

Initial Outcomes of Cochlear Implantation: a Comparison of Round Window Membrane and Conventional Bony Cochleostomy

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Abstract

Introduction: In 1972, William House introduced cochlear implantation and developed the House/3M single-channel device. This was the first implant to be implanted worldwide in over 1,000 patients from 1972 to 1980. **Objective:** To describe and assess the multi-channel cochlear implantation results at the Ear-Nose-Throat (ENT) Hospital, Ho Chi Minh City, in southern Vietnam. **Method:** This was a descriptive case study. 94 patients (100 ears) had cochlear implantation with multi-channel devices from 2015–2017. **Results:** The incision, at 4 cm long, is similar to that used in normal ear surgery. Complications rates were 3.19%. The electrodes were inserted through the round window membrane in 44 cases. The operation time was approximately 105.67 minutes with some technical improvements. The cochleae included 94 normal (94%) and 6 (6%) abnormal cochleae (most with common cavity deformities). All cases were successful. **Conclusions:** Cochlear implantation with some technical improvements helps surgeons select the optimal technique for their patients and decreases operative and post-operative complications, while simultaneously shortening the surgery and hospitalization times.

Keywords: Cochlear implant, Round window membrane, Minimally invasive surgery

INTRODUCTION

In 1972, William House introduced the cochlear implantation and developed the House/3M single-channel device. This was the first implant worldwide to be implanted in over 1000 patients from 1972 to 1980. [1] In 1984, the multi-channel devices were introduced and improved so far.

Since the introduction of the cochlear implant in 1984 and its first clinical approval by the United States Food and Drug Administration (FDA), many efforts have been aimed at improving its benefits. Intracranial injury and new tissue formation (new bone and fibrous tissue) caused by electrode insertion should be minimized through surgical techniques and electrode design. The first review of the cochlear implant injury was published in 1985, and researchers have been studying intracranial changes due to implants since then. This has led to increase user interest in performing soft surgery to maintain residual hearing.

The location of the cochlear implant in the eardrum was first described by the round window technique. Since then, various methods have been proposed to improve the image, alleviate the hassle of electrode insertion, and improve the methods to emphasize the retention of residual hearing. When performing a cochlear implant, the surgeon can choose to insert electrodes into the tympanic drum through a round

window, whether or not it drills out of its edge, or through the cochlea adjacent to the round window.

Choice of RWM surgery and/or cochleostomy surgery.

When facilitating round window surgery, direct insertion through the round window is considered the least invasive method. When the surgical effect is poor and the patient has no residual hearing, the area of the round window and hook can be enlarged for better observation of the eardrum. Ultimately, cochlear surgery may be the method of choice when hearing surgery is still required or according to the

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surgeon's preference, as it has the advantage of involving fewer drill holes.

Specific electrode design.

Some authors use the term "cochleostomy" to specify the extension of a circular window, referring to removing the circular bone as a modified circular edge. Others have combined this technique with round window inserts instead of cochleostomy.

Two methods are used worldwide for electrode insertion: the round window membrane (RWM) approach and standard bony promontory cochleostomy (SBC). The RWM is not always exposed fully with complete facial recess dissection. The St Thomas's Hospital (STH) classification was devised to evaluate the accessibility of the RWM for electrode insertion (Figure 1). Visibility of the RWM was graded in the present study according to the STH classification after

performing an "optimal" posterior tympanotomy and removing any overhang of the bony round window niche without breaching the RWM. The STH classification was divided into four types, as specified in Table 1.^[2]

The STH classification was used to propose the following practical management system: in type I or IIa, a pure RWM insertion (also known as a membranous cochleostomy) is primarily recommended. However, in some type IIa cases, extending the bony round window by 1–2 mm antero-inferiorly may sometimes be necessary (extended membranous cochleostomy). In type IIb, a similar extension to the bony round window or even a conventional bony promontory cochleostomy should be undertaken. In type III, a bony cochleostomy, carefully drilled antero-inferior to the presumed RWM in the direction of the basal turn, is indicated (Figure 2).

