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Original Article

# Observational Study of Pediatric Cochlear Implant Recipients: Two-year Follow-up Outcomes

## *Pediatrik Koklear İmplant Kullanıcıları Gözlemsel Çalışması: İki Yıllık Takip Sonuçları*

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## ABSTRACT

**Objective:** The aim of this study was to evaluate the improvements in quality of life and auditory performance via a descriptive report using patient-related outcomes measures in a group of children with cochlear implants (CI).

**Methods:** This was a longitudinal and retrospective study based on the analysis of patient records of a total of 28 children with CI, 18 of whom had bilateral (64.3%) and 10 had unilateral (35.7%). The study included repeated within-subject measures of Hearing Implants Quality of Life (CuHI-QoL), Categories of Auditory Performance (CAP-II), Speech, Spatial, and Qualities of Hearing scale-Parents' version (SSQ-P) scales, and Implant Recipient Follow-up (IRF) form at 6-month intervals from baseline up to 24 months.

**Results:** During the 2-year follow-up assessments, all children with CI showed statistically significant improvement over time in their CAP-II, SSQ-P, CuHI-QoL, and IRF scores ($p<0.001$). The most significant increase in scores occurred within the first six months following the baseline and then continued to increase gradually at a slower pace over time. A moderate negative relationship was found between the age of implantation and SSQ-P and family satisfaction scores of IRF ($p<0.05$).

**Conclusions:** Family expectations, overall well-being, quality of life, auditory, and verbal skills increase positively with earlier CI intervention. Moreover, the subjective assessment results showed that parents-positive attitudes toward implantation, and willingness to recommend it to others have steadily increased in time. Although the cohort is relatively small and variable, the results offer a descriptive view to outcomes in real-world practice.

**Keywords:** Cochlear implants, auditory performance, speech development, family perspective, quality of life

## ÖZ

**Amaç:** Çalışmada bir grup koklear implantlı (Kİ) çocukta hastayla ilişkili değerlendirme anketleri yoluyla yaşam kalitesi ve işitsel performanstaki gelişmelerin değerlendirilmesi amaçlanmıştır.

**Yöntemler:** Bu çalışma, 18'i çift taraflı (%64,3), 10'u tek taraflı (%35,7) olmak üzere toplam 28 Kİ'li çocuğun hasta kayıtlarının incelenmesini içeren uzunlamasına ve retrospektif bir çalışmadır. Çalışma, İşitsel İmplantlar Yaşam Kalitesi (İİYK), İşitsel Performans Kategorileri (İPK-II), Konuşma, Uzaysal Algı ve İşitme Kalitesi ölçeği-Ebeveyn versiyonu (KUAİK-E) ölçekleri ve İmplant Kullanıcısı Takip (İKT) formunun açılıştan itibaren 24 ay boyunca her 6 ayda bir tekrarlanan öznel ölçümlerini içermektedir.

**Bulgular:** İki yıllık takip değerlendirmeleri sırasında, Kİ'li tüm çocukların İPK-II, KUAİK-E, İİYK ve İKT skorlarında zaman içinde istatistiksel olarak anlamlı iyileşmeler görülmüştür ($p<0,001$). Puanlardaki en önemli artış, başlangıç çizgisini takip eden ilk altı ay içinde ortaya çıkmış, ardından zaman içinde daha yavaş bir hızda kademeli olarak artmaya devam etmiştir. İmplantasyon yaşı ile KUAİK-E ve İKT formu aile memnuniyet puanları arasında orta düzeyde negatif bir ilişki bulunmuştur ($p<0,05$).

**Sonuçlar:** Aile beklentileri, genel refah, yaşam kalitesi, işitsel ve sözel beceriler erken Kİ müdahalesi ile olumlu yönde artmaktadır. Ayrıca, subjektif değerlendirme sonuçları ebeveynlerin implantasyona yönelik olumlu tutumlarının ve implantı başkalarına tavsiye etme isteklerinin zaman içinde istikrarlı bir şekilde arttığını göstermiştir. Kohort nispeten küçük ve değişken olmasına rağmen, sonuçlar gerçek dünyadaki uygulamalara ilişkin tanımlayıcı bir görüş sunması açısından önemlidir.

**Anahtar kelimeler:** Koklear implantlar, işitsel performans, konuşma gelişimi, aile perspektifi, yaşam kalitesi

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## INTRODUCTION

Official records from neonatal hearing screening show that permanent congenital sensorineural hearing loss occurs in one to three out of every thousand births, with the rate being ten times higher in neonatal intensive care units. It is well-known that exposure to acoustic stimuli in early childhood is vital for language and speech development. Therefore, children with hearing loss should be fitted with proper amplification devices as soon as possible and followed by objective and subjective assessment tools.

