

Multicenter evaluation of Neurelec Digisonic[®] SP cochlear implant reliability

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Abstract Over the past decade, the adoption of universal hearing screening in newborns has led to earlier detection of hearing problems and significant lowering of the age of first cochlear implantation. As a consequence, recipients are now expected to keep their cochlear implants (CIs) for a longer period of time. Comprehensive longitudinal information on CI reliability is essential for device choice. The aim of this study was to assess the reliability (in children and adults) of the latest generation of the Digisonic[®] SP CI launched in 2006 by Neurelec. Failure rate (FR) and cumulative survival rate (CSR) for a 5-year period were calculated. This survey is a multicenter retrospective study. A questionnaire was sent to nine CI centers requesting information about patients implanted with Neurelec Digisonic[®] SP CIs. FR and CSR over a 5-year period were calculated on this group. Collaborating centers collected data on 672 patients (362 children and 310 adults) implanted between March 2006 and March 2011. The overall rate of explantation was 2.23 % (15

cases); six devices were explanted due to device failure (0.89 %) and nine were explanted for medical reasons (1.34 %). Four patients were lost to follow-up. The CSR at 5 years was 98.51 % on all patients, 98.48 % for children and 98.57 % for adults. FR was 0.97 % for adults and 0.83 % for children. This first independent study that assesses FR and CSR on the current generation of Digisonic[®] SP CI represents an important resource that can help clinicians and patients during their device choice.

Keywords Failure rate · Cumulative survival rate · Reliability · Cochlear implant

Introduction

Cochlear implants (CIs) restore functional hearing in individuals with profound to severe sensorineural hearing loss. They consist of two main components: the external

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part (microphone, speech processor, transmitter coil, and batteries) and the implanted part (receiver electronics, magnet and electrode array). The internal components require surgical implantation: the electrode array is inserted into the cochlea and the receiver package is either fixed onto or partly embedded in the temporal bone. Cochlear implantees use their device for daily communication. Most wear their systems throughout the day. Obviously, implanted parts of the CI need to be reliable and remain functional for many years (ideally for the life-time of the patient). In recent years, partly due to increasing hearing screening in newborns, implantation of very young children has become more common [1]. This practice has effectively increased the expected lifespan of CIs.

Providing a safe implant on a long-term basis requires that (1) devices must be designed with biocompatible materials, (2) the sterilization process must be effective, (3) design and materials must minimize chronic mechanical tissue trauma and resist mechanical impact, and (4) levels of electrical charge produced by the implant should not exceed those that can be safely supported by human tissues (including neural tissue) without damage. The design and the materials of the implant play a key role in meeting the requirements mentioned above.

The average survival time of implanted CI components has not yet been established. Commercially available CIs have been in routine clinical use for about 20 years, and so the technology is relatively new. Manufacturers typically provide a 10 year warranty. Reliability may be reported in terms of average failure rate (FR, i.e., failed to implanted devices ratio). To evaluate the incidence of device failures over time, CI reliability is usually reported in terms of “cumulative survival rate” (CSR), i.e., the proportion of devices still functioning normally after a given time period. This measure is commonly used for other implantable devices such as cardiac pacemakers [2]. For CIs, the longest time-period CSR was reported after 12 and 20 years, depending on the manufacturer [3]. Survival rates after longer periods are not yet known.

Device reliability is a very important consideration for both surgeons and patients when considering a particular device. There are currently four main CI systems on the market and it can be hard to get comparable and unbiased CSRs for comparison. Also, CI reliability is a major metric for the manufacturer that can be used to improve their products and manufacturing processes.

Several studies have reported reliability in terms of FR and CSR for various CI devices provided by Cochlear Ltd (Sydney, Australia), Clarion-Advanced Bionics LLC (Valencia, CA, USA) and Med-El (Innsbruck, Austria) [3–8]. Only FR on a limited number of mixed generations of

MXM-Neurelec CIs (Vallauris, France) has been reported in three studies [5, 7, 8] that were not specifically looking at Neurelec data. Over the past 5 years, more and more centers are using Neurelec CIs, thus more comprehensive data regarding the reliability of this system are urgently needed.

The aim of this study was to assess CSR and average FR of the Digisonic[®] SP, the latest generation of CIs released by Neurelec in March 2006, in a large group of implanted adults and children over a time frame of 5 years.

Materials and methods

A multicenter retrospective case series was conducted in this study, independent of the manufacturer.

