

# Cochlear implantation at King Abdallah Medical City, Makkah, Saudi Arabia

## Single institution experience, a 5-years retrospective analysis

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### ABSTRACT

**الأهداف:** مراجعة نتائج برنامج زراعة القوقعة الصناعية في مركز الملك عبدالله الطبي بمكة المكرمة منذ إنطلاقه في عام 2018 إلى عام 2023، مع التركيز على التركيبة السكانية للمرضى والتفاصيل الإجرائية والمضاعفات.

**المنهجية:** أجرينا تحليل بأثر رجعي على 133 مريضاً خضعوا لزراعة القوقعة الصناعية في مدينة الملك عبد الله الطبية خلال الفترة من مايو 2018م ويونيو 2023م. وتضمنت البيانات التي تم جمعها التركيبة السكانية، وأنواع فقدان السمع، والنتائج التشريحية من التصوير، وأنواع أجهزة زراعة القوقعة الصناعية، والتحديات الإجرائية، والمضاعفات.

**النتائج:** كان متوسط عمر المرضى  $9.27 \pm 15.18$  سنة، و56.4% منهم ذكور. كان 96.2% من السعوديين و50.4% من مكة. كان لدى 19.5% تاريخ عائلي لفقدان السمع، و20.8% كانوا خدجا. استخدمت أجهزة «مد-إل» في 63.9% من الحالات، و37.6% كان لديهم زراعة ثنائية. حدثت مضاعفات أثناء العملية في 5.3%، وبعد العملية في 11.3% من المرضى.

**الخلاصة:** أظهرت زراعة القوقعة في KAMC نتائج إيجابية مع مضاعفات قليلة، والتزام عالي بالمتابعة.

**Objectives:** To review the outcomes of the cochlear implantation program at King Abdallah Medical Center (KAMC) in Makkah from its launch in 2018 to 2023, focusing on patient demographics, procedural details, and complications.

**Methods:** A retrospective analysis was conducted on 133 patients who underwent cochlear implantation (CI) at KAMC between May 2018 and June 2023. Data collected included demographics, hearing loss types, anatomical findings from imaging, types of CI devices, procedural challenges, and complications.

**Results:** The average age of the patients was 9 years (108 months) with 56.4% males and 96.2% Saudi nationals. Most patients (50.4%) were from Makkah, and 19.5% had a family history of hearing loss. Med-El implants were used in 63.9% of cases, and 37.6%

had simultaneous bilateral implants. Intraoperative complications occurred in 7 (5.3%) patients, while 11 (8.3%) patients experienced postoperative complications. Follow-up adherence was high at 94%, with 18.8% of patients using telehealth services for monitoring.

**Conclusion:** The CI program at KAMC has demonstrated to be a safe and effective approach for treating severe-to-profound hearing loss. Minor complications were observed, and follow-up adherence was strong. The study emphasizes the importance of ongoing accreditation and support for the program to ensure its success in hearing rehabilitation.

**Keywords:** cochlear implantation, cochlear implants, cochlear nerve, hearing loss

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According to the World Health Organization (WHO) in 2023, around 1.5 billion people globally have hearing loss, with 1.1 billion young individuals at risk of permanent hearing impairment. This is believed to reach 2.5 billion individuals with disabling hearing loss

by 2050.<sup>1</sup> While Saudi Arabia is the second country in the Middle East with a higher incidence of hearing loss, the prevalence of hearing loss in Saudi Arabia differs according to the region, as we have a country with vast areas.<sup>2</sup> Additionally, it is considered high prevalence due to lots of congenital conditions, consanguineous marriages, and early childhood hearing impairment.<sup>3-5</sup>

After reviewing Saudi Studies, 0.7% of Saudi people had severe to profound sensory-neural hearing loss, and Saudi children with sensory-neural hearing loss were ranging from 7.7% to 13%.<sup>6-9</sup>

Nowadays, Saudi Arabia is a leader in hearing restoration and rehabilitation, including CI programs. According to the Ministry of Health, the CI program conducts over 500 surgeries annually.<sup>10</sup>

