Auris Nasus Larynx 41 (2014) 331–336

Contents lists available at ScienceDirect

Auris Nasus Larynx

journal homepage: www.elsevier.com/locate/anl

A new cochlear implant electrode with a "cork"-type stopper for inner ear malformations

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ARTICLE INFO

Article history:
Received 16 May 2013
Accepted 28 January 2014
Available online 20 February 2014

Keywords:
Inner ear anomaly
Gusher
Cochlear implantation

ABSTRACT

Objective: Gusher in inner ear malformations is common in patients with incomplete partition type I and type III. It is also common in less severe form as oozing in incomplete partition type II and large vestibular aqueduct. It is important to prevent cerebrospinal fluid (CSF) escape around the electrode to prevent meningitis.

Methods: The custom-made device was produced by Med-El Company. It has a "cork"-like stopper instead of the usual silicon ring to prevent gusher. There are two types of electrodes of different lengths. The standard one is 25 mm (contact space 1.7 mm) and the short one is 20 mm (contact space 1.3 mm). It was used in 50 patients with different inner ear malformations.

Results: Thirteen patients had gusher, and 11 patients oozing during cochleostomy. One patient with initial prototype of the cork electrode had to be revised because of persistent oozing around the electrode. Another patient had slow extrusion of the electrode most probably due to CSF pulsation and had to be revised. Both patients had no more CSF fistula.

Conclusion: CSF fistula in inner ear malformations is a serious situation which may lead to recurrent meningitis. The new electrode with "cork" stopper looks promising in preventing the postoperative CSF leak around the electrode.

1. Introduction

Inner ear malformations (IEMs) are present in about 20% of patients with congenital sensorineural hearing loss [1]. During cochlear implant surgery in an ear with IEM, a surgeon may be faced with two challenging situations [2]: anomalous course of the facial nerve and cerebrospinal fluid (CSF) gusher. Facial nerve anomaly is usually due to abnormal development of the inner ear, which may result in an unusual location of the facial canal. The second difficulty is the outflow of CSF at the time of cochleostomy, which results from the abnormal connection between the internal auditory canal (IAC) and the cochlea. The latter condition may lead to meningitis if the cochleostomy is not properly sealed.

In patients with normal anatomy, CSF fills the IAC, but it is not present inside the cochlea. In some cases with IEMs, CSF is in contact with the oval and round windows. This may result in CSF gusher during cochleostomy. High and pulsating CSF pressure acting against the stapes footplate may produce a spontaneous CSF fistula in the oval window, which may be unrelated to any kind of middle or inner ear surgery [2–7]. Pathology similar to that at the oval window is less commonly encountered at the round window. Postoperatively, CSF fistula at the cochleostomy is also occasionally reported [8]. Whatever the location of the fistula, the leak should be closed completely until no fluid is seen escaping through the opening. If CSF continues to efflux either through an oval window fistula or around the cochleostomy, this may lead to meningitis. Recurrent meningitis is also a possible consequence of this condition. If meningitis results from cochlear implant surgery in an ear with IEM, the surgeon is faced with a lethal complication of an elective surgery performed for hearing restoration.

A child with incomplete partition type I (IP-I) anomaly, who was operated on in our department in August 2006, had severe gusher during surgery. In spite of proper control of gusher with several pieces of fascia located around the electrode at the cochleostomy during surgery and no complications in the immediate postoperative period, she developed meningitis 3 months postoperatively. She presented to hospital in a comatose state. Despite all efforts, she died after 2 months. This unfortunate

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http://dx.doi.org/10.1016/j.anl.2013.12.011

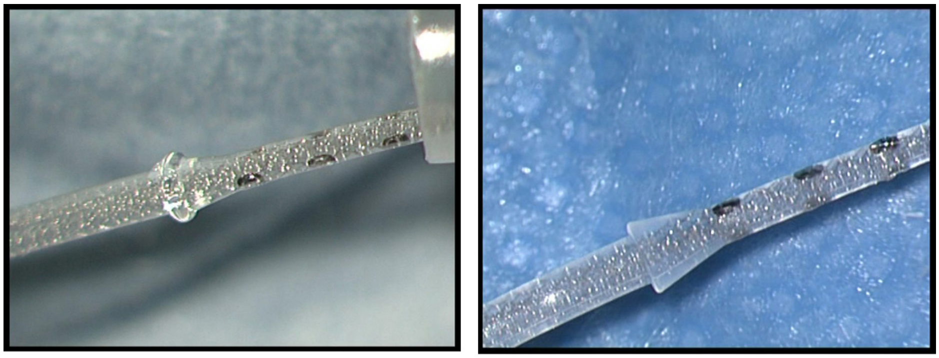

Fig. 1. Comparison of initial and final models of the cork electrode.

event made the author look for a more efficient way to control CSF gusher during surgery. After several discussions about the shape of the electrode, an electrode with a cork-like stopper for the control of CSF gusher during surgery was developed.