A questionnaire recording details of implantations was sent (by the first author) to nine CI centers (five in France, one in Poland, one in Greece, one in Algeria, and one in Romania) chosen for using significant numbers of the Digisonic devices in children and adults. The questionnaire recorded the following patient details:

- Date of birth
- Dates of first implantation, explantation, and re-implantation (if applicable)
- Reasons for explantation (medical or apparent device problem)
- Cases lost to follow-up (with reasons and date of the last visit)
- Data on explanted device, including serial numbers, date of manufacture, and technical report from manufacturer documenting test outcomes.

Moreover, in case of re-implantation, centers were asked if outcomes were worse, equal, or better with the new device.

The general method to measure reliability (device failure, survival time, specifications, and classification categories included in the device failure reports) was in accordance with the International Consensus Group for CI Reliability Reporting [9]. Consequently, for explantation following auditory symptoms, non-auditory symptoms, or loss of performance (i.e. “soft failure” cases [10, 11]), if clinical benefit was observed after re-implantation, the device was considered failed regardless of the conclusion of technical analysis by the manufacturer.

Consistent with reliability reporting, loss to follow-up was reported in a specific category.

FR is the ratio between failed devices and total implanted devices. CSR was calculated in accordance with the methodology described in ISO standard 5841-2:2002

[2]. CSR and FR were calculated for all patients, and then separately for the adults and children subgroups.

Results

Over the nine participating centers, 672 patients (362 children and 310 adults) were implanted with Digisonic® SP between March 2006 and March 2011 and all were included in the present study. Among these 672 patients, 4 (all adults) were lost to follow up and 15 explantations were noted. Explantations were performed due to device failures in six cases and medical reasons in nine cases.

Four adult patients were lost to follow-up (1.3 % of adult group), one of whom had died from a cause unrelated to the implant, and another was diagnosed with Alzheimer disease.

Table 1 shows the causes for device failures according to the manufacturer’s technical analysis and the duration of device use before the occurrence of failure. The causes for device failure included three cases of hermeticity failure (1 child and 2 adults; hermeticity compromised the external ceramic case), head trauma (1 child), electrode array malfunction (1 child; 3 electrodes not properly connected to internal stimulator), and one of unknown cause (1 adult; progressive drop in performance, clinical benefit observed after re-implantation with a new device). For this last case, technical analysis did not reveal any implant malfunction.

Nine devices were explanted due to medical reasons (1.35 %). These included three cases of infection of the skin flap covering the receiver/stimulator and one case of cholesteatoma in the implanted ear. Three patients with ossified cochleae were explanted because they had no clinical benefit with the CI (all of them refused re-implantation). One patient was explanted because he had been diagnosed with Neurofibromatosis type 2 after implantation, and one patient was explanted following a loss of clinical benefit (no benefit observed after re-implantation with new device from the same manufacturer). In this last case, the technical report from the manufacturer showed that the device was functioning within specifications.

The overall FR was 0.89; 0.83 % for children (patients younger than 18 years), and 0.97 % for adults (Table 2).

Table 1 Number of device failures by failure mode and duration of device use (in months) before failure is indicated in brackets

	Hermeticity	Trauma	Electrode array	Electronic	Soft failure
Children (n = 362)	1 (5)	1 (14)	1 (48)	0	0
Adults (n = 310)	2 (8, 27)	0	0	0	1 (17)
Total (n = 672)	3	1	1	0	1

Table 2 Failure rates and cumulative survival rates for children, adults, and combined

	Failure rates (%)	Cumulative survival rates
Children (n = 362)	0.8	98.48
Adults (n = 306)*	1	98.57
Total (n = 668)*	0.9	98.51