Cochlear implantation has revolutionized the management of profound sensorineural hearing loss, providing significant auditory and communicative benefits to pediatric and adult populations. Since its introduction, CI has been recognized as a highly effective intervention for individuals who do not benefit from conventional hearing aids. The global success of CI is evidenced by numerous studies reporting substantial improvements in auditory thresholds, speech recognition, and quality of life across diverse patient demographics.<sup>11-13</sup>

The Kingdom of Saudi Arabia has seen a marked increase in the adoption of CI, with several medical centers, including King Abdallah Medical City (KAMC), establishing robust CI programs. These programs are tailored to address the needs of an increasing number of patients with hearing loss. Driven by advancements in surgical techniques and technology, as well as the increasing awareness and diagnosis of hearing impairments.<sup>14</sup> However, while CI has been extensively studied in Western populations, there is a relative paucity of data from Middle Eastern countries, particularly regarding long-term outcomes and patient satisfaction in this region.<sup>15</sup>

Recent studies have highlighted the importance of early intervention, particularly in pediatric patients, to maximize CI's auditory and speech development benefits. Early CI has been associated with better speech perception and language acquisition outcomes, making it a critical area of focus for CI programs worldwide.<sup>16</sup> In adults, particularly those with postlingual hearing

loss, CI has been shown to significantly enhance speech recognition in both quiet and noisy environments, leading to improved communication abilities and social integration.<sup>17</sup>

Makkah is a big city in Saudi Arabia, with a population of more than 8 million. KAMC started providing a service for Makkah residents in 2009, and the CI program began in 2018. It is the only program in Makkah City offering state-of-the-art surgical and rehabilitative services to a diverse patient population.<sup>18</sup>

This study aims to evaluate the outcomes of the CI program at KAMC, focusing on surgical success, auditory gains, complication rates, and patient satisfaction. This research seeks to add valuable data to the growing body of literature on CI by comparing its outcomes with those documented in similar studies globally, with a particular focus on the Middle Eastern context.<sup>19</sup>

**Methods.** This retrospective study was carried out at King Abdullah Medical City (KAMC) in Makkah, Saudi Arabia, covering the period from May 2018 to June 2023. It included all patients who underwent CI at KAMC during this time. The study included 133 patients from various age groups who underwent CI at KAMC between May 2018 and June 2023. All participants had severe-to-profound sensorineural hearing loss and received multi-channel electrode cochlear implants. Patients were excluded from the study if there was insufficient data or if their surgeries were performed at other hospitals.

Data were collected using a pre-designed checklist, which included patient demographics, type of hearing loss, anatomical variations observed in temporal CT scans and MRI images, cochlear implant device used, procedural difficulties, and complications encountered. Major complications that have serious consequences impacting the success of the implantation and often require medical intervention, surgical procedure, or even prolonged treatment, such as meningitis, implant extrusion, cerebrospinal fluid (CSF) leakage, and facial palsy, and minor complications that are short-term non-life-threatening conditions and typically resolved with minimal conservative management, such as wound hematoma and infection were meticulously documented. Data were extracted from electronic medical records and recorded in an electronic data collection sheet. Further, patients were anonymized using serial study codes and initials, with identifiable information kept secure in a separate log sheet stored in a secure location. Finally, data entry was performed by 2

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independent individuals to ensure accuracy. This study utilized 3 CI systems: Cochlear, Med-El, and Advanced Bionics. The system choice depended on various factors, including patient-specific needs and device availability.

The study protocol was approved by the King Abdullah Medical City Research Ethics Committee, Makkah, Saudi Arabia. All patient data were handled in compliance with ethical standards to ensure confidentiality and integrity.

**Data analysis.** Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software for Windows, version 26 (IBM Corp., Armonk, NY, USA). Qualitative data were presented as frequencies and percentages, while quantitative data were expressed as means and standard deviations (mean  $\pm$  SD). The relationships between various variables were evaluated using appropriate statistical tests.

**Results.** A total of 133 patients from various age groups were included in this study. As outlined in **Table 1**, the average age of pediatric patients was 3 years, and of adult patients was 36 years. Of the total, 56.4% were males, and 96.2% held Saudi nationality. Additionally, nearly half of the participants (50.4%)

were from Makkah City. Only 26% of the patients had a positive medical history, with the most common condition being unilateral CI (18%). Only 19.5% of the patients had a positive family history of hearing loss.

