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Methods for measuring pre-, intra-, and postoperative skin thickness for cochlear implants

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Objective: This study was conducted to determine whether there is a reliable method for measuring the thickness of the retroauricular skin before, during, and after cochlear implantation, which allows the assessment of the optimal force of the external magnet of the cochlear implant (CI).
Methods: The retroauricular skin thickness of 83 patients who received a CI was measured using three different methods. The thickness was measured on pre- and postoperative CT images, as well as intra-operatively. The magnet category chosen by the surgeon was recorded when the implant was switched on and during the first follow-up visit. Correlation analyses were performed on the different skin thickness measurements and between the skin thickness and magnet strength categories.
Results: Only six patients required an exchange of the magnet until the follow-up. Although the median absolute thickness differed significantly between the three measures ($p < 0.0001$), their thickness values showed highly significant correlations (Pearson's $r = 0.457–0.585$; $p < 0.01$). In addition, magnet strength, was significantly correlated with the flap thickness determined pre-, post-, and during surgery. The lowest correlation with magnet strength was found in the intraoperative needle method.
Conclusion: All three measurements methods provided a suitable base for determining the ideal magnetic force. However, of particular interest were the pre- and postoperative CT measurements. The first enabled the early assessment of the required magnetic strength and thus a timely postoperative supply, whereas the latter helped to estimate the need for magnetic strength reduction during follow-up care and the feasibility of an early swith-on.

1. Introduction

Since their development in the 1960s, cochlear implants (CI) have become the treatment of choice for patients with severe to complete sensorineural hearing loss (Lenarz 2017). CI captures environmental sounds and transduces them into electrical signals, which are transferred through the skin to the implanted parts of the CI (Roche and Hansen 2015; Carlson et al., 2012). Currently, Oticon Medical (Smørum, Denmark), Med-EL (Innsbruck, Austria), Cochlear (Lane Cove, Australia), and Advanced Bionics (Stäfa, Switzerland) are the four CI manufacturers that are approved in Europe. The basic structure of all CIs is similar and includes an external component with microphones, a sound processor for sound preprocessing and conversion into electrical impulses, a battery, and a transmitting coil for sending signals to the implanted component (Zeng et al., 2008). The implanted parts comprise a radio frequency receiver coil, a stimulator with a signal processor for generating electrical pulses, and a multi-channel electrode for transmitting the pulses to the auditory nerve (Lenarz 2017; Carlson 2020). Both the external transmitting coil and the implanted receiver coil contain a magnet, which ensures the exact positioning

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of the transmitting over the receiver coil, which guarantees the optimal transmission of the electromagnetic signals to the cochlea (Weber et al. 1998). Therefore, the thickness of the skin flap overlying the internal receiver coil affects signal transmission, battery life span (Ozturan et al., 2017), and the retention force required to keep the external headpiece in place.

Several possible postoperative complications have been attributed to inadequate magnetic strength. Problems caused by excessive strength include headaches and local skin reactions, such as itching, skin necrosis, and flushing (Gunther et al. 2018; Gartner et al., 2016). Difficulties caused by insufficient external magnet retention include frequent dropping and detachment of the magnet. In addition, poor coupling between transmitting and receiving coils may lead to noisy and interrupted signal transmission (Posner et al., 2010).

At present, the choice of magnet strength depends on the experience of the CI surgeon, who usually estimates the class of magnetic strength based on the assumed thickness of the retroauricular skin flap. Following implantation, the external sound processor is adjusted before hearing rehabilitation starts. The time delay between implantation and the first activation (i.e., switch-on) of the CI has been around four weeks to allow sufficient wound healing (Roux-Vaillard et al., 2020). This duration has become shorter because the surgery has become less invasive (Sun et al., 2019). There are several reasons for an early switch-on. The most important goal for patients is their ability to hear with the implant as soon as possible. Furthermore, traveling costs and time can be saved for patients who have to travel a long distance (Alsabellha et al., 2014). Most importantly for the function of the CI is that an early switch-on may prevent tissue reactions in the surrounding area of the intra-cochlear electrode carrier, which otherwise might increase impedance (Hagr et al., 2015; Sun et al., 2019). Lower impedances have been found in early activation. A possible cause of increasing impedances is tissue fibrosis, which occurs within a few weeks and leads to the increased protein coating of the electrode contacts (Newbold et al., 2010; Marsella et al., 2014; Alsabellha et al., 2014). However, a potential problem incurred by an early switch-on is skin swelling due to postoperative subcutaneous hematoma and/ or edema. Yet, Chen et al. showed that minimally invasive surgical approaches, minimization of electrocautery and pressure dressings may provide sufficient conditions for an early switch-on within 24h with good hearing results (Chen et al., 2015).

