Laryngoscope Investigative Otolaryngology

Age-Dependent Variations of Scalp Thickness in the Area Designated for a Cochlear Implant Receiver Stimulator

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Objective: The integrity of the scalp overlying a cochlear implant receiver stimulator (RS) is critical for the long-term survival of the implant. Exposure or extrusion of the device will likely result in the need for its removal. There is a global trend of acceleration of population aging, thus raising the prevalence of cochlear implantation (CI) in the elderly. The aim of this study was to define age-dependent changes in scalp thickness and discuss the implication of that anatomical characteristic for CI in the geriatric population.

Methods: Scalp thickness over the location of the RS in the temporo-parietal area was measured directly with a needle in patients of various ages.

Results: Two-hundred thirty-six temporo-parietal scalps were measured in patients aged 18 to 85 years. A strong inverse correlation was found between age and scalp thickness (rs = -0.723, $P < .001$). Scalp thickness decreased with age from a mean of 8 mm in the third decade of life to 5 mm in the ninth decade of life.

Conclusion: The human scalp thins with age and most likely undergoes a reduction in its strength. As a consequence, implantable hearing devices that are shielded by the scalp can be at increased risk of exposure and extrusion in the aging recipient. This needs to be taken into account when considering an implantation procedure, the surgical approach and patient instructions on need for and venues for continuing care over time.

Key Words: Scalp, cochlear implantation, extrusion.

Level of Evidence: 2B

INTRODUCTION

Hearing loss affects approximately 70% of individuals above the age of 70 years in the western world[1,2] and hearing aids are used by 19.1% of elderly individuals with reduced hearing.[3] Conventional amplification may not provide adequate benefit to patients with severe-to-profound sensorineural hearing loss (SNHL), and cochlear implants (CI) have become the treatment of choice for them. Although some data show that age has a certain negative impact on the outcome of rehabilitation with CI, it is widely agreed that age should not be a contraindication to CI.[4–6] It is also widely agreed that the global trend of increase in the elderly, will continue along the 21st century. It was estimated that 15% of the population in North America was older than 60 years in 2015, and that this age group will constitute 30% and 40% of the population in 2050 and 2100, respectively.[7]

As the skin ages, the dermo-epidermal junction flattens[8] and the epidermal cell turnover halves between the third and seventh decades of life,[9] resulting in deteriorated wound healing capacity.[10] In addition, the subcutaneous layer atrophies, skin appendages become more scarce, blood flow decreases and there is general atrophy of the extracellular matrix accompanied by fewer fibroblasts and altered collagen.[11]

During CI, the body of the receiver-stimulator (RS) is placed in a sub-periosteal pocket of the temporo-parietal skull. Structural integrity of the overlying scalp is critical for the long-term survival of the implant, because exposure or extrusion of the device will likely result in the need for its removal. Given the combination of the processes of aging of the population with reduced skin integrity combined with the high and rising prevalence of CI among the elderly, the aim of this study was to evaluate the change in scalp thickness over the location of the RS of a CI as a function of age.

METHODS

The study was approved by the research ethics committee of a tertiary referral medical center (0256-16-TLV) and informed patient consent was obtained. Adult patients were recruited from the patients treated in our department of otolaryngology. The study population was arbitrarily divided into 10-year age groups (18–27, 28–37 … 78–87), and up to 20 patients were randomly recruited from each age increment, with equal numbers of males and females.

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Editor's Note: This Manuscript was accepted for publication 00 Month 2018.

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DOI: 10.1002/lio2.218

Scalp thickness over the location of the RS in the temporo-parietal area was measured directly with a needle in patients that underwent an elective surgery under general anesthesia for various reasons, by a single examiner. After induction of general anesthesia and before the initiation of the surgical procedure, scalp thickness over the temporoparietal area suitable for the location of an RS was measured. The point of interest was located 70 mm from the external ear canal and in 60 degrees from the Frankfurt horizontal plane (Fig. 1). It was measured using a 25 G needle that penetrated the perpendicular to the scalp to the level of the bony skull. Due to intra-subject variability, each hemi-scalp was evaluated independently. The measurement of the thinner of the two sides was used for the purpose of data analysis. Patients with superior vena cava syndrome, previous radiotherapy treatment, systemic steroid treatment or any dermatitis were excluded from the study.