Cochlear implants (CI) is the most popular intervention method for individuals with severe and/or profound hearing loss[1]. These devices transmit acoustic signals to the auditory nerve by converting them into electrical signals to allow many people to regain hearing and obtain significant improvements in health-related quality of life and real-life hearing function[2]. Although cochlear implantation is often successful, it is not always so, as there are many factors affecting outcomes: such as the age of implantation, the duration of hearing loss, residual hearing, and auditory environment[3,4]. While many children with early intervention can achieve normal or near-normal speech and language development after CI, others may have some delays in language development, speech production, literacy, academic and social skills, and these developmental delays can persist through to adulthood[5-13].

With unilateral CI, many children have good listening skills and speech understanding in a controlled listening environment, such as a quiet room[14,15]. These tests, however, do not fully represent daily living conditions. Children with bilateral severe to profound hearing loss who use CI in only one ear may struggle to understand speech in more challenging listening situations in the real world, such as playgrounds, noisy classrooms, and crowded family environments. Understanding low-intensity speech and locating sound sources in a group conversation are two examples. These perceptual difficulties can have an adverse effect on children's learning abilities and social development. For this reason, bilateral cochlear implantation has become the standard of care for children under four years of age in many countries[16]. The goal is for children to hear better in noisy environments and succeed in their academic and social lives.

Simultaneous bilateral cochlear implantation is suggested to be advantageous in supporting the tandem development of bilateral auditory pathways[16]. However, it is unclear whether the asymmetries in sequential implantation will persist over time. Although some studies have show that patients with bilateral and simultaneous implants perform better in terms of speech perception than patients with sequential implants, these studies show considerable heterogeneity in terms of the age of the first (CI1) and second CI (CI2) and the optimal delay between the two implants[17-20]. Furthermore, longitudinal studies on the impact of sequential or simultaneous implantation on the quality of life are limited. The effects of hearing impairment on the daily life of CI recipients can vary among individuals, regardless of the severity of the hearing loss. Therefore, in evaluating the post-postimplant results, it is essential to measure the hearing and daily life benefits of CI. Thus, early action can be taken to address the factors that impede success, and an effective rehabilitation plan can be developed. This longitudinal study evaluated the improvements in the auditory performance in terms of the unilateral, sequential, or simultaneous bilateral implantation via a descriptive report using patient-related outcomes measures in a group of children implanted.

## MATERIALS and METHODS

### Patient Cohort

This study includes a longitudinal and retrospective analysis of the 2-year patient data of 28 children (13 female, 15 male) aged 1-4 years (the age at which participants were included in the study), diagnosed with severe to profound prelingual hearing loss at Marmara University Pendik Training and Research Hospital, and received CI treatment. Of the 28 children, ten were unilateral, and 18 were bilateral CI users: 8 of them simultaneously, 10 of them sequentially implanted. Children with unilateral CI were included in the study after implantation in one ear, whereas children with bilateral CI were included after their second implantation. None of the children had inner ear anomalies or any additional neurological, physical, or mental health problems.

The study was performed out retrospectively by revisiting data entered the Cochlear P-IROS (The Cochlear™ Pediatric Implanted Recipient Observational Study) secure database recording log. Data were gathered via a voluntary online international observational registry for hearing implants initiated by Cochlear Ltd. (Sydney, NSW, Australia) by the Declaration of Helsinki.

The study design included repeated within-subject measures of children using the Hearing Implants Quality of Life (CuHI-QoL) questionnaire, Categories of Auditory Performance (CAP-II), Speech, Spatial, and Qualities of Hearing scale-Parents' version (SSQ-P), and Implant

Recipient Follow-up (IRF) form[21]. All scales and forms were filled out by the parent/caregiver.

CuHI-QoL is a customized quality-of-life instrument that consists of 25 questions developed to evaluate the hearing-related quality of life of children with CI, the impact of CI use on the family, and expectations about the child through parental observations and the well-being of the family over time[21].

The IRF form was used to obtain information about families' satisfaction with their child's hearing, listening, language, and speech development, their thoughts on implantation, and whether they will recommend the implant to other people in their situation[21].

The auditory performance skills of the children were evaluated using CAP-II, a hierarchical rating scale consisting of nine points that covers the range of auditory abilities in daily situations and accounts for varying developmental rates[21,22].

SSQ-P is a questionnaire developed to evaluate children's hearing experiences and abilities with CI based on family observations in different listening conditions. SSQ-P assesss the implant user's understanding of speech in silence and noise, spatial hearing, and other hearing characteristics[23].

Speech processors were activated at four weeks post-operation. The forms were filled before initial device activation (baseline) and at six-monthly follow-up intervals up to 24 months by the parent/caregiver in parallel to routine clinical visits of children.

