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ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Symmetrical placement of bilateral percutaneous bone-anchored hearing systems via guide-marker

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Abstract

Objectives: To investigate the use of a novel technique to estimate the symmetrical placement of percutaneous bone-anchored hearing systems (BAHS) with a guide-marker in patients undergoing bilateral surgery with this device.

Study Design: Prospective cohort study.

Methods: A guide-marker and anatomical landmarks were used to estimate the implant placement and transferred to the contralateral ear in 12 subjects eligible for bilateral BAHS surgery. To investigate the bilateral symmetry, preoperative tri-dimensional (3D) computed tomography (CT) image reconstruction was used to compare the distances between the mandibular condyle and implant placement estimation (mandible-implant distance) in both the right and left ears of the subjects.

Results: The guide-marker could be used to estimate the bilateral implant placement in all subjects included in this study, simply and easily, including one subject with craniofacial malformation. The mean mandible-implant distances were 5.37 and 5.38 cm, in the right and left ears of the subjects, respectively, and no differences were observed between them, thereby indicating optimal bilateral symmetry.

Conclusion: The use of the guide-marker proved to be an effective tool to provide symmetrical placement of bilateral BAHS. We propose a novel method employing a simple guide-marker and tracing based on symmetrical anatomical landmarks to achieve precise placement and optimal symmetry and which may be easily adopted in the surgical routine of BAHS.

Level of Evidence: 3.

KEYWORDS

bone drilling; bone anchored hearing aid, symmetry; bone conduction

1 | INTRODUCTION

Bone-anchored hearing system (BAHS) is an effective treatment option for patients with conductive or mixed hearing loss, and single-sided deafness (SSD). It relies on direct bone conduction,[1] that is, sound transmission via percutaneous vibration through the titanium implant installed into the temporoparietal skull region to the inner ear. Excellent long-term success and low rates of major complications were reported with this device usage.[2]

Current recommendations for BAHS implant placement include the implant installation at 5–7 cm posterosuperior to the external auditory canal (EAC) in adult patients, to avoid the sigmoid sinus when placing the implant in the calvarial bone, as well as that the sound processor touches the pinna.[3] For this purpose, a surgical ruler is usually employed to measure the distance of 5.5 cm from the entrance of the EAC at an angular distance of approximately 45 degrees (similar height as the center of the upper half of the pinna of the subjects), visually determined. The use of the line extending from the lateral margin of the ipsilateral eye to the upper border of the pinna as an anatomical landmark was also proposed to improve the precision of the angular distance from the EAC for the implant BAHS installation,[4] however, it may be limited and does not ensure bilateral symmetry in patients with large facial asymmetry or those with craniofacial malformations, who show alteration or absence of these anatomical structures.

It is known that symmetry is an important goal in achieving successful in bilateral implantation of hearing devices, since it is directly related to the cosmetic appearance and patient's satisfaction with the device.[5] Zawawi et al.[6] carried out a prospective cohort study of 100 consecutive new candidates to BAHS and found that the main reason for surgery refusal was cosmetic and social acceptance, even in those patients with satisfactory preoperative audiometric improvements with the device. Other study[7] also showed that up to 19% of patients implanted with BAHS consider that the device is less appealing socially and, one subject, reported that would not choose to have BAHS again due to his unsatisfaction with cosmetic appearance, although he was very satisfied overall with the device.

Previous studies, based on laser Doppler vibrometry[8–10] and bone conduction thresholds and ear-canal sound pressure (ECSP) in normal-hearing patients,[4] also showed that the placement of bone conduction devices may affect the amplification and hearing outcomes. Based on this, although it is unclear in the Literature, to achieve optimal symmetry should also enable improved bilateral hearing outcomes for these patients.

Hallwachs et al.[5] proposed a method with the use of a mirror template to improve the bilateral symmetry in cochlear implant (CI) surgery. They found improved symmetry perceived by the patients, and high patient and family satisfaction regarding aesthetics, although they did not employ an objective tool to precisely investigate the bilateral symmetry. We propose a novel method for symmetrical placement of bilateral BAHS, employing a simple guide-marker and tracing based on symmetrical anatomical landmarks to achieve precise placement and optimal symmetry and which may be easily adopted in the surgical routine of this device. We also used 3D image processing techniques, based on preoperative CT scans, to objectively investigate the bilateral symmetry in these patients. To the best of our knowledge, this is the first study investigating the use of a technique including the use of a guide-marker to improve symmetry in bilateral BAHS surgery.

