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Vestibular Outcome After Cochlear Implantation Is Not Related to Surgical Technique: A Double Blinded, Randomized Clinical Trial of Round Window Approach Versus Cochleostomy

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Objective: To establish whether the round window approach (RWA) leads to less vestibular dysfunction and dizziness than the standard cochleostomy approach (SCA) during cochlear implant (CI) surgery, as assessed using the video head impulse test (vHIT).

Additionally, objective findings were compared with the subjective dizziness perceived by the patient.

Study Design: Double blinded, clinical randomized trial.

Setting: University Hospital.

Patients: Fifty-two ears from 46 patients were included. Inclusion criterion was a gain value more than 0.50.

Intervention: Patients were randomized to the RWA or the SCA. Evaluation with the vHIT was performed before surgery, 1 day after surgery, and 1 month after surgery. Subjective dizziness was measured using a visual analogue scale (VAS) and the dizziness handicap inventory (DHI).

Main Outcome Measures: Gain values and the incidence of catch-up saccades.

Results: Three out of 23 patients in the SCA group experienced catch-up saccades compared with no patients in the RWA group, indicating the occurrence of objective vestibular dysfunction after CI surgery; the difference was not statistically significant. The VAS increased in both groups the day after surgery. The difference between the groups was not statistically significant. No statistically significant changes in the gain value or the DHI score could be observed between the two groups.

Conclusion: No statistically significant difference between the cochleostomy approach and the round window approach using the vHIT and subjective dizziness perceived by the patient was found. **Key Words:** Cochlear implant—Cochleostomy—Round window approach—Vestibular function—Video head impulse test.

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Vestibular dysfunction and dizziness are well-known side effects of cochlear implant (CI) surgery. Data on the incidence of both parameters differ (1). The incidence of subjective dizziness varies from 2 to 49% whereas the vestibular dysfunction following surgery varies from 3.1 to 77% (1,2). No correlation between the severity of vestibular dysfunction and subjective dizziness has been found (3).

Video head impulse test (vHIT) is a new diagnostic tool to investigate the function of the semicircular canals in the vestibular organ. The test is quick and easily performed and it is, to our concern, more frequently used instead of the caloric test. The incidence of postoperative dysfunction of the lateral semicircular canal varied from 3.6 to 30% when tested with vHIT (4,5).

The insertion of an electrode into the cochlea can be performed using two surgical approaches. For the standard cochleostomy approach (SCA), a burr is used to drill a hole in the cochlea anterior and inferior to the round window. For the round window approach (RWA), a paracentesis is made in the membrane of the round window.

Histopathological studies have demonstrated that the cochleostomy site affects the likelihood of preservation of vestibular receptors (6). Several studies have, therefore, evaluated vestibular function and the incidence of subjective dizziness following CI surgery comparing the SCA to the RWA (1,7–9). Todt et al. (1) detected a significant difference in the postoperative vestibular

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outcome when measured with evoked myogenic potential (VEMP) and electronystagmography (ENG) responses, as well as for the incidence of subjective dizziness determined by dizziness handicap inventory (DHI), and suggested that RWA had more favorable treatment outcomes than SCA. In a non-randomized, prospective study Klünter et al. (7) evaluated 52 patients using the caloric test and the dynamic and static postural control test using a computerized force plate (Balance Master, NeuroCom), before and after CI surgery. They did not find any significant differences between the clinical outcomes of SCA and RWA. Similarly, Klenzner et al. (8) did not detect any differences in the clinical outcomes between SCA and RWA measured with caloric testing.

In addition to differing results, the aforementioned studies suffer from significant methodological weaknesses including a lack of randomization, an unequal distribution of patients, or involve differences in the electrode types between the approaches that limit their applicability to the general cochlear implant population.

The aim of this randomized, double-blinded study was to clarify how different surgical approaches to the cochlea influence the measured objective and subjective vestibular outcomes using vHIT, a visual analogue scale (VAS) score and DHI of patients receiving a cochlear implant following either SCA or RWA.

Our main hypothesis was that the decrease in the gain value would be greater in the SCA group compared with the RWA group, postoperatively. Secondly, we hypothesized that there would be a greater increase in the VAS and DHI scores, and in the incidence of saccades postoperatively in the SCA group compared with the RWA group (1).