The Marmara University Faculty of Medicine Clinical Research Ethics Committee approved the study with the protocol code 09.2021.149 (date: 05.03.2021). All parents with implanted children gave written informed consent and assent forms before beginning filling questionnaires.

### Statistical Analysis

IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY) was used to analyze the study data. Descriptive statistics are given using mean and standard deviation (Avg, SD) for quantitative data, and numbers and percentages (N, %) for qualitative data. Shapiro-Wilk tests were performed to evaluate the normality, and it was found that the data were not normally distributed. Multiple comparisons of the same group over time (baseline to 2$^{nd}$-year) were made with Friedman's repeated measures of ANOVA. Conover's post-hoc test was used for pairwise comparisons. Mann-Whitney U test was used to determine the difference between independent variables (sex, bilateral or unilateral CI usage, and sequential or simultaneous bilateral implantation). The correlation between Family Satisfaction scores of the IRF form with CAP-II and SSQ-P scores and between CAP-II and SSQ-P scores was evaluated by Spearman correlation analysis. A p-value of 0.05 was accepted as the significance level, and Bonferroni correction was applied when needed.

## RESULTS

Age at the CI1 ranged from 12 to 44 months (mean ± SD: 25.61±9.35 months). Age at the CI2 ranged from 13 to 48 months (mean ± SD: 30.05±11.83 months). For sequentially implanted children, the mean inter-implant interval time was (mean ± SD) 14.33±5.74 months. All unilateral CI users had hearing aids in their non-implanted ears and wore them consistently throughout the day. The demographic characteristics and etiological factors of the patients are provided in Table 1.

### CuHI-QoL Questionnaire

CuHI-QoL questionnaire evaluations were made at 6-month intervals for two years from the first fitting (baseline). The results of the Friedman's test showed a significant change in family expectation [$x^2(4)=52.92$, $p<0.001$], impact on family [$x^2(4)=53.02$, $p<0.001$], and quality of life [$x^2(4)=78.29$, $p<0.001$] parts of CuHI-QoL at the different time points after the cochlear implantation.

Post-hoc comparisons showed significant increases in family expectation scores of CuHI-QoL between the baseline and 6$^{th}$ (p=0.019), 12$^{th}$ (p=0.002), 18$^{th}$ (p<0.001) and 24$^{th}$ months (p<0.001), 6$^{th}$ and 24$^{th}$ months (p<0.003), and 12$^{th}$ and 24$^{th}$ months (p=0.025); in impact on family scores of CuHI-QoL between the baseline and 6$^{th}$ (p<0.001), 12$^{th}$ (p<0.001), 18$^{th}$ (p<0.001), and 24$^{th}$ months (p<0.001); in quality of life scores of CuHI-QoL between the baseline and 12$^{th}$ (p<0.001), 18$^{th}$ (p<0.001), and 24$^{th}$ months (p<0.001), 6$^{th}$ and 24$^{th}$ months (p=0.003), and 18$^{th}$ and 24$^{th}$ months (p=0.036) (Figure 1). No statistically significant differences were observed in CuHI-QoL scores for sex, bilateral or unilateral CI use, or sequential or simultaneous bilateral implantation at any time point during the evaluations (p>0.05).

### Implant Recipient Follow-up

IRF was applied at 6-month intervals starting from the 6$^{th}$ month. The results of Friedman's test showed that there was considerable improvement in parental satisfaction scores regarding hearing, listening, and speech and language development of children, CI decision, and recommend the CI to others compared to the previous one in almost all measurements performed at 6-month intervals from the first 6 months The results

