope, magnification between x0.6 – x2.5) and the damage to and possible penetration of the dural tissue was determined according to a 4-graded scale (0 = intact dura, 1 = partially damaged dura, 2 = severely damaged dura and 3 = penetrated dura).

The results showed that if bone thickness was (less than) 1 mm thinner than the maximum drilling depth (penetration depth PD of 1 mm,) the damage to the dura was limited or non-existent (Figure 6B). If the bone thickness was 2 mm thinner than the maximum drilling depth (PD 2 mm), the damage increased or the dura was penetrated. Interestingly, there was a trend towards more damage and dural penetration for both the round burr and MIPS guide drill compared with the MONO drill. For an even thinner bone (PD 3-4 mm), the majority of sites were penetrated, irrespective of drill system.

From this experimental *ex vivo* study it can be concluded that, should the dura be encountered, the MONO system is not more inclined to penetrate the dura compared with the conventional and MIPS systems.



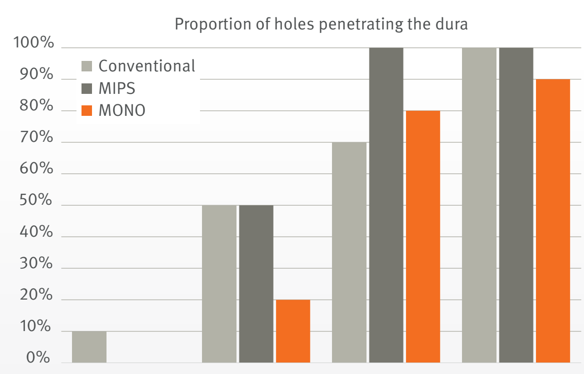




*Figure 6A: Illustration of penetration depth. The drill penetrates beyond the base of the bone to different depths (B). Proportion of holes penetrating the dura for the different drill systems and penetration depth.*

## The MONO procedure step-by-step

The main steps of the MONO procedure are similar to the MIPS procedure and the same Cannula is used for both (Figure 7). For a detailed description of how to perform the MONO procedure, please refer to the Addendum to the Surgical Manual including the MONO procedure.

The implant position is chosen as in any bone anchored implant surgery and abutment length is selected. The incision is made using a biopsy punch. Ensure that the bone is exposed at the entire site, and that all periosteum and soft tissue are removed from the bone surface before inserting the Cannula. This is important to allow the correct placement of the Cannula and to ensure the correct drill depth in the proceeding steps. Insert the Cannula. The Cannula should always remain in place during drilling and until the implant is ready to be installed. The Cannula is filled with saline solution to facilitate cooling ahead of the drilling step, and a gene-rous amount of saline is used during and after drilling. A single downward and upward drilling motion is utilized. The drilling procedure should be kept below 4 seconds to avoid overheating the bone. The Cannula is removed and implant installation is performed with a pre-set torque setting between 40 and 50 Ncm for normal adult bone quality. Five turns of the Insertion indicator indicates that the implant is fully inserted. If the implant engages 4 turns or less, consider reversing the drill and re-inserting or carefully manually tighten the implant until it reaches 4.5 to 5 turns. The Soft healing cap is attached and aftercare is handled in the same way as for any other tissue preservation surgery.

Selecting the MONO procedure

Use of the MONO procedure is indicated for the following subpopulation of patients indicated for the Ponto bone anchored hearing system:

- Adult patients (18 years and above) with normal anatomy and expected bone thickness of at least 5 mm, where no complications during surgery are expected.
- Patients, as per above, with a soft tissue thickness of 12 mm or less.

Use of the MONO procedure is contraindicated for children and patients with expected bone thickness below 5 mm.

## MONO is a preferred, minimally invasive procedure for installation of Ponto in adults

In order to evaluate user experience of the MONO procedure, a controlled market release was performed in the USA and Europe, and a survey evaluating the participating surgeons' perception of the MONO procedure was performed. The survey investigated the surgeons' subjective experiences and how likely it was that they would continue using the MONO procedure. In addition, a clinical study of the MONO procedure is currently ongoing at seven centres in Europe with the aim of following 50 patients for 12 months after surgery; the results from this study are expected to be published in 2022 (see clinicaltrials.gov / NCT04606823).


