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Research paper

Insertion site and sealing technique affect residual hearing and tissue formation after cochlear implantation

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ABSTRACT

Tissue formation around the electrode array of a cochlear implant has been suggested to influence preservation of residual hearing as well as electrical hearing performance of implanted subjects. Further, inhomogeneity in the electrical properties of the scala tympani shape the electrical field and affect current spread. Intracochlear trauma due to electrode insertion and the insertion site itself are commonly seen as triggers for the tissue formation. The present study investigates whether the insertion site, round window membrane (RWM) vs. cochleostomy (CS), or the sealing material, no seal vs. muscle graft vs. carboxylate cement, have an influence on the amount of fibrous tissue and/or new bone formation after CI implantation in the guinea pig. Hearing thresholds were determined by auditory brainstem response (ABR) measurements prior to implantation and after 28 days. The amount of tissue formation was quantified by evaluation of microscopic images obtained by a grinding/polishing procedure to keep the CI in place during histological processing.

An insertion via the round window membrane resulted after 28 days in less tissue formation in the no seal and muscle seal condition compared to the cochleostomy approach. Between these two sealing techniques there was no difference. Sealing the cochlea with carboxylate cement resulted always in a strong new bone formation and almost total loss of residual hearing. The amount of tissue formation and the hearing loss correlated at 1–8 kHz. Consequently, the use of carboxylate cement as a sealing material in cochlear implantation should be avoided even in animal studies, whereas sealing the insertion site with a muscle graft did not induce an additional tissue growth compared to omitting a seal. For hearing preservation the round window approach should be used.

1. Introduction

Subjects with severe to profound hearing loss can benefit from a cochlear implant (CI). Even though this is the method of choice, some challenges still remain with this treatment, especially with regard to preservation of residual hearing for electro-acoustic stimulation (EAS).

After implantation a fibrous tissue sheath or, in some cases, new bone develops around the electrode carrier, particularly in the basal turn (Li et al., 2007). Impedances also increase after implantation (Busby et al., 2002). As shown in cats (Clark et al., 1995), these impedances correlate with the amount of fibrous tissue found around the CI electrode. Additionally, the formation of tissue seems to start at the cochleostomy, as the impedance increases are fastest and largest at the basal electrodes (Paasche et al., 2006). Furthermore, Kawano et al. (1998) report a correlation between the amount of fibrous tissue and/or new bone formation and the hearing performance of the individuals, probably due to an increased distance between electrodes and Rosenthal's canal and an altered current spread. Not only electrical stimulation is influenced by the formation of fibrous and bony tissue, also the residual hearing may be influenced by it (Choi and Oghalai, 2005; O'Leary et al., 2013). Generally, the post-operative tissue formation is considered to be a component of the late cochlear damage and a contributor to the host response following CI implantation (Li et al., 2007; Somdas et al., 2007).

Abbreviations: ABR, auditory brainstem response; CF, characteristic frequency; CI, cochlear implant; CS, cochleostomy; DS, Durelon™ seal; EAS, electro-acoustic stimulation; i.m., intramuscular; MS, muscle seal; NS, no seal; p.o., per os; Pt, platinum; RWM, round window membrane; s.c., subcutaneously; SPL, sound pressure level; ST, scala tympani; SV, scala vestibuli

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Provided that the source of the tissue formation is the insertion site, this site and the sealing thereof may determine the amount of fibrous tissue after CI implantation. Currently, there are two main insertion sites used for cochlear implantation: An incision of the round window membrane (RWM) or a cochleostomy (CS), usually in the basal turn of the cochlea. The insertion via a cochleostomy allows a straight insertion of the implant and is thus often considered the standard implantation site. However, it involves drilling of an opening in the bony wall of the cochlea, which can lead to noise exposure up to 130 dB sound pressure level (SPL) (Pau et al., 2007) and risks the entry of bone particles into the cochlea. Additionally, it may damage the stria vascularis or cochlear vessels. The round window approach leads to less insertion trauma in the basal turn of the cochlea (Richard et al., 2012) and is therefore recommended if hearing preservation is desired after implantation (Lenarz et al., 2006).

Several different sealing techniques are used in human or animal studies to seal the insertion site; including no seal (Purser et al., 1991; Kral et al., 2002) as well as an autologous muscle or fascia graft (Friedland and Runge-Samuelson, 2009) and the use of carboxylate cement (Scheper et al., 2009). The aim of the current study was to investigate the influence of the different insertion and sealing techniques on the formation of fibrous tissue and/or new bone and on the hearing performance after CI model implantation in normal hearing guinea pigs.

2. Materials and methods

All experiments had been approved by the Institutional Animal Care and Research Advisory Committee and the local ethics committee. The study has been conducted in accordance with the German “Law on Protecting Animals” and with the European Communities Council Directive 86/609/EEC for the protection of animals used for experimental purposes.

