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The IPS-scale: A new soft tissue assessment scale for percutaneous and transcutaneous implants for bone conduction devices

1 | INTRODUCTION

Percutaneous titanium implants for bone conduction devices (BCDs) have offered, since 1977, a solution for patients with hearing loss not treatable by conventional hearing aids, such as patients with chronic ear infections or microtia and/or ear canal atresia.[1] Percutaneous implants imply a continuous breach in the mechanical defensive barrier of the skin. To compensate for this breach, immunological mechanisms in the subcutaneous tissue surrounding the implant become more active.[2] Nonetheless, in a study, adverse skin reactions around the abutment were reported in 2.4%-38.1% of patients.[3] A grading system to standardise the reporting of soft tissue reactions around percutaneous implants for BCDs was introduced by Holgers et al.[4] Recently, surgical techniques for soft tissue handling have evolved and have become less invasive. With new implant/abutment designs, this has resulted in fewer adverse skin reactions. Moreover, other parameters are becoming important in reporting soft tissue status.[5-7] Furthermore, BCDs not relying on percutaneous coupling have been developed, where the vibrations are transferred through the intact skin to the skull. Although this transcutaneous coupling does not cause a permanent breach of the skin's mechanical barrier, soft tissue complications have been reported.[8] To date, a standardised assessment scale for skin complications after transcutaneous BCD implantation is lacking. We therefore propose a new consistent, uniform and easy assessment scale for both percutaneous and transcutaneous implants for BCDs. Furthermore, we have attempted to determine standardised treatments based on this scale.

2 | METHODS

Ethical considerations: Ethical committee approval was not required for this evaluation.

With the widely used Holgers scale as reference, we interviewed surgeons and healthcare professionals experienced in postoperative care for BCD-implant recipients within our tertiary referral centre.

First, we evaluated the current suitability of the Holgers scale, identifying its strengths and weaknesses concerning current percutaneous implants. Second, we identified clinical signs and symptoms relevant in the follow-up of percutaneous BCDs that are not encompassed by the Holgers scale. Third, we designed a soft tissue assessment scale for transcutaneous implants, which is currently lacking. Finally, we aimed to create a similar structure for assessing percutaneous and transcutaneous implants with standardised clinical treatment decisions, while retaining the ease of use, reliability and a standardised measurement.

3 | RESULTS AND DISCUSSION

3.1 | Evaluation of the Holgers scale for percutaneous implants

The Holgers scale is determined solely based on observations made by healthcare professionals. It consists of serial observations regarding severity with a dichotomous outcome, that is present/not present. The scale can be used to indicate treatment, for example topical treatment for Holgers grade 2 or revision surgery for Holgers grade 4; however, these treatment decisions are not standardised worldwide. The advantages of the currently used Holgers scale are its ordinal scale and overall simplicity that result in its high usability. The Holgers scale has three disadvantages, in addition to being subject to personal interpretations in indicating treatment. First, the current scale was originally developed to start evaluating the skin three months after implantation. It therefore lacks the ability to describe complications in wound healing, such as (often minimal) dehiscence. Second, the scale lacks possibly the most important signal function, namely pain. Pain can result from skin infection, but may be caused by peri-implantitis, as is seen in dental implants.[9] Third, skin height is not incorporated in the Holgers scale. This is relevant in case a soft tissue preservation technique is applied, as skin can thicken around the abutment without infection signs, which can result in the inability to couple the sound processor, in the worst case requiring abutment change or skin revision.

3.2 | Requirements for a scale for transcutaneous implants

We evaluated possible pressure-related signs and symptoms based on our experience with postoperative skin inspection of patients with transcutaneous BCDs. Observations regarding skin integrity, colour and oedema were found to suggest intervention, such as reducing magnet strength. In addition, reporting of pain and numbness of the surgical flap area was found to be important factors influencing daily usage and patient satisfaction.

3.3 | Introduction of the IPS-scale

We aimed to incorporate all elements that are essential in soft tissue grading around implants into a new scale with three parts, namely I-scale (Inflammation-scale), P-scale (Pain-scale) and S-scale (Skin height/numbness-scale). These abbreviations have a different meaning based on implant type being scored, that is percutaneous or transcutaneous. A higher score reflects a more severe complication. The whole scale is presented in Figure 1 and is clarified below.

Keypoints

- Developments in the design of percutaneous implants/abutments for bone conduction devices, as well as surgical techniques, have resulted in other parameters becoming important in reporting soft tissue status.
- BCDs do not result in a permanent breach of the mechanical barrier of the skin. Nonetheless, soft tissue complications have been reported.
- To date, a standardised assessment scale for skin complications after transcutaneous BCD implantation is lacking.
- The new IPS-scale is a complete assessment scale for reporting soft tissue status in patients with either percutaneous or transcutaneous implants for BCDs.
- Standardised treatment advice is provided, based on the IPS-scale.