**Table 1. Demographic information for the CI subjects.**

| N | Sex | GA (month) | Use of CI | Age of CI1 (month) | Age of CI2 (month) | 1st Imp ear | 2nd Imp ear | Imp sequence | Etiology | Refer | 1st ear device type | 2nd ear device type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4 | M | 36+ | Unilateral | 21 | NA | R | none | NA | Hereditary | NHS | Nuc 5 | None |
| 5 | M | 30-32 | Unilateral | 17 | NA | R | none | NA | Prematurity | NHS | Nuc 6 | None |
| 6 | M | 36+ | Unilateral | 27 | NA | L | none | NA | Hereditary | NHS | Nuc 6 | None |
| 7 | M | 36+ | Unilateral | 12 | NA | R | none | NA | Hereditary | NHS | Nuc 6 | None |
| 8 | M | 32-34 | Unilateral | 44 | NA | R | none | NA | Hyperbilirubinemia | Pediatrist | Nuc 5 | None |
| 12 | F | 34-36 | Unilateral | 41 | NA | L | none | NA | Prematurity | Parents | Nuc 5 | None |
| 13 | F | 36+ | Unilateral | 29 | NA | R | none | NA | Hereditary | NHS | Nuc 6 | None |
| 22 | F | 36+ | Unilateral | 16 | NA | R | none | NA | Hereditary | NHS | Nuc 6 | None |
| 27 | M | 36+ | Unilateral | 32 | NA | R | none | NA | Hereditary | Parents | Nuc 6 | None |
| 20 | F | 36+ | Unilateral | 18 | NA | R | none | NA | Hereditary | NHS | Nuc 6 | None |
| 1 | F | 36+ | Bilateral | 24 | 48 | R | L | Seq. | Hereditary | NHS | Nuc 6 | None |
| 2 | M | 36+ | Bilateral | 16 | 34 | R | L | Seq. | Hyperthyroidy | NHS | Nuc 6 | Nuc 6 |
| 3 | F | 36+ | Bilateral | 19 | 31 | R | L | Seq. | Hereditary | Parents | Nuc 6 | Nuc 6 |
| 9 | F | 36+ | Bilateral | 23 | 23 | R | L | Sim. | Hereditary | Parents | Nuc 6 | Nuc 6 |
| 10 | M | <30 | Bilateral | 36 | 36 | R | L | Sim. | Hyperbilirubinemia | NHS | Nuc 6 | Nuc 6 |
| 14 | M | 36+ | Bilateral | 19 | 23 | R | L | Seq. | Hereditary | HBS | Nuc 6 | Nuc 6 |
| 15 | M | 34-36 | Bilateral | 20 | 24 | R | L | Seq. | Hyperbilirubinemia | NHS | Nuc 6 | Nuc 6 |
| 16 | F | 36+ | Bilateral | 15 | 19 | R | L | Seq. | Hereditary | NHS | Nuc 6 | Nuc 6 |
| 17 | F | 36+ | Bilateral | 15 | 15 | R | L | Sim. | Hereditary | NHS | Nuc 6 | Nuc 6 |
| 18 | M | 36+ | Bilateral | 15 | 48 | R | L | Seq. | Hereditary | NHS | Nuc 6 | Kanso |
| 19 | F | 36+ | Bilateral | 16 | 16 | R | L | Sim. | Hereditary | NHS | Nuc 6 | Nuc 6 |
| 11 | F | 36+ | Bilateral | 21 | 45 | R | L | Seq. | Hereditary | NHS | Nuc 5 | Nuc 6 |
| 21 | M | 36+ | Bilateral | 24 | 24 | R | L | Sim. | Hereditary | NHS | Nuc 6 | Nuc 6 |
| 23 | F | 36+ | Bilateral | 32 | 38 | L | R | Seq. | Hereditary | NHS | Nuc 6 | Nuc 6 |
| 24 | M | 36+ | Bilateral | 41 | 41 | R | L | Sim. | Hereditary | NHS | Nuc 6 | Nuc 6 |
| 25 | F | 36+ | Bilateral | 13 | 13 | R | L | Sim. | Hereditary | NHS | Nuc 6 | Nuc 6 |
| 26 | M | 36+ | Bilateral | 20 | 20 | R | L | Sim. | Hereditary | NHS | Kanso | Kanso |
| 28 | M | 36+ | Bilateral | 38 | 43 | L | R | Seq. | Hereditary | NHS | Nuc 6 | Nuc 6 |

M: Male, F: Female, R: Right, L: Left, CI: Cochlear implants, CI1: The first cochlear implantation, CI2: The second cochlear implantation, GA: Gestation age, Imp: Implantation, NA: Not applicable, Seq.: Sequential, Sim.: Simultaneus, NHS: Newborn hearing screening, Nuc: Nucleus cochlear implant model

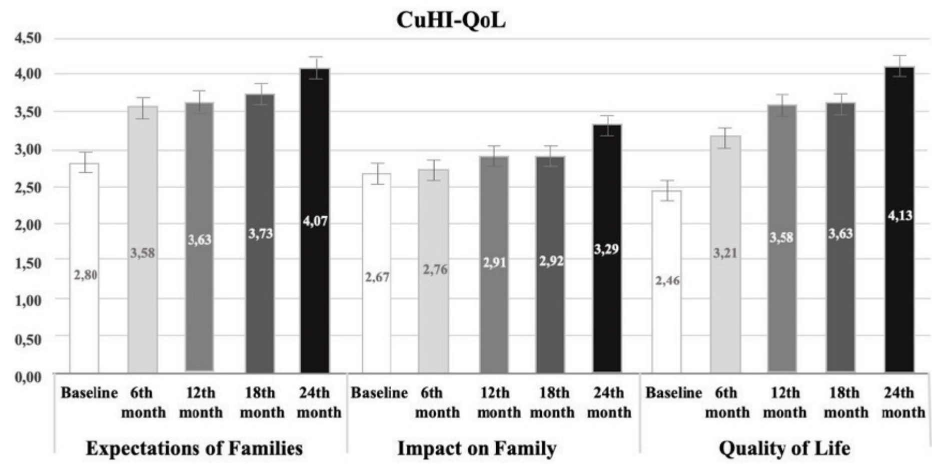


**Figure 1.** Quality of life for families of children using hearing implants parental perspective. Each column, gradually darkening from white to black, represents the scores obtained from the expectations of families, the impact on family and quality of life parts of the CuHI-QoL questionnaire at 6-month intervals from baseline to 24-month.