MATERIALS AND METHODS

Ethics

The Regional Scientific Ethical Committees of Southern Denmark approved this study with the approval number S-20150084. Informed consent was obtained from all patients. The study took place at the Department of ENT–Head & Neck Surgery, and the Department of Audiology at Odense University Hospital. The study has been registered in the database of clinicaltrials.gov with the identifier *NCT02584361*.

Patients

Fifty-two ears from 46 patients recruited from August 2015 to June 2016 were included in this study (Table 1). The patients were consecutive enrolled following a consultation before surgery. All patients scheduled for cochlear implantation underwent a preoperative vHIT examination. Inclusion criteria were the following: age over 18 years and a preoperative gain value over 0.50 measured with vHIT (EyeSeeCam from Interacoustics a/s, Middelfart, Denmark). Exclusion criteria were a gain below 0.50 measured with vHIT, and a previous history of implantation on the same ear. Forty-seven patients met the inclusion criteria. One patient denied participation in the study. The participation rate was therefore 98% (Fig. 1). Patients were recruited from all regions of Denmark, but were primarily from the region of Southern Denmark.

TABLE 1. Baseline data on included patients

	RWA	SCA	<i>p</i>
Demographics:	n = 29	n = 23	
No (%) women	18 (62)	10 (43)	0.01
No (%) right ear	13 (45)	12 (52)	0.30
Age (yr)	57.8 (25–85)	59.5 (26–82)	0.74
Mean preoperative gain value	1.01	0.96	0.36
Electrodes:			
No (%) AB HiRes MidScala	8 (28)	5 (22)	
No (%) Nucleus CI522	17 (59)	16 (69)	
No (%) Med-El Flex 24	4 (13)	2 (9)	
Cause of hearing loss:			
No (%) progressive	8 (27)	4 (17)	
No (%) congenital	5 (17)	8 (35)	
No (%) age-related	6 (21)	6 (26)	
No (%) Menière's disease	3 (10)	1 (4)	
No (%) otosclerosis	2 (7)	1 (4)	
No (%) pendred syndrome	1 (3)	1 (4)	
No (%) other	4 (14)	2 (9)	

Age-related hearing loss is defined as a decrease in hearing level of maximum 20 dB per octave. It is affecting people over 60 years and is most marked in the higher frequencies. Progressive hearing loss is defined as a decline in hearing greater than the age-related hearing loss. Congenital hearing loss is defined as a hearing loss that has been present since birth or early childhood.

RWA indicates round window approach; SCA, standard cochleostomy approach.

Four patients were excluded from the study perioperatively. Three were excluded due to infection in the middle ear for which cause they were not implanted. One was excluded due to ossification of the round window. The round window approach could, therefore, not be performed in this patient.

Randomization

Randomization was carried out using computer software from OPEN (Odense Patient Explorative Network). Patients were randomized in blocks according to age (± 60 yr), residual hearing (yes/no), and gain value before surgery (± 0.68). Residual hearing was defined by a hearing threshold more than 60 dB HL detected in at least two of the following frequencies: 125, 250, 500 Hz. The surgeon performed the randomization before the surgery. For bilateral implantations, each ear was randomized separately. Different approaches could, therefore, be used in each of the two ears of the patient. For bilateral patients, implantations were performed during the same operation.

The study was double-blinded, so that neither the vHIT examiner nor the patient knew which approach was used. The result of the randomization was revealed to the examiner during analysis of the data. Each patient was informed after all data were collected.

Surgery

Three experienced surgeons performed the implantations. The surgeons had a minimum of 5 years' experience with cochlear implant surgery. The surgical method was standardized for all surgeons. The approach to the cochlea was the only variable factor.