Currently at our center, two magnets of different strengths are ordered preoperatively based on the surgeon's personal assessment. If the selected magnet strength is not optimal, it may be necessary to replace the magnet, which then may lead to delayed rehabilitation, decreased patient satisfaction, and increased costs. However, when the time between the surgery and the CI switch-on is decreased, the preoperative order of the external magnet becomes mandatory. Therefore, a reliable method for the early determination of magnet strength is needed. It is reasonable to assume that a significant correlation exists between the thickness of the retroauricular flap and the required magnetic strength (Searle et al., 2020). Furthermore, most CI manufacturers recommend that the thickness of the retroauricular skin flap should be below 7 mm; otherwise, they recommend intraoperative thinning of the skin (Raine et al., 2007; Ozturan et al., 2017). This decision is facilitated by reliable non-invasive measurements of skin thickness before surgery.

The aim of this study was to determine a reliable non-invasive method for measuring the thickness of the retroauricular skin flap, to assess optimal magnet strength, and to recognize the need to thin the retroauricular flap promptly without further diagnostics. In addition, a reliable method for the postoperative measurement of skin thickness could indicate the need to reduce magnet strength during the follow-up.

2. Material and methods

In a prospective study, the retroauricular skin thickness of 83 patients who received a CI between July 2017 and August 2019 at our Department of Otorhinolaryngology, Head and Neck Surgery, was measured using three different methods. In accordance with the current clinical routine, preoperative CT scans of the temporal bone on the side to be implanted were performed. CT images were made using a Siemens Sensation 64 computer tomograph (Siemens, Munich, Germany). A thin-layer spiral CT mode was used over the petrous bone with a 1-mm reconstruction of the three semicircular canals and the cochlea (both corona and axial) in the bone window. Skin thickness was measured on the CT images at the prospective implantation site orthogonally to the skull bone by an experienced neuroradiologist. On the horizontal plane, the measurement was located at the level of the auricle attachment and about 2 cm retroauricularly (Fig. 1 and Fig. 2). Within one to three days after implantation, all patients routinely received another CT to verify the correct position of the CI. Postoperative skin thickness was again determined based on the recorded image, measured along a straight line that was drawn orthogonally to the skull bone into the center of the implanted magnet. Intraoperative measurements of skin thickness were carried out using a needle, as described by Mylanus et al. (Mylanus et al. 1994). To determine skin thickness, the retroauricular skin around the implantation site was punctured directly before the beginning of surgery and before injection of local anesthetic under sterile conditions. A sterile 27gauge needle was used and the skin was punctured at a right angle down to the bone. The punctures were performed retroauricularly 2.5 cm from the base of the ear canal with protrusion at an apical angle of 45°. The depth was marked on the needle and then determined using a ruler. Magnetic strength was recorded at switch-on (M1) and at the first follow-up visit (M2).

The study was approved by the responsible local ethics committee (2017-547N-MA). Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

The statistical analysis was performed using SPSS25 (SPSS/IBM, Chicago, IL; USA). Because only the pre-surgery CT measurement showed a normal distribution, medians with 95% confidence

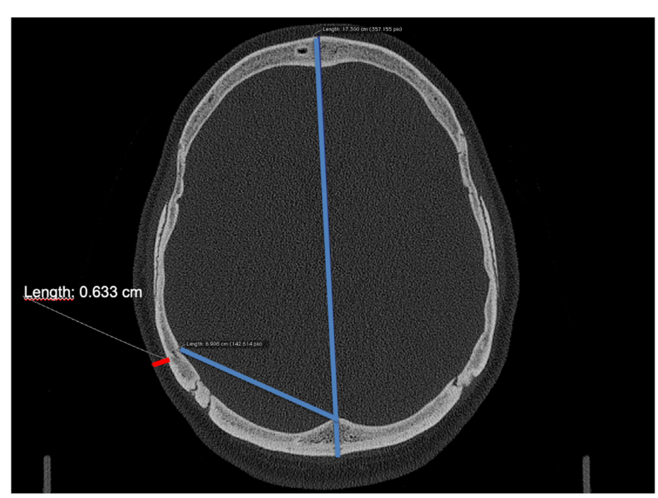

Fig. 1. Measurements of skin thicknesses on preoperative CT images skin thickness was measured along a straight line that was drawn orthogonally to the skull bone (red line) into the center of the implanted magnet (green line).

