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### ► To cite this version:

N. Loundon, F. Simon, K. Aubry, Philippe Bordure, A. Bozorg-Grayeli, et al.. The French Cochlear Implant Registry (EPIIC): Perception and language results in infants with cochlear implantation under the age of 24 months. *European Annals of Otorhinolaryngology, Head and Neck Diseases*, 2020, 137, pp.S11-S18. 10.1016/j.anorl.2020.07.010 . hal-03125467

**HAL Id: hal-03125467**

**<https://hal.science/hal-03125467>**

Submitted on 17 Oct 2022

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## **The French Cochlear Implant Registry (EPIIC): perception and language results in infants with cochlear implantation under the age of 24 months**

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## **Abstract**

**Objective:** Multi-centre study of the National French Registry (EPIIC) of patients with cochlear implants, focusing on infants who were operated-on under the age of 24 months between 2012 and 2016.

**Patients and methods:** 615 profoundly deaf infants, who received cochlear implants (CIs) before their second birthday, were included in the registry by different CI centers. Epidemiological, surgical, speech-therapy and school, follow-up data were included in the registry, 12, 24, 36 and 48 months thereafter. The following parameters were studied: type of implantation (uni- or bilateral), complications, cause of deafness, category of auditory perception (CAP), Open-set word recognition score (OSW), speech intelligibility rating, lexical comprehension with EVIP (Peabody), communication mode and type of schooling. Bilateral simultaneous CI (BiCI) and unilateral CI (UniCI) groups were compared.

**Results:** There were 744 implantations. The explantation-reimplantation rate, within the four-year follow-up, was just 3.6%. Mean implantation age was 16.0 months, and similar in the two groups (BiCI/UniCI). 51% of children had their first implant between 12 and 18 months, and 15% before 12 months. Implantation was unilateral in 52% of cases. Fifty-six percent of the bilateral procedures were sequential, with a mean delay of 16.8 months for the second implantation. The cause of deafness was unknown in 52% of cases. Of the 48% (297/615) of attributed cases, 32% had clear genetic causes. The remaining deafness was due to cytomegalovirus (CMV, 8%), inner-ear malformation (5%) and meningitis (3%). The main complications were from infections (47%) and internal device failure (25%). Four years post-operation, 84% of the UniCI and 75% of BiCI groups had a CAP  $\geq$  5, and 83% of UniCI and 100% BiCI had OSW  $\geq$  80%. Furthermore 74% of UniCI and 77% of BiCI communicated orally and 85% of UniCI and 90% of BiCI integrated into mainstream schooling.

**Conclusion:** The French Registry of cochlear implants (EPIIC) is the only such national registry in the world. Our analysis illustrates the immediate benefits of, either single or double, cochlear implantation for language, perception skills and schooling.

**Key words:** cohort, child, cochlear implant, national registry, oral language, perception

## **1. Introduction**

Since 2011 The French EPIIC registry has been compiling key clinical and social data from patients with cochlear implants. The volume of patients in each participating cochlear implant (CI) center directly depends on its area of referral. Overall, 5837 surgical procedures were included in the registry from January 2012 to December 2016, of which 2305 concerned pediatric patients (Figure 1). This corresponds to 5051 patients, of which 1873 were children. Demographic, surgical and materio-vigilance data as well as language and perception progress are collected. To be collected in the registry, data must be included yearly, within +/- three months of the anniversary date of the first surgery.

## **2. Patients**

During the observation time-frame (January 2012 to December 2016), 615 children were implanted before their second birthday, corresponding to 123 children per year in this age group. The reported surgeries were 744 implantations and 27 explantation-re-implantations (3.6%). There were thus 771 total cochlear implants placed over this period.

Mean implantation age was 16.0 months in both the unilateral implantation (UniCI) and bilateral cochlear implantation (BiCI) groups. Fifty-one percent of the children had their first implant at between 12 and 18 month old, and 15% before their first birthday (Table 1). Implantation was unilateral in 52% of cases and bilateral in 48%. When bilateral, procedures were simultaneous in 44% of cases and sequential in 56% with a mean delay of 16.8 months. 45.5% of children who had surgery at under 12 months of age had unilateral implantation at last follow-up (Table 2).

Of the 615 implanted children, 444 (72.2%) had at least one speech-therapy follow-up, 140 (22.8%) had not reached the 12-month follow-up mark, and 31 (5.0%) did not have any data included in the registry.

### **3. Cause of deafness and surgery procedure**

The cause of deafness was unknown in 52% of cases. The 48% of attributed cases (297/615) fell into four categories: genetic 32%, CMV 8%, inner-ear malformation 5%, and meningitis 3%. The explanation rate varied according to implantation age from 2.5 to 6.6%. The main complications were subcutaneous or cutaneous infections (47%), internal device failure (25%) and implant misplacement or migration (14.5%), see Table 3.

### **4. Analysis of child evolution regarding language and perception skills and schooling**

Analysis of speech therapy and schooling data was limited to children with follow-up collected in the registry and was divided in two groups according to implantation type: bilateral simultaneous CI (BiCI) and unilateral CI (UniCI). Overall there were no significant differences between the two groups (Table 4). The results from children with sequential bilateral CIs over this period (166 patients) were not studied due to the great variability in delay times between the operations, and consequent variability in the subsequent follow-up.