The surgical procedures consisted of a cortical mastoidectomy and a posterior tympanotomy. The round window was identified. The overhang of the niche was carefully removed

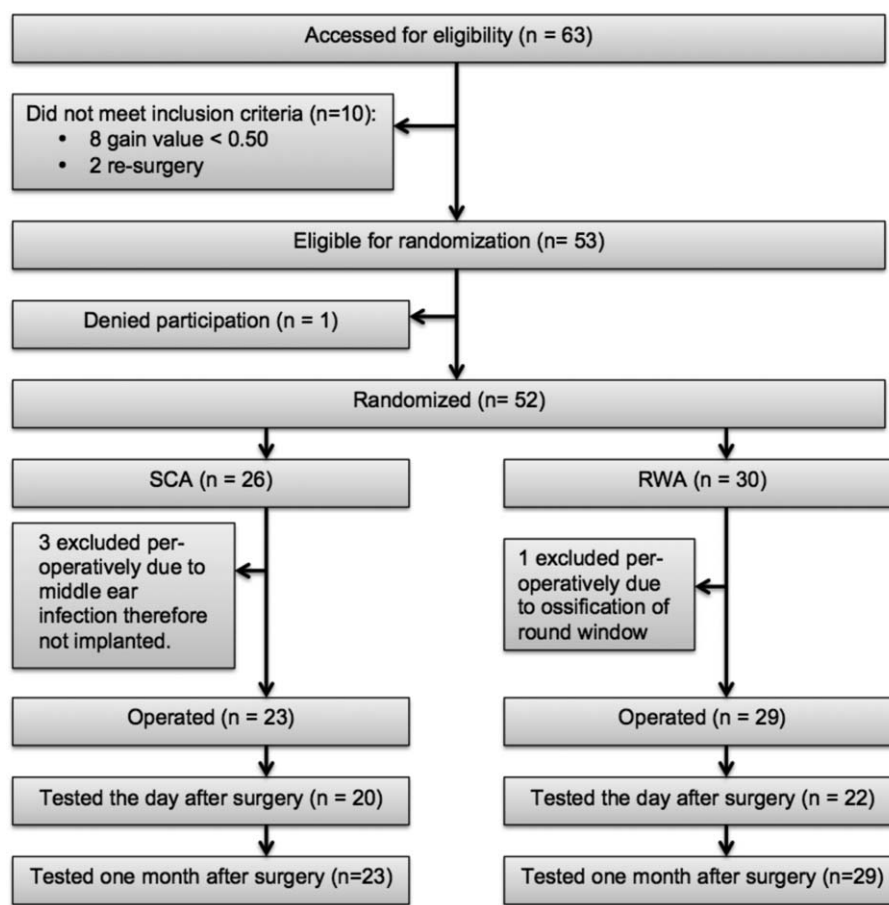


FIG. 1. Flowchart of included participants. n = number of included ears.

with a diamond burr to display the round window membrane. In the RWA group, a partial circumferential incision was made anteriorly-inferiorly in the membrane (paracentesis). In the cochleostomy group, a cochleostomy was performed anterior to the RW niche. The electrode was inserted in its full length over a duration of 1 minute. Minimal suction was used. One milliliter triamcinolone acetate (40 mg/ml) was injected intratympanically. Cefuroxime (1.5 g) was administered intravenously during surgery, and three doses of 1.5 g were administered intravenously during the following 24 hours.

Vestibular testing

Measurement of the lateral semicircular canal function was performed using the vHIT (EyeSeeCam from Interacoustics a/s, Middelfart, Denmark).

Patients were seated 1.5 m from a wall. The video goggle was tightened around their head and the camera was adjusted according to the manual of the manufacturer. While standing behind the patient, the examiner held the patient's head in a horizontal plane. The examiner was careful not to move the goggle during the head movement. Calibration of the goggles was performed according to the manufacturer's instruction. The calibration was accepted if the four outer positions of the eye movements were clearly marked and demonstrated a right-angled cross without artifacts.

The head impulses were performed by rotating the patient's head 10 to 20 degrees in a horizontal plane with a peak velocity

of more than 150 degrees/ms and a duration of 150 to 200 ms. At least 10 impulses were performed to each side. The same examiner performed all the tests. The computer software calculated instantaneous gain values at 40, 60, and 80 ms after head movement had started. Gain values at 60 ms were obtained and used for further analysis.

Catch-up saccades were defined by a change in velocity of the eye movement relative to the head rotation with a peak velocity over 100 degrees/ms. The saccades were defined with similar duration and amplitude, and appeared in each vHIT tracking curve for the eye movements, if head rotation speed exceeded 150 degrees/ms. Peak velocities below 100 degrees/ms were considered as artifacts. Catch-up saccades occurring during head rotation (covert catch-up saccades) and catch-up saccades occurring after head rotation had stopped (overt catch-up saccades) were included in the analysis.