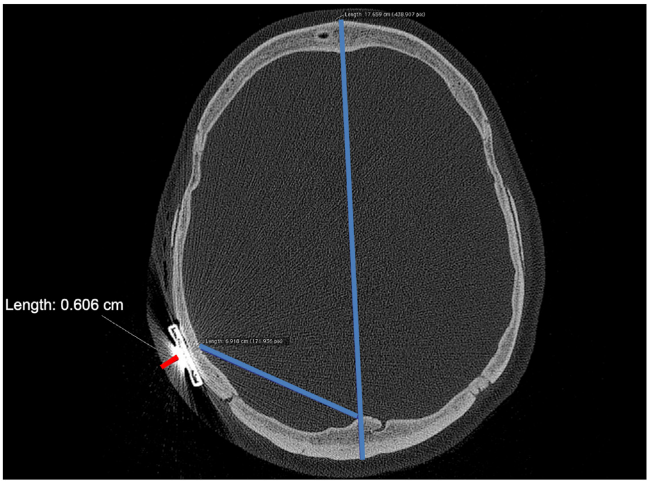

Fig. 2. Measurements of skin thicknesses on postoperative CT images skin thickness was measured along a straight line that was drawn orthogonally to the skull bone (red line) into the center of the implanted magnet (green line).

intervals were presented for flap thickness, and differences in measurements made using the different methods and at different time points were compared with non-parametric Friedman tests, followed by post-hoc Wilcoxon tests. The p-values were corrected for multiple comparisons. Moreover, correlation analyses were performed on the three different methods to determine skin thickness using Pearson's correlation coefficient, and Spearman's rho was calculated between skin thickness and magnet categories. The correlation between magnetic strength and skin thickness was conducted within the cohorts, which were separated according to the manufacturers. Statistical p-values below 0.05 (uncorrected) were considered significant, and values below 0.01 (uncorrected) were considered highly significant. Uncorrected p-values were presented. To correct for the number of correlations, Bonferroni-corrected p-values were calculated by dividing the number of comparisons in an analysis.

The cohort included 48 women (57.8%) and 35 men (42.2%). The mean age was 56.8 years with a standard deviation of 16.03 years (age range 18–85 yrs). All four manufacturers, which had been approved in Germany, were represented among the implanted CIs: 50 patients had been implanted with a CI from Advanced Bionics,18 patients had been implanted with a CI from Cochlear, 10 patients had been implanted with a CI from Med-EL, and five patients had been implanted with a CI from Oticon. Depending on the model, the Cochlear CI has seven or eight different magnet classes. From MED-EL, four or five different magnetic levels are available, depending on the CI model. Advanced Bionics offers from five to seven magnet classes, depending on the model. Nine different strengths are available from Oticon. The distribution of magnet strengths is shown in Table 1. Apart from the preoperative measurements based on CT images, the skin thicknesses were not normally distributed. Therefore, and for comparison, median values were determined for all the measurements.

3. Results

The median skin thickness on the preoperative CT images was 7.5 mm (95% confidence interval: 7.3–8.2 mm), with a minimum of 3.9 mm and a maximum of 15.3 mm. Based on the postoperative CT images, the median thickness was 8.4 mm (95% confidence interval: 8.2–9.3 mm; range 4.7–15.4 mm). The median thickness determined using a needle during surgery was 6.0 mm (95% confidence interval: 6.2–6.6 mm; range 4.0–8.0 mm). The results of the different measurements are shown in Fig. 3. The average difference between pre- and postoperative skin thicknesses based on CT images was 0.80 mm (SD = 2.43 mm), with a maximum of 7.1 mm. The skin thickness measurements differed significantly, with a Chi-square of 60,687 ($p < 0.0001$) and highly significant post-hoc comparisons (preop CT/postop CT: $z = 3.641$; $p < 0.0001$). Significant differences also existed between flap thicknesses determined on the CT images compared with the intraoperative needle method (preop CT/needle: $z = 6.197$; $p < 0.0001$; postop CT/needle: $z = 6.9777$; $p < 0.0001$). The Pearson correlations between the different methods of determining skin thickness were highly significant even after Bonferroni corrections: all p-values remained below the corrected $p = 0.003$. Moderate correlations were found between the needle measurement and the preoperative CT-based measurement ($r = 0.585$; $p < 0.0001$) and between the needle method and the postoperative CT measurements ($r = 0.486$; $p < 0.0001$). Similar correlation strength was found between the pre- and post-surgical CT-based measurements ($r = 0.457$; $p < 0.0001$). These results are visualized in Fig. 4.