Speech therapy data covering **perception**, **language** and **schooling** was noted separately for single implants, +/- contralateral hearing aid. **Perception** results included Category of Auditory Perception (CAP) and Open-Set Word recognition score (OSW) (Figures 2 and 3). **Language** development data included speech intelligibility rating (Nottingham scale, SIR), lexical comprehension with EVIP (French version of Peabody Picture Vocabulary test) and the child's communication mode (Figures 4 and 5). Type of **schooling** is noted in Figure 6. Statistical



analyses were performed with SAS® 9.1 software (Cary, North Carolina, USA). A paired student's t-test was used to compare scores from one year to the next and to compare unilateral and bilateral implants groups. A  $p$  value  $< 0.05$  was considered significant.

#### **4.1 One year follow up**

##### *4.1.1 Eligible population to analyze 1 year follow up*

#### **BILATERAL SIMULTANEOUS Implantation (n= 91)**

Of the 106 children with bilateral simultaneous implantation and 12 months' follow up, five (4.7%) did not have their check-ups in the registry, and 10 (9.4%) had their yearly appointment outside of the accepted +/- 3 months range. Therefore 91 cases (86.7%) could be analyzed.

#### **UNILATERAL Implantation (n= 172)**

Of the 216 children with unilateral implantation, 30 (13.8%) did not have any follow-up in the registry, and 14 (6.4%) had their first annual check-up outside of the accepted +/- 3 months range. Therefore 172 cases (86.8%) were further analyzed

##### *4.1.2 Results of first annual check up*

#### Speech perception after 12 months

Mean CAP scores were 3.1 and 2.8 for the UniCI and BiCI groups respectively ( $p > 0.05$ ).

64% of UniCI children and 51% of the BiCI group could identify sounds from the environment. 16% of UniCI and 13% of BiCI understood everyday sentences. Mean disyllabic OSW scores were 48% for UniCI and 37% for the BiCI groups ( $p > 0.05$ ).

#### Intelligibility at 12 months

37% of UniCI and 51% of BiCI were in their pre-linguistic stage and 21% of UniCI and BiCI exclusively used oral language. Mean SIR score was 1.7 for UniCI and 1.5 for BiCI.

#### Schooling at 12 months post operation

73% of UniCI and 70% of BiCI were preschoolers and 22% of UniCI and 25% of BiCI were in integrated schooling.

### **4.2 Progress 2 years after implantation**

#### *4.2.1 Eligible Population for data analysis*

##### **BILATERAL SIMULTANEOUS Implantation (n=47)**

Of the 78 children who underwent bilateral simultaneous implantation, eighteen (23%) did not have any follow-up in the registry at two-years post-operation, and thirteen (16.7%) had their follow-up outside of the specified 24 +/- 3 months range. Therefore 47 cases (60.2%) could be analyzed.

##### **UNILATERAL Implantation (n=95)**

Of the 156 children with unilateral implantation, forty (25.6%) did not have a two-year follow-up in the registry, and twenty-one (13.5%) had their appointment outside of the +/- 3 months range. Therefore 95 cases (60.9%) were further analyzed.

#### *4.2.2 Progress 24-months after CI*

##### Speech perception

Mean CAP scores at the two-year follow-up were 3.9 for the UniCI and 3.6 for the BiCI group; 43% of UniCI and 31% of BiCI had a CAP score  $\geq 5$  (including everyday sentences

without lip-reading). Mean OSW scores were 68% for UniCI and 70% for the BiCI group; 76% of UniCI and 81% of BiCI had an OSW score  $\geq 5$ .

#### Intelligibility at 2 year follow up

82% of UniCI and 72% of BiCI had started to speak; 30% of UniCI and 36% of BiCI exclusively used oral language and 36% of UniCI and 25% of BiCI used spoken and sign language. Mean SIR score was 2.5 for UniCI and 2.4 for BiCI; 46% of UniCI and BiCI had a SIR score  $\geq 3$ .

#### Schooling two years post operation

79% of UniCI and 67% of BiCI were in schooling. 65% of the UniCI group were in integrated schooling and 14% in specialized schooling. Amongst the BiCI group, 57% were in integrated and 11% in specialized schools.

### **4.3 Progress three years after implantation**

#### *4.3.1 Eligible Population*

##### **BILATERAL SIMULTANEOUS Implantation (n=19)**

Of the forty children with bilateral simultaneous implantation, nineteen (47.5%) did not have three-year follow-up in the registry, while two (5%) had their appointment outside of the 36 +/- 3 months range. Therefore nineteen cases (47.5%) could be analyzed.

##### **UNILATERAL Implantation (n=43)**

Of the 95 children with unilateral implantation, thirty-eight (40%) did not have any follow-up in the registry, and fourteen (14.7%) had their three-year follow-up outside of the accepted +/- 3 months variability. Therefore 43 cases (45.2%) could be analyzed.

#### *4.3.2 Progress after 36-months by category*

##### Speech perception

55% of UniCI and 67% of BiCI had a CAP score  $\geq 5$ ; just 17% of UniCI and 5% of BiCI were unable to identify everyday noises at three years post-implantation.