The patients were asked to record their VAS regarding their sensation of dizziness before surgery, 1 day, after and 1 month after surgery. Zero represented a lack of dizziness, and 10 represented extreme dizziness. Patients also filled in the DHI questionnaire before surgery and 1 month after surgery.

Power calculation

A sample size calculation was performed to determine the minimum number of patients necessary for adequate power in the study. With a power of 0.80, significance level of 0.05, a minimum relevant difference of 0.16 in gain value (10), and a

TABLE 2. Age, sex, and side influence on gain value between approaches

	Round Window Approach	Cochleostomy	<i>p</i>
Age	0.01 (−0.01–0.01)	−0.01 (−0.01–0.05)	0.18
Sex	0.03 (−0.13–0.18)	0.07 (−0.07–0.22)	0.08
The day after surgery	−0.03 (−0.15–0.08)	−0.05 (−0.20–0.10)	0.84
One month after surgery	0.01 (−0.07–0.09)	−0.07 (−0.19–0.04)	0.99

Male sex and left side were used as reference group. Gain value before surgery was reference group and compared with the day after surgery and 1 month after surgery. *p* values indicate whether the differences in gain values were significant different between approaches

standard deviation of 0.068 (11), the minimum number of patients needed in each group were 16.

Statistics

All analyses were performed using STATA Corp 14.0 (College Station, TX).

Linear regression analysis was used to investigate the correlation between the gain value as an outcome and the incidence of catch-up saccades, surgical method, age, sex, and side as explanatory variables.

Logistic regression analysis was used to test the incidence of catch-up saccades as an outcome depending on the surgical method.

The right and left ear from each subject were correlated as well as repeated measurements from the same subject. To account for correlated ears and multiple vHIT examinations from the same subject, a cluster option was applied in all analyses, and robust standard errors were used in the statistical tests.

The non-parametric Kolmogorov–Smirnov test was used to investigate the changes in DHI and VAS following surgery.

RESULTS

Baseline

Patients were randomized in blocks according to age, residual hearing, and gain value previous surgery. There were no significant differences in mean age, side of implantation, and preoperative gain value between the groups (Table 1). There was a significant sex difference between the groups (Table 1). Sex was used as a variable in the regression analysis and showed to have no influence on the gain value (Table 2).

Gain value

No significant differences in the mean gain values between the RWA group and the SCA group were detected (−0.09 [95% confidence interval [CI] = −1.13–1.13 to −0.06], *p* = 0.09). Furthermore, there was no difference in mean gain values the day after surgery, or 1 month after surgery with reference to the gain values before surgery (Table 3). No significant differences in the mean gain values between the RWA group and the SCA group were found when correlating for age, sex, and time of testing (Table 2). Age and sex had no significant effect on the gain value (Table 2). No significant correlation between gain values and VAS was detected (*p* = 0.054).

Incidence of saccades

None of the 29 operated ears in the RWA group experienced the incidence of catch-up saccades at

day 1 after surgery or 1 month after surgery. The incidences of catch-up saccades were noted for three of the 23 operated ears in the SCA group after surgery. The odds ratio for the onset of catch-up saccades was 2.26 (*p* = 0.43) in the SCA group compared with the RWA group.

VAS

The changes in VAS following surgery were not statistically significantly different between the two groups (*p* = 0.90). VAS increased statistically significantly (*p* = 0.01) in the SCA group from a mean VAS of 0.92 (±0.25) before surgery, to 3.22 (±0.72) the day after surgery (Fig. 2). In the RWA group, the VAS increased from a mean of 1.47 (±0.30) before surgery, to 2.45 (±0.30) the day after surgery which was not significant (*p* = 0.13). From the day after surgery until 1 month after surgery, the VAS decreased to 1.03 (±0.28) in the SCA group, and 1.30 (±0.35) in the RWA group. The decrease was significant for both groups (*p* = 0.04). For those subjects who experienced the incidence of catch-up saccades after surgery, the VAS score increased significantly with 0.37 points (*p* = 0.04).

