Minimally Invasive Surgical Procedures for Percutaneous Bone Conduction Devices: A Review of Recent Research

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- [Nicole] Right, thank you for that nice introduction, and welcome everyone. Thank you for joining today. So I am a clinical project manager at Oticon Medical. I'm based in the US as part of our very active global clinical affairs and clinical research team. We work on sponsor research, investigator initiation, initiated, excuse me, research, and I've been a member of Oticon Medical since March of last year. Just briefly about me, my background is a neuroscience. I have a PhD in neuroscience from Brandeis University. My work focused on downstream effects of listening effort, specifically effects of age and hearing QD on speech comprehension memory for speech. My postdoctoral work at Brown University was in a very similar vein, looking at listening effort and language processing with more of a focus on pathological aging, people at risk for Alzheimer's.

But what I'm here to talk to you about today is some of the recent research in the world of percutaneous bone conduction devices and the procedures that are associated with their placement. So here are our learning objectives. So to start, this is introductory level, and hopefully after this course you'll all be able to describe some of these surgical outcomes in terms of skin reactions and cosmetic appearance. For some of these procedures, we're gonna focus on two kinds most often. Also after this course, hopefully you'll be able to describe differences in cost in terms of financial as well as resource cost between various techniques. And you should be able to describe the feasibility and safety of using some of these minimally invasive procedures out of the OR and in an office setting.

So with that, what I'd like to start with is a brief overview for those of you who aren't familiar with bone anchored hearing systems, which I'll refer to as BAHS. So two pathways by which physical sound waves can be transformed into mechanical vibration that stimulate the cochlear in the inner ear. So air conduction as well as bone conduction. So I'm sure you're all very familiar with air conduction where an acoustic signal travels through the outer and middle ear arriving at the cochlea. In bone conduction, that acoustic signal is going to bypass the outer and middle ear, vibrating

the bones of the skull, and intern stimulates the cochlea. So for people who are unable to reliably transmit acoustic signals through air conduction, bone conduction hearing systems can be used to bypass whatever conductive impairment in the ear canal or middle ear and simulate the cochlea directly, again, taking advantage of the skull bone vibrations.

So bone anchored hearing systems, or BAHS, can be appropriate for any number of individuals. So here I'm showing you an audiogram with the, what we call the bone air gap. So this individual with an audiogram like this would be probably a pretty suitable candidate for a BAHS. So individuals with conductive hearing losses. Also mixed hearing losses are appropriate if hearing loss following a middle ear disease. Also, we see BAHS being effectively used to treat malformations such as oral atresia or other deformities that don't permit that air conduction process to occur. And they're also effective for those who have single-sided deafness, right? One can utilize the vibrations transmitted in the same manner across the skull to the functioning cochlea on the contralateral side.

So here is the system that we are talking about. So the BAHS has been used since about the late 1970s, and these devices can be divided into two types. So the first is a skin drive where there's a layer of soft tissue between the transducer and the bone. For example, when you're using a headband or a soft band. And there's also direct drive where vibrations are transmitted directly to the bone. So bypassing the skin entirely, soft tissue entirely. And percutaneous direct drive is the most common type with over 150,000 users worldwide. Now on the top left of the slide, I'm showing you the Oticon Medical Ponto system with its three main parts. So going from outside in, or left to right, we have an external sound processor, which takes the acoustic sound signal from the environment and transforms it into vibrations.

That sound processor is attached to an abutment, which is in the middle there at this small post, which will vary in length depending upon the skin thickness. And that abutment is connected to a very small titanium implant, which is secured in the bone of the skull. So bone anchored hearing systems like the Ponto system, again, take advantage of another natural process called osteointegration. So when the titanium implant is placed in the skull bone, the bone itself begins to grow around and on the implant creating a really strong physical bonded connection between them. So on the bottom left of the slide is a close up of this osseointegration process of bone onto the titanium implant. So you can actually see the bone sort of extending onto those ridges of the implant.