Spearman's correlations between skin thickness (measured with each method, i.e. needle and CT at the different points of time) and the magnet strength categories at switch-on (M1) and at first follow-up (M2) were calculated. This was performed separately for each of the CI brands, as magnet categories differ between manufacturers. The median time delay between surgery and M1 was 19 days, and at M2, the difference was a median of 49 days after implantation. In the 50 subjects that received an Advanced Bionics implant, there were highly significant, moderate to strong positive correlations between needle measurements and magnet strength at M1 ($r = 0.468$; $p = 0.001$), as well as at M2 ($r = 0.502$; $p < 0.0001$). In addition, the skin thicknesses measured by pre- and postoperative CT were positively correlated with the magnet strength at M1 and at M2. Regarding the preoperative CT and the magnetic force, the correlation coefficient was 0.526 ($p < 0.0001$) at M1 and 0.544 ($p < 0.0001$) at M2. Skin thicknesses determined by postoperative CT showed correlation coefficients of 0.440 ($p = 0.001$) at M1 and 0.442 ($p = 0.001$) at M2.

Table 1
Distribution of chosen magnet strengths for each manufacturer.

Manufacturer	Magnet Strength	Number of patients (%)
Advanced Bionics (n = 50)	1	1 (2%)
	2	3 (6%)
	3	17 (34%)
	4	15 (30%)
	5	14 (28%)
	6	0 (0%)
Cochlear (n = 18)	0.1	0 (0%)
	1.5	0(0%)
	1	1 (6%)
	2	2 (11%)
	3	6 (33%)
	4	7 (39%)
	5	2 (11%)
Med-el (n = 10)	1	0 (0%)
	2	0 (0%)
	3	7 (70%)
	4	2 (20%)
	5	1 (10%)
Oticon (n = 5)	0.5	0 (0%)
	1	1 (20%)
	3	1 (20%)
	4	0 (0%)
	5	3 (60%)
	8	0 (0%)
	10	0 (0%)

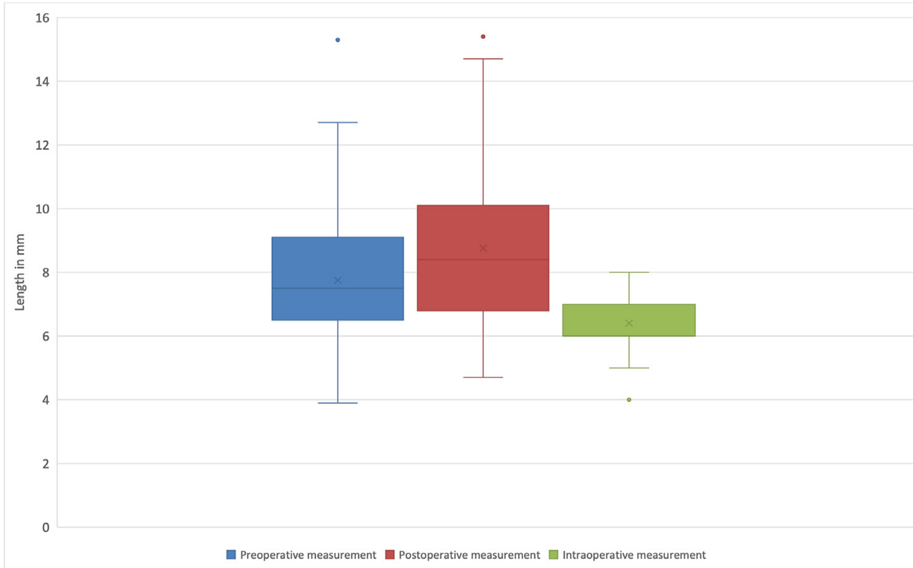

Fig. 3. Results of the three different measurement methods.