OSW tests were possible in 58% of UniCI and 42% of BiCI patients; 68% of UniCI and 75% of BiCI had an OSW score  $\geq 80\%$ .

##### Intelligibility after 36 months

55% of UniCI and 59% of BiCI used spoken language. 30% of children in both groups used signs as well as oral language. 25% of UniCI and 42% of BiCI had a SIR = 5 (intelligible to everyone). Lexical comprehension scores with EVIP (Peabody): 30% of UniCI and 20% of BiCI were able to take the test and 31% of UniCI and 55% of BiCI had score superior or equal to average for the general population.

##### Schooling

83% of UniCI and 85% of BiCI were in integrated or inclusive schooling 3 years post-operation.

#### **4.4 Survey at 4 years post CI**

##### *4.4.1 Eligible Population*

##### **BILATERAL SIMULTANEOUS Implantation (n=11)**

Of the fourteen children with bilateral simultaneous implantation, three (21.4%) had no four-year follow-up in the registry. Eleven cases (78.5%) could therefore be analyzed.

## **UNILATERAL Implantation (n=19)**

Of the 44 children with unilateral implantation, 22 (45.8%) no longer had follow-up in the registry, and three (6.8%) had a yearly follow-up outside of the +/- 3 months range. Therefore nineteen cases (43.2%) were analyzed.

### *4.4.2 Progress after 4 years*

#### Speech perception

84% of UniCI and 75% of BiCI had a CAP score  $\geq 5$ ; 26% of UniCI and 42% of BiCI could talk over the phone with a familiar person. OSW tests were possible in 63% of UniCI and 33% of BiCI patients; 83% of UniCI and 100% of BiCI had an OSW score  $\geq 80\%$ .

#### Intelligibility 4 years post operation

74% of UniCI and 77% of BiCI used spoken language. 67 % of UniCI and 61% of BiCI had a SIR score  $\geq 4$ . 31% of UniCI and 42% of BiCI had an EVIP (Peabody) score: 17% of UniCI and 60% of BiCI scored average or above. 50% of UniCI and 20% of BiCI had a low EVIP score.

#### Schooling

85% of UniCI and 100% of BiCI were in integrated or inclusive schooling 4 years post-CI.

## **5- Discussion**

### *5.1 Population*

The studied population was homogenous and all subjects were implanted early with a mean implantation age under 18 months. The unilateral CI and simultaneous bilateral CI groups had similar age and follow-up duration, which enabled us to compare the data. Half of the implanted children in France had bilateral implantation and a half of these were implanted simultaneously. The proportion of implanted infants under the age of 12 months is low when compared to other European countries (1-3). It should be noted that universal new-born hearing-loss screening in France was only implemented between 2012 and 2014 and that since then patient care networks have been progressively established (4); local difficulties and consultation or surgery appointment delays in reference centers might also have contributed to delayed CI surgery. It would therefore be interesting to examine the evolution of implantation age in France over the next 5 years.

In 50% of cases, deafness can be linked to a specific cause, whether acquired (meningitis, CMV, etc.) or genetic. In the other cases it is labelled 'of unknown cause'; in this latter category either the genetic tests came up negative or the parents declined the test or had no access to it.

Concerning complications, the explantation rate we found was similar to those in the literature for similar age groups, which are 4% (5); skin problems or local infections accounted for most of the reported complications, and these have already been discussed in other pediatric implant series (6).

## *5.2 Perception and language results*

Regarding language and perception, there was swift progress for the clear majority of children implanted before their second birthday. This enabled schooling in a normal environment and good comprehension of spoken language and diversified oral expression. Oral communication was efficient for more than 80% of the patients. Progress in hearing was measurable, as from the 12-month follow-up, in both the unilateral and bilateral groups. Regarding spoken language, after 12 months, more than half of the operated children could initiate a few words or more of oral communication. After 24 months, language perception progress is measurable and there was comprehension of simple phrases in a third of cases and the children used spoken language as their main communication mode. At the three-year check-up, two-thirds of children understood out-of-context sentences, and the clear majority used spoken language to communicate. Four years post-CI, there was no measurable difference between the unilateral and bilateral groups concerning schooling, speech perception or intelligibility. However, lexical comprehension (vocabulary) was better in bilaterally implanted children. The fine-analysis of the children's lexical comprehension was limited, as this item was not systematically included in the registry at the 4-year point. Although not significant then, the data nevertheless indicate a greater impact of simultaneous bilateral versus unilateral implantation.

The literature reveals links between perception landmarks, language development and long-term schooling and social integration prospects (7-12). It is interesting to note that cued speech is seldom used by the subjects in this study. In these very young children, the communication mode is either purely oral, or oral with gesticulation, followed by pure oral. The good perception effects of CI likely explain the reliance on this 'hearing only' modality.

Finally then, in about 15% of the children, spoken language development was significantly delayed even 4 years after CI. Causes in these patients varied from Usher syndrome, Connexin-26 mutation and fetopathies, to CMV. The registry did not enable us to more specifically analyze any deafness-associated difficulties that might hinder spoken language progress.