**Table 2** shows that 24 (18%) of the studied patients had an eventful perinatal history, including prematurity (20.8%), birth asphyxia, infection during pregnancy, and congenital anomaly (16.6%). Of those with an eventful perinatal history, 70.8% required neonatal intensive care unit admission. Additionally, most patients (78.9%) were up-to-date with vaccines at the presentation time. Moreover, 72.9% of the patients had bilateral profound sensorineural hearing loss.

**Cochlear implant devices and companies.** The cochlear implant program at KAMC mainly utilized devices from three companies: Cochlear, MEDEL, and AB. MEDEL devices were the most frequently used, comprising approximately 63.9% of the total implants (**Table 3**).

**Surgery and implantation details.** Ninety-six percent of cases were primary implantations. Right-side implantation was prevalent, accounting for 37 cases. The most common electrode type was "Flex 28" (used in 43 cases). The types of processors used varied, with "synchrony" being the most frequently utilized processor, and it appeared in 33 cases (**Table 3**).

**Intraoperative and postoperative complications** (**Table 4**). Intraoperative complications were observed in 7 patients, representing 5.3% of the total cohort. The specific intraoperative complications included:

**Electrode insertion difficulty:** Some patients experienced challenges with proper electrode insertion into the cochlea. This entity was managed preoperatively by evaluating the patient's history for patient-specific considerations like a history of trauma or infection, comprehensive imaging assessment, and proper electrode array choice; intraoperatively by the possibility of extended round window versus cochleostomy insertion, gradual insertion, and electrophysiological monitoring; and postoperatively by imaging, follow-up, and rehabilitation.

**Procedure termination due to perforated tympanic membrane:** In certain cases, the procedure had to be terminated because of an iatrogenic tympanic membrane perforation.

**Difficulty visualizing the round window:** Sometimes, the round window is not clearly visible, which can be predicted preoperatively in imaging assessment or faced intraoperatively after making posterior tympanotomy, complicating electrode placement and necessitating the possibility of an extended round window or cochleostomy insertion.

**Table 1 -** Distribution of studied patients according to their demographics, comorbidity and family history of hearing loss (N=33).

Variable	n (%)
<b>Age (mean 9 years, 108 months)</b>	
Pediatric (mean 3 years, 36 months)	108 (81.2)
Adult (mean 36 years, 432 months)	25 (18.8)
<b>Gender</b>	
Female	58 (43.6)
Male	75 (56.4)
<b>Nationality</b>	
Non-Saudi	5 (3.8)
Saudi	128 (96.2)
<b>Residency</b>	
From Makkah	67 (50.4)
From outside Makkah	66 (49.6)
<b>Comorbidity</b>	
No	77 (74.0)
Yes	27 (26.0)
<b>If having comorbidity, specify ?(n=27)</b>	
Sudden sensory neural hearing loss (SSNHL)	5 (3.8)
Consanguinity	10 (7.5)
Cochlear implantation	24 (18)
Cardiac disease	7 (5.3)
Dihydroliipoamide dehydrogenase (DLD)	3 (2.3)
Enlarged vestibular aqueduct syndrome (EVAS)	3 (2.3)
Epilepsy	2 (1.5)
Pierre Roben sequel	4 (3.0)
Cogan syndrome	2 (1.6)
Other	26 (19.5)
<b>Family history of hearing loss</b>	
No	107 (80.5)
Yes	26 (19.5)

**Table 2 -** Distribution of studied patients according to peri natal history, vaccination status, auditory brainstem response (ABR)– pure-tone audiometry (PTA) (N=133).

Variable	n (%)
<i>Abnormal perinatal history</i>	
No	109 (82)
Yes	24 (18)
<i>If abnormal perinatal history, specify: (n=24)</i>	
Birth asphyxia	4 (16.6)
Infection during pregnancy	4 (16.6)
NICU admission	17 (70.8)
Cytomegalovirus	2 (8.3)
High grade fever and meningitis	3 (12.5)
Prematurity	5 (20.8)
Congenital anomaly	4 (16.6)
<i>Vaccination status</i>	
Needing vaccines pre-operative	28 (21.1)
Vaccinated up to date at time of presentation	105 (78.9)
<i>ABR – PTA</i>	
Bilateral profound SNHL	97 (72.9)
Bilateral severe to profound SNHL	1 (0.8)
Bilateral severe to profound SNHL with DLD	2 (1.5)
Bilateral total hearing loss	5 (3.8)
Bilateral total SNHL	19 (14.3)
Left total hearing loss and right moderately severe hearing loss	1 (0.8)
Right profound SNHL and left total SNHL	2 (1.5)
Right severe SNHL and left severe to profound SNHL	2 (1.5)
Right side had channels working and open circuit	1 (0.8)
Right total hearing loss and left severe MHL with excellent speech	1 (0.8)
Right total SNHL	1 (0.8)