2.1. Electrode model

A platinum (Pt) wire with a diameter of 0.19 mm was dip-coated with medical grade silicone (Nusil™ Med 4234; NuSil Technology LLC, Carpinteria, USA). The diameter of the CI implant model was kept between 0.4 and 0.6 mm with a length of 7 mm. Additionally 4 electrode models with the same diameter and length as the other CI models but without Pt wires were manufactured in a mold. Prior to implantation the CI models were sterilized in an autoclave to allow aseptic insertion.

2.2. Study design

In this study 60 normal hearing Dunkin Hartley guinea pigs (Charles River Laboratories International Inc., Sulzfeld, Germany) were implanted unilaterally with a CI electrode model. Half of the animals were implanted via the round window membrane (RWM), the other half via a cochleostomy. After implantation the insertion site was either left open (no seal, NS) or sealed with a muscle tissue graft (muscle seal, MS) or carboxylate cement (Durelon™, 3M ESPE AG, Seefeld, Germany) (Durelon™ seal, DS). Thus 6 groups combining each insertion site with each sealing technique were implanted. The hearing thresholds of the animals were determined on day 0 prior to surgery and on day 28.

2.3. Anesthesia

Implantations and measurements were performed under general anesthesia. The animals were anesthetized with an intramuscular (i.m.) injection of a combination of 0.025 mg/kg fentanyl citrate (Janssen-Cilag GmbH, Neuss, Germany), 0.2 mg/kg medetomidine hydrochloride (Janssen-Cilag GmbH) and 1 mg/kg midazolam (Ratiopharm GmbH, Ulm, Germany). Pretreatment was done with 0.05 mg/kg atropine sulfate (B. Braun Melsungen AG, Melsungen, Germany) applied subcutaneously (s.c.). The animals received supplementary doses of anesthetics i.m. to maintain anesthesia if needed.

The animals were supplemented s.c. with 26 mL/kg Ringer acetate and glucose 5% (ratio 1:1) at the beginning of the anesthesia as well as after finishing the surgery. For analgesia the animals received 5 mg/kg carprofen (Pfizer GmbH, Berlin, Germany) s.c. Additionally, animals received 10 mg/kg enrofloxacin (Bayer AG, Leverkusen, Germany) s.c. as antibiotic treatment during surgery as well as the 5 following days per os (p.o.).

After surgery on day 0 the anesthesia was reversed with an i.m. injection of a combination of 1 mg/kg naloxone hydrochloride (Inresa Arzneimittel GmbH, Freiburg, Germany), 0.1 mg/kg flumazenil (Inresa Arzneimittel GmbH) and 0.03 mg/kg atipamezole hydrochloride (Janssen-Cilag GmbH).

To prevent any disturbances of the gastro-intestinal tract the animals were fed 0.5 g BeneBac® Gel (Albrecht GmbH, Aulendorf, Germany) p.o. one day prior to surgery, the day of surgery and the following day.

During all experiments the animals were kept on a heating pad to avoid hypothermia.

2.4. ABR measurements

To determine the hearing threshold of the animals prior to surgery, and to detect any threshold shift during the experiment, acoustically evoked auditory brainstem response (aABR) measurements were performed under general anesthesia at the beginning of the experiment (day 0) as well as at the end (day 28).

In a sound-attenuated chamber the animals were presented frequency specific acoustic tone stimuli (10 ms tone bursts with a square cosine rise and fall time of 1 ms) with a loudspeaker connected via a calibrated tube to the outer ear canal.

The animals were stimulated with a TDT System (Tucker–Davis Technologies, Alachua, USA) at frequencies of 1, 4, 8, 16, 32, 40 kHz from 0 to 90 dB in 10 dB steps. Each stimulus was presented 85 times per set and 3 sets were obtained.

Subdermal needle electrodes (CareFusion Nicolet, CareFusion Corporation, San Diego, USA) were placed on the left and right mastoid (references), in the neck (ground) and at the vertex (common positive).

Acquisition and analysis were performed with BioSigRP software (Tucker–Davis Technologies). Obtained signals were amplified (20 times), bandpass filtered (300–3000 Hz) and every set of 85 signals was averaged. All 3 sets were averaged together and the lowest intensity which evoked a visually replicable waveform with decrements of peak latencies with increasing sound pressure level was defined as the hearing threshold.

2.5. Surgery

Following the ABR measurements the animals underwent surgery under aseptic conditions. After a postauricular incision the muscle was dissected until the bulla was in plain view. The bulla was opened with a scalpel. Then the cochlea and the round window (RW) were visualized and either the latter was incised with a stiletto or a hole was drilled into the cochlea ventral of the RW with a 0.6 mm diamond burr (cochleostomy, CS).

After insertion of the CI model the insertion site was either left “open” (NS), sealed with a small autologous muscle graft (MS) or the gap between CI model and the opening of the cochlea was