*Figure 7: The main steps of the MONO procedure*

1. *Use the punch to incise the skin and create a hole*
2. *Insert the Cannula into the hole*
3. *Drill once using the MONO drill and ensure cooling*
4. *Insert the implant into the drilled hole*
5. *Apply the Soft healing cap and dressing*

To date, survey data from 28 surgeons performing 60 MONO procedures has been gathered. Overall, the impression of the MONO procedure was very positive (n=42). The surgeons' comfort level with the MONO procedure was rated 4.6 out of a maximum score of 5. The surgeons´ perception of speed, ease of use and drill force required using the MONO procedure were also evaluated and the vast majority of surgeons judged MONO as fast and easy to use. Minimal or medium amount of drill force was required to generate the osteotomy in the majority of cases.

In 90% of cases, MONO was preferred by the participating surgeons over their currently used surgical technique (Figure 8A). When asked to rate (between 1-100) how likely it was that they would continue using the MONO procedure, the surgeons rated it as very likely (rated as 96 of 100) (Figure 8B). Overall, the MONO system was rated 4.8 (of 5).

## Conclusion

The MONO procedure for installation of the Ponto system is a new, ground-breaking development and the world's first one drill step procedure for bone anchored hearing implants in adults. With the novel parabolic drill design, a Ponto implant can now be installed using one single drill step, in contrast to the available systems that employ a three-step drill sequence. An extensive preclinical research programme evaluating the mechanical, thermal and functional aspects of the MONO procedure showed that the MONO drill, with its parabolic twist drill design, is more efficient in terms of cutting performance compared to existing drills, enabling the preparation of the full osteotomy in only one short drill step. Importantly, less heat was generated when preparing the osteotomy using the MONO system compared with the existing drill systems despite the fact that the entire bone volume is removed in one sequence. The user experience with MONO was evaluated in a controlled market release, where the surgeons rated the MONO system very positively. Among the participants, the vast majority reported that they prefer the MONO procedure over their currently used surgical technique.

In conclusion, the MONO system provides a minimally invasive, safe and clinically efficient procedure for installation of the Ponto implant system in adult patients.

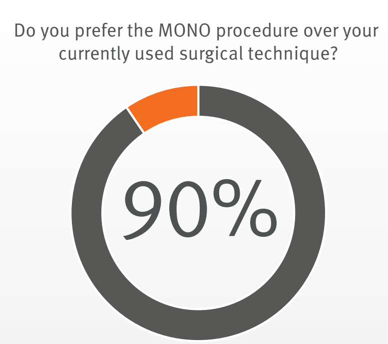



*Figure 8A: Evaluation of surgeons' preference of surgical technique*

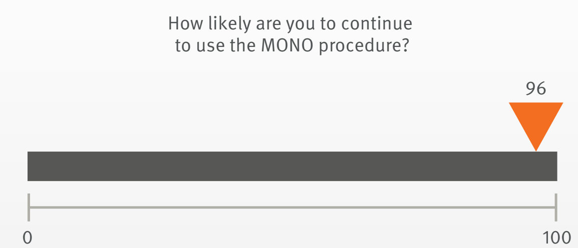



*Figure 8B: Evaluation of likelihood of continuing with the MONO procedure*

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Addendum to Surgical Manual including the MONO procedure UK. 223523UK

Ponto Implantation Using a Minimally Invasive Surgical Technique. At clinicaltrials.gov /NCT04606823

## Notes

## Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the power of sound to people at every stage of life. As part of the Demant group, a global leader in hearing healthcare with more than 16,500 people in over 30 countries and users benefitting from our products and solutions in more than 130 countries, we have access to one of the world's strongest research and development teams, the latest technological advances and insights into hearing care.

Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology. We work collaboratively with patients, physicians and hearing care professionals to ensure that every solution we create is designed with users' needs in mind. We have a strong passion to provide innovative solutions and support that enhance quality of life and help people live full lives – now and in the future.
Because we know how much sound matters.

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