For percutaneous implants (the pIPS-scale), the Inflammation-scale ranges from 0 to 4, comprising four dichotomous objective observations made by healthcare professionals, namely skin integrity, erythema, oedema and granulation tissue. The latter three are derived from the Holgers scale; however, skin integrity was added. Skin integrity encompasses the observation of a blood crust or persistent minimal blood loss at the skin-abutment junction. These breaches of mechanical barrier function could make the peri-abutment soft tissue more prone to infections and should be included.

The Pain-scale reflects pain around the implant, developed immediately after surgery or after an initial postoperative pain-free period. The Pain-scale ranges from 0 to 2 and is scored based on the presence, duration and increase of pain during abutment manipulation that is tightening of or tapping on the abutment. If increase in pain is observed after an initial postoperative pain-free period, it could indicate possible peri-implantitis, as seen in dental implants.[10] Early detection is crucial, because immediate treatment is necessary to avoid implant loss or elective removal because of chronic pain.

The introduction of soft tissue preservation surgery has resulted in an additional possible complication, that is skin thickening around the abutment without infection signs. The S-scale therefore represents skin height in relation to the abutment. It ranges from 0 to 2 and is scored based on the presence of skin thickening and the ability or inability to couple the sound processor onto the abutment, possibly requiring an abutment change or skin revision.

For transcutaneous implants (tIPS-scale), the Inflammation-scale ranges from 0 to 4 and comprises three observations, that is skin integrity, erythema and oedema. Granulation tissue cannot be observed in these implants. To retain similarity to the pIPS-scale, skin integrity weighs for two points, because lacerated skin is the result of prolonged excessive pressure, requiring immediate treatment.