Statistical Methods

Categorical variables were described as frequency and percentage. Continuous variables were evaluated for normal distribution using histograms and reported as mean and standard deviation or median and interquartile range (IQR). Correlations between continuous variables were evaluated using Spearman's correlations. Continuous variables were compared between sides using the Wilcoxon signed-rank test. The Mann-Whitney test was used to compare continuous variables between categories. All the statistical analyses were two-tailed. A *P* value less than .05 was considered statistically significant. SPSS (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY, USAwas used for all the statistical analyses.

RESULTS

One hundred twenty patients were recruited, yielding 236 (117 right and 119 left) temporo-parietal scalp regions for measurement and statistical analysis. The cohort was composed of 59 (49%) males, and 60 (51%) females, aged 18 to 85 years (mean 47.5, IQR 30–64). The mean (IQR) height and weight were 1.68 m (1.61–1.75) and 73.6 kg (61.3–83.5), respectively, resulting in a mean (IQR) body mass index (BMI) of 25.9 kg/m^2 (22.1–28.4).

Four patients who had been admitted for elective otologic surgery consented to measurement only on the side ipsilateral to the operated ear and not the contralateral one.

There was no measurement-related complication There was also no intra-subject side-to-side variability of temporo-parietal scalp thickness in the majority of subjects (73 out of 119), and a variability of 1 mm in 42 patients and 2 mm in one patient (the latter was morbidly obese and had a BMI above 50.5 kg/m^2. The mean difference between right and left temporo-parietal scalp thickness was 0.86 mm and there was no significant side-to-side variability (P = .14). There was also no significant gender-related difference in scalp thickness (P = .482).

A strong inverse correlation was found between age and scalp thickness (r_s = -0.723, P < .001). Scalp thickness decreased with age from a mean of 8 mm in the third decade to 5 mm in the ninth decade (Fig. 2). There was a weak correlation between the patient's height and scalp thickness (r_s = 0.194, P = .034), and a nonsignificant correlation between the patient's weight or BMI and scalp thickness (r_s = -0.025, P = .789 and r_s = -0.118, P = .201, respectively).

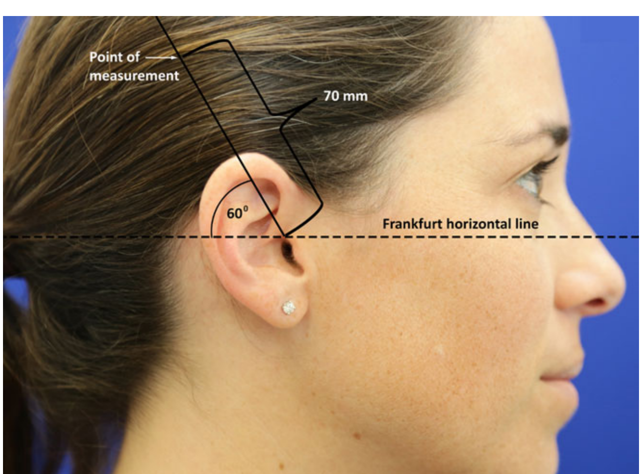

Fig. 1. Point of measurement of scalp thickness, using uniform method.

DISCUSSION

Hearing loss is prevalent among the elderly and its incidence increases with age.[3] CI is the treatment of choice for many patients with SNHL insufficiently rehabilitated with hearing aids. Age is not a contraindication for implantation. The elderly generally do well with CI even if time to achieve maximal speech understanding may be longer and speech/noise understanding somewhat lower[12,13] than their younger implanted peers. The stress associated with CI surgery and associated anesthesia is well tolerated by the elderly, and side effects are uncommon and mostly mild.[14–16]

There are, however, certain aspects of aging that do have important bearing on CI. Breach of the scalp overlying the RS will often ultimately result in the need to remove the device. Since extruding hardware is typically infected, reimplantation must be delayed until the area is infection-free again (usually 3–6 months after device removal). This hiatus is added to the time needed to learn a new and altered location and pitch of the electrodes, resulting in a longer period of auditory deprivation and isolation.