Okay, so this is the system that we're talking about, and next we're gonna talk about the procedure involved in placing this implant into the skull as part of this system. Okay, so a little history to start. So on entering the market, the BAHS surgery was, well, exactly that. It was a surgery. It was very lengthy. It was very invasive. And one of the first surgical approaches that was used for many years was a technique that involved making a straight incision, AKA a linear incision through the skin and soft tissue down to the skull where drills are able to create the appropriate death and width to place the implant. The early linear incision techniques also involved thinning, reducing, or in some way removing some of the skin and soft tissue that would surround the abutment.

Now, at the time it was thought that minimizing the movement between the skin and the abutment would result in the most optimal outcomes. And so the best way to do that therefore was to reduce the amount of skin and subdermal tissue. So that would hopefully lead to the best outcomes. However, it's been shown that in fact, reducing the skin thickness is associated with some pretty adverse outcomes. That is tissue removal can destroy the blood supply, and it can increase scarring and scar formation around the abutment, which further reduces the chance of skin to regenerate. And

furthermore, nerve fibers are also removed in that process, or they can be damaged, and that can cause numbness or a loss of sensation in the area.

So knowing this, surgical procedures began to change, moving towards still using that linear incision technique, but without reducing or thinning the soft tissue. And indeed, most often if linear incision is still done today, it is done with tissue preservation or without any tissue removal. Now, I think here's a good time to note that there really is no consensus in the field on terminology. So the term skin or tissue preservation is also referred to as without tissue reduction or without tissue removal. So those you'll see used a little interchangeably, but they do mean the same thing. So another method that gained some more popularity around this time as well is the punch technique, and that's a technique that performs without any linear skin incisions at all.

So linear incision with tissue preservation, I'll talk through those first. Those are up at the top. So again, you make a straight incision through the skin, down through the periosteum, which is that membrane of blood vessels and nerves that wraps around the bone. Then a hole is drilled into the skull to accommodate the length of the implant, as well as the width is drilled, and the implant and abutment screwed into place. The incision is closed, and a healing cap is applied. In the punch technique, so that series of pictures on the bottom, the implant site is marked, and then a biopsy punch tool, so your just kind of standard surgical biopsy punch tool is used to remove all that tissue down to the skull, excuse me, skull surface as well.

And then through there a hole is drilled into the skull for the appropriate implant length and width, and then implant and abutment put into place, and a healing cap also applied. So those two techniques, linear incision with tissue preservation and the biopsy punch techniques became a large focus of research between 2011 and 2014, looking to quantify as well as compare various surgical and other outcomes in both adult and pediatric populations. So through this work and across this time, again, that

previously held belief that if you remove or reduce tissue around the abutment, you will have fewer adverse skin reactions was really shown to be false. And linear incision with tissue reduction was largely replaced with these two techniques.

Then in 2015, Oticon Medical launched the minimally invasive Ponto surgery, what we call the MIPS. In the MIPS procedure, a biopsy punch is also used. We will place a cannula to guide the drill, where then we will place a guide drill followed by a widening drill, and then the implant abutment placed and healing cap attached. And more recently, Oticon Medical also introduced the MONO procedure. In the MONO procedure, a biopsy punch is placed, a cannula placed, but only one drill is required. Unlike all the previous other procedures, the unique shape of that MONO drill really eliminates the need for a separate widening drill like in other procedures. So the MIPS and MONO are really minimally invasive, especially when you look at sort of where we came from procedure-wise.

They reduced surgery time, improve implant survival rates, and we've shown that they improve patient reported quality of life as well. And now these two procedures are really commonly used for fast vision BAHS placement with really good outcomes. So in the future, I think we're gonna see more research going forward confirming these great outcomes. But today, we're gonna share more recently published research, mostly in the last two years from the field on BAHS placement procedure outcomes such as implant stability and survival, skin assessments and reactions. And then towards the end we're gonna talk about some investigations into financial and resource costs and some innovations. So again, this is really an introductory level. And so this is going to be pretty much a surface level overview of all these studies, because my goal here really is to share the current trends and directions in research.