DHI scale

No significant differences in the change in DHI scores between the groups were detected (*p* = 0.47). Age, side of implantation, and sex did not affect the DHI either.

Before surgery, the RWA group had a mean DHI score of 8.14 (±3.00), whereas the SCA group had a mean DHI score of 3.95 (±1.25). The difference in preoperative DHI was not statistically significantly different between the groups (*p* = 0.23) (Fig. 3). In the RWA group, the DHI score decreased to 6.62 (±2.26) following surgery (*p* = 0.69). In the SCA group, the DHI score increased to 7.17 (±3.47) (*p* = 0.39) following surgery. The changes

TABLE 3. Shows mean gain values with standard errors between approaches

	Round Window Approach	Cochleostomy	<i>p</i> ^a
Before surgery	1.01 (±0.04)	0.96 (±0.03)	>0.82
The day after surgery	0.98 (±0.06)	0.91 (±0.08)	>0.76
One month after surgery	1.02 (±0.03)	0.89 (±0.04)	>0.99

^aStudent’s *t* test was used to test differences of means.

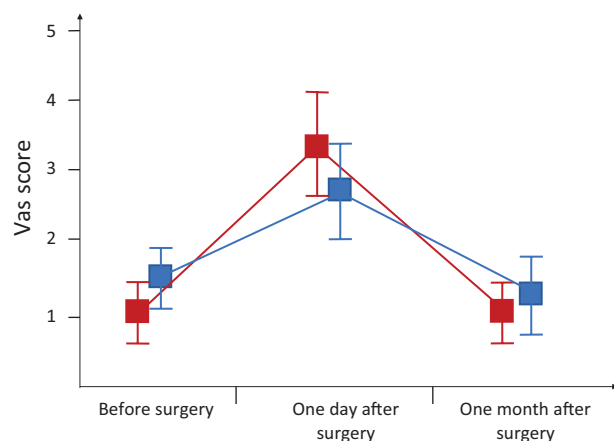


FIG. 2. Mean VAS before surgery, 1 day after surgery and 1 month after surgery. Whiskers represent, standard deviations. Red line represents the SCA group and the blue line represents the RWA group. RWA indicates round window approach; SCA, standard cochleostomy approach; VAS, visual analogue scale.

in the DHI scores were not statistically significant in any of the groups.

Narrative

The first patient in the SCA group, who experienced the onset of catch-up saccades, was a 71-year-old man. The preoperative computed tomography (CT) scan demonstrated a normal cochlea and vestibule, but compact mastoids. During surgery, ossification was evident at the location of the round window. A cochleostomy was performed, for which he was randomized and the HiFocus Mid-Scala electrode (Advanced Bionics, Stäfa, Switzerland) was inserted. The following day after surgery, he experienced the onset of catch-up saccades, followed by a low gain value (0.47 ± 0.10) in the implanted ear. However, 1 month after surgery no catch-up saccades occurred and the gain value had returned to normal (0.91 ± 0.05).

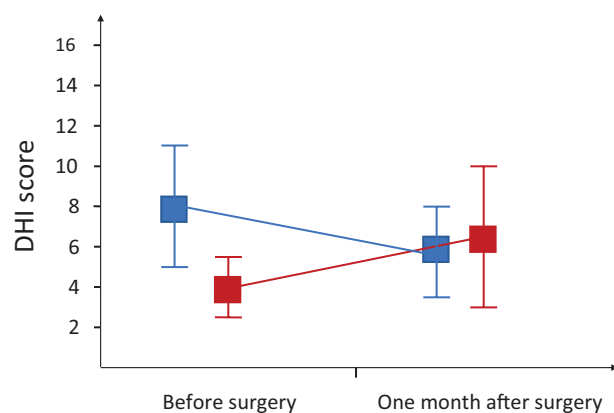


FIG. 3. Mean DHI score before and 1 month after surgery. Whiskers represent 95% confidence intervals. Red line represents the SCA group and blue line represents RWA group. 0 represents no balance problems or dizziness. Maximum score is 100. DHI indicates dizziness handicap inventory; RWA, round window approach; SCA, standard cochleostomy approach.