CuHI-QoL: Children using the Hearing Implants Quality of Life

of the Friedman's test showed significant change in family expectation [$x^2(4)=52.92$, $p<0.001$], impact on family [$x^2(4)=53.02$, $p<0.001$], and quality of life [$x^2(4)=78.29$, $p<0.001$] parts of CuHI-QoL at the different time points after the cochlear implantation [$x^2(3)=63.14$, $p<0.001$]. Nearly all scores statistically improved between the subsequent time points ($p<0.001$), the only exceptions being between scores at the 12$^{th}$ and 18$^{th}$ month (p=0.302), and at the 18$^{th}$ and 24$^{th}$ month (p=0.206). The statistical analysis results showed that the variables of sex, bilateral or unilateral CI use, and sequential or simultaneous bilateral implantation did not have a significant impact on family satisfaction scores at any time point during the evaluations ($p>0.05$).

## Categories of Auditory Performance

CAP-II scores were statistically significantly different at the different time points after the cochlear implantation intervention one in both unilateral and bilateral CI users. [$x^2(4)=107.01$, $p<0.001$). Post-hoc analysis showed a significant increase in CAP-II scores at all-time intervals from baseline to 24$^{th}$ months ($p<0.05$), excluding between scores at the baseline and 6$^{th}$ month (p=0.340), at the 6$^{th}$ and 12$^{th}$ month (p=0.079), at the 12$^{th}$ and 18$^{th}$ month (p=0.143), and at the 18$^{th}$ and 24$^{th}$ months (p=1.000). The most significant difference between consecutive measurements was observed between the baseline and 6-month time points in the subcategories of expectation of families and quality of life, while the impact on the family was observed between 18 and 24 months (Figure 2).

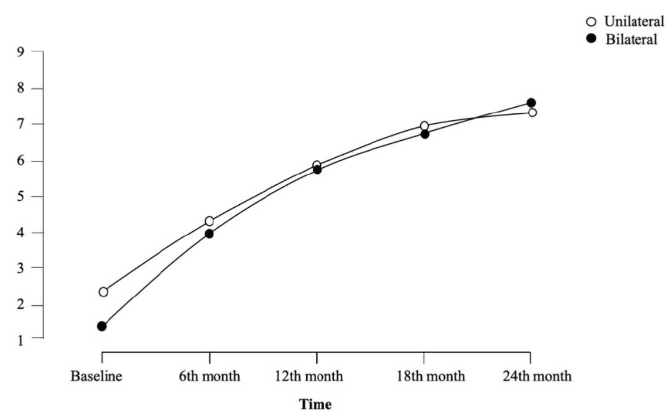


**Figure 2.** Comparison of the difference between CAP-II scores obtained at 6-months intervals in bilateral and unilateral CI users. Each point shows the changes over time of the CAP-II scores at 6-month intervals from baseline to 24-month. The white points indicate unilateral CI users' scores, and the black points bilateral CI users' scores.

CAP-II: Categories of Auditory Performance, CI: Cochlear implants

## The Speech, Spatial, and Qualities of Hearing Scale-parents' Version

The SSQ-P scores obtained at 6-month intervals after the CI1 activation were statistically significantly increased in each control compared with the previous one in both unilateral and bilateral CI users. Friedman's test shows that time has a significant effect on speech perception

[$x^2(3)=82.84$, $p<0.001$], spatial hearing [$x^2(3)=82.84$, $p<0.001$], and other qualities of hearing [$x^2(3)=78.39$ $p<0.001$] parts of SSQ-P. Post-hoc comparisons with Bonferroni correction showed significant increases on speech perception scores of SSQ-P between baseline and 6th (p=0.022), 12th (p<0.001), 24th (p<0.001) months, 6th (p<0.001) and 24th months (p<0.001), and 12th and 24th months (p=0.022); on spatial hearing scores of SSQ-P between baseline and 6th (p=0.030), 12th (p<0.001), 24th months (p<0.001), and 6th month and 12th (p=0.022) and 24th months (p<0.001); on other qualities of hearing scores of SSQ-P between baseline and 6th (p=0.022), 12th, 24th months (p<0.001), and 6th month and 12th (p=0.014) and 24th months (p<0.001).The most significant difference in consecutive measurements of SSQ was observed between the baseline and the 6th month evaluations in both unilateral and bilateral CI users in all subcategories (Figure 3).