1.1 | Level of evidence

Non-randomized controlled cohort/follow-up study (Level 3).

2 | MATERIALS AND METHODS

2.1 | Ethics statement

This study was approved by the institutional Research Ethics Committee under protocol number 36517820.5.0000.5440, and all individuals signed an informed consent form prior to participation in the study.

2.2 | Subjects

The inclusion criteria comprised subjects eligible for bilateral bone anchored hearing systems (BAHS) surgery in 2020 and 2021, in a University Hospital in São Paulo, Brazil. The exclusion criteria comprised subjects with unilateral hearing loss or those with bilateral hearing loss but asymmetrical BC thresholds, with no indication for bilateral BAHS surgery. Twelve patients from 6 to 67 years old (Mean = 50.3, SD = ±19.1), were included in this study. Table 1 shows demographic data of subjects.

2.3 | Guide-marker

The guide-marker was designed in acetate material, flexible and transparent, which allows the visualization of the necessary anatomical landmarks for choosing the surgical site. It contains horizontal (x-axis) and vertical (y-axis) lines corresponding to the angular positions of 0 and 90 degrees, respectively. The angular positions of 30, 45, and 60 degrees are determined by three different lines between them. The linear distances, in the horizontal plane (x-axis), between the angular positions and the origin (O) are indicated by the numbers 4–9, which correspond to the distances from 4 to 9 centimeters (cm), respectively. In the vertical plane (y-axis), linear distances are indicated by alphabet letters, equally separated by 2 cm. The first and second quadrants of the guide-marker, named as "right" and "left," were designed to estimate the implant placement according to the ear it will be installed. The two faces of the transparent guide-marker allow to transfer the marked points to the contralateral ear, ensuring their identical alignment (Figure 1).

2.4 | Procedure

Prior to the surgical procedure, the guide-marker was positioned in the subjects to estimate the implant placement. The origin point (O) and 0 degrees line (x-axis) of the guide-marker were placed at the entrance of the EAC and lateral margin of the ipsilateral eye (anatomical landmark A) of the subjects, respectively. The implant placement point (IPP) was estimated at a linear distance of 5.5 cm from the origin point and marked using a demographic pen, plus two alternative points corresponding to the linear distances of 6.5 and 7.5 cm from the origin (Figure 1B). The processor dummy, provided by the BAHS manufacturer, was used to investigate the viability of the IPP for the

TABLE 1 Subject demographics.

Subject	Sex	Age (Y)	Etiology
S1	M	30	Acoustic trauma
S2	M	65	Cronic otitis media
S3	F	51	Otosclerosis
S4	M	34	Acquired EAC stenosis
S5	F	63	Glomus tympanicum
S6	F	39	Cronic otitis media
S7	M	65	External otitis malignant
S8	F	60	Chronic otitis media with cholesteatoma
S9	F	6	Congenital microtia
S10	F	67	Cronic otitis media
S11	M	59	Perilymphatic fistula
S12	M	64	Acoustic trauma

Abbreviations: F, female; M, male; S1-S12, subjects 1–12; Y, years old.

