

## Reliability of Med-El Cochlear Implants in children. The Romania Experience.

Eugen Horatiu Stefanescu<sup>1¶\*</sup>, Marioara Poenaru<sup>1¶</sup>, Nicolae Constantin Balica<sup>1¶</sup>, Anca Tudor<sup>2¶</sup>, Andreea Marinescu<sup>3¶</sup>, Madalina Georgescu<sup>3¶</sup>, Luminita Radulescu<sup>4¶</sup>, Sebastian Cozma<sup>4¶</sup>, Violeta Necula<sup>5¶</sup>, Marcel Cosgarea<sup>5¶</sup>

<sup>1</sup>Department of Otolaryngology, "Victor Babes" University of Medicine and Pharmacy Timisoara, Romania

<sup>2</sup>Department of Medical Informatics and Biostatistics, "Victor Babes" University of Medicine and Pharmacy Timisoara, Romania

<sup>3</sup>Department of Otolaryngology, Institute of Phono-Audiology and Functional Surgery, "Carol Davila" University of Medicine and Pharmacy Bucuresti, Romania

<sup>4</sup>Department of Otolaryngology, "Grigore T. Popa" University of Medicine and Pharmacy Iasi, Romania

<sup>5</sup>Department of Otolaryngology, ¶"Iuliu Hateganu" University of Medicine and Pharmacy Cluj Napoca, Romania

### ABSTRACT

**Introduction:** Early detection of hearing loss significantly lowered the age of cochlear implantation. A failed CI is a very problematic issue for the child and family and seems to be, for the moment, inevitable. This is a retrospective review aimed to evaluate the reliability of Med-El devices implanted in children in Romania.

**Materials and Methods:** We designed a questionnaire to assess the incidence, the time elapsed and the reason of total device failure. Medical-surgical data were collected from children who received Med-El cochlear implants since the start of the National Cochlear Implant Program in 2001.

**Results:** There were 256 patients included. Failure Rate (6,64%) and Cumulative Survival Rate (95,31%) at 5 years were calculated. The majority of the hard and soft failures were encountered in Pulsar devices. Flap necrosis was the most frequent medical/surgical reason for re-plantation. There was only one case of posttraumatic device failure. Time elapsed to device failure was short – 22 months on average.

**Conclusion:** Cochlear implant reliability data should be considered during the choice of an implant for each individual patient. This study confirms the safety and efficacy of Med-El cochlear implants in children for both ceramic and non-ceramic devices.

### I. INTRODUCTION

Device reliability is a very important issue for both surgeons and patients (their parents, to be more specific, as we are talking about children) when considering a particular device for implantation. Device failure is defined as when the device is not functioning inside the manufacturer's specification and/or there is no or just insufficient clinical benefit for the patient [1]. There also are situations when the device needs to be removed for medical/surgical reasons, such as infection or flap necrosis.

Device failure is classified according to the guidelines of the 2005 Cochlear Implant Soft Failures Consensus Development Conference Statement into hard and soft failures [2]. According to these guidelines, a hard failure refers to detectable hardware problem and a soft failure refers to underperformance, hearing and/or non-hearing related problems and side effects, or discontinuous function of the device.

One should always keep in mind that the manufacturer's examination of the explanted device takes place after the surgical removal that can, by itself, create a trauma to the device and can result in failure that is sometimes difficult to be distinguished from a previous (pre-explantation) problem. Bearing this in mind is sometimes difficult to accurately defining failures into hard or soft. The reliability of cochlear implants over time is an important issue for doctors and the calculation of cumulative survival rate (CSR) is an objective tool when reporting about this issue. Failure Rate (FR, i.e., failed to implanted devices ratio) is another method to evaluate reliability.

In this study we followed the ISO reporting standards (ISO 5841-2, 2002) for cardiac pacemakers and we considered the Cumulative Survival Rate a reliable measure that indicates that a device will probably still be functioning after a certain period of time. The Cumulative Survival Rate (CSR) is the cumulative percentage of functioning implant over time and can be used to

predict the reliability of the device within a given time period.

All implanted children are expected to wear their devices the entire life – much longer than the 10 year warranty offered by manufacturers –so the chance of a device failure or a complication followed by surgical replacement of the device will become a situation that will be experienced by more and more patients.

The aim of this study was to assess the reliability of Med-El devices in children throughout Romania as this manufacturer holds a very important share on the Romanian market and worldwide also. This is a multicenter retrospective study and a questionnaire was sent by the first author to the other 3 major CI centers requesting information about patients implanted with Med-El devices. Failure Rate (FR) and Cumulative Survival Rate (CSR) over a 5 year period were calculated for this group.