So that said, if you would like to dive into the details, I've cited each study in the slide footer, and all these studies are open access. So last thing before we get there, I

promise, last thing is in case some of you are not familiar, I'd just like to take a moment to introduce the Holger's grading scale because we're gonna see it a lot as we go through all these studies. So the Holger's grading scale is not the only scale, but perhaps it is the most commonly used scale to assess skin tolerability and skin reactions after implantations. The Holger's classification evaluates factors such as redness, swelling, moistness, and granulation around the implant. And important to note that skin and tissue reactions are influenced by surgery related factors, such as what kind of surgical or procedure approach, implant type, location, abutment length, postoperative dressing.

They can also be influenced by patient related factors like skin or skull thickness, as well as factors that influence healing such as personal hygiene or diseases such as diabetes. Most studies define a Holger's grade two or higher as an adverse soft tissue reaction, because at that point the indication is treating with topical treatments. However, there really is no consensus on our standard cutoff for classifying the skin reaction as, quote unquote, abnormal. But certainly something to keep in mind as we go forward, which now I promise we will do. All right, so first study I'd like to talk about was published last year. It was conducted in Turkey, and the aim was to examine both surgical as well as audiological outcomes of BAHS surgery in patients either undergoing the punch biopsy technique that I talked about previously, or a linear incision with tissue preservation.

This study is interesting because all of the 22 patients for both procedures, they had surgery of the same surgeon, right? So the same surgeon is doing both procedures for all subjects and patients, excuse me. So any variability in skill and experience that exists between surgeons is held constant, so to speak. So the patients were both adults and children. In the punch group, the average age was 32, and there were two children in that group, age six and age seven. The linear group was fairly closely matched in age with an average age of 29 years, and had one pediatric patient aged

five. So their outcome measures of operative complications in surgical duration were evaluated retrospectively from video recordings that were made of the surgeries, postoperative complications, the audiologic results, in which they used a speech and noise test were assessed through a review of patient records.

And the authors also assessed patient satisfaction with a Turkish translated version of the commonly used Glasgow Benefit Inventory or the GBI. It's commonly used as a measure of quality of life. And this was done at one year after surgery. So the authors contacted these patients a year after and asked them to complete the GBI. So what did they find? Well, first is that the, excuse me, punch technique was significantly faster than the linear technique. So on average 9.7 minutes compared to 47.7 minutes, quite a large difference. Complications in the punch group, granulation of the tissue with skin necrosis was noted and scored a Holger's grade three, but a full recovery was made some time during that one year follow up.

And in the linear group, a patient had granulation of the tissue, scored Holger's grade three as well, and a full recovery was also made. So other than that, no other complications were reported, and that was not different between the two groups. Audiological results. So interesting inclusion here. One would predict that the audiological results shouldn't really differ between the groups because the working principle of both implants is the same, right? However, the authors said it would be beneficial to show whether there is a difference in audiological results when comparing the advantages and disadvantages of these two different surgical techniques. And they concluded, as you would expect, there is not. And with regard to patient reported satisfaction, the GBI scores, there were evaluated between the two groups, but no significant differences were found.

So taking all of this together, the authors concluded that as the punch technique demonstrated an advantage in terms of a much shorter surgery duration and no greater

risk of surgical complications than the linear incision with tissue preservation, the punch technique seems to be the preferable surgical method. Okay, so next study that I'm gonna talk about, it was published in 2021. This is another retrospective study where the procedures were performed by two experienced surgeons, although it is not noted if the surgeons were counterbalanced across the techniques, so to speak. We just don't know. However, all of these procedures, these BAHS placements were done under local anesthesia except for two patients. 48 adult patients were included with 35 of them comprising the MIPS cohort.

So that minimally invasive Ponto surgery I talked about earlier. And it's important to note here that in the study the follow up time differs quite a bit, I would say, between the two groups. And that is because those linear incision procedures were performed from 2014 to 2017, and the MIPS, once released, this center switched over to the MIPS for its advantages from 2017 to 2019, if you will. But this is important to keep in mind when evaluating the implant survival and skin reactions reported. We have a much longer time period of follow up for those individuals who had their procedure with a linear incision. And the authors here, their primary aim was to compare surgical duration, surgery complications, implant survival, as well as skin reactions.

