Long-term data on children implanted with a short electrode array

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Summary Ossification and cochlear malformations are no longer seen as a contra-indication to cochlear implantation. The MED-EL COMBI 40+ short electrode was designed specifically for cases where major ossification has occurred, or where full insertion of an electrode may not be possible due to abnormal structure of the cochlea. This study investigates outcomes of 18 children implanted with the short electrode array. These children were assessed using the EARS test battery pre-operatively and at a number of intervals thereafter. Results show a consistent improvement in time on most tests; these results appear to be independent of aetiology. Data from these children were compared to 18 matched pairs implanted with the standard COMBI 40+ electrode array. The short electrode children do not perform as well as the standard children initially, but do tend to catch-up at later test intervals. Results indicate the benefit of using a short electrode when complete insertion of the standard electrode is not viable.

1. Introduction

Cochlear implantation is now an accepted treatment method for both adults and children with severe to profound sensorineural hearing loss. A common cause of such hearing loss may be meningitis or cochlear malformations. For many years, these aetiologies were considered contra-indications for cochlear implantation. However, advances in surgical techniques have resulted in positive outcomes.

Proposed surgical techniques for ossification have included the total drill-out procedure [1], short inferior tunnel insertion [2], the scala vestibuli insertion [3], and the intact canal wall drill-out procedure [4,5]. Balkany et al. [4,5] described...
the most commonly used procedure for managing partially ossified cochlea, namely tunnelling through the ossified portion of the lower basal turn of the scala tympani. If there is sufficient drill out of the ossified bone, then full insertion of a standard electrode array can take place. Some reports suggest that results match those of patients with intact cochlea [3,6,7]. In instances where insufficient drill-out for a full or partial insertion occurs, a double cochleostomy procedure using a split array is recommended [8].

However, in many instances, and despite using appropriate surgical procedures, only partial insertion of the electrode array can take place. In these instances audiological outcomes are not as favourable. Harker et al. [9] report on a single case study where a child received a Clarion Multi-Strategy CI electrode. It took 5–6 months for audiological responses to emerge and results were poorer than in children with patent cochlea, with the child scoring at chance at the 12 month interval. Poor performance was reported in four subjects with complete ossification, who obtain no open-set speech understanding [10]. Children with ossification and partial insertion showed the same relative improvement over time as a group with full insertion; however, there was a significant difference in actual performance [11]. Long-term data on eight children reported only three children progressing; the remainder only showed some progress in the first 3 months of intensive training, with little improvement thereafter [12]. One study in children with partial insertion due to complete ossification suggests minimal difference in scores when compared to children with a patent cochlea [13].

In order to deal with such cases where full insertion cannot be achieved, MED-EL developed a compressed electrode array. The aim was to have full electrode insertion, with the hope of achieving better speech perception scores.

The COMBI 40+ S is an implant variant of the COMBI 40+ cochlear implant, with a compressed electrode array. The 12 electrode contacts are arranged closer together on the distal end of the electrode array. They are spaced over a distance of 12.1 mm, with a spacing of 1.1 mm between contacts. This configuration enhances the likelihood of all the electrode contacts being inserted into the cochlea when there is insufficient lumen, and only a shallow insertion is possible. This might be the case for obliterated, ossified or malformed cochleae.

This article aims to demonstrate speech perception outcomes in children implanted with the C40+ S electrode array. Long-term results will be reported on to demonstrate improvement over time. Results will also be compared to a matched group implanted with the standard C40+ electrode. Effects of aetiology on outcomes will also be explored.

2. Method

2.1. Subjects

The MED-EL international children’s study database was reviewed for children (under the age of 18) implanted with a MED-EL C40+ S cochlear implant system. Eighteen children in this database were found to be implanted with a MED-EL C40+ S, and their results are reported on. There are 6 boys and 12 girls in the sample. Age at implantation ranged from 1.11 to 14.4 years (mean: 6.6 years, median: 5.7 years). Aetiologies included: meningitis (10), cochlear malformations (5), unknown (2) and familial (1).