We studied the effect of aging on scalp thickness. Aiming for noninvasive indirect measurements, we first performed a retrospective analysis of the patients' CT scans and selected the area from the overlying skin to the bone in a uniform location based on three-dimensional reconstructions, like previously done in other studies.[17,18] We spotted an important inaccuracy of measurement due to compression of the soft tissue by the weight of the head (Fig. 3).

The direct measurement method, that was used in the current study and described above, overcame that soft tissue compression and accurately reflected the soft tissue thickness overlying the location designated for the RS of

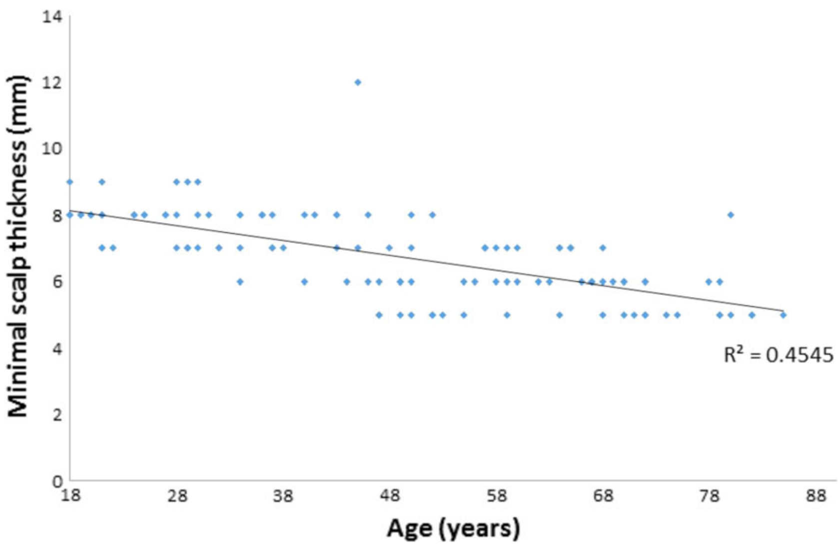

Fig. 2. Mean scalp thickness (mm) over the temporo-parietal area as a function of age (years).

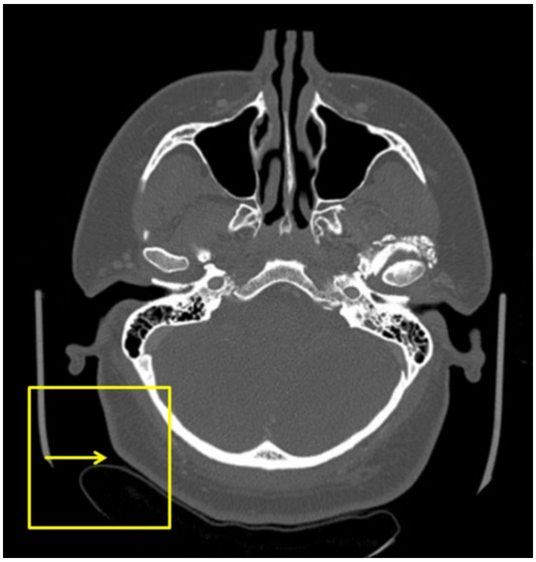

Fig. 3. Axial head CT scan which was used initially to serve as a model for scalp measurement but was found to be inaccurate due to soft tissue compression (arrow).

the CI. Direct measurement revealed that the human scalp thickness decreases with age, from a mean of 8 mm in the third decade to 5 mm in the ninth decade. Thinning of the scalp represents a change in the quality of the scalp. The composition of the skin and its appendages and the crucial blood supply to the RS all deteriorate with age.[8–11] This may pose an increased risk for scalp-related RS safety issues, but the rarity of these complications[19,20] make it difficult to statistically validate to what extent this is a concern.