All right, so what did they find? Surgery duration was significantly faster with that MIPS procedure. So on average, about 15 minutes for the MIPS and 36 minutes for those in the linear incision group. So no surgical complications were reported in either group, and no implant losses reported in either group as well. Both groups had their first follow up around 15 days after surgery, and a second follow up between one to two months later. And this is around the time that they would then load that sound processor onto the abutment. Additional follow up times were included in the study, but they weren't specified by the others what they were. So soft tissue reactions. They used the Holger's classification scale, and they reported that one patient had a Holger's score of three.

So that's one out of 13, or 7.7%. And nobody in the MIPS cohort at that adverse follow up had any adverse reactions. And there were no reactions, adverse reactions, I should say, reported on subsequent follow ups as well. So here the authors conclude that these two techniques demonstrate really similar, really good surgical outcomes in terms of skin reaction and equally good in terms of implant survival. And they concluded that the surgical time for the MIPS was shorter than the surgical time for the linear incision. And so all else being equal, that may be the preferred procedure. Okay. So also published 2021 is another study comparing the outcomes of the MIPS technique and linear incision with tissue preservation. Now this study is not a retrospective design like the previous two I just spoke about, but it is, I would say inarguably, a better design because it's a randomized control trial.

So prior to surgery or assignment to procedure group, 64 adult patients were then randomly assigned to each group. So either MIPS or linear incision with tissue preservation. And it's important to note that these two cohorts were well-matched for things like age, gender, and other factors such as type of hearing loss. The incidence of soft tissue reactions is the primary outcome of interest here. The others also did examine and report pain, numbness, cosmetic outcomes, and implant survival. All right, so we'll start with the primary outcome of interest here. So that was the incidence and severity of skin reactions. So the stacked bar chart here shows the percentage of observed Holger scores across follow up visits, across time of nine days, three weeks, three months, one year, and the entire follow up period end of 22 months.

And this is for both procedures. So overall there were no significant differences between the groups in terms of adverse reactions. Again, these authors characterize an adverse skin reaction of a Holger score of equal to or greater than two. And that was true for the entire time across the 22 month follow up. So pain and numbness was also examined, and loss of sensitivity was found to be significantly less in the MIPS cohort

and compared to the linear group for follow up visits until after three months of surgery. So after this time point, so a year follow up, in that 22 month follow up, there wasn't any difference between the two groups. The outcomes of natural skin position, presence or extent of baldness, scarring, and overall cosmetics, which was assessed by both the surgeon as well as the the patient, were significantly better in the MIPS group at three months and a year post follow up.

And then implant loss. So there were a total of six implants, or about nine and a half percent of the total sample, so all 64, were extruded or lost, with five of those implants, or 15% in the MIPS group, and one implant in the linear group. The implant losses were registered on the earlier end between 26 in 99 days. So the authors note that these concerns about osteointegration and implant extrusion after the MIPS procedure might be explained by less exposure or surgical experience or other factors, but hard to know. This implant loss rate though, I will note, is higher than what it I've seen elsewhere in the literature, but certainly not a great outcome. So moving right along. Our next study is a retrospective cohort study, again, looking at outcomes of the MIPS procedure and linear incision with tissue preservation.

The cohort included both adult and pediatric patients, and all procedures were done by the same surgeon. So again, that's a good confound held constant. 59 implants were placed with 31 of those patients having their BAHS placed with a linear incision with tissue preservation. And those procedures occurred between 2013 and 2018. And 21 patients had BAHS placement done with the MIPS technique, and those were done between 2015 and 2018. So the mean age of the MIPS was 40 years. The linear group, their mean age was 16 years, which is statistically significantly different. So I think it is fair to point out that these groups weren't really well matched in age. Nevertheless, what did they find? So no implant losses, or postoperative, or intraoperative complications as well across either group.

Local anesthesia with IV sedation was chosen. So anesthesia was also chosen to be measured. So local anesthesia with IV sedation was chosen more often in the MIPS group than the linear incision group. So 67% of patients who had the MIPS procedure used just local anesthesia as opposed to general. And that is 16% for those in the linear incision group. However, I'd like to give you a note of caution with this interpretation to keep in mind that the linear group was composed of mostly younger patients, and thus the type of anesthesia may be more age dependent than procedure dependent. But that is certainly a difference between those two groups. And surgical duration was also different between the groups with those MIPS procedures taking on average about 40 minutes less than the linear incision procedures.