### *5.3 The future of the EPIIC registry*

We believe it is paramount to continue this unique National registry, which enables the long-term follow-up of a large cohort of implanted patients, incorporating data from an entire country. It remains important to optimize certain items, to enable full analysis of the included data. Indeed, for certain items, we observed a 'floor effect' (where the tests are too difficult) or a 'ceiling effect' (too easy), but also sometimes insufficient understanding of test modalities leads to mistakes, or lack of answers, and impedes our analysis of the data. In further analysis



it will be necessary to include the children with bilateral sequential implantation, taking into account the effect of the second implant and the delay between the two operations.

## **Conclusion**

The data in the French National Registry is of high-enough quality to enable thorough surgery follow-up, which confirms its relevance. Four complete years of speech therapy follow-up is collected in over 75% of cases, despite the constraints of having to see the children in a restricted time-window. Our fine-analysis demonstrates the benefits of implantation in young children, on language and perception skills and on schooling, starting immediately in the very first years after surgery.

Conflicts of interest: None of the authors have any conflicts of interests to declare.

## **Acknowledgments**

The authors would like to express their sincere gratitude to Samantha CHESNE and to the POPISCUBE team for their help with statistics and figures.

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<b>Age at first CI</b>	<b>Unilateral</b>	<b>Sequential Bilateral</b>	<b>Simultaneous Bilateral</b>	<b>Total</b>
≤ 12 months	41 (18.2%)	29 (17.4%)	20 (15.5%)	90 (14.6%)
> 12 and ≤ 18 months	<b>170 (53%)</b>	<b>85 (51.2%)</b>	<b>61 (47.2%)</b>	<b>316 (51%)</b>
> 18 and ≤ 24 months	109 (34%)	52 (31.3%)	48 (37.2%)	209 (33.9%)
Total	<b>320 (52%)</b>	<b>166 (27%)</b>	<b>129 (21%)</b>	<b>615</b>

**Table 1: Types of cochlear implantation**

	<b>Unilateral with follow-up</b>
<b>Mean age at CI</b>	1 year and 4 months
<b>Mean follow-up (months)</b>	36,58
	<b>Sequential with follow-up</b>
<b>Mean age at first CI</b>	1 year and 4 months
<b>Mean age at second CI</b>	2 years and 9 months
<b>Mean delay between CIs (months)</b>	16,83 [2-50]
<b>Mean follow-up after first CI (months)</b>	39,52

**Table 2: Age and follow up of Cochlear implantation patients**

<b>Secondary complications</b>	<b>N=55</b>
<b>Infections/ Cutaneous problems / Hematoma</b>	<b>26 (47.2%)</b>
<b>Implant electrode misplacement / migration</b>	<b>8 (14.5%)</b>
<b>Internal device failure</b>	<b>14 (25%)</b>
<b>Pain</b>	<b>2 (3.6%)</b>
<b>Facial paralysis</b>	<b>2 (3.6%)</b>
<b>Tympanic membrane perforation</b>	<b>1 (1.8%)</b>

**Table 3: Secondary surgical complications**

<b>Follow up point</b>	<b>CAP</b>	<b>OSW</b>	<b>SIR</b>
<b>1 year</b>	0.075	0.784	0.234
<b>2 years</b>	0.211	0.197	0.441
<b>3 years</b>	0.840	0.876	0.864
<b>4 years</b>	0.012	0.324	0.927

**Table 4: Unilateral vs bilateral simultaneous implants.** Statistical significance (student's t-test) of the difference in scores, between unilateral implants and bilateral simultaneous implants, according to number of years of follow-up after surgical procedure. The only significant difference was in the CAP scores at the 4-year time-point. No other scores were statistically significant between groups. *CAP* Category of auditory performance score, *OSW* Open-set word score, *SIR* Score of intelligibility rate.

**Figure 1: Distribution of cochlear implants at Hospital centers:** 2,305 cochlear implant procedures in children were included in the registry from January 2012 to January 2017. Pediatric cases from hospitals all over France were included, as indicated underneath.

**Figure 2:** Categories of auditory performance scores (CAP) in children with unilateral and bilateral cochlear implants (CIs). Means and standard deviations are shown. Stars indicate significant differences : \*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$ , and *NS* = Not Significant. CAP score increases progressively as of the first year after implantation in both groups but the bilateral CI group had significantly better results after four years, ( $p = 0.012$ , see also Table 4).