2. Materials and methods

2.1. Patients

The new electrode was used in 50 patients with various IEMs between January 2008 and March 2013. There were 18 male and 32 female patients. All patients had HRCT and MRI. IEMs were classified according to a paper by Sennaroglu published in 2010 [2]. Of the 50 patients in the current study, 11 were classified with IP-I, 22 with IP-II, 7 with cochlear hypoplasia, 3 with IP-III, 3 with common cavity, 1 with large vestibular aqueduct, 1 with cochlear aperture stenosis and 2 with defective cochlear base. The latter patients were unique: their inner ear pathology did not fit any category within the present classification system. Three patients, where a revision surgery had to be performed, were presented in more detail.

Before surgery the possibility of CSF leakage and the potential complication of meningitis were explained to all families. They were also informed about the use of the newly developed electrode, which had a better chance of preventing CSF leakage.

2.2. Electrode with cork stopper

The custom-made device was produced by Med-El Company. The new electrode, which was designed for IEMs, has three main characteristics (Fig. 1).

2.2.1. Cork-type stopper

It has a cork-like stopper instead of the usual silicon ring at the proximal end of the intracochlear electrode to prevent CSF fistula after insertion. This was designed to close the cochleostomy more efficiently to stop the escape of CSF around the electrode. The preliminary model (Fig. 1) had a stopper with an outer diameter of 1.4 mm. This was very close to the diameter of the active electrode, which is 1 mm. A cochleostomy created with a burr size of 1.2 mm was necessary for the active electrode to pass through without resistance, but the cork electrode was not large enough to effectively close a cochleostomy of 1.2 mm in diameter.

Accordingly, the diameter of the cork stopper was increased to 1.9 mm. A 1.2-mm cochleostomy was sufficient for the active electrode to pass through, without allowing the stopper with a diameter of 1.9 mm to pass through, thereby efficiently sealing the cochleostomy.

2.2.2. The length of the electrode

In an earlier study [9] the dimensions of various IEMs were measured. The average diameter of the basal turn of IP-I was 8.45 mm and of IP-II was 8.10 mm. Using these measurements and the formula $L = 2\pi r$, the length of an electrode needed to make one full turn around the basal turn was calculated as 25 mm. Taking these measurements into consideration, the length of the new electrode was designed to be 25 mm.

After working with hypoplastic cochleae, it became necessary to have a shorter form of this electrode. At this time, two types of electrodes with cork stopper have been devised then. The diameter of the intracochlear part of both electrodes is 1 mm. The contact surfaces of the electrodes are evenly distributed along the electrode, from the tip to a few millimeters proximal to the stopper. The distance between the stopper and the last electrode was designed to be 3.5 mm to prevent damage to the last contact during insertion.

a. Standard cork electrode (Fig. 2): The length of the standard electrode is 25 mm. The contact spacing between active electrodes is 1.7 mm. This is preferred in cochleae such as IP-I, IP-II, and IP-III and in large vestibular aqueduct patients where the outer dimensions of the cochlea are similar to normal. It is also preferred in patients with a large common cavity.
b. Short cork electrode (Fig. 3): The length of the shorter electrode is 20 mm. The contact spacing is 1.3 mm. This is preferred in hypoplastic cochlea and in patients with a small common cavity.

2.2.3. Contact surface on both sides of the electrode array

In cases where the modiolus is missing (IP-I, IP-III and common cavity), the exact location of the neural tissue is unknown. Modiolar hugging electrodes may have a disadvantage in this respect. The new electrode has contact surface on both sides of the electrode array to stimulate the neural tissue present in the anomalous cochlea more effectively.

2.3. Technique for the cochleostomy

As already indicated, the diameter of the active part of the electrode is 1 mm. The diameter of the cochleostomy must be 1.2 mm in order to allow smooth passage of the active electrode but not the cork stopper. At this stage, if the electrode is passed through a tiny piece of fascia, which covers it circumferentially, and positioned at the cochleostomy, it is possible to have an even better seal (Fig. 4).

It is important to use the tissue glue after each layer of soft tissue is added. Similar to the “first line of defense”, the first layer of the soft tissue, which is prepared by perforating a tiny piece of