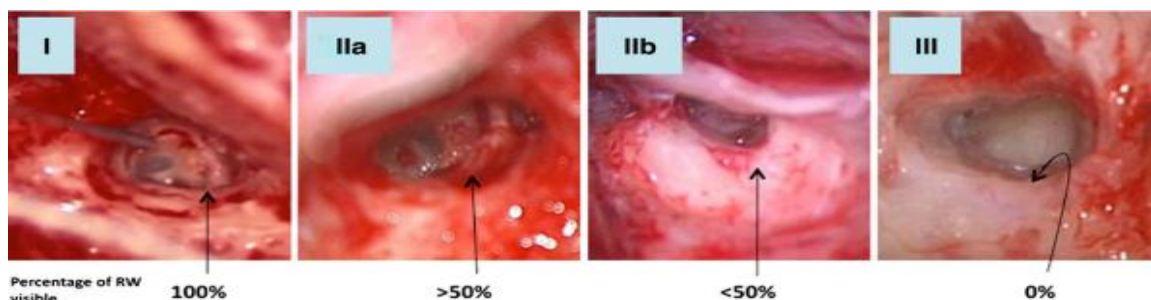


Figure 1. St. Thomas's Hospital (STH) classification of approachability of the round window membrane (RWM) in the round window-intentioned approach

Table 1. St. Thomas's Hospital (STH) classification

Type	Definition
Type I	Full exposure of the RWM is achieved
Type IIa	More than 50% of the RWM
Type IIb	Less than 50% of the RWM
Type III	None of the RWM is visible

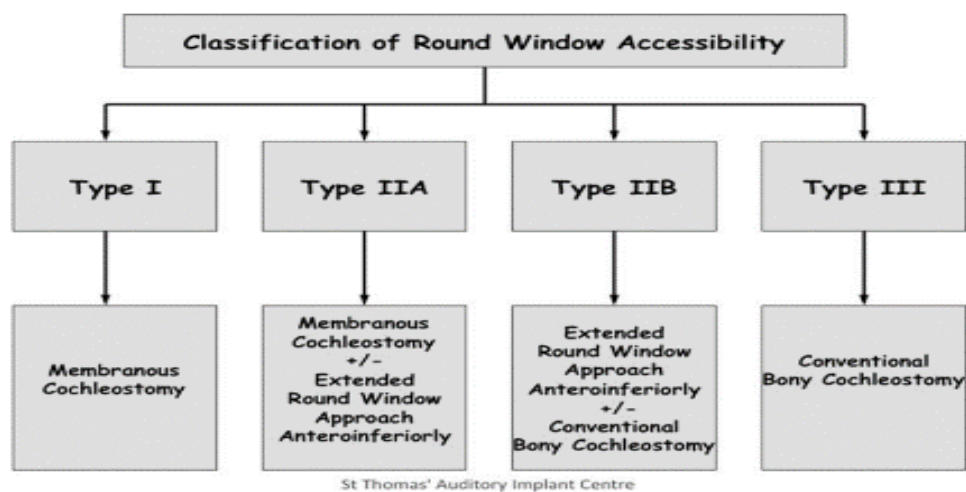


Figure 2. St. Thomas's Hospital (STH) classification of round window accessibility with the recommended type of surgical approach

MATERIALS AND METHODS

Study setting

The Ear-Nose-Throat (ENT) Hospital in Ho Chi Minh City was chosen as the study site. This is the largest healthcare facility that receives severe cases related to otology, rhinology, and laryngology in the whole of southern Vietnam. At ENT Hospital in Ho Chi Minh City in southern Vietnam, we had the first three cases of cochlear implantation with a single-channel device in 1998, conducted with the assistance of some professors from other countries. Since 2000, we have performed cochlear implantation with multi-channel devices on nearly 400 patients. From June 2015 to June 2017, we researched cochlear implant surgery with electrode insertion via the round window membrane in 44 cases.

Study design

This was a descriptive case study of 94 patients (100 ears) undergoing cochlear implantation at ENT Hospital in Ho Chi Minh City from June 2015 to June 2017.

Sampling

A total sampling technique was applied for data collection. All patients who were over 12 months of age and had profound sensorineural hearing loss and a normal cochlear nerve were included. The exclusion criteria were the lack of data for the study in the medical record, discharge without permission, and mortal cases.

Data analysis

Data were extracted from the medical records. These included the electronic version and paper version (if any), using a pre-designed form. Microsoft Excel 2010 for Windows was used for data management and descriptive statistics.

Ethical consideration

The protocol was approved by the Ethical Council of ENT Hospital Ho Chi Minh City. Personal information of patients was coded for anonymity and used solely for scientific research.

RESULTS AND DISCUSSION

Patient characteristics

The study included 51 males (54.26%) and 43 females (45.74%); this difference was not statistically significant (**Figure 3**). We divided the patients into five age groups (**Figure 4**). Some studies proposed that the implantation outcomes were significantly better in children younger than 2 years than in older children.^[3, 4] Before 6 years of age, children attend infant school and prepare for primary school. Therefore, they still have opportunities to study listening and speaking, but they are not as good a group as the children younger than 2 years. The percentages of children in each age group were as follows: under 2 years old: 6 (6.38%); 2 to under 6 years old: 49 (52.13%); 6 to under 10 years old: 23 (24.47%); 10 to under 15 years old: 13 (13.83%); and over 15

years old: 3 (3.19%). The most common age was from 2 to under 6 years old (52.13%). Research on pediatric cochlear implantation has shown that language outcomes are better for children who are implanted earlier in life than later.^[5, 6] In total, 88 patients (93.62%) had congenital hearing loss and 6 patients (6.38%) had acquired hearing loss.