And skin reactions, the authors reported on the Holger's scale as well here. And most observations, their follow up period showed no or slight irritation across both groups and really no statistical difference between these two groups. And this grading was assessed most commonly at time points of a week post implantation, between one and three weeks, and then it varied frequencies depending on patient progression. We don't know what those are, but no difference between the groups. So the last outcome that this study was sought to measure was implant stability. So I'd like to take a moment here on this slide and talk about implant stability and how it is analyzed most commonly, or what will be I think most commonly used.

And that's the resonant frequency analysis model, or the RFA model. So this is a non-invasive method where there's a small transducer rod that is attached to the top of the implant. The signal is delivered, and then the frequency response, the out is measured. So I'm gonna spare you all the details of how the physics of all this works. All you need to know is that the frequency response that's measured is placed on a scale called the ISQ, which is the implant stability quotient. And this ranges from one to 100, and a higher score correlates with a more stable implant. Okay? Also good to note

these responses are measured twice perpendicular to each other. So if you can think of a compass, North and South and East and West, right?

Those two perpendicular directions of force are measured, and this results in a lower score and a higher score. So this RFA analysis was done with these individuals in this cohort. So here we have these stability measures. They were again, conducted twice to give us a low score and a high score. And this was done across time. So I'm showing you the low score on left, high score on the right, and time points are at the bottom there. So these ISQ scores were significantly higher in the MIPS cohort at all the time points tested, which indicates again, a more stable implant. So the higher the score, the more stable. And it's also important to note these measures were taken across time to show the overall average progression or regression of implant stability.

Normally we expect these scores to increase over time as that osseointegration process progresses, and therefore the implant becomes more stable. So the authors also however calculated threshold shifts. Again, I will spare you the details. Just know that differences in implants and abutment sizes and lengths can influence these ISQ scores. So these scores were submitted to a calculation to sort of account for these implant specific differences. So here the low and high ISQ scores were significantly higher in the MIPS cohort in the early follow up, the first one to two weeks period, indicating a more stable implant was achieved early on. And then if we look at later time points, the stability scores really become comparable between both MIPS and the linear groups.

Okay. So we are changing things up here a little bit. So we're leaving our MIPS and our linear incision with tissue preservation, that is a lot of the research recently, to share with you, this was just published this year. And this is important, and I'm sharing it even though linear incision with soft tissue reduction isn't done much these days, but it is the longest follow up term for linear incision to date. So this was a perspective

design where the authors contacted patients who had completed a previous study, and then invited them to come in for a single visit. And that was timed so that it was five years after their BAHS placement. So quite a long follow up time.

And well, no differences, I think the takeaway here. So at five years after surgery for both groups, there were really no significant differences across any of these outcome measures, such as implant survival, soft tissue reactions, skin height sensitivity, or numbness. So the authors did refer back to the original study done five years previously where many of these patients had participated, and this is where they were recruited from. They were able to obtain the surgery time. And so the authors concluded, there was really comparable, no difference between these clinical outcomes at five years. But looking back there was a, excuse me, shorter surgery time for the linear incision with tissue preservation group. So that should be preferred, if nothing else, over linear incision tissue reduction.

Published 2021. And this will be the last recent study that's been published before we shift gears to talk about two other studies that are again, have a different focus. So this is another retrospective cohort study where the authors conducted a review of electronic medical records of both adults and pediatric patients who had BAHS placement done either via the MIPS procedure or via linear incision with tissue preservation. And this was any time between 2015 and 2018 at the Louisiana State University Shreveport Hospital. So during that time period, they were able to pull together a population of 17 adults and five children who had undergone the MIPS procedure, as well as 19 adults and five children who had a linear incision with tissue preservation to place their BAHS.