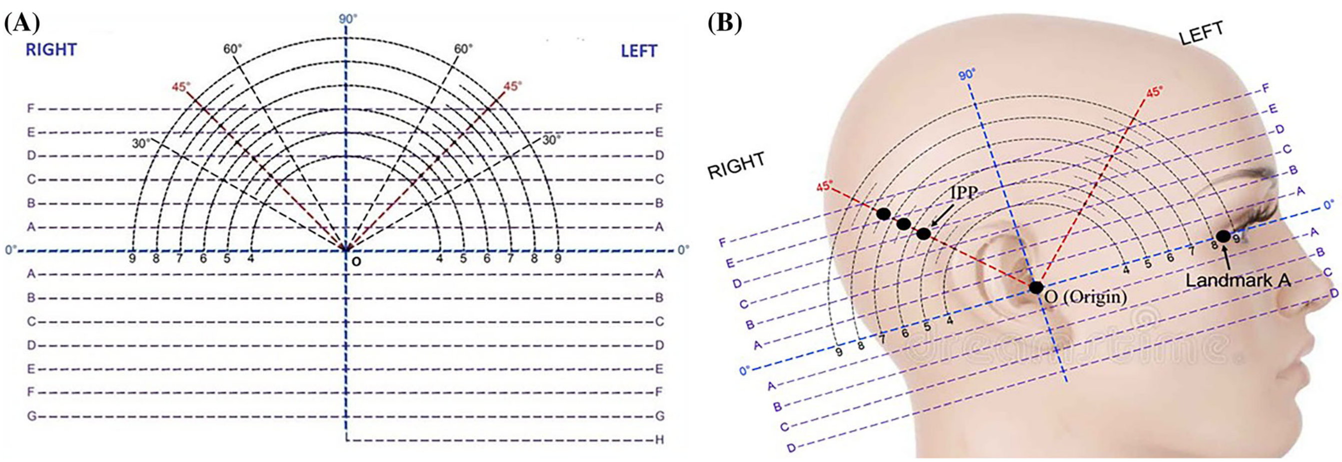

FIGURE 1 (A) Guide-marker used in this study. Linear and angular distances in relation to the origin (O) are provided. The transparent material allows to clearly identify the anatomical landmarks and to estimate the optimal position for implant placement. These points may be marked and transferred to the contralateral ear, providing bilateral symmetry. (B) Positioning the guide-marker into the subjects: the origin point (O) and 0 degrees line (x-axis) were aligned at the entrance of the EAC and lateral margin of the ipsilateral eye (anatomical landmark A), respectively. The implant placement point (IPP) and two alternative points corresponding to the linear distances of 5.5, 6.5, and 7.5 cm, respectively, were marked in the guide-marker and skin of the subjects using a demographic pen.

implant installation. When external physical barriers were observed, such as the processor touching the subject's pinna or glasses arms, a new position for IPP was then estimated using the linear distances of 6.5 and 7.5 cm from the origin, respectively.

These marked points, related to the first ear investigated, were then transferred to the contralateral ear via guide-marker. The angular and linear distance lines of the guide-marker were then positioned considering the same anatomical landmarks to ensure identical alignment of the guide on the contralateral ear. This procedure aimed to estimate the implant placement in the contralateral ear and to also ensure the bilateral symmetry between both the right and left ears (Figure 2).

In subjects with craniofacial malformations, who shows alteration or absence of the EAC and anatomical landmark A, or those without craniofacial anomalies but with accentuated facial asymmetry involving these structures between right and left sides, the origin point (O) was positioned at the center of the mandibular fossa and three alternative anatomical landmarks were used to estimate the IPP (Figure 3). In these subjects, the implant placement estimation with the use of the guide-marker was performed in the side without or with less severe craniofacial anomalies first.

2.5 | Radiological images

Preoperative CT scans of the subjects were performed to investigate the bilateral symmetry of the implant placement position, previously estimated via guide-marker. For this purpose, the IPP were highlighted

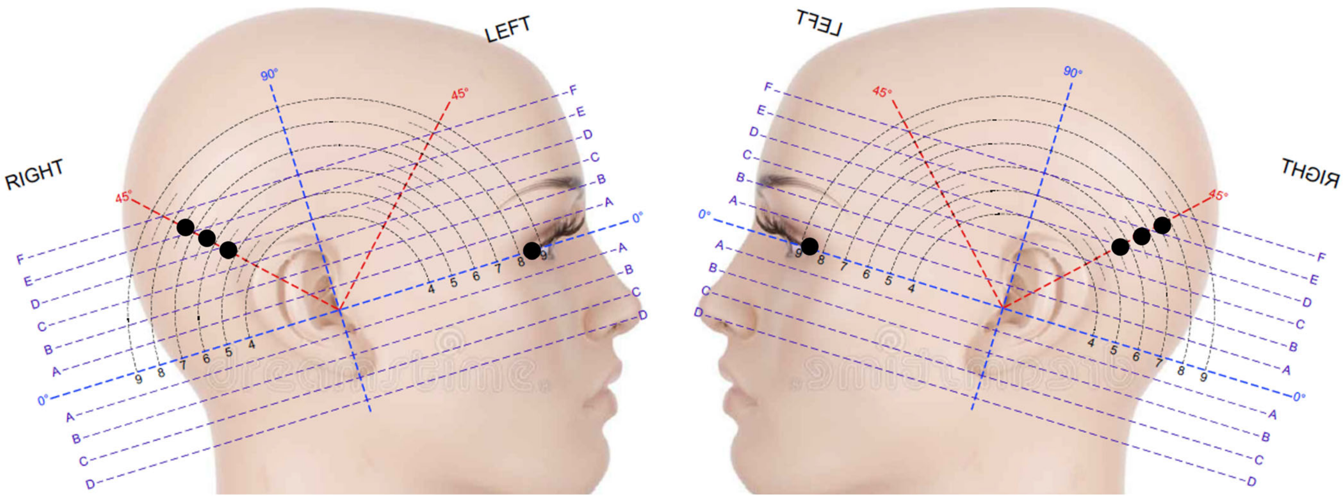

FIGURE 2 Bilateral implant placement estimation via guide-marker.