Data of this group is compared to a matched sample from the MED-EL International Children’s study database. Matched-pairs were based on age of implantation, aetiology and the onset of deafness. All children were age-matched within 3 months, except two older children who were 10 years 8 months and 13 years 6 months, as there are fewer older children in the database to select from. They differ by 1 year and 11 months and 2 years and 2 months, respectively. Only children with meningitis as an aetiology were matched and compared, providing a sample of 10 children, the other aetiologies were not considered as matching criteria due to the small sample size.

As far as the matching of the onset of deafness is concerned, 14 out of 18 cases match within a timeframe of 3 months. Two matched pairs do not have information about their onset of deafness and a further two cases show differences in onset of 8 months. All children in the matched sample group were inserted with the standard MED-EL C40+ cochlear implant system, and all had complete insertion of electrodes.

2.2. Test material

Subjects were assessed using the EARS test battery [14]. A description of the test battery and results of a larger sample population are reported elsewhere [15]. Tests used in this analysis include: listening progress profile (LiP) [16], monosyllable—trisyllable test (MTP) [17], closed-set words [14], open-set words [14] and the meaningful auditory integration scale (MAIS) [18] and the meaningful use of speech scale (MUSS) [19] questionnaires. Test and questionnaires were conducted pre-operatively, at the initial fitting session, 1, 3, 6, 12, 18 and 24
months post-fitting and then annually thereafter up to 5 years. Data analysed here are up to the 3-year test interval as there is insufficient data at the later intervals to conduct any real analysis.

2.3. Statistics

In some cases, test intervals were missed and thus missing values had to be estimated. Two means of estimation were required. In the case of a child receiving the maximum score at an earlier test interval and were not assessed further on this test, the maximum score was inserted for all further intervals. If a child missed a test interval, the mean of the previous and following interval was calculated and inserted.

As we are dealing with a small sample size, our data failed to meet any of the underlying assumptions (e.g. asymmetric distribution). Non-parametric tests were used and exact significance was calculated as far as possible.

To determine significant overall improvements over time, the Friedman test for $k$-related samples ($k > 2$) was used. We used the Wilcoxon signed rank test for related samples to determine significant improvement between two test intervals. This test was also used for matched-pairs analysis. We used the Mann–Whitney $U$-test for two independent samples to determine significant difference on aetiology.

3. Results

3.1. LiP

Three children were not tested with LiP and seven children were not tested in all test intervals, thus we excluded these cases from a repeated measures analysis. LiP scores show significant improvement over time (Friedman test, $p < 0.001$) for all test intervals up to 3 years post implantation for the short-electrode group (Fig. 1). Significant differences between the following test intervals were determined by assessing the Wilcoxon signed ranks test: preoperative and first fitting ($p = 0.004$), 2 days and 1 month ($p < 0.001$), 1 month and 3 months ($p < 0.001$), 6 months and 1 year ($p = 0.012$) and 18 months and 2 years ($p = 0.02$).

When comparing the short electrode children to matched normal electrode children (assessing the Wilcoxon signed ranks test for all pair-wise comparisons) we found significant differences at the 1 month ($p = 0.035$), 3 months ($p = 0.036$), 6 months ($p = 0.004$), 1 year ($p = 0.008$) and 18 months ($p = 0.008$) test intervals. The preoperative, first fitting, 2 year and 3 year tests did not show sig-

![Fig. 1](image1.png) **LiP** scores over time. The LiP can be scored from 0 to 42 points.

![Fig. 2](image2.png) **LiP** scores over time comparing children implanted with a short electrode to matched children implanted with a standard electrode. The coloured blocks show children implanted with the standard electrode array, the clear blocks show children implanted with the short electrode array.

![Fig. 3](image3.png) **Fig. 1** LiP scores over time. The LiP can be scored from 0 to 42 points.

ificant differences in the LiP scores (in Fig. 2 all available data from both groups are plotted).