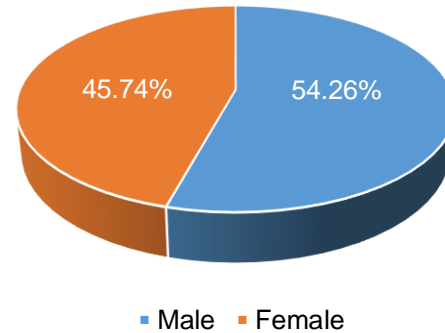


Figure 3. Gender of the included participants.

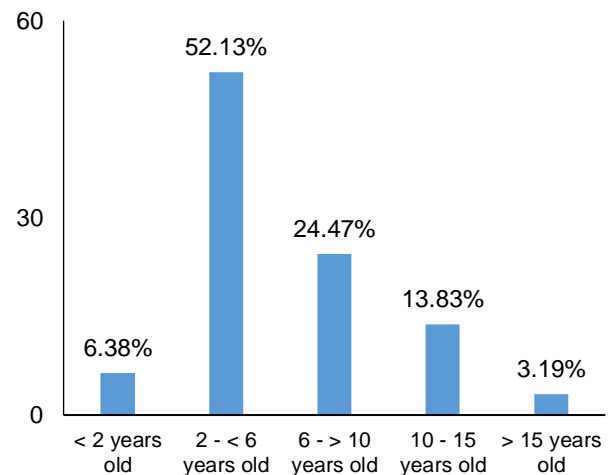


Figure 4. Age of the included participants.

High-resolution computed tomography (HRCT) and high-resolution magnetic resonance (HRMR) imaging

In total, 88 patients (93.62%) had normal anatomy of the inner ear, as determined by HRCT. Six patients (6.38%) had inner ear malformations determined by HRCT (we performed unilateral cochlear implant surgery on these cases). All 94 patients (100%) had a normal cochlear nerve determined by HRMR. Preoperative imaging has an important role in the evaluation of the surgical landmarks, especially in cases of meningitis and ossification of the inner ear structures. Imaging provides clinically relevant information to the implant team.^[7, 8]

Unilateral and bilateral cochlear implantation:

Overall, 52 patients (55.32%) received an implant in the right ear, 36 were implanted in the left (38.3%), and 6 were implanted in both ears (6.38%).

Cochlear implant procedure

We used a small skin incision and minimal dissection procedure to avoid injury. Any large defect of the posterior canal wall was covered using a Palva flap (*Figures 5 to 9*).



Figure 5A. The retroauricular small skin incision.



Figure 5B. The dissection for the Palva flap.



Figure 6. The posterior tympanotomy is complete ^[9]



Figure 7. The round window membrane is entirely visible.



Figure 8A. The round window is opened carefully.



Figure 8B. The tip of the electrode array is inserted through the opened round window.

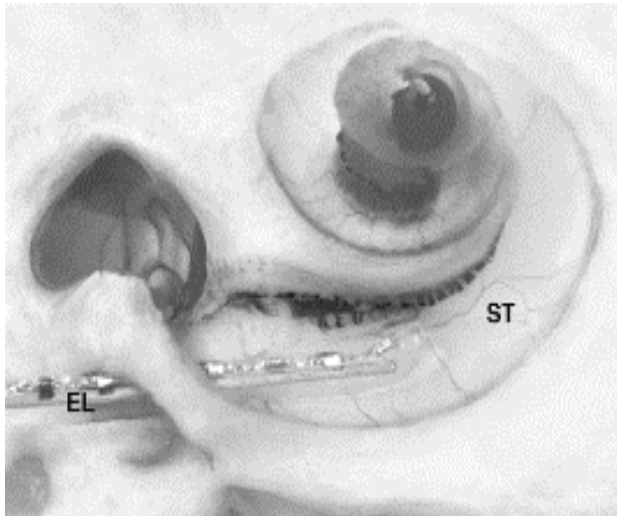


Figure 9. The electrode (EL) is entered into the midportion of the scala tympani (ST) [10]

In total, 50 patients (56 ears) were managed with a conventional bony cochleostomy and 44 patients (44 ears) were managed through RWM cochleostomy. The six patients (6.38%) who had inner ear malformations had a common cavity as the most common malformation. We used straight 24-electrode arrays for all patients.