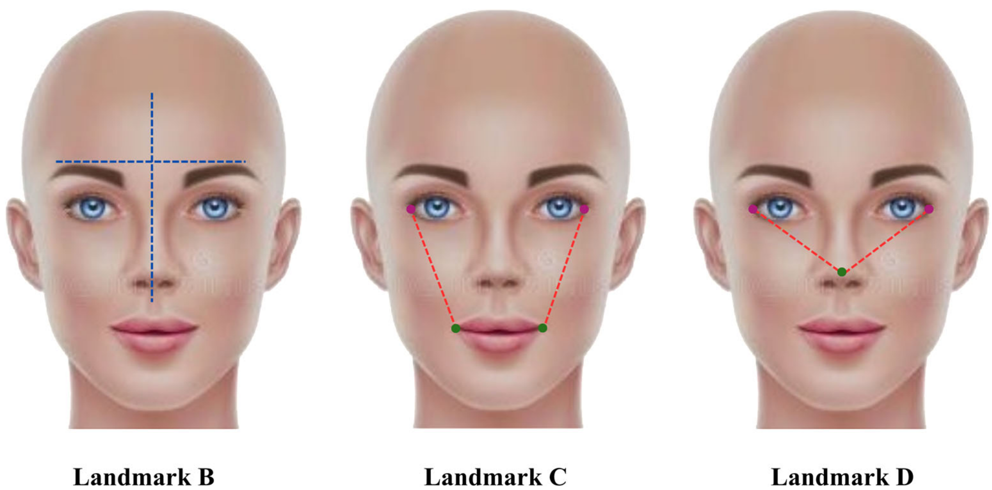

FIGURE 3 Example of the alternative anatomical landmarks used in subjects with alteration/absence of the landmark A: the eyebrows and nose (through the perpendicular lines) (landmark B), the corners of the mouth and eyes (landmark C) and the corner of the eye and the tip of the nose (landmark D).

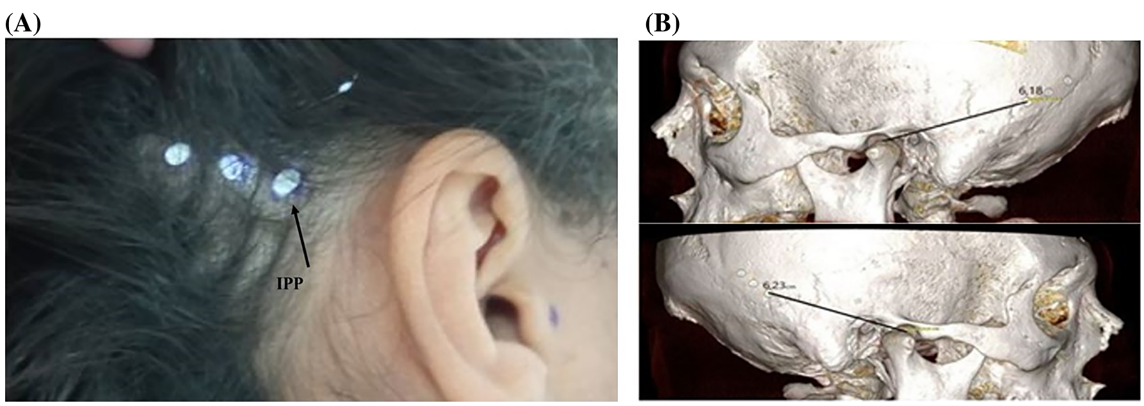

FIGURE 4 (A) Example of the IPP highlighted with a radiopaque marker in the right ear of the subject #S9. (B) Three-dimensional (3D) reconstructed skull view with the estimation of the mandible-implant distances in the left and right ears in the subject #S2.

with a radiopaque marker in the left and right ears of the subjects. CT scans were acquired at a resolution of $0.4 \times 0.4 \times 0.5$ mm^3. Three-dimensional CT images reconstruction from a volumetric rendering was performed using the software Extended Brillance Workspace™, version 3.5.2.2250 (Philips Medical Systems, Amsterdam, The Netherlands) and Vitrea® Enterprise Suite, version 6.8.0 (Toshiba Medical Systems Group Company, Tokyo, Japan). Three-dimensional (3D) reconstructed skull view was used to estimate the distance

TABLE 2 Mandible-implant distance estimation between right and left sides of the subjects.