There was a moderately significant negative correlation between the age of CI1 of all CI users and SSQ-P scores in all evaluation times (SSQ-P at baseline and age of CI1, r=-0.453, p=0.015; SSQ-P at 6th month and age of CI1, r=-0.533, p=0.004; SSQ-P at 12th month and age of CI1, r=-0.511, p=0.005; SSQ-P at 24th month and age of CI1, r=-0.379, p=0.047). Similarly, a moderate negative correlation was obtained between the age of CI1 and family's satisfaction scores obtained in the assessments at 18th and 24th months (Satisfaction at 18th month and age of CI1, r=-0.406, p=0.032; satisfaction at 24th month and age of CI1, r=-0.409, p=0.031).

There was no statistically significant relationship between the age of CI1, CAP II, and CuHI-QoL scores (p>0.05). There was no statistically significant relationship between CuHI-QoL scores with SSQ-P and CAP-II scores in any evaluation time.

There was a moderately significant positive correlation between SSQ-P and CAP-II scores in all evaluation times, except the SSQ-P scores at baseline (Table 2).

There was a moderately significant relationship between family satisfaction with SSQ-P and CAP-II scores at only a few evaluation times (Table 3).

## DISCUSSION

In this study, we evaluated the two-year retrospective follow-up results of unilateral and bilateral cochlear implanted children, focusing on the auditory performances, social skills, parental expectations, satisfaction, and experiences of children. The unique part of the current study is the use of cross-cultural holistic measures with validated translation; this provides an

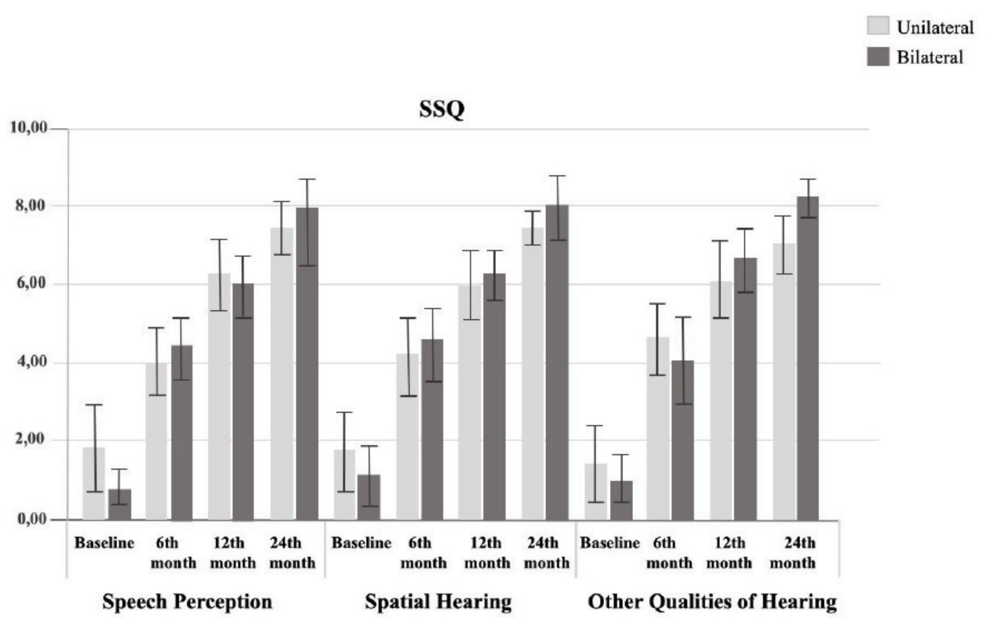


**Figure 3.** Comparison of the difference between SSQ-P scores obtained at 6-months intervals in bilateral and unilateral CI users. Each column shows the changes over time of the scores obtained from the speech hearing, spatial hearing, and other qualities of hearing parts of the SSQ-P questionnaire at 6-month intervals from baseline to 24-month. The grey columns indicate unilateral CI users' scores, and the black columns are bilateral CI users' scores.

SSQ-P: Speech, Spatial, and Qualities of Hearing scale-Parents', CI: Cochlear implants opinion of the parents in judgment and assessment as well as the clinical carers. During the study, all data were entered in the Cochlear P-IROS, which is an evidence-based data recording platform developed to collect clinical, demographic information, and patient-related results obtained in the preoperative and postoperative routine assessment of CI users[21]. This database, which allows longitudinal monitoring of the development of the auditory performance of CI recipients using standardized questionnaires, also provides a unique opportunity to improve auditory, speech, and language outcomes in CI recipients[24]. Therefore, we evaluated any improvements in auditory performance and patient-related benefits of unilateral and bilateral implanted patients, longitudinally, for 24 months at 6-month intervals from the first fitting, and compared the long-term CI outcomes in terms of parameters such as quality of life, patient satisfaction, and auditory performance in unilateral and bilateral configurations.