The well-accepted need for careful tissue handling and flap design could be even more crucial in the elderly recipient. A less uniformly accepted concept is the need for drilling a well for the thickest part of the RS. The bony well serves two main purposes: stabilization of the RS to reduce the risk for migration, and lowering of the overall projection of the RS from the level of the skull. RS anchorage is performed to avoid any RS migration that might result in electrode displacement, implant extrusion and wire fatigue, resulting in device failure.[21] Several methods of RS anchorage for the adult population have been proposed, including bony well drilling, tight subperiosteal pocket alignment, miniplate adaptation and sutures.[22–25] Well drilling has been abandoned by some surgeons in favor of other alternative RS fixation techniques in an effort to reduce operative time. Although it would appear that alternative fixating techniques, such as placing the RS under a tightly fitting subperiosteal pocket, serve to prevent migration, device projection from the skull remains an unresolved issue. We believe that in light of the age-dependent changes to scalp thickness and quality, fashioning a bony well is advisable in the elderly and in recipients expected to age with their implant. Similarly, special attention should be paid to fitting suitable-strength magnets.

One way to monitor the well-being of the scalp overlying the RS is by visual inspection. Redness, edema, pitting by the magnet or tenderness may all represent early signs of trouble. The elderly tend to have fewer interpersonal interactions that can be used for the purpose of surveillance. A spouse or other person living in constant proximity to the implantee can look for early signs of impeding complication. As elderly recipients may lack these interactions they should therefore be made aware of and be instructed to actively look for these signs and contact the implant center or another suitable source of treatment as soon as a problem arises.

Although the skin is known to change with age, it is difficult to prove that such aging poses an actual increased risk to the integrity of a CI. Since extrusions and exposure of the device are rare and often preventable complications, it is also difficult to demonstrate a statistically significant increased risk for the elderly. As scalp thickness attenuates over time, the RS unit and the

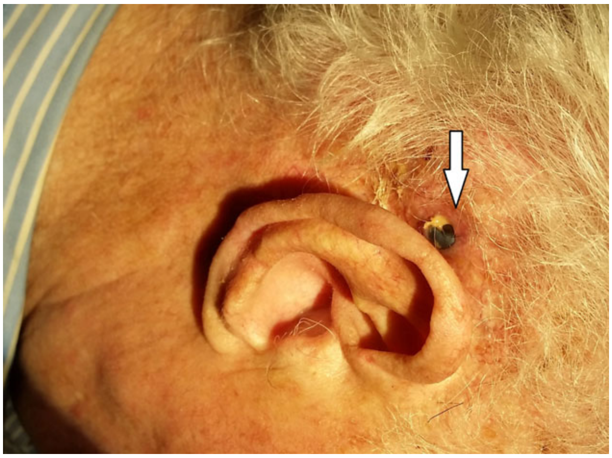

Fig. 4. Extrusion and exposure of the receiver stimulator unit of a CI in an 89-year-old patient, 14 months postoperatively.

magnet become closer, attract each other with greater force per area. This increased pressure, when combined by reduced mitotic activity[9] and impaired wound healing,[10] can result in an unhealed pressure necrosis and eventually hardware extrusion. We encountered an 89-year-old who represents a "perfect-storm" example of complications in a geriatric CI recipient. He is the only patient who had any serious complications in a series of 154 adult implant recipients in our database. He had undergone bilateral canal wall-down mastoidectomies before adulthood which left him with a bilaterally symmetrical profound SNHL. His right ear had a dry stable cavity and was it implanted by a subtotal petrosectomy, blind sac closure and obliteration with an abdominal fat approach. His scalp was 5 mm thick. Surgery and the first postoperative year were uneventful. Hearing rehabilitation was slow, partly because of limited social and familial daily interactions. At 15 months after implantation, he presented with an extruded and infected device (Fig. 4). He denied having experienced any trauma. The device had to be extracted (with the electrode left in the cochlea).

The discussion is relevant not only to CI but can be expanded to devices such as the MED-EL (MED-EL, Innsbruck, Austria) Vibrant Soundbridge and Bonebridge and Cochlear's (Cochlear LTD, Macquarie University, Australia) Carina.

In conclusion, the human scalp thins with age and inevitably undergoes a process of decreased strength. As a consequence, implantable hearing devices that are shielded by the scalp can be at increased risk of exposure and extrusion in the aging recipient. This needs to be taken into account when considering an implantation procedure, the surgical approach and post-surgical care should be adjusted accordingly.

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