Side	Mean (cm)	SD (cm)	Median (cm)	IIQ (cm)	Min (cm)	Max (cm)
Right	5.37	0.49	5.38	0.55	4.52	6.18
Left	5.38	0.41	5.32	0.51	4.74	6.23

Abbreviations: cm, centimeters; IIQ, interquartile interval; SD, standard deviation.

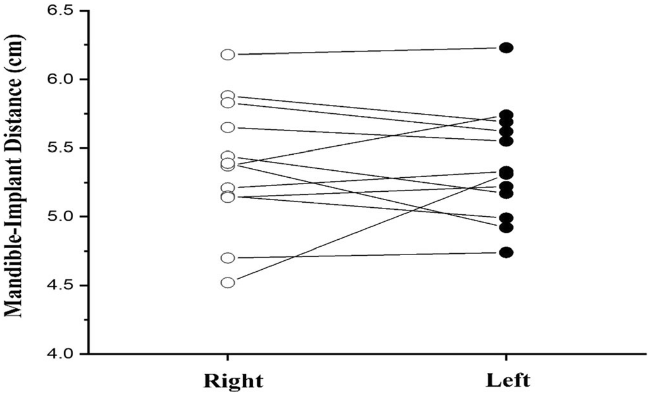

FIGURE 5 Comparison of the mandible-implant distance estimation between the right and left ears in each subject.

between the center of the mandibular condyle and IPP (mandible-implant distance) in both the right and left ears in each subject (Figure 4).

To investigate the bilateral symmetry of the implant placement, the mandible-implant distances were compared between the right and left ears of the subjects using the paired Student's *t* and Cohen's d effect size tests. Lin's concordance correlation coefficient (ρ_c) and the Bland–Altman plots (confidence interval = lower limit; upper limit) were used to evaluate the concordance of the mandible-implant distances estimation between the different ears in each subject. A significance level of 5% was adopted for statistical analysis.

3 | RESULTS

The guide-marker could be used to estimate the bilateral implant placement in all subjects included in this study. The entrance of the CAE and landmark A were used to estimate their implant placement, except in the subject #S9, with congenital bilateral microtia. In this subject, due to the abnormalities of the CAE caused by the craniofacial malformation, the mandibular condyle and anatomical landmark B were used, since these structures were present and symmetrical between both ears. The IPP was marked at a linear distance of 5.5 cm from the origin (O) in all subjects, including the subject #S9, with congenital bilateral microtia.

The mean mandible-implant distances in the left and right ears of the subjects are shown in Table 2. Figure 5 shows the comparison of the mandible-implant distance estimation between right and left ears in each subject. There was no difference in the mandible-implant distances between them ($t = 0.044$; $p = 0.97$; d = 0.013).

Figure 6 shows the concordance between mandible-implant estimation in the right and left sides of the subjects. The Lin's concordance correlation coefficient showed no predominance of one ear ($\rho_c = 0.73$; CI95%: 0.31; 0.91) and the scatter plot of the differences was uniform in relation to the mean amplitude of the measurements (CI95%: −0.65; 0.64), thereby confirming their symmetry.

4 | DISCUSSION

We propose a novel technique for symmetrical placement of bilateral percutaneous bone-anchored hearing systems, with the use of a simple guide-marker made of transparent acetate material which may be easily replicable and adopted in the surgical routine of BAHS implantation.

In this study, the guide-marker was used to estimate the implant placement in 12 subjects eligible for bilateral BAHS surgery, and this position was identically transferred to the contralateral side, thereby resulting in optimal symmetry, confirmed by the 3D image reconstruction. There were no differences in the mandible-implant distances between the right and left ears of the subjects using the paired Student's *t* test at $p < 0.05$ and the effect size was negligible. Additionally, Lin's concordance correlation coefficient showed no predominance of one ear, confirming bilateral symmetry.