According to the data obtained from CuHI-QoL questionnaire, it was observed that cochlear implantation in children led to improvements over time in expectations of families and quality of life. Still, the responsibility of having a child with a hearing loss and the logistical impact of that hearing loss on the family did not change much over time. It was also observed that as the child's auditory-verbal language skills improved, the

**Table 2. Relationship between SSQ and CAP-II scores.**

| | | N | Spearman correlation | SSQ | | | |
|---|---|---|---|---|---|---|---|
| | | | | Baseline | 6th month | 12th month | 24th month |
| CAP-II | 6th month | 28 | r | 0.034 | 0.518** | 0.546** | 0.433* |
| | | | Sig. (2-tailed) | 0.863 | 0.005 | 0.003 | 0.021 |
| | 12th month | 28 | r | 0.076 | 0.484* | 0.423* | 0.340 |
| | | | Sig. (2-tailed) | 0.701 | 0.009 | 0.025 | 0.076 |
| | 18th month | 28 | r | 0.188 | 0.589** | 0.594** | 0.415* |
| | | | Sig. (2-tailed) | 0.337 | 0.001 | 0.001 | 0.028 |
| | 24th month | 28 | r | 0.098 | 0.521** | 0.488* | 0.397** |
| | | | Sig. (2-tailed) | 0.620 | 0.004 | 0.012 | 0.036 |

*p<0.05, **p<0.001, N: Number of subjects, SSQ: Speech, Spatial, and Qualities of Hearing scale, CAP-II: Categories of Auditory Performance

**Table 3. Relationship between Family Satisfaction scores of the IRF form with SSQ and CAP-II scores.**

| | | N | Spearman correlation | Satisfaction | | | |
|---|---|---|---|---|---|---|---|
| | | | | 6th month | 12th month | 18th month | 24th month |
| SSQ | 6th month | 28 | r | 0.086 | 0.455* | 0.154 | 0.289 |
| | | | Sig. (2-tailed) | 0.664 | 0.015 | 0.434 | 0.136 |
| | 12th month | 28 | r | 0.199 | 0.573** | 0.357 | 0.364 |
| | | | Sig. (2-tailed) | 0.310 | 0.001 | 0.062 | 0.057 |
| | 18th month | 28 | r | 0.155 | 0.606** | 0.502** | 0.521* |
| | | | Sig. (2-tailed) | 0.431 | 0.001 | 0.006 | 0.004 |
| | 24th month | 28 | r | 0.229 | 0.488** | 0.448* | 0.348 |
| | | | Sig. (2-tailed) | 0.242 | 0.008 | 0.017 | 0.069 |
| CAP-II | Baseline | 28 | r | 0.183 | 0.458* | 0.302 | 0.001 |
| | | | Sig. (2-tailed) | 0.352 | 0.014 | 0.118 | 0.994 |
| | 6th month | 28 | r | 0.230 | 0.591** | 0.370 | 0.151 |
| | | | Sig. (2-tailed) | 0.240 | 0.001 | 0.052 | 0.444 |
| | 12th month | 28 | r | -0.064 | 0.319 | 0.238 | 0.165 |
| | | | Sig. (2-tailed) | 0.747 | 0.098 | 0.222 | 0.400 |
| | 24th month | 28 | r | -0.008 | 0.348 | 0.198 | -0.047 |
| | | | Sig. (2-tailed) | 0.967 | 0.070 | 0.313 | 0.814 |

*p<0.05, **p< 0.001, N: Number of subjects, SSQ: Speech, Spatial, and Qualities of Hearing scale, CAP-II: Categories of Auditory Performance, IRF: Implant Recipient Follow-up family's outlook on their children's future success and happiness and their quality of life improved. A previous study that evaluated the one-year experiences of pediatric CI users conducted by Singh et al.[25] Found that the children's quality of life and the impact on the family improved significantly in one year. In contrast, parents' expectations from their children decreased during the first three months. Another study by Loy et al.[26] reported that the quality of life increased significantly in the first year with early implantation and long-term implant use and did not show a significant difference in the period from one year to two years. These results are broadly consistent with our observations of a spike in the quality of life score in the first six months, followed by a gentle accrual after that. Although it is thought that this finding based on a family perspective may be related to the increase in the auditory performance of their children in the first year, the lack of a meaningful relationship between SSQ-P scores and quality of life scores did not support this view. On the other hand, in the study by Necula et al.[27], it was determined that the quality of life was positively correlated with auditory performance and speech intelligibility.