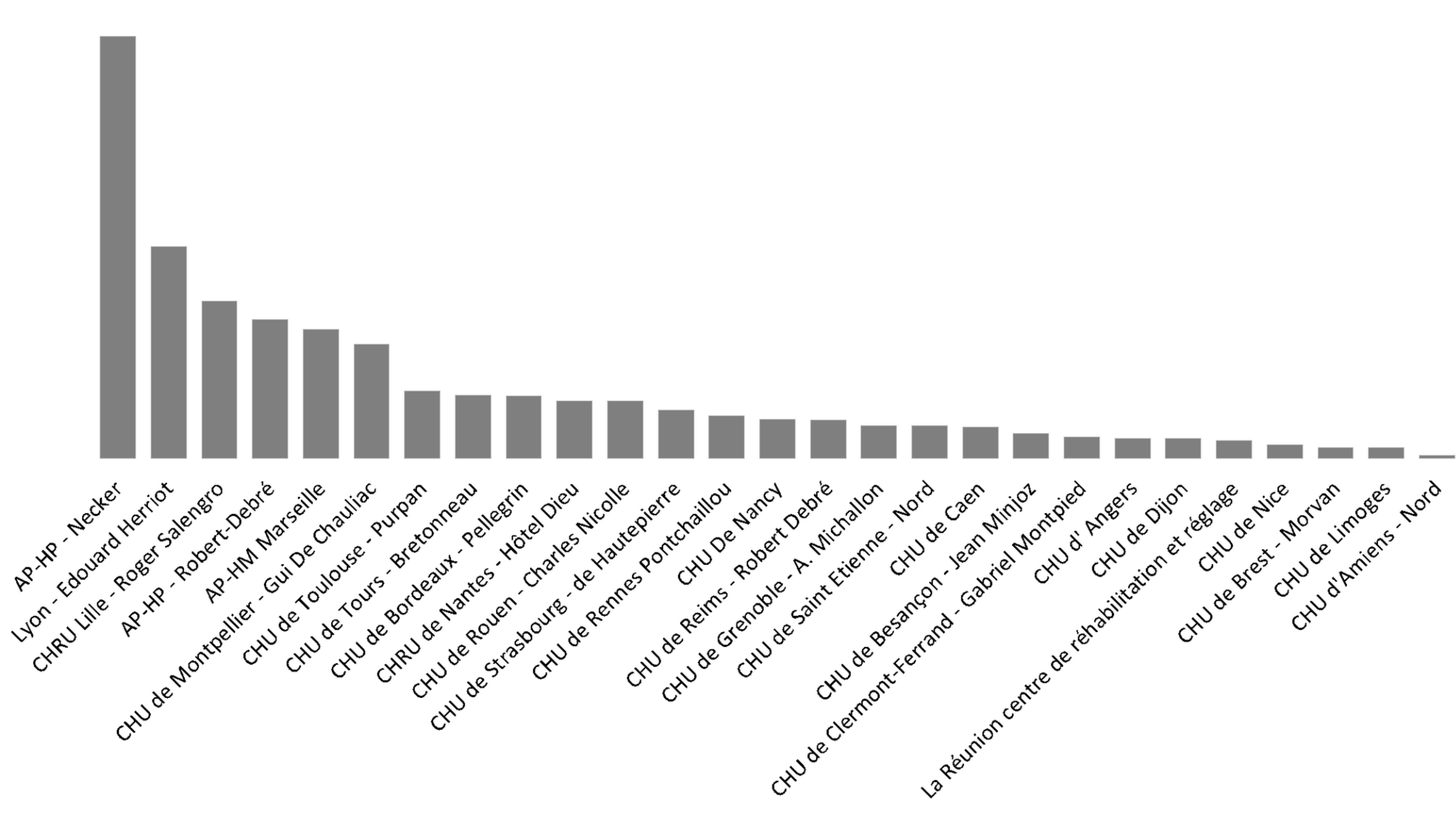
**Figure 3:** Open set words scores (OSW) in children with unilateral and bilateral cochlear implants (CIs). Results shown are mean and standard deviation. In both groups, OSW increases as of the first year after implantation (no significant difference found between groups, see also Table 4).

**Figure 4:** Scores of intelligibility rate (SIR) in children with unilateral and bilateral cochlear implants (CIs). Results shown are mean and standard deviation. Stars denote significant differences: \*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$  and *NS*, Not Significant. SIR increases progressively as of the first year after implantation and stabilizes in years three and four. There was no significant differences between the two groups (see also Table 4).

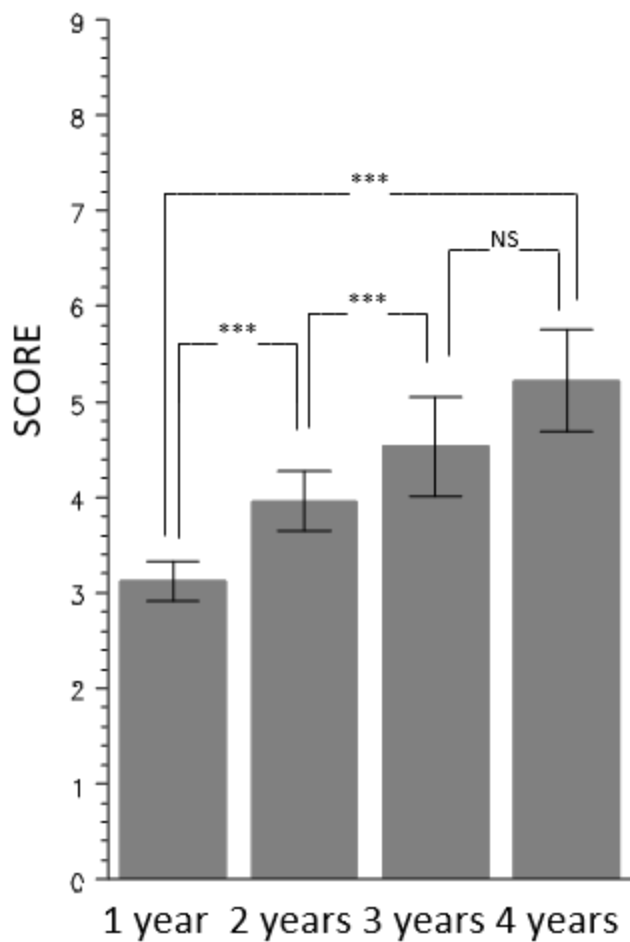
**Figure 5:** Communication mode in children with (A) unilateral and (B) bilateral cochlear implants. Most children in the two groups used spoken language at three-year follow-up. *CS*, Cued Speech.