It is known that bilateral symmetry of hearing implantable devices is directly related to cosmetic appearance.[5] Considering it, our results suggest that the use of the method proposed in this study employing the guide-marker could improve cosmetic appearance of bilateral percutaneous BAHS users and therefore their effectiveness in daily life.

One subject (#S9) presented abnormalities of the CAE caused by bilateral congenital microtia, and the implant placement was precisely estimated using the guide-marker with tracing based on alternative anatomical landmarks, and symmetry was also achieved for this subject. Precise implant placement and symmetry may be a challenge in patients with craniofacial malformation due to the absence or alteration of anatomical structures and our results suggest that the guide-marker seems to be an effective tool to achieve them in this population. However, as only one subject with craniofacial malformation was eligible to a bilateral BAHS surgery in the period of this study, further studies with a larger number of subjects and different types of craniofacial malformations are needed to better investigate the use of the guide-marker in these patients.

Based on the preoperative CT scans, we noted that, for one subject (#S6), the implant was estimated to be placed into a suture line in the left side, at 5.5 cm from the origin (O), although the 3D image reconstruction showed that the mandible-implant distance was

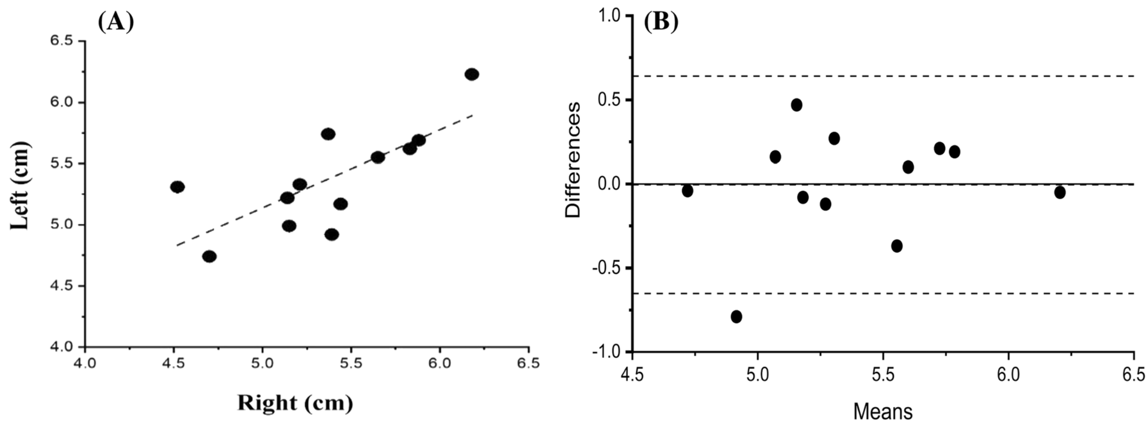

FIGURE 6 Scatter (A) and Bland–Altman (B) plots comparing the concordance of the mandible-implant estimation values between the right and left ears of the patients.

symmetrical between both the right and left sides. Previous studies[11,12] showed that the placement of BAHS implants into soft tissue as suture lines and bone marrow or into air cells, may compromise the osseointegration, thereby causing their extrusion. Thus, a subsequent image-guided surgical planning was carried out combining both the guide-marker and preoperative CT scans, and a new position for implant installation was then estimated at the distance of 6.5 cm from the origin (O), in both sides, to avoid implant complications and aiming to optimize the surgical outcomes for this subject.

In this study, preoperative CT scans were only used to objectively investigate the symmetrical placement estimation of bilateral BAHS implants, however, our experience on the subsequent image-guided surgical planning with the combination of both the preoperative CT scans and the guide-marker suggests that it may be useful in specified patients, mainly those with craniofacial malformations or previous otologic surgeries, who also present a higher risk of additional surgical complications, such as dural or lateral sinus exposure.[12]

Although the preoperative surgical planning based on CT scans for BAHS implant installation in pediatric population was previously reported[13] and it was also considered on an individual basis in the surgical routine of BAHS in adult patients,[12] we believe that, using both, CT scans and the guide-marker in these patients, should optimize the BAHS implant placement, considering the bone thickness and inner calvarial table, and, still, it could also promote bilateral symmetry.

5 | CONCLUSION

The use of the guide-marker proved to be an effective tool to provide symmetrical placement of bilateral percutaneous BAHS. We propose a novel method employing a simple guide-marker and tracing based on symmetrical anatomical landmarks to achieve precise placement and optimal symmetry and which may be easily adopted in the surgical routine of BAHS.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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