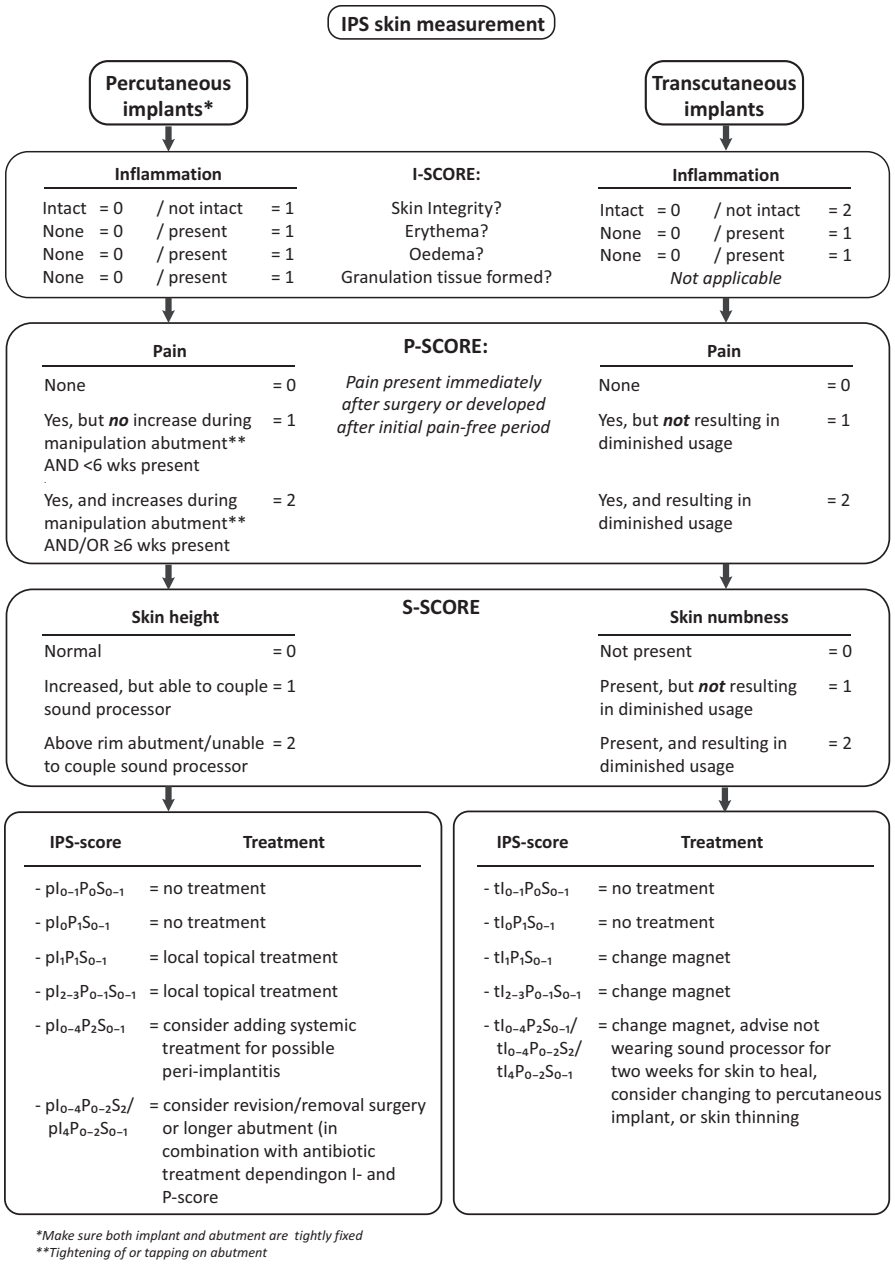

FIGURE 1 Flow chart of the IPS-scale and treatment advice

Erythema and oedema weigh in for one point, because the observation of one of these two does not make treatment necessary per se.

The Pain-scale refers to pain at the implant site and ranges from 0 to 2. It is scored, unlike the pIPS-scale, based on the presence of pain together with the normal or diminished usage of the BCD. In our experience with transcutaneous implants, pain severity is closely related to a change in daily usage.

The S-scale refers, in transcutaneous implants, to the presence of skin numbness instead of skin height, but also ranges from 0 to 2. Skin numbness is common in patients with a transcutaneous implant, possibly due to the c-shaped flap created during surgery. It can result in patients being unable to feel excessive pressure, compromising skin vascularisation and possibly resulting in necrosis. The S-scale is scored based on the presence of numbness and normal or diminished usage of the BCD.

Prior to IPS-scoring in patients with a transcutaneous implant (tIPS-scale), it is important to verify normal daily usage, because most complications are pressure-related. In patients wearing the sound processor only a few hours a day, development of minor signs is, hence, the result of exceedingly high skin pressure during usage.

Although not yet evaluated, the tIPS-scale might also be useful as a standardised assessment scale for skin complications in patients with a cochlear implant or middle ear implant.

3.4 | Standardised treatment derived from the IPS-scale

In contrast to the Holgers scale, we propose a standardised treatment advice for each IPS-scale (see Figure 1), based on our expert opinion. In patients with a percutaneous implant, an $I_{2\text{-}3}$ should be

treated topically and for I_4, systemic treatment and/or removal surgery should be considered. However, if a P_1 is found, we advise commencing topical treatment for $I_{1\text{-}3}$. A P_2 (indicating possible peri-implantitis) should be treated with systemic antibiotics, regardless of the I-scale. However, it is important to distinguish between pain manifesting immediately after implantation or after a pain-free period. The first is unlikely to result from infection, but can be due to peri-operative occipital nerve trauma; hence, pain medication is sufficient. The second is probably infection-caused, requiring antibiotic treatment. An S_2 implies the necessity of revision surgery or changing to a longer abutment.

In patients with a transcutaneous implant, an $I_{2\text{-}3}$ indicates unduly high skin pressure and should be treated by reducing magnet strength and by the non-use of the sound processor for two weeks. Like pIPS, if an P_1 is found, magnet strength change for $I_{1\text{-}3}$ is advised. If pain or numbness results in diminished usage (thus P_2 or S_2) and/or I_4 is found, changing to a percutaneous implant should also be suggested. In case of chronic pain without signs of infection and/or antibiotic treatment does not result in improvement for either type of implant, advanced pain treatment, such as occipital nerve block, should be considered.

By adding standardised treatment, the IPS-score has another advantage, namely its usefulness in research. Much research has been undertaken for percutaneous and transcutaneous implants; however, comparison across studies and interventions is difficult, because of the different methods of reporting complications that is skin reactions or treatments administered.[3] By providing a standardised, easy-to-use and objective reporting method for soft tissue status and treatment indications, the IPS-scale should result in higher reproducibility and comparability in future research.

4 | CONCLUSION

The Holgers scale has become less useful as a single measure for reporting soft tissue status around percutaneous and non-useful for transcutaneous implants for BCDs. We have therefore proposed a new assessment scale, the IPS-scale comprising three parts: inflammation, pain and skin height/skin numbness, with higher scores reflecting more severe complication. For transcutaneous BCDs, the tIPS-scale is the first standardised assessment scale for soft tissue assessment. Altogether, the IPS-scale is a complete assessment scale for reporting soft tissue status in combination with standardised treatment advice for each IPS-scale in patients with percutaneous or transcutaneous implants for BCDs.

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CONFLICT OF INTEREST

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