**Figure 6:** Schooling in children with unilateral and bilateral cochlear implants according to years of follow up from the initial procedure. Most attend integrated schooling. *BiCI* Bilateral Cochlear Implant, *UniCI* Unilateral Cochlear Implant.

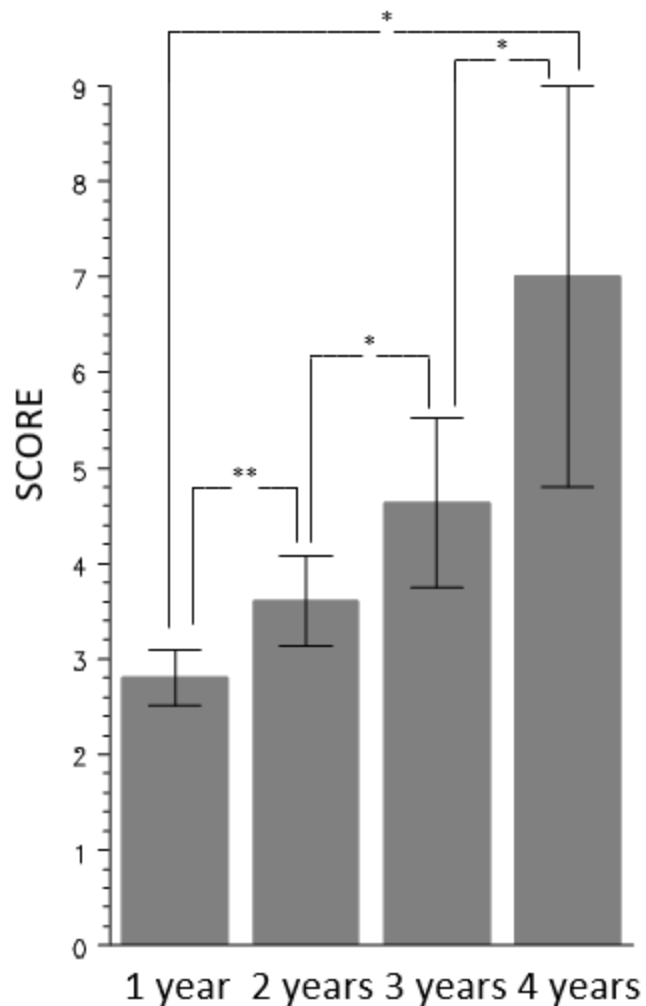




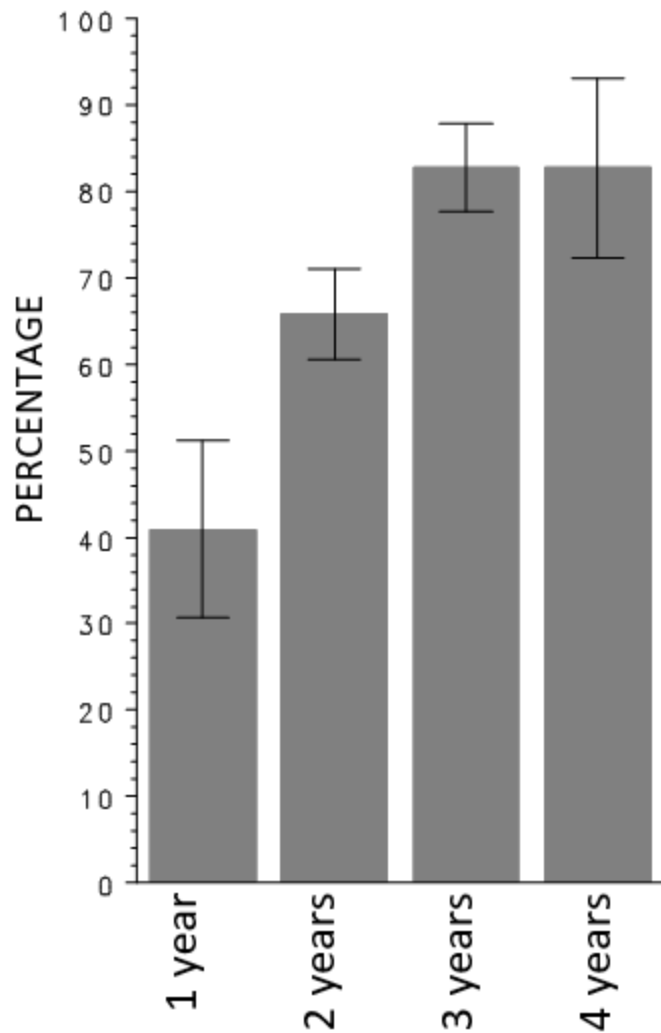
## CAP unilateral CI



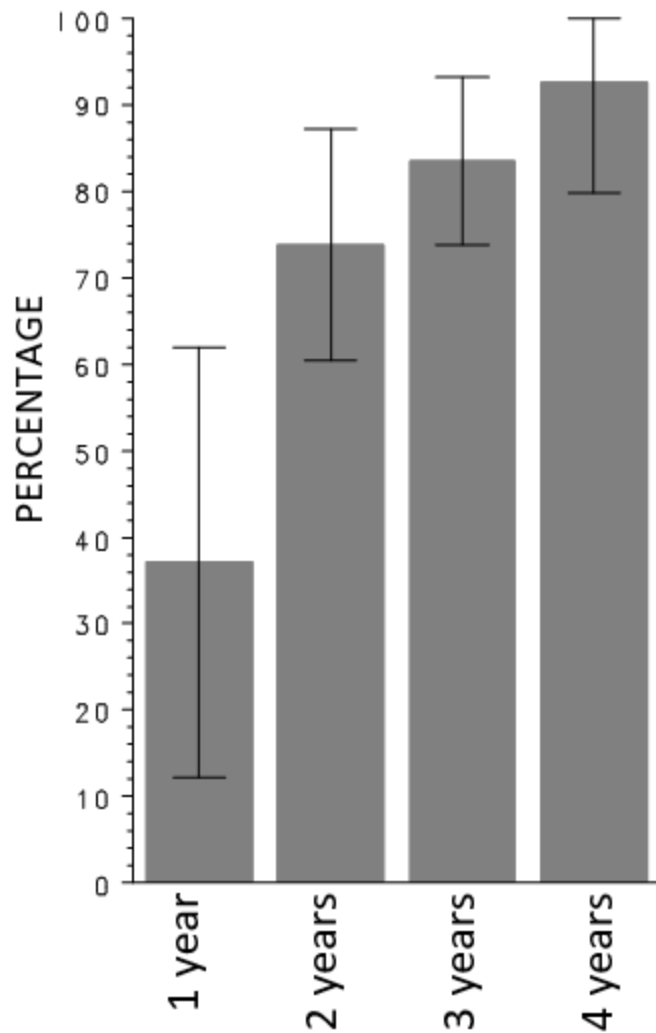
## CAP bilateral CI



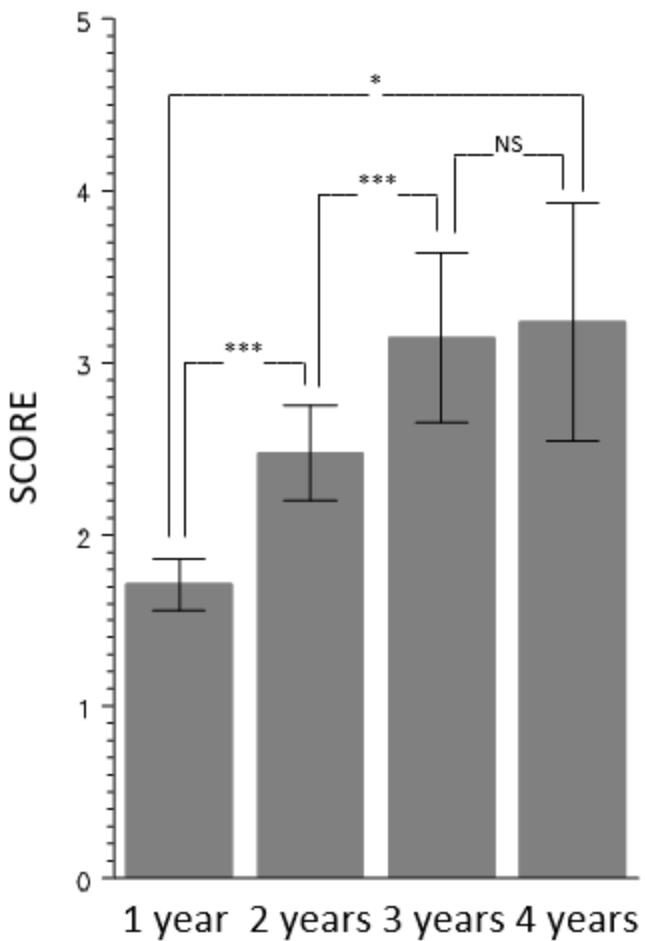