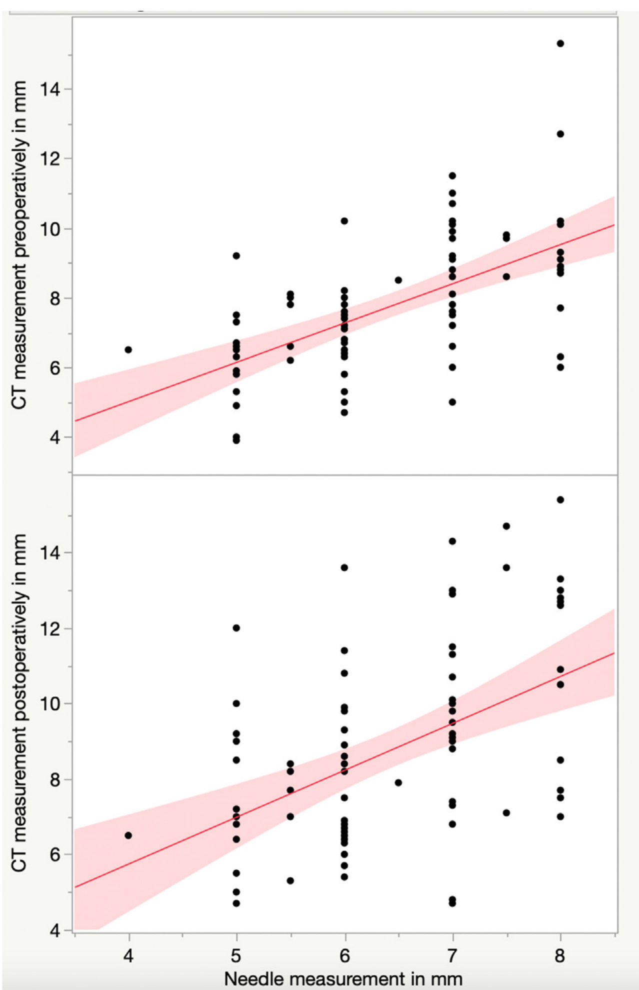

Fig. 4. Correlation between preoperative, postoperative measurement and the needle methods (95%-CI of the fitted curve is shown by the red area).

In patient groups who had received a CI from Cochlear or Med-EL, no significant correlation between any of the skin thickness measurements and magnetic categories was found ($p > 0.05$). In the five patients with a CI from Oticon, a significant positive correlation between skin thickness measured by the needle method and magnetic strength was found at switch-on (M1: rho = 0.913; p = 0.030) and at follow-up (M2: rho = 0.884; p = 0.047).

Between switch-on and follow-up, the magnet in the headpiece was exchanged in six patients. It was reduced in four patients, by one category in two patients, and by two categories in two patients. In two patients, magnetic strength was increased by one or two categories. All four manufacturers were represented: three patients had an CI from Advanced Bionics, one patient had a CI from Cochlear, one patient had a CI from Med-EL, and one patient had a CI from Oticon.

4. Discussion

In our study, between the switch-on and first follow-up, magnets were exchanged in only six of the 83 participants (7.2%). The selection of the magnet category was based on the personal judgment of the CI surgeon, which suggests that experienced surgeons can select the proper magnet with sufficient precision. However, the quantifiable measures that are used to guide the selection may improve the choice of magnet. Ideally, such measures are non-invasive and do not require additional clinical examinations.

In our trial, we found highly significant correlations between retroauricular flap thickness and magnet strength in all three measures, indicating that thicknesses determined based on routine CT images taken before and following surgery, as well as during surgery with a needle, serve this purpose. Because flap thickness estimates differed significantly between methods, recommendations for flap thinning need to be adjusted to the method used. The fact, that no correlation was found for Med-el and Cochlear may possibly be due to small sample size. As there is a higher span of different magnets for Cochlear implants, it may be plausible that a larger sample size is required. Regarding this aspect, the significant correlations found for Oticon has to be interpreted with caution.

In our study, a noteworthy finding was that skin thickness measured by postoperative CT was significantly thicker, which may have been caused by postoperative swelling and edema (Sun et al., 2019). The time between postoperative CT, which was taken within three days after surgery, and switch-on was about 19 days. Some authors have advocated activation within the first week after implantation (Gunther et al. 2018; Alsabellha et al., 2014; Hagr et al., 2015; Sun et al., 2019; Chen et al., 2015). The arguments against earlier switch-on have included postoperative wound healing, the risk of wound infection, postoperative swelling (Sun et al., 2019; Gunther et al. 2018), and tissue reactions around the electrode, such as air bubbles (Sun et al., 2019; Hagr et al., 2015). Thus, differences between pre- and postoperative flap thicknesses may provide an estimate of potential swelling and, most importantly, they may help in decisions regarding early switch-on. One risk associated with early switch-on may be the increased impedance caused by postoperative edema and hematoma. However, in several studies, no increased impedance was shown immediately after implantation, and impedance did not increase until a few days later (Chen et al., 2015). In case of extensive thinning of the skin flap, necrosis could occur under the pressure of the magnet. Therefore, sufficient wound healing should first be ensured (Alsabellha et al., 2014). Indications of a good point in time for the activation of the CI may be obtained according to the postoperative skin thickness measurement based on postoperative CT images.