NICU: neonatal intensive care unit, DLD: Dihydroliipoamide dehydrogenase, SNHL: sensory neural hearing loss

**Table 3 -** Distribution of studied patients according to case, unplanted side, and cochlear implant (CI) company (N=133).

Variable	n (%)
<i>Primary versus revision</i>	
Revision case	5 (3.8)
Primary case	128 (96.3)
<i>Implanted side</i>	
Bilateral simultaneous	50 (37.6)
Left	34 (25.6)
Right	49 (36.8)
<i>CI company</i>	
AB	10 (7.5)
Cochlear	38 (28.6)
Medel	85 (63.9)

**Fibrosis of the round window post-meningitis:** In patients with a history of meningitis, fibrosis of the round window was noted, leading to stiffening and scarring that impacted the surgical procedure.

**Moderate gusher:** CSF gushed from the round window before introducing the electrode in one of our cases, which was managed by minimizing the drilling, slowing the electrode insertion, sealing around the electrode using a small piece of fascia, and close monitoring postoperatively.

Postoperative complications occurred in 11 patients, accounting for 8.3% of the study population. The identified postoperative complications were:

**Minor complications:** Forehead trauma, which unfortunately happened in one patient. Delayed wound healing: One included patient experienced a prolonged wound healing period post-surgery. Postoperative vertigo, nausea, and vomiting: Several patients reported experiencing vertigo and associated symptoms of nausea and vomiting in the postoperative period. Ear infection: including acute otitis media and recurrent ear infections.

**Major complications:** Wound infection and dehiscence: Sometimes, the surgical wound dehisced, necessitating further medical intervention. Facial nerve palsy: One patient with transient grade 4 facial palsy and another patient with grade 6 facial palsy did not improve on steroids, and surgical exploration was mandatory.<sup>23</sup>

**Outcomes and follow-up** (Table 5). A full CI insertion was achieved in most patients in this study, with no significant intraoperative deviations from the planned procedures. During follow-up, the most common observations were related to the successful integration of the implant and its processor, indicating



**Table 4** - Distribution of studied patients according to intraoperative and postoperative complications (N=133).

Variable	n (%)
<i>Intraoperative complications</i>	
No	126 (94.7)
Yes	7 (5.3)
Electrode insertion difficulty	1
Procedure termination due to perforated tympanic membrane	1
Difficulty visualizing the round window	2
Fibrosis of the round window post-meningitis	2
Moderate gusher	1
<i>Post-operative complications</i>	
No	122 (91.7)
Yes	11 (8.3)
Forehead trauma	1
Delayed wound healing	1
Wound infection	2
Wound dehiscence	1
Postoperative vertigo, nausea, and vomiting	2
Ear infection	2
Facial nerve palsy	2

**Table 5** - The follow-up and tele-practice during the COVID crisis.

Variable	n (%)
<i>Follow-up</i>	
No	8 (6.0)
Yes	125 (94.0)
<i>Tele-practice</i>	
No	108 (81.3)
Yes	25 (18.8)

positive outcomes in terms of auditory function and device performance. Not forgetting quality of life improvement, which is considered one of the outcomes of measuring successful CI as it positively impacts patients' lives, their families, and society, leaving them as influential, interactive, and productive persons.

Additionally, due to the constraints imposed by the COVID-19 pandemic, some patients were followed up through telemedicine. This approach allowed for continued monitoring of implant performance and patient progress while adhering to public health guidelines. The use of telemedicine proved to be an effective alternative for post-operative care during follow-up.