## OSW unilateral CI



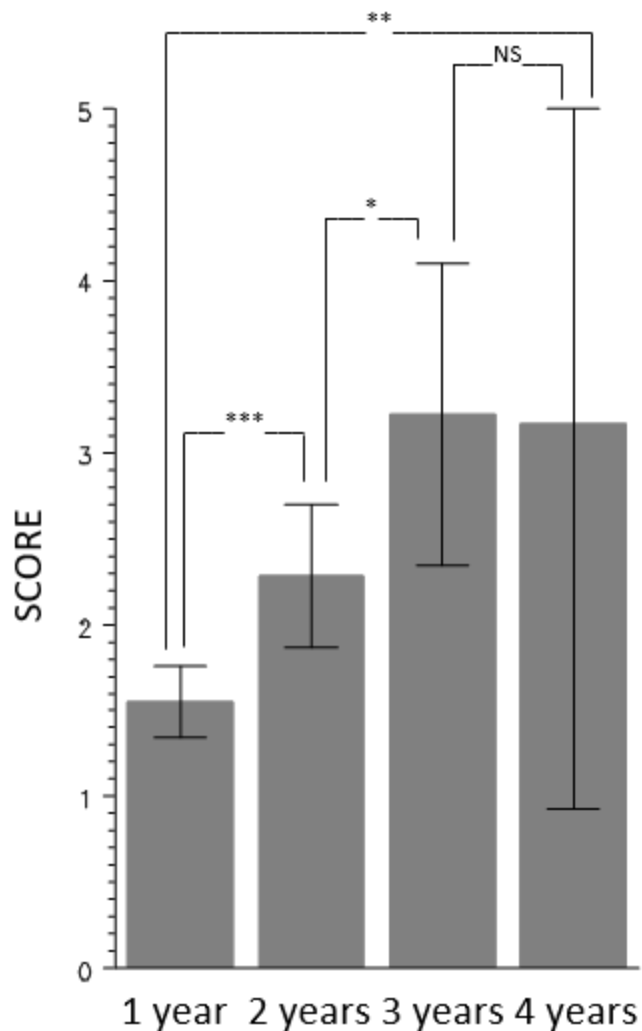
## OSW bilateral CI

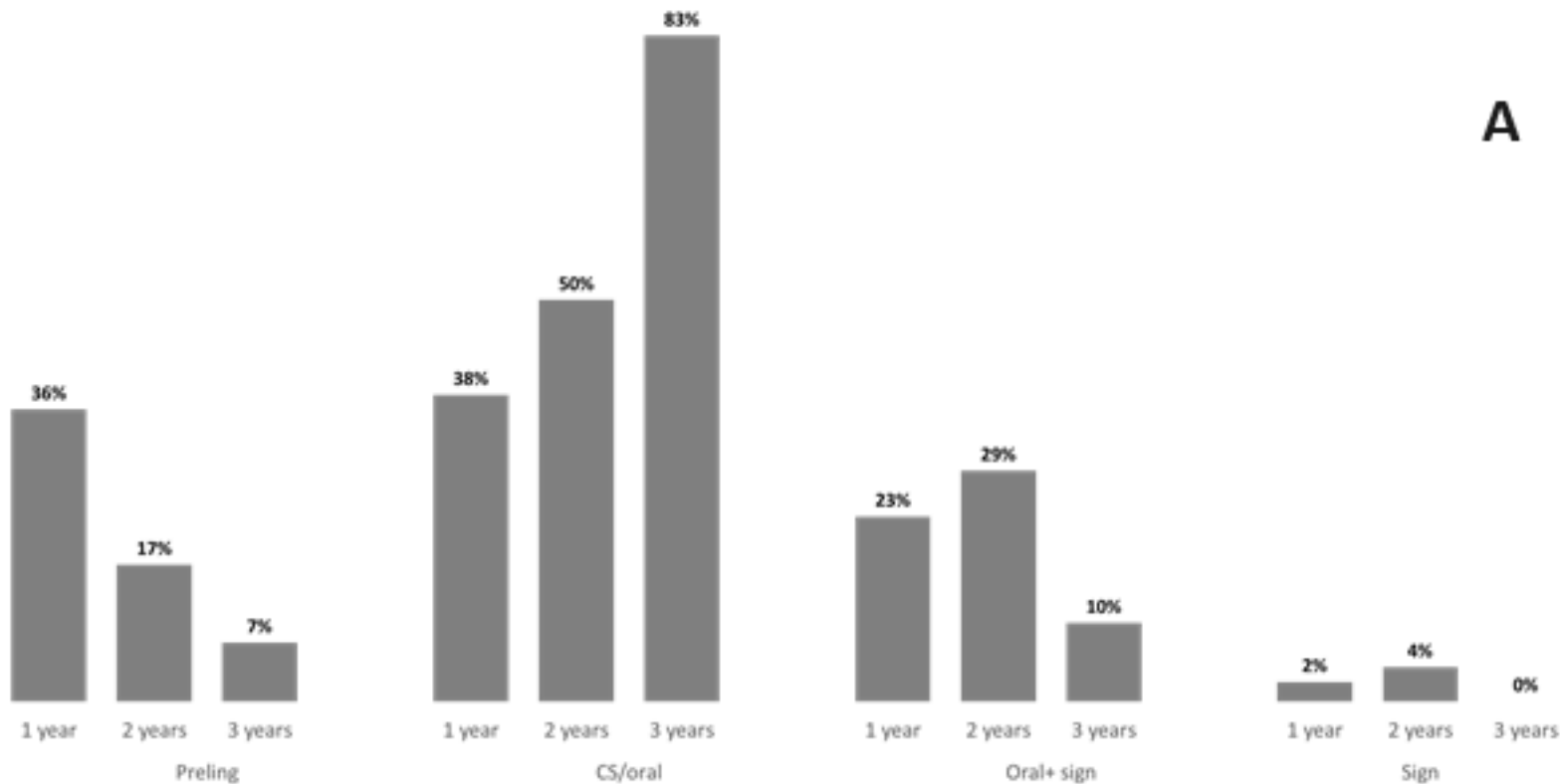


## SIR unilateral CI



## SIR bilateral CI



**A****B**