The positive correlation between skin thickness, regardless of the method, and the strength of the magnet indicated that a stronger external magnet is required for thicker skin. This finding is consistent with former studies on this matter (Ozturan et al., 2017; Posner et al., 2010; Searle et al., 2020). In addition, these studies found a significant correlation between skin thickness and body mass index (BMI) (Searle et al., 2020; Ozturan et al., 2017) and that obesity may be associated with the insufficient holding force of the external magnet (Posner et al., 2010). In this study, the highly significant difference between the preoperative CT-derived and needle measurements was likely due to methodological differences. Measurements taken by the needle may underestimate flap thickness because of possible compression during insertion (Lupin and Gardiner 2001). In our study, the lower skin thickness measured by the needle method supports this assumption. On one hand, an advantage of this intraoperative measure is that flap thickness is determined at the exact position of the CI. On the other hand, higher thicknesses observed in CT images may be due to indistinct boundaries between tissue layers or small artifacts that lead to the overestimation of tissue boundaries. Furthermore, even though we tried to correlate the measurement in CT images with the intraoperative measurement by constructing the position of measurement with the lines shown in Figs. 1 and 2, the exact same measurement position cannot be guaranteed. Nevertheless, previous studies have shown that facial skin thickness is determined accurately by a spiral CT scan (Cho et al., 2011), whereas inaccuracies are likely to emerge in anatomical sites with strong surface curvatures, such as the nasion (Kim et al., 2005). Yet, as our CT measurements were performed by only one neuroradiologist, the limitation applies, that the accuracy of measurement cannot be assessed. Additionally, a comparison with MRI data may have given us further insights at least in the preoperative setting.

Some CI manufacturers recommend thinning the retroauricular skin flap if its thickness exceeds 7 mm. This recommendation has been supported by previous results (Ozturan et al., 2017; Posner et al., 2010; Raine et al., 2007). If the magnetic strength is too low, conservative methods, such as using a stronger external magnet, shaving the hair, and an elastic headband, do not always lead to sufficient retention of the external magnet, and only revision of the CI or thinning of the skin flap can improve the situation (Posner et al., 2010). However, possible risks from excessive thinning are skin necrosis, ulcerations, and an exposed magnet (Posner et al., 2010). The recommendation for flap thinning is based on flap thickness derived from the needle method, which is in accordance with our results. In our study, intraoperative needle measurements produced a median of 6.0 mm, and only 15 patients had a thickness exceeding 7.0 mm, whereas median skin thickness in the preoperative CT images was 7.5 mm, indicating that more than 50% of patients exceeded this limit. Therefore, methodological differences must be considered, and recommendations for flap thinning need to be adjusted according to the method used to determine flap thickness.

In addition, postoperative assessments of skin thickness help to identify patients for whom a later reduction in magnetic strength may be beneficial. Examples are patients with severe postoperative swelling who require increased magnetic strength at switch-on (Gunther et al. 2018; Gartner et al., 2016).

Our findings showed that differing predictions were derived from the different measurements. Preoperative measurements allowed for the early ordering of the magnet, thus saving cost and material. Intraoperative measurements using the needle provided information regarding whether thinning of the retroauricular skin flap during implantation was required. Lastly, postoperative measurements provide information regarding whether the early switch-on of the CI was possible. Due to small group size for each magnet category and each manufacturer, no calculation of cut-off values was performed. Future studies with larger sample size are needed to determine a magnet strength on basis of the skin thickness.

5. Conclusion

Skin thickness estimates derived from pre- and postoperative CT and intraoperative needle measurements appeared suitable for determining the thickness of the skin overlying the CI implant. Different recommendations may derive from our study. Preoperative CT measurements may reduce costs as the needed magnet force may be determined by this measurement. Intraoperative measurement is useful to determine the need for flap thinning. The feasibility of an early switch-on may be indicated by the postoperative measurement by CT.

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Declaration of competing interest

The Author(s) declare(s) that there is no conflict of interest.

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