TABLE 4. Shows the correlation between the occurrence of catch-up saccades with the gain value, age, and sex

	Coefficient	<i>p</i>	95% CI
Gain value implanted ear	-0.57	0.00	(-0.860 to -0.281)
Age	-0.01	0.24	(-0.005 to 0.001)
Sex	0.08	0.11	(-0.019 to 0.178)

A significant decrease at -0.57 in gain value is detected if catch-up saccades occurred. Age or sex did not correlate with the occurrence of catch-up saccades.

The second patient was a 50-year-old man who had experienced hearing loss since childhood. Nucleus CI522 electrodes (Cochlear, Sydney, Australia) were bilaterally implanted in both ears using cochleostomy. The gain values were within the normal ranges and no catch-up saccades occurred on either ear the day after surgery. However, 1 month after surgery, covert and overt catch-up saccades occurred in the left ear, and the gain value had dropped to $0.39 (\pm 0.06)$.

The third patient was an 80-year-old man, who was implanted with a Med-El FlexSoft electrode in the left ear. The preoperative CT scan showed normal cochlea. No complications occurred during surgery. The day after surgery, we measured a low gain value (0.39 ± 0.08) and recorded the incidence of catch-up saccades in the implanted ear. One month after surgery, catch-up saccades still occurred and the gain value was low (0.20 ± 0.18). However, the VAS had decreased from a value of 10 on the day after surgery, to 1.5 1 month after surgery.

The onset of catch-up saccades after surgery was followed by a significant decrease in the gain value by the amount of -0.57 ($p < 0.001$). No significant correlation between the onset of catch-up saccades and age or sex was detected (Table 4).

DISCUSSION

We did not find any statistically significant differences in the incidence of catch-up saccades postoperatively between the RWA group and the SCA group ($p = 0.43$). Additionally, no significant differences in the gain values between the two surgical approaches were evident ($p = 0.09$). Therefore, we reject our hypothesis that the SCA predisposed further incidences of vestibular dysfunction compared with the RWA.

The results of the present study are in line with previous works demonstrating that cochlear implant electrode insertion technique does not impact the development of postoperative vestibular dysfunction (7,8). Nordfalk et al. (9) found an insignificant higher prevalence of vestibular loss, but a lower prevalence of vertigo symptoms in the RWA group using cervical vestibular evoked myogenic potential (cVEMP), videonystagmography (VNG), caloric test, and the subjective visual horizontal/vertical (SVH/SVV) test in a study, which compared 17 patients for each group. Only Med-El Flex Soft electrodes (Med-El, Innsbruck, Austria) were used

in the RWA group, and shorter perimodiolar electrodes were used in the SCA group. This led to the speculation whether the approach alone, or the use of different electrodes, was attributable to these results. This was supported by Mittmann et al. (12), who observed significantly greater intracochlear fluid pressure changes when the perimodiolar high-volume electrode was inserted compared with the straight electrode in artificial cochlear models. We used only slim and flexible electrodes designed for atraumatic insertion in this study. The slim and flexible design of the electrode may preserve the structures of the cochlea regardless of the surgical approach to cochlea. This may explain why we did not detect any differences between the approaches (12). The insertional speed is also related to the intracochlear fluid pressure changes (13). We inserted the electrode within a 1-minute timeframe for both approaches, which may have preserved the structures of the cochlea, and may have been attributable to the lack of detectable differences between the approaches. Despite this, no studies have investigated the intracochlear pressure changes associated with the surgical approach to the cochlea.

Briggs et al. (14) found an increased risk of scala vestibuli insertion when the cochleostomy was performed more anteriorly than inferiorly to the round window. The surgeons in this study used an anterior–inferior approach for the cochleostomy, thereby minimizing the risk of scala vestibuli insertion. Since we did not perform a postoperative CT scan of our CI recipients, we cannot completely rule out that the electrode was inserted into the scala vestibuli in some cases. We considered postoperative CT-scans to have been beyond the purposes of this study.

The lack of detecting possible differences between the approaches could be explained by using vHIT. Gain values obtained using vHIT are known to vary for several reasons, which include differences in hand placement, head velocity, calibration, experience of the examiner, or due to the incidence of artifacts (10). The variability in gain values makes it difficult to detect even minor alterations in the vestibular system. The changes in gain value following surgery in our study were often small and may be the result of gain variations.