**II. MATERIALS AND METHODS**

In 2001 Romania started a National Program for Cochlear Implantation, and since then 256 children received different types of Med-El devices in the four major Romanian Cochlear Implant Centers (Bucuresti, Iasi, Cluj, and Timisoara). There is a single CI Center in each of these cities.

We did not considered data from other two Centers as they started later on and do not have children with a 5 year follow-up period nor were private patients as their number is very small and follow up data not entirely available. Written Informed Consent was obtained from parents when entering the Romanian National Cochlear Implant Program.

A retrospective review of the cochlear implant database and the medical records of implanted patients were performed: total number of patients implanted with Med-El devices, patients for each type of device, demographic data, age at implantation, cause of deafness, malformations, and complications. The median (SD) age at initial implantation was 49 (23) months. A 60 month follow up period was mandatory for including in the study.

We designed a questionnaire to assess the incidence, the time elapsed and the mode of device failure and we sent it to the other three major cochlear implant centers in Romania. We also collected information on reasons for re-implantation and data on explanted devices (serial numbers and manufacturer’s technical report). Table 1

**Table 1. Questionnaire**

|  |  |   |   |  |
|--|--|---|---|--|
| Total nr of children implanted with Med-El devices,<br>- Nr of cases / type of device,<br>- follow up period for each patient (Months) | - Date of first implantation<br>MM/YYYY<br>- Type of Med-El Device<br>-Intraoperative complications:<br>Yes/No<br>-Specify | - Date of device failure, explantation/ re-implantation<br>MM/YYYY<br>- Type of re-implanted Device<br>- Reason for explantation<br>- Problems at explantation/ reimplantation<br>Specify | -Type of explanted device<br>-Manufacturer raport<br>- Cause of failure<br>- serial number<br>- other - specify | Speech perception evaluation after reimplantation<br>-improving<br>- same<br>- deteriorating |
|--|--|---|---|--|

We did not include the children that have received the cochlear implant in a center outside Romania in this study. The devices included in this study were: Combi 40+, Pulsar and Sonata. All explanted

children were re-implanted using Med-El devices. Data regarding the patients requiring re-implantation are shown in Table 2.

**Table2. Re -implanted children**

|  |    |        |
|--|----|--------|
| <b>Children requiring reimplantation</b> | 17 |        |
| Male                                     | 10 | 59%    |
| Prelingual onset of hearing loss         | 16 | 94%    |
| Age at implantation, median/range, mo    | 49 | 12-156 |
| Time to reimplantation, median/range, mo | 22 | 5-54   |
| Same side reimplanted                    | 14 | 82%    |
| Complications at first implantation      | 2  | 12%    |
| Same model reimplanted                   | 13 | 76%    |
| Cause of deafness                        |    |        |
| Congenital; unknown                      | 13 | 76%    |
| Congenital; genetic                      | 3  | 18%    |
| Other (CMV infection)                    | 1  | 6%     |

We also evaluated hearing and speech after re-implantation. The speech perception battery included a parental questionnaire, closed-set tests and open set tests. We just wanted to evaluate if the initial progress of the re-implanted children continues, but the results of these tests are beyond the purpose of the study.

Cochlear implantation in all four centers was performed using the classic technique with mastoidectomy and posterior tympanotomy. The insertion of the electrode was performed either through a cochleostomy or through the round window. In all cases it was used a double flap technique with either a large or a small incision. Small incision technique was performed in only one center. The fixation of the device with intraosseous sutures was performed in all but 32 cases. All these 32 cases were operated in one center, on very small children with a very thin skull using the small incision technique. In such cases the periosteal pocket technique as described by Adunka and Buchmann was used even for ceramic devices.

The policy of re-implantation consists of using the ipsilateral side whenever possible and to preserve the opposite ear. In case of flap necrosis that could not be reconstructed or active infection that was nonresponsive to treatment, the device was removed leaving the electrode in the cochlea to prevent cochlear obstruction. The same ear was re-implanted later on. If not possible, the opposite side was considered.

Informed consent for using patients data in clinical studies was obtained from all patients (parents, care-givers) when entering the National Cochlear Implant Program as a prerequisite. The data were analyzed anonymously and de-identified prior to analysis. This Program is running under the Romanian Ministry of Health and was approved by the Board for Cochlear Implantation.