Since 2015, we performed 94 cochlear implantations, with 44 cases of RWM cochleostomy and 50 cases of conventional bony cochleostomy. Impedance measurements were routinely performed during the cochlear implantation. These measurements allowed confirmation that all electrodes were working correctly. All patients had good outcomes.

Cochlear implantation via the round window membrane was shown to minimize trauma to the cochlear structures, especially the basilar membrane and the osseous spiral lamina. It also reduced the tissue reactions from bony drilling and helped the wounds to heal faster. One limitation is that

the drilling procedure for a bony cochleostomy may affect the inner ear with a very high sound pressure level (~130dB). This is a particular risk if the endosteal membrane is left intact and comes into contact with the running burr and may endanger any residual cochlear function [3, 4, 11]. In addition, cochlear implantation via the round window membrane had a 2 mm difference in the length of the stimulated spiral lamina when compared to standard bony promontory cochleostomy (Figures 10, 11). [12]

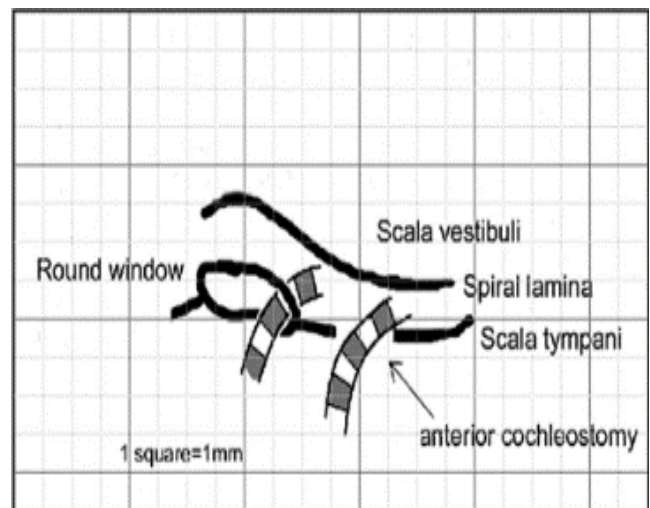


Figure 10. Method of assessment of the contact point between the electrode and the spiral lamina.



Figure 11. The cochlear implant used at the ENT Hospital, Ho Chi Minh City.

However, for type IIb or III classifications, where less than 50% of the RWM or no RWM is visible, a bony promontory cochleostomy is indicated. After electrode insertion was complete, intraoperative measurements of electrode impedance were made using Custom Sound EP software. Radiology of the temporal bone with Stenver's view was made 48 hours after surgery. All electrode arrays were placed in the correct position in the cochlea.

In the early days of cochlear implants, patients were required to have a hearing threshold of 100 dB or more. Recently, selection criteria have been reassessed and expanded for patients with other hearing levels, making hearing conservation an important issue. Many experts suggest that even very conserved residual hearing under 500Hz may be sufficient to significantly improve speech perception results. However, minimizing the impact of a cochlear implant on the remaining hearing is still challenging, as the damage of the cochlea can worsen or destroy this residual hearing in most patients. In response to the desire to conserve residual

hearing, a special focus has been placed on surgical techniques.

This study has some limitations that should be mentioned. One was that a small number of cases reduced the statistical power and generality of the study. Nevertheless, some results were sufficiently relevant to achieve statistical significance. Another limitation is that the surgery involving the inclusion of implant electrodes in the circular window insertion group is no longer performed. However, the findings from short electrodes are relevant, especially when the length of the electrode is being reviewed when new hearing protection models or hearing aids are being designed. A third limitation is the small number of cases with any combination of electrode type and insertion technique, which precluded the elimination of the potential interference of the electrode type. Other limitations included the fact that long-term changes due to cochlear implants cannot be studied in normal patient samples, and histopathological results in transplant patients are always delayed with the current technology and techniques.

Complications

Three patients had complications (3.19%): one case had a mild hematoma and two cases had transient grade II facial palsy according to the House-Brackmann classification. These complications were relieved completely seven days after surgery, and all patients had good outcomes after cochlear implantation.

CONCLUSIONS

From the procedural aspect, each of the two methods (RWM approach and standard bony promontory cochleostomy) has several advantages and disadvantages. With the same proportion of cases for each method (53.19% and 46.81%, respectively), the availability of both methods is necessary to allow surgeons to select the optimum technique for each patient. We will continue to follow all these patients in terms of their speech and language development after cochlear implantation, and we will report the outcomes in the future.

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Conflicts of interest

The authors have no conflicts of interest to declare.

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