**Discussion.** The CI program at King Abdallah Medical City (KAMC) has yielded highly favorable outcomes, underscoring the program's effectiveness as a treatment for profound sensorineural hearing loss. The study has several significant findings:

**High success rates:** The surgical success rate for CI at KAMC was exceptionally high—a complete electrode array insertion was achieved in nearly all patients.

This success is indicative of the precision and skill of the surgical team and the efficacy of the preoperative planning protocols followed in our center, which was discussed and analyzed in a separate research paper, including CT scans and MRI imaging checklist, and the follow-up and rehabilitation plan.

**Low complication rates:** The study found a low incidence of surgical and postoperative complications, such as electrode misplacement or infections. This low rate can be attributed to stringent adherence to surgical protocols and rigorous postoperative care, which were critical in minimizing risks.

**Positive long-term outcomes:** Follow-up assessments indicated that the benefits of CI were sustained over time, with most patients maintaining or improving their auditory performance in the months and years following surgery. This was especially true for young patients, who continued to develop speech and language skills at a pace comparable to that of their hearing peers.

**Patient satisfaction:** Patient-reported outcomes indicated high satisfaction levels with the CI process and the results. Many patients and their families reported significant improvements in their quality of life, social interactions, and overall well-being. This high satisfaction reflects the program's success in meeting the patient's needs and expectations.

The results of this study are in line with those of numerous similar studies conducted both regionally and internationally. For instance, Al-Muhaimeed et al<sup>14</sup> carried out a 12-year study on CI at King Abdulaziz University Hospital in Riyadh, reporting comparable success rates with minimal complications. Their results suggest that the outcomes achieved at KAMC align

with those of other leading institutions in Saudi Arabia.

Recent studies continue to validate CIs' effectiveness in adults and children. For instance, Buchman et al<sup>20</sup> provided updated guidelines emphasizing tailored approaches to electrode selection and mapping strategies, which have likely contributed to the positive outcomes observed in the present study. Similarly, Mertens et al<sup>17</sup> conducted a systematic review and meta-analysis, confirming significant auditory and quality-of-life improvements in adults with postlingual hearing loss who underwent CI. These findings are mirrored in the adult population at KAMC. For pediatric patients, Manzoor et al<sup>16</sup> reported that there were benefits resulting from bilateral CI, particularly regarding speech recognition and spatial hearing, which aligns with the successful outcomes observed among the children treated at KAMC. These results align with the findings by Sladen et al,<sup>19</sup> who reviewed long-term outcomes and found sustained auditory and speech improvements in adults and children, underscoring the importance of continuous follow-up care as practiced at KAMC.<sup>17,21</sup> In elderly patients, Berrettini et al<sup>22</sup> demonstrated that CI remains an effective and cost-efficient intervention, with outcomes in this demographic being significant auditory improvements comparable to those seen in the older patients treated at KAMC.<sup>22</sup>

**Study limitations.** Despite the promising results, the study at KAMC has limitations that should be acknowledged. The study's retrospective nature may have introduced biases related to data collection and reporting. Additionally, the follow-up periods varied among patients, which could impact the long-term assessment of outcomes.

**Implications for Future Practice.** The findings of this study have significant implications for the ongoing advancement of the CI program at KAMC. The program's success, as demonstrated by high rates of positive outcomes, suggests that current surgical and postoperative protocols are effective. However, continuous monitoring and adaptation of the protocols used, especially as new technologies emerge, will be crucial. Addressing the barriers to long-term follow-up and incorporating telehealth innovations while ensuring comprehensive assessments can enhance patient care.

Moreover, the success observed at KAMC highlights the importance of accreditation and ongoing professional development for healthcare providers involved in the CI program. This professional development could include training on new technologies and techniques and enhancing patient support systems to improve long-term outcomes. Future studies could explore the long-term

benefits of different implant types and processors and investigate the impact of continuous follow-up on patient satisfaction and auditory rehabilitation.

In conclusion, the KAMC CI program has successfully delivered effective auditory rehabilitation to a diverse patient population. While the program's outcomes are comparable to those reported by recent studies globally, ongoing research and program evaluation will be essential to maintaining and improving these outcomes. By addressing the limitations identified and leveraging the lessons learned from this study and similar programs worldwide, KAMC can continue to provide high-quality care to patients with profound hearing loss, ensuring they achieve the best possible auditory and quality-of-life outcomes.

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