Furthermore, the minimal clinically important difference in gain value, indicating vestibular dysfunction, is still unknown. Owing to the lack of information on this topic, we made the following assumption. A 0.16 difference in the gain value following surgery was defined as the minimal clinically important difference. This value was based on a previous study of ours where we detected a 0.16-point variation in the gain value between two examiners (10). Therefore, values less than 0.16 were considered to be attributable to gain variability. However, for three patients, who experienced further incidences of catch-up saccades after surgery in this study, indicating a loss of vestibular function, the decrease in gain values ranged from 0.44 to 0.82 points. As such, for the total loss of vestibular function, the minimal clinically important difference appeared to be a gain value

decrease of greater than 0.44 points. This indicated that we may have underestimated the clinical change in the gain value associated with vestibular function loss when we used a minimal clinically important gain value difference of 0.16 for our power calculations.

The change in gain value following surgery with any of the two procedures in our study were often small and only a few patients showed a change in the gain value greater than 0.16. The actual difference in gain values, if any, between the two surgical approaches may, therefore, be less than 0.16. This would require a substantial number of additional patients to indicate a significant difference in gain value change between the two surgical approaches. However, the clinical relevance of such a finding would be questionable, if more than 52 ears are needed to demonstrate a possible significant difference between the two surgical approaches.

Finally, it should also be considered that the horizontal canal, which we tested in this study, is not directly affected by cochlear implantation. Jutila et al. (15) did not detect any significant decreases in gain value following CI surgery while evaluating the horizontal canal with vHIT. The subjects were tested before cochlear implantation, immediately after, and 19 months after. This can be anatomically attributable to the connection between the semicircular canals and the cochlea via the sacculus and utriculus, reducing the potential for damage due to their distal location.

VAS increased immediately after surgery despite our inability to find a meaningful change in gain value. The lack of correlation between the objective and subjective findings is consistent with previous studies (4,5). These findings may be attributable to the lack of testing all components of the vestibular organ. We only evaluated the horizontal semicircular canals. Nonetheless, the incidence of dizziness may be explained by the dysfunction of the posterior and anterior semicircular canals, or of the utriculus and sacculus. These were not evaluated in this study.

The use of VEMP after CI surgery revealed a remarkably higher prevalence of vestibular dysfunction in the sacculus compared with the horizontal semicircular canal (4,16). Melvin et al. (4) evaluated 36 CI ears using the quantitative 3D head impulse test (qHIT), clinical head impulse test (cHIT), ENG, cVEMP, and dynamic visual acuity (DVA). The incidence of vestibular dysfunction after surgery was also the highest when VEMP was used. The high frequency of sacculus dysfunction may be due to its close relation to the cochlea, which potentially predisposes a higher risk of damage. The use of only vHIT to measure the vestibular function after CI surgery may lead to the underdiagnosis of the vestibular dysfunction.

No significant changes between DHI and VAS measured before surgery compared with 1 month after surgery were observed in either of the two groups. The incidence of dizziness is usually temporary due to central compensation, which may explain why no significant changes were observed. The result is consistent with previous studies, which did not detect any differences in the DHI scores after CI surgery (17–19).

No significant difference in VAS was detected between the approaches. Although this study lacked the statistical power to evaluate the statistical significance between the approaches for subjective dizziness, the relevance of this finding is questionable as dizziness is only temporary and decreases to preoperative levels within 1 month of surgery (2).

Strength and Limitations of This Study

The strengths of this study are the randomized, controlled trial design with the blinding of patients and vHIT examiner, and the high rate of participation (98%).

Additionally, the use of vHIT to examine the patients at two different time points after surgery allows for the evaluation of changes during the onset of vestibular dysfunction. We recorded the onset of vestibulopathy in one patient a day after surgery. One month after surgery, full vestibular function was regained. A larger portion of patients may have experienced the incidence of temporary vestibulopathy. However, not all patients were tested the day after surgery due to a lack of attendance. Hence, the reported figures for vestibulopathy for the day after surgery may have been underestimated, which would have been a limitation for this study.

CONCLUSION

We did not find a statistically significant difference in the gain values obtained using vHIT or subjective VAS and DHI between the cochleostomy approach and the round window approach following cochlear implantation.

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