3.2. MTP

The MTP test consists of two complexity levels: a three-word test and a six-word test. These tests can be scored by correct word identified and correct pattern identified. Fig. 3 details the results of this
test. Comparing 1-month and 1-year test results, Wilcoxon signed ranks test revealed significant improvements of MTP 3 patterns test results \((p = 0.016, \text{one-tailed})\) and of MTP 3 words test results \((p = 0.016, \text{one-tailed})\). No significant improvements of MTP six patterns or six words could be detected due to ceiling effects.

No matched pair comparison could be made as there were too few data and too many missing test intervals.

### 3.3. Closed-set words

On inspection of Fig. 4, we see that ceiling on this test is reached by 3 years post-implantation and the mean values of this test increased from 58.33% at 3 months to 100% at 3 years test. Again, insufficient data was available for a matched-pairs comparison.

### 3.4. Open-set words

The open-set words test can be scored according to phonemes correct and whole word correct.

Due to the fact that only a maximum of 4 pairs of scores were available on two consecutive test intervals from 3 months to 18 months after fitting, we could not do any statistical testing. No significant differences were found from 18 months up to the 3-year test interval on whole word scoring (a more difficult task). However, a significant difference was found (Wilcoxon signed ranks test, \(p = 0.031, \text{one-tailed}\)) on phoneme scoring from 18 to 24 months (Fig. 5). Insufficient data was available for a matched-pairs comparison.

### 3.5. MAIS

We found a significant improvement over the first seven test intervals (preoperative, 1 month up to 24 months; Friedman TEST, \(p < 0.001\)). Three conseq...
cutive test periods also showed pair wise significant score differences: preoperative vs. 1 month test (Wilcoxon signed rank test, \( p = 0.004 \), one-tailed), 1 month versus 3 month test (Wilcoxon signed rank test, \( p = 0.02 \), one-tailed) and 18 months versus 24 months (Wilcoxon signed rank test, \( p = 0.031 \), one-tailed). The matched-pairs comparison (done with at least 5 matching pairs at test interval 3 months, 6 months and 12 months) showed no significant differences (Wilcoxon signed rank test, \( p > 0.05 \), one-tailed) between the MAIS parents’ scores of the short and normal electrode children (Fig. 6).

3.6. MUSS

Large variations in answering MUSS resulted in large standard deviations of the mean scores over all test periods. Only one significant improvement over time could be found (3 months versus 6 months, \( p = 0.032 \), one-tailed, Wilcoxon signed rank test). Furthermore, the sizes of the mean score increased from 9.88 preoperatively to 38 at 3 years test interval. No comparisons between matched-pairs could be made due to too small sample sizes. Reviewing Fig. 7, we can see a trend for improvement in both cases, where the short-electrode children perform slightly poorer than the standard electrode group. However, they do reach the same score-levels by 3 years post-implantation.

3.7. Aetiology comparison

The data from children with meningitis as an aetiology was compared to the rest of the children with a...
short electrode. This was to determine if aetiology had an influence on outcomes. Ten children with a mean age of 7 years 2 months (S.D. = 3 years 8 months) had meningitis as an aetiology. The remaining children (mean age: 6 years, S.D. = 3.11 years) had aetiologies of cochlear malformation, familial or unknown.

Although children suffering from Meningitis do score significantly lower preoperatively (Mann–Whitney U-test, \( p = 0.012 \), one-tailed), and at 1 months (Mann–Whitney U-test, \( p = 0.04 \), one-tailed) and 3 months (Mann–Whitney U-test, \( p = 0.31 \), one-tailed) test interval, after 6 months of device use no significant differences could be found.