The FR and the CSR of the Med-El devices were calculated in accordance with the new consensus statement proposed by International Consensus Group for CI Reliability Reporting (i.e., re-implantation following loss of performance - soft failure - if resulted in clinical benefit for the patient was considered device failure).

### III. RESULTS

There were 256 patients included in this study. The Cumulative Survival Rate (95.31%) and Failure Rate (6.64%) at 5 years were calculated. (Figs.1 and 2)

**Fig.1 Cumulative Survival Rate at 5 Years.**  
Overall rate – 95.31%

**Fig.2 Failure Rate of Med – El Devices.** Failed-red; implanted devices-green

There were no significant differences between the four centers regarding the CSR at 5 years (Mantel-Cox log-rank test,  $p=0.541$ , significant level  $\alpha=0.05$ ) but the number of cases was significantly different and the total number of cases is quite small. (Fig.3)

**Fig.3 Cumulative Survival Rates in the four Centers.** Yellow-Bucharest; Green-Cluj; Red-Iasi; Purple-Timisoara

None of the cases was lost to follow-up. There were seventeen (6.64%) cochlear re-implantations in this group with a mean duration of usage before failure of 22 months (range 5–54 months). This was especially the case with Pulsar devices. The number of Pulsar devices that failed exceeded by far the other types of Med-El devices (Fig 4).

**Fig.4 Med-El failures by device type.** Pulsar devices-red; Other types-yellow

There were 12 device failures and another 5 cases that required re-implantation due to medical/surgical reasons so, in all, 17 devices had to be replaced by the end of the 60 month follow-up period.(Fig.5)

**Fig.5 Cause of explantation.** Hard Failures-green; Soft Failures-red; Medical/Surgical Failures-blue. Flap-related problems were the main medical/surgical reason for re-implantation.

There was only one case of posttraumatic device failure. We did not find any correlation between meningitis and device failure as none of the children requiring revision surgery had meningitis as cause of deafness.

The type of failure for seven of the devices in the present study was described by the manufacturer as a hermiticity failure. One implant failed secondary to a problem to the ground electrode. In four patients, no clear reason for failure has been found. Four patients requiring re-implantation received a different device model (23%); Regarding functional results –speech perception - all patients performed well after re-implantation continuing, more or less, their initial improvement.

### IV. DISCUSSIONS

The Cochlear Implant re-implantation rate in children in the literature ranges from 4% to 15.4% [3,4,5,6,7], so our rate (6.64%) is closer to the better end but there was a very short duration of usage before re-implantation: 22 months.

### **Surgical Technique**

The intraosseous suture fixation of the implant was used in all but 32 cases. In these 32 cases the fixation of the ceramic device was performed by using the periosteal pocket technique as described by Adunka and Buchmann [8]. In this group there was only one case that required re-implantation and the reason was a progressive decrement in performance of the device (soft failure). The failure rate in this group was 3.12% but the group was too small to come to any conclusion. Alexander et al [9] saw no association between non suture fixation methods they used and failure rate in a series of 320 devices monitored for a median of 26 months.

In our series re-implantations were performed due to medical/surgical reasons in 5 cases: 3 cases of infection/ necrosis of the skin flap and 2 cases of chronic infection/ cholesteatoma in the implanted ear. Flap-related problems are reported to be the most common complication after cochlear implantation. The cause of flap related problems seems to be the degree of vascular disruption caused by the surgery. This is supported by all studies that have assessed minimal invasive surgery, for which less flap complications were reported [10, 11]. In our study more than half of the devices had ceramic housing and a large incision was used (except for the 32 cases already discussed and for the non ceramic ones).

Revision surgery implies at least the same risks and complications as the first operation. As we do not know how many times we need/can successfully replace the electrode array, the insertion of the electrode should be as gentle as possible and every surgery as atraumatic as possible [12]. The caliber of the intra cochlear tract is strongly dependent on the diameter of the explanted array, and so we re-implanted with arrays of the same diameter whenever possible (76% of cases).

### **Etiology of Deafness**

In our series none of the patients requiring CI re-implantation had bacterial meningitis as the cause of hearing loss. Overall meningitis as an etiologic factor accounts for 6% of all patients in our group. The failure rate in children with meningitis in our study was 0%, which is not common. According to other reports, this usually exceeds the failure rate in children in whom deafness resulted from other causes.

### **Type of Device**

In our series of Med-El device users, we assessed the survival rate of different device generations from the same manufacturer. We found that, at this time, the Combi 40+ shows the best

survival and the smallest failure rate.. The Pulsar has the worst results and also the shortest time to failure. For Sonata devices we do not have a significant number of cases that completed the 60 month follow up period when comparing to Pulsar and Combi 40+.