* Less 4 adults that were lost to follow up

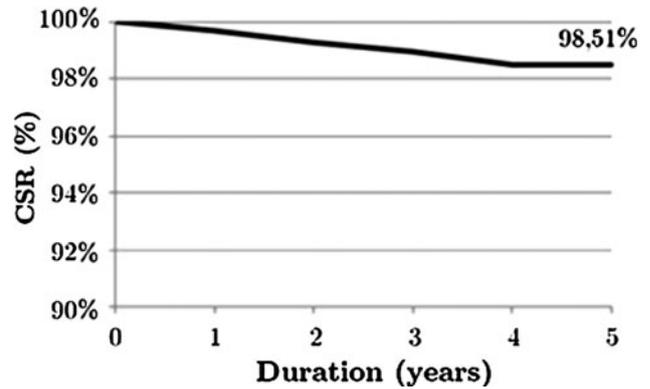


Fig. 1 Cumulative survival rates of all 672 patients over a 5-year period

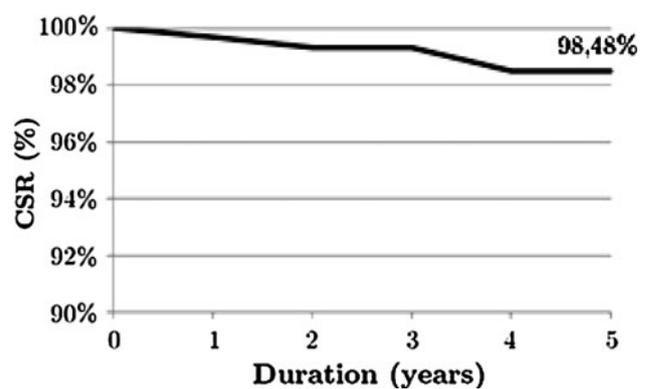


Fig. 2 Cumulative survival rates of the 362 children over a 5-year period

The overall CSR over a 5 year period was 98.51 % (Table 2, Fig. 1), with 98.48 % for children (Table 2, Fig. 2) only and 98.57 % for adults only (Table 2, Fig. 3).

Discussions

Device reliability

Most explantation procedures are carried out following device failure, even though manufacturer analysis does not always confirm a device out of specification [12]. Most device failures are spontaneous or due to head trauma [3], but a small number (particularly “soft” failures) involved

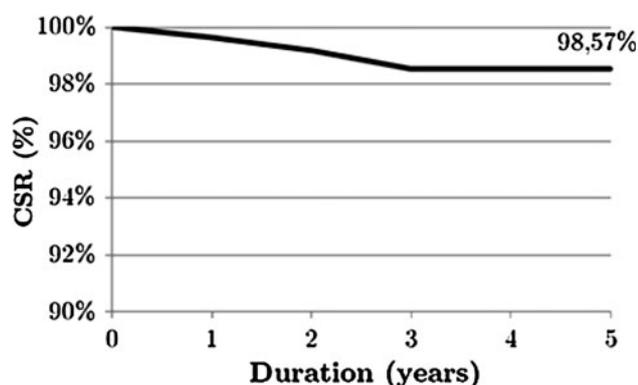


Fig. 3 Cumulative survival rates of the 310 adults over a 5-year period

breakage of electrode or receiver coil wires due to device/electrode movement. Besides, duration of device use prior to failure did not show any specific pattern, as failures occurred 5–48 months after implantation. The failure modes observed in the present study appear to be consistent with other reports, though numbers were too small to obtain definitive rates for individual failure modes. Overall, device failure rates from previous studies are mostly in the 3–6 % range; however, as mentioned above, these reports cover a wide range of durations of CI use. A failure rate below 1 % was observed in the present study in a large cohort of Digisonic SP recipients at up to 5 years of device use.

In a previous study on CI failure on a very large number of implanted CIs [7], mixing all CI generations for each manufacturer (including old generations of CIs) on a long time-span (since beginning of CI programs), the FR for mixed generation of Neurelec devices was 3.2 % (17 cases out of 527), compared to 2 % for Cochlear CIs (617 out of 8,581), 7 % for Advanced Bionics CIs (123 out of 1,761), and 9 % for MedEl CIs (179 out of 1,987). In the present study, the overall FR for Digisonic SP was 6 cases out of 627 (0.97 %). This difference underlines that Neurelec CIs are still improving in terms of reliability.

In this cohort, a CSR of 98.51 % at 5 years was noted. This compares favourably with independently published reports on devices from other manufacturers. For example, it was reported a 5 year CSR of 90.2 % for the Advanced Bionics HiRes 90 K device [3], and 99.6 and 97 % for the Cochlear CI24 device [3, 8]. Such statistics are helpful for CI candidates considering which device to elect for. In this context, it is important that valid comparisons can be made, which can only be ensured by standardized reporting in accordance with the definitions provided by the International Consensus Group [9].