A comparison of matched pairs for aetiology (meningitis) showed significant differences at the 1 month (Wilcoxon signed ranks test, \( p = 0.035 \), one-tailed), 3 months (Wilcoxon signed ranks test, \( p = 0.036 \), one-tailed), 6 months (Wilcoxon signed ranks test, \( p = 0.004 \), one-tailed), 12 months (Wilcoxon signed ranks test, \( p = 0.008 \), one-tailed) and 18 months (Wilcoxon signed ranks test, \( p = 0.008 \), one-tailed) test intervals (Fig. 8). There was no significant difference beyond this point.

No further matched-pair analysis could be conducted for aetiology due to too small sample size.

4. Discussion

Results of children implanted with the short electrode show that, generally, their speech perception scores improve over time. LiP scores show early and rapid improvement, with a significant improvement shown at each test interval. However, by the 3-year test interval, ceiling is reached and this test is limited in showing further long-term improvement. The LiP mainly assesses core early listening skills such as response to environmental sounds, basic pattern perception, identification and discrimination skills. What this shows is that children implanted with a short electrode have early access to essential core listening skills. The MTP-3 word test showed significant improvement over time, but this was not the case with the MTP-6 group. The MTP-6 test is a more difficult test and children are only tested on this when they have achieved close to 100% on the MTP-3 test. Closer inspection of the MTP-6 data revealed that only older children have results at the first few test intervals. As many of these children had pre-operative hearing, and possibly longer auditory training, they start out with high results. Thus, when further intervals are compared, a significant difference cannot be shown, although the slope of the graph suggests improvement over time. More children are included in the sample at later intervals as they progress from MTP-3 to MTP-6. This is, in itself, an improvement and it also demonstrates good pattern perception performance, as they join in with higher scores. Three children were consistently the lower three scorers in the MTP-3 test. For example, at the 1-month interval the MTP-3 word mean score was 40.1%, excluding these 3 children raised the mean to 60.7%. A similar pattern was observed for the 3- and 6-month test intervals. Closed-set words (monosyllables in all languages except Spanish) showed little significant improvement beyond the 1-year period, yet there was improvement generally. The converse is seen in the open-set test where results are only reported from 3 months. No data are reported from earlier as children are not able to perform the complexity of this listening task at this age, and this may influence the reason as to why significant improvement is only seen from 18 months.

The issue of late development of listening skills has been addressed in previous literature [9,12,20]. The Truc Trihn [11] sample showed limited progression, which was put down to limited electrode insertion. The other two authors had very small sample sizes (three children and a single case study) and results may reflect this, as well as the impact of test complexity. Our children showed delayed progress in the more difficult tasks, yet rapid improve-
ment in core listening skills; which allows them early access to linguistic learning.

Knowledge of outcomes with the short electrode is important when counselling parents about possible use. Available literature only compares partial insertion of an electrode (in the case of severe ossification) to full insertion (in the case of partial ossification) [10,21]. In the Hodges article [21], the partial ossification group performed similarly to a no-ossification group, however, the major ossification group had the poorest (though not significantly so) performance. However, there were only two cases of major ossification reported on. Poor performance on four subjects with complete ossification was demonstrated in one study [10], to the point that none had achieved any open-set scoring. As far as we are aware, ours is the first article demonstrating results with a short electrode. However, although we show that there may be differences between ossified and non-ossified groups in the early stages, we cannot make conclusive statements about this, as we do not complete information about degree of ossification in our study subjects. Although there is a difference in performance between the test and control groups up to 18 months on the LiP, we see that the short electrode still achieve ceiling on this test, and within a similar timeframe. A further study [13] with 12 cases with partial electrode insertion and 9 with full insertion, noted that the partial insertion group performed significantly poorer that the full insertion group on other tests was insufficient number of patients to make a clear judgement on this. The children implanted with the short electrode follow a similar listening development pattern when compared to their peers implanted with a standard electrode and matched to aetiology, age at implantation and duration of deafness. These results demonstrate the benefit of having a short electrode available in surgery in instances when full insertion of a standard electrode is not possible.

References


5. Conclusion

Results demonstrate improvement over time on all tests for children implanted with a short electrode.