### **Cause of Device Failure**

Most revision surgeries were performed following device failure, though manufacturer's report does not always confirm a certain cause for this. Most device failures are spontaneous [13]. The time elapsed to failure did not show any specific pattern, as failures occurred 5–54 months after implantation. Hermiticity problems seemed to be much more frequent – 7 out of 12 devices (58%) and were encountered mostly in ceramic devices. This issue was also observed in other studies - Brown et al. [14] reported that 31 % (9 out of 29) of device failure was due to hermiticity issues in a group of 806 patients with various types of cochlear implants.

In our center we noticed that we did not have further failures of the devices included in this study though some of the implants (21 devices) have a 10 year or longer follow-up period. This observation has also been made by other centers but the total number of children that have a 10 year follow-up period is small (less than 100). It seems that the longer the follow-up time, the smaller the number of re-implantations but only time will tell if this is accurate.

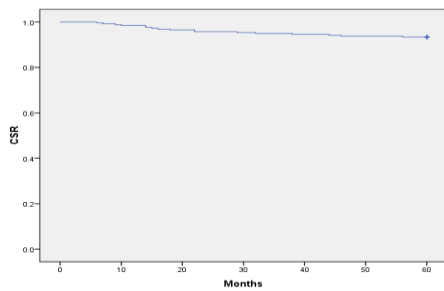
The results in our study compares favorably with other published reports on device failures from other manufacturers. Failure Rate for Neurelec devices was 3.2 % (17 / 527), 2 % for Cochlear (617 / 8,581), 7 % for Advanced Bionics (123 / 1,761), and 9 % for Med-El (179 /1,987) [15].

## **V. CONCLUSIONS**

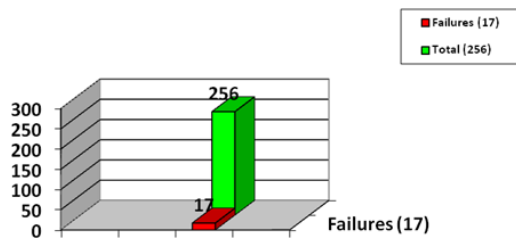
Cochlear implant revision surgery is an increasing part of the surgical activity in a cochlear implant center. Outcomes after re-implantation are usually excellent despite the concerns. Cochlear implant reliability data should be considered during the choice of an implant for each individual patient. The MED-EL cochlear implants have proven to be excellent devices for children with profound hearing loss. CSR was found to be comparable to that of other cochlear implants (from different manufacturers) available on the market.

To find out more about reliability of cochlear implants all studies on long term survival should be standardized and they should take into account all kind of failures and complications that require re-implantation (design, mechanical, electronic, medical/surgical).

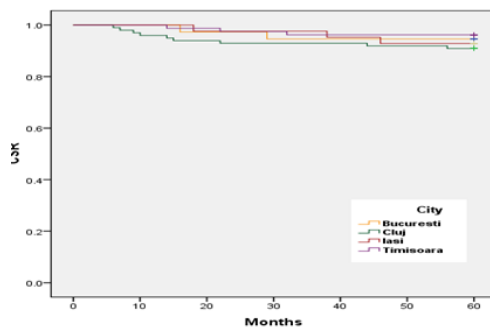




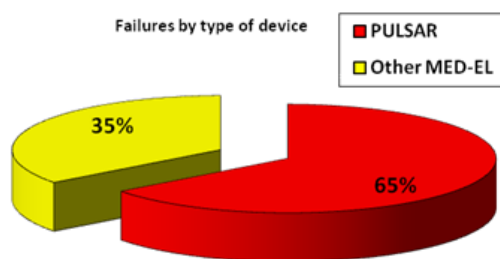
**Figure 1** Overall CSR at 5 Years - 95,31%



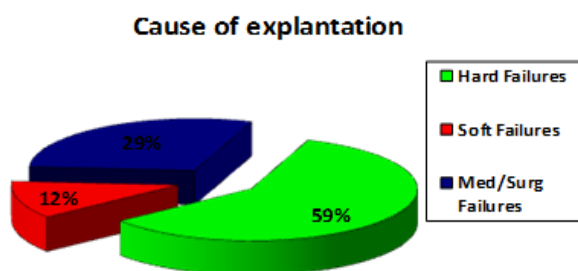
**Figure 2** Failure Rate of Med-El Devices



**Figure 3** CSR at 5 Years in the four Centers



**Figure 4** Failure by device Type



**Figure 5** Cause of explantation

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