The causes of device failures are of major interest, not least for the manufacturer to implement corrective measures if indicated. In the present study, three device failures were due to hermeticity breakdown. As with other ceramic

encased devices [3], the most important rate of the device failures for the Digisonic SP were due to the hermeticity leakage (3 cases out of 6). While this failure mode still shows a low rate of incidence, similar problems have been reported for devices from all the other major manufacturers using non-ceramic technology [4, 13]: for example, Brown et al. [4] reported that 31 % (9 out of 29) of device failure was due to hermeticity issues on a group of 806 patients with various CIs. One failure due to head trauma in a child was reported, but numbers were too low to indicate any differences between CSR in children and in adults.

The CSR of the last generation of implants from Neurelec cannot be compared to that of previous generations' because published data are not available.

Explantation for medical reasons

Many studies have reported on a wide range of complications after CI surgery. Reports distinguished between “minor” and “major” complications, the latter being usually related to issues that require explantation. Minor complications include problems that can be solved with revision surgery without explantation, or without surgery. For example, tinnitus, facial stimulation, and pain can sometimes be relieved by electrode deactivation [8]. In the present study, only major complications were reported.

Revision surgery rates reported in the literature vary from 2.9 % [14] to 11.2 % [8], several factors might account for this range. One revision surgery rate reported specifically for Digisonic SP CI users was 2.4 % [15]. A source of variability is the duration of follow-up for studied cohort. Longer duration will inevitably result in a higher total number of complications, in particular device failure. Even some recent reports include subjects who were implanted before 1990 [12, 16], it is possible that prevalence of some failure modes may have changed over time.

Medical complications resulted in nine explantations in the present study (1.35 %), the most common of which was ‘flap problems’. Flap-related problems are reported to be the most common major complication after device failure, and appeared to occur in about 1 % of cases in a previous study [17]. Strategies are proposed to avoid explantation in infected patients, considering primary immunodeficiency [18], but the most important factor appears to be the degree of vascular disruption caused by the surgery. This is clearly evidenced by all studies that have assessed minimal access surgery, for which less flap complications were reported [17, 19]. The present study also included three cases with significant pre-operative ossification, which were eventually explanted due to limited clinical benefit. Strictly speaking, these do not represent either device failures or medical complications, and if these were excluded from

statistics then the incidence of explantation due to medical complications would drop from 1.35 to 0.9 %.

Reliability reporting

There are multiple factors reflected in the CSR number. These include patient characteristics (age, malformations of the cochlea, ossification of the inner ear, etc.), features of the implanted device, surgical technique, and surgical skill. Taking these individuals and often interconnected factors apart is not possible.

The same standards and factors have to be followed by all studies reporting device reliability, thus making the results comparable to guide patients, clinicians, CI centers, and manufacturers. To be truly useful, a study regarding CI reliability would require:

- Conformance with International Consensus Group guidelines [9–11].
- The reliability measure has to be quantified with common methods—CSR and FR in the present study.
- Each and every CI model has to be assessed separately to compare reliability between them.
- The duration of device use must be long enough to be consistent in assessing the device FR. Counter-intuitively, a previous study has shown that 24 % of re-implantations due to device failure or infections occurred before 2.5 years and 72 % of them before the fifth year of implantation, suggesting that the longer the follow-up time, the smaller the number of re-implantations [8].
- Device failure data has to be systematically reported by all CI centers.
- Device failure assessment has to be conducted on a large number of implants. As observed by Battmer et al. [3] the size of the studied cohort varies extremely from one study to another, influencing statistical robustness—smaller samples creating the greater uncertainties. In addition, multicenter studies should be employed when a specific model of device is assessed to avoid any peculiarities linked to an individual center.
- The centers participating in studies must be chosen randomly. Cochlear implantation is performed by otologists with widely ranging skill levels and the study must give a reasonable impression regarding device reliability even in the hands of less experienced surgeons. The relation between FR and surgical skills was already emphasized in medical literature [20]. The inclusion of centers with surgeons showing different levels of experience in cochlear implantation strengthens the results of reliability studies.

Conclusions

The FR and the CSR of the Digisonic SP were calculated in accordance with the new consensus statement designed by International Consensus Group for CI Reliability Reporting. The FR was better when compared to previous generation of Neurelec CIs, and was comparable to FR from other manufacturers. CSR was found to be comparable or better, in specific cases, to that of other CIs available on the market.

In order to allow comparison between different CI systems' reliability studies, it is crucial to keep the rules for device failures reporting and for CSR calculation unchanged in the future.

Conflict of interest The authors declare that they have no conflict of interest.

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