The populations were pretty well-matched in age, gender, ethnicity, other conditions. And they were followed for about 18 months was the average. So checking their EMRs for 18 months passed that original procedure. Primary outcome measure here was

present severity of skin reactions. They also looked at secondary objectives that considered cosmetic outcomes such as incidence of scarring, skin laxity, or anything else that really was at the point where it bothered the patient to have it documented. They also looked at incident and rate of revision surgeries, any adverse events, and they also did track average sound processor use once they had that loaded, as well as SRTs. All right, so first, skin reactions. So this was again, assessed by that Holger's grading scale, and there were significantly fewer negative abnormal skin reactions observed in the MIPS group as compared to the linear group.

So again, an adverse skin reaction is anything they defined equal or greater than two on the Holger's scale. So 4.5% versus 33% across that entire follow up period. So the authors then examined that Holger's data, the skin assessment data by not just group but by age. So pediatric patients often have a higher incidence of skin reactions than adults. This is seen and pretty well established across literature, and this is the case here. You can see in these figures we have the pediatric patients on left, adult patients on the right. It's delineated by procedure as well. So number of patients across the Holger scale. And just overall, we do have more pediatric patients having more adverse skin reactions as compared to the adult patients.

So the secondary outcomes were then analyzed across procedure group and collapsed back across age. The poor cosmetic outcomes, they were reported significantly less for those individuals in the MIPS group than the linear incision group. Rate of revision surgery was also significantly less for the MIPS group compared with the linear incision group. And then adverse events, sound processor usage, and speech reception thresholds were not statistically different between the groups. So the authors concluded that the MIPS does seem to be superior than the linear incision with tissue preservation by offering better healing, better cosmetic outcomes, and possibly decreasing the need for frequent follow-up. I.e. fewer revision surgeries. As procedures such as the MIPS and more recently the MONO have been shown to lead to excellent

outcomes, research in the field has begin to consider other aspects of BAHS placement such as financial and resource cost factors, and expanding access to the procedure to everyone who may benefit from it.

So traditionally the largest financial, and resource costs, and bottlenecks, so to speak, have really existed at the the OR level, the operating level. And with the surgery itself, there is only so much or time available, and direct surgical costs such as surgeon fee, anesthesia fee, et cetera, are really the largest costs associated with this procedure. So these aspects of the BAHS placement procedures are really important ones. And so I'm going to share with you now a couple of recent studies that focus on these aspects rather than surgical and performance outcomes that we've been talking about. Okay, so. So this is just a smidge outside of our recent window, quote unquote. So this was published in 2017, and it is a study that really wanted to examine the costs of the MIPS procedure compared with any other surgical approach.

The authors call it open approaches. So this could be linear incision with tissue preservation, or linear incision tissue removal. It was conducted in a public hospital in Canada. So yes, the generalizability to the US or other healthcare systems is slightly limited, but regardless, I think it's important to examine the cost and feasibility of taking these less invasive procedures such as the MIPS, moving them out of the OR and what kind of costs are we looking at. So I'll take a moment here to just say also, this study was looking at direct costs, but hopefully future and other research really to truly evaluate the monetary value of a healthcare intervention should consider, yes, direct costs, but also indirect and future costs.

So indirect costs are those costs of care that patient face that may not necessarily be tied to a medical bill, such as the cost of travel or time off of work. They can also comprise costs born by the healthcare service, such as general administrative costs. And future costs are those costs like follow up care, et cetera. So indirect and future

costs, to be fair, are very difficult to quantify, and they're not considered within the study. But I think it's worth pointing out that they exist. The authors, basically what they did was they looked at costs, anything that was similar between any open approach and MIPS procedures, and sort of negated them in the analysis. So any preoperative workout and consultation that was the same between the two procedures, the cost of hospital admission and post-op follow up were not included.

So what did they find? Okay, so the table here summarizes the findings, and they're pretty straightforward, no surprises here. The first thing you'll see in this table that jumps out, I think, is that there are more healthcare providers needed when you're performing the linear incision approaches, namely three nurses, one surgeon, and an anesthesiologist. So a total of five. Those staffing needs are greatly reduced when the MIPS was conducted outside of the operating room. So you have one nurse and one surgeon. So that's kind of a very large economic benefit that the MIPS does not need to be in an OR with a staff of five. Second, the MIPS technique was performed on average about an hour faster than the open approaches, and the cost savings of the MIPS approach really primarily reflects this reduction in procedure time, right?