One of the main objectives of this study was to determine whether there was a difference in the impact on family and quality of life between unilateral or bilateral CI use, and simultaneous or sequential bilateral implantation. However, no significant differences were found based on these variables at any subcategories of the CuHI-QoL. This is especially important it reveals that the second implantation does not increase the impact and burden on the family. Similarly, in a cross-sectional study by Lovett et al.[28] No difference was found between bilateral and unilateral users in terms of health benefits. This result has been interpreted in different ways. First, bilateral implantation outcomes may not be associated with CuHI-QoL scores. Second, it may take longer for the advantages of bilateral implantation to emerge and for families to realize these advantages. Third, the parents of unilaterally implanted children may have left little headroom for any advantages of bilateral implantation, giving a higher rating of health utility and quality of life. Fourth, the studies may not be well-designed to detect small differences in health utility gain associated with bilateral implantation[28].

Another parameter we studied was sex, and we found no significant difference in CuHI-QoL scores between girls and boys. Studies conducted with children with normal hearing in the literature show that there is a tendency for sex differences in issues that may affect the quality of life[29-32]. The studies report that boys are more prone to psychosocial difficulties and problems with peer relationships than girls, who are generally more sensitive and socially mature and who score better on language measures, indicating that have better communication skills[30,31]. It has been reported that trends in sex-related traits are also similar among children with hearing loss. Sach and Barton[33] previously found that among unilaterally implanted children, boys scored lower than girls in a general HR-QOL questionnaire filled out by parents. It is possible that the differences between the sex become evident and increase with age. It is thought that the reason why there was no difference in the quality of life scores in terms of sex in our study may be the low average age of the children in our study of just 26-month of age at implantation.

Data obtained from the IRF form showed that parents' satisfaction with the progress of their children's hearing, listening, speech, and language development changed positively over time. Parents' positive thoughts about implantation and their determination to recommend implantation to others have also steadily increased. In addition, there was no significant difference in the 6-month to 24-month evaluations of total IRF scores in terms of sex, bilateral or unilateral implant use, and the sequential and simultaneous implantation model. However, the total family satisfaction score in unilateral users exhibited a marginal increase between 6-month and 12-month, whereas it increased gradually in all evaluation intervals in bilateral implant users. When performed at the appropriate time, children with CIs demonstrate rapid progress in hearing, language, and speech development within a few months after the implantation. This progress is usually noticeable to the child's family and caregivers, as they start to respond to sounds, recognize voices and develop new vocabulary. The benefits of a CI2, however, are more related to the spatial aspects of hearing, such as the ability to localize sounds and separate speech from background noise. These benefits may be more difficult to assess through observation alone, and may require more specialized testing and evaluation. Therefore, family satisfaction scores may have shown a sharper increase in the early period after the first implantation compared with the second implantation.

Data obtained from SSQ-P and CAP-II tests show that all children with CI, both bilateral and unilateral, have significantly improved in auditory and verbal skills over time. There are many studies in the literature that support this finding[34-36]. In our study, it was observed that the most significant improvement was in the first 6 months in both groups, and it continued to increase gradually in the following processes. This indicates that the maturation of the auditory pathways begins to recover very quickly with auditory stimulation by CI. In addition, the correlation obtained between the age of the first implantation and SSQ-P scores, reveals the positive effect of early neuroplastic processes on CI outcomes.

This study has some limitations due to its retrospective nature. We gathered the data with parent questionnaires, and the possible bias in the data collection should be kept in mind. We did not compare/crosscheck P-IROS results with behavioral and objective audiological measure; the results obtained reflect the parents' viewpoint. Another limitation is that the participants of the study are recruited from the parents willing to participate in the study, potentially limiting the demographic of the study sample. Future research conducted over a longer period with more detailed parameters will likely resolve some complexities discussed above.

## CONCLUSION

Regardless of whether CI is implanted unilateral or bilateral, sequentially or simultaneously, family expectations, well-being, quality of life, and auditory and language skills all improve with adequate and earlier CI intervention. Parents' positive sentiments toward implantation have progressively improved in both groups, as has their desire to suggest it to others. Although the cohort is relatively small and variable, the results offer a descriptive view to outcomes in real-world practice.

### Ethics

**Ethics Committee Approval:** The Marmara University Faculty of Medicine Clinical Research Ethics Committee approved the study with the protocol code 09.2021.149 (date: 05.03.2021).

**Informed Consent:** All parents with implanted children gave written informed consent and assent forms before beginning filling questionnaires.

**Peer-review:** Externally and internally peer-reviewed.

### Author Contributions

Concept: S.C., Design: S.C., S.T., Data Collection and/or Processing: S.C., A.C., S.T., Analysis and/or Interpretation: S.C., A.C., Literature Search: S.C., Writing: S.C., A.C., S.T.

**Conflict of Interest:** The authors have no conflict of interest to declare.

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