You're paying a smaller amount of staff costs. Yeah. So all in all, they found the MIPS technique produced a total cost savings of over $400 compared to other open approaches. Important to note, this was a small patient population. There were 12 patients included. And in fact that large difference in surgical time when considering staff costs per hour is of course a bit confounding, and a lack of postoperative costs again, is a considerable limitation. But I think it's important to consider these, and certainly the feasibility of moving these procedures that are becoming, moving from truly a surgery to more of a procedure that's really minimally invasive if it can be done out of OR. So the last study that I'm gonna talk about addresses exactly that.

So the feasibility and safety of minimally invasive techniques in an in office setting. So this was published last year. So this was done at the VA system, Northern California Healthcare. There were 20 patients. They were all male, all veterans of course. And they, all 20 underwent BAHS placement with the MIPS procedure. And all underwent the MIPS procedure in an office setting. So not the OR. And they all underwent placement with local anesthesia without sedation. So outcome measures here. There were two that they primarily wanted to look at, and that was procedure time. So looking at this BAHS placement, undergoing using the MIPS procedure in an office, and they compared that time to average published times for traditional placement in an OR.

And their second outcome measure, the patient satisfaction. So patients were contacted after the procedure and surveyed using a surgical satisfaction questionnaire. So here's what they found. So based on what they report, there was a five minute reduction in time performing this procedure in the clinic or the office versus the OR. Furthermore, they report there was a 20 minute reduction of total time from the OR versus the office, and 120 minute reduction of total time that was spent in the hospital versus the clinic. So their intraoperative complication rates were similar to or better than those described in the literature. There were no adverse skin reactions. Again, they used Holger's score greater than a regal to two. Only two patients had a mild skin reaction that resolved.

They did have four implant losses, which is high. These implant losses, however, were not sort of spontaneous. They were all due to trauma. Trauma, we know about three of them. So one was a injury from a, direct injury from a electric hair cutting razor, a basketball taken directly to the implant, and a swinging tree branch. So really traumatic things. And then for the final outcome, or their second outcome, I should say, was satisfaction. So of the 20 patients who initially received an implant and were contacted to complete the surgical satisfaction questionnaire, four were deceased by the time of

survey collection. Of the remaining 16, 14 did complete the survey, and they all indicated they'd undergo the procedure again and would recommend it to somebody else.

So this is far from a gold standard study, but what we can take from this is that the MIPS is really a potentially feasible and safe procedure that can be done in the clinic under local anesthesia. That said, the sample consisted of all veterans who may have had a better ability to tolerate an awake procedure under a local anesthetic only, probably more so than the general population. So this population limits how much of this is generalizable, and certainly further studies should and will be done. But nevertheless, it's I think a really good proof of concept, so to speak. Okay, so conclusions, overall trends, future directions. So, as I hopefully have shown through summarizing the past recent research over the past few years, generally the more minimally invasive a procedure is, such as the MIPS procedure, the better the litany of outcomes we tend to see.

And recent research really has focused on surgical outcomes specifically, excuse me, implant stability, survival, as well as these skin assessments and skin tolerability. I think it's reasonable to expect to see further studies exploring providing evidence for the use minimally invasive procedures to be done in an office setting, and furthermore elucidating the presumed cost and resource savings that may come along with this shift. Finally, I didn't discuss this last point to this talk, but as I am talking about future directions, I think it's important to note that we'll probably see more research addressing patient populations that have traditionally been more challenging, more specifically pediatrics and older adults who tend to have more challenges with bone quality or thickness, and in addition to healing challenges.

And I also believe we're gonna start seeing more research into understanding and addressing the needs of syndromic patients, like individuals who have Down

syndrome, for example, where we often see irregular bone surfaces. And so addressing sort of procedure and BAHS placement challenges in these other populations as well. Okay. And with that, I would like to thank you all very much for your time over the last hour. If you have any questions, you can add them into the Q&A there, and I will be happy to answer them. Yeah, thank you.