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ORIGINAL RESEARCH ARTICLE

Cochlear implant technology: Previous, present and future

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ABSTRACT

Cochlear implant (CI) technology can help the majority of patients with severe to profound sensorineural deafness to restore hearing. This technology was first launched in 1800 by the Italian physicist Alessandro Volta who found that electrical stimulation of the normal ear can produce hearing. In the 1960s, it began to enter the practical stage, and underwent technological development in two directions, single-channel and multi-channel. In 1979, the single-channel cochlear implant was successfully developed in Peking Union Medical College Hospital (PUMCH), and the first cochlear implantation in China was performed in 1980 in PUMCH. The first multi-channel cochlear implantation in China was also performed in PUMCH in 1995. As the technology progressed, cochlear implantation with electric-acoustic stimulation (EAS), bilateral cochlear implantation, and robot-assisted cochlear implantation gradually went on stage. The first EAS cochlear implantation in China was performed in 2012 in PUMCH, and research on bilateral cochlear implantation in PUMCH ranks at the forefront in China. With increasing successful cases of surgery, the indications for cochlear implantation have gradually extended. In 2008, preoperative electrical stimulation auditory evoked potential technology was successfully developed in PUMCH, which is novel in China, and by which many difficult and complex cases were successfully implanted with CI. Cochlear implantation for unilateral deafness and tinnitus and robot-assisted cochlear implantation have also been carried out worldwide. The first robot-assisted cochlear implantation in China was successfully performed in 2020 in Shanghai 9th People's Hospital. At the same time, the research of optical cochlear implant has entered the experimental stage. This paper summarizes the development of cochlear implant technology in China and abroad, the current technical expansion and the future development trend, to provide reference for technological progress.

Keywords: cochlear implant; history; development; trend

1. Introduction

In 2021, the World Health Organization issued the first World Hearing Report[1], which pointed out that at present, more than 1.5 billion people in the world have hearing loss, of which 430 million have moderate hearing loss or above. It is estimated that by 2050, the number of people with hearing impairment may reach 3 billion, and more than 700 million people need hearing rehabilitation assistance. According to China's second national sample survey of disabled people[2], 23,000 deaf children are added every year. Among them, 74% of children with severe and extremely severe hearing loss need active attention and timely hearing rehabilitation.

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Cochlear prosthesis is a very successful biomedical engineering technology in clinical medicine, which can help most patients with severe to very severe sensorineural hearing loss recover their hearing, regain the ability of speech and understanding close to normal people, and integrate into the mainstream society. The successful development of cochlear implants is the result of multidisciplinary efforts, including the coordination and joint efforts of professionals in different fields such as engineering, otology, audiology, auditory neurophysiology and acoustic psychology. At present, more than 700,000 cochlear implant operations have been carried out in the world, including more than 70,000 cochlear implant operations in China, and more than 10,000 deaf children meeting the indications of cochlear implant operations are added every year. Therefore, we summarized the development history of cochlear implant technology at home and abroad, the scope of current technology expansion, and looked forward to the future development trend, hoping to provide reference for the progress of cochlear implant technology.

2. History of cochlear implantation

2.1. Early stage

In 1800, Alessandro Volta of Italy conducted electrical stimulation on his ears and found that electrical stimulation of normal ears could produce hearing. In 1940, Clark Jones et al. of the United States used electrode stimulation in the middle ear of 20 patients with otitis media, and the patients' heard voices. Several important inventions in the first half of the 20th century had an important impact on the early development of the artificial cochlea, including the speech synthesis vocoder invented by Homer Dudley, the cochlear microphonic potential discovered by Glenn Wever, and the electric hearing principle described by SS Stevens.

Dudley[3] used the circuit designed by himself in 1939 to extract the strength of the fundamental frequency and frequency components and the total energy of the frequency domain in speech to synthesize understandable speech, and named this device "vocoder". Dudley's principle of speech sound processing provides the basis for early multi-channel cochlear implant speech processing. In 1930, Wever and Bray[4] recorded and described the cochlear potential, which refers to the potential measured after the cochlea is stimulated by sound. This phenomenon is later known as the "Wever Bray" effect Stevens[5] discussed the classic principle of electric stimulation of the cochlea to produce hearing in the 1930s. This response is called "electric hearing". Now it is generally believed that electric hearing comes from the mechanical vibration response of the basement membrane to the voltage change in the cochlea, and the basis of the generation is the complete cochlea.

2.2. Practical stage

The development of cochlear implants has gone through three stages: The first pioneering and experimental stage began in 1957 and continued throughout the 1960s. The second stage occurred in the 1970s, focusing on the feasibility of implants. The third stage focuses on the production of commercial multi-channel cochlear implant. Its three main inventors (Graeme Clark of Australia, Ingeborg Hochamir of Austria and Black Wilson of the United States) won the 2014 Lasker DeBakey Clinical Medical Research Award for their outstanding contributions.

The earliest report on electric stimulation of auditory nerve to produce hearing was the work of Djourno and Eyries[6] in 1957. Their operation on February 25, 1957 was considered to be the first artificial cochlear implantation operation. In 1961, William House and John Doyle of the United States used an electric drill to make a hole in front of the round window of the cochlea. Through this hole, a single electrode was put into the patient's tympanic cavity, which was considered to be the first true cochlear surgery. With the progress and development of pacemaker and ventricular shunt surgery in the late 1960s, House has more confidence in the safety and efficacy of implanted devices. Six years later, William House and Jack Urban worked together to

design a new path for cochlear implant surgery. The first wearable single channel cochlear implant was developed using the button of the percutaneous induction coil House and Urban[7] actively promoted the implantation of single channel devices in patients, and found that a 16,000 Hz carrier frequency signal can help patients appreciate higher frequencies, and the voice after amplitude modulation of speech signals is the best. The signal processor strategy becomes the standard speech processing strategy of the 3M cochlear implant developed by House Another important early research result of them was to abandon multi-channel system and use single channel system instead. They established 3M Company. The 3M single channel implant device of House was implanted into thousands of patients in the early 1980s, and was approved by the Food and Drug Administration (FDA) in 1984.

The development direction of cochlear implant technology is single line multi-channel technology. Other research centers focus on research and development of multi-channel equipment, including Simmons and White teams, Michelson teams and Clark teams. At the same time, other European countries also have teams to carry out human or animal experiments to develop multi-channel systems. On May 7, 1964, the team of Blair Simmons and Robert White of the United States implanted a 6-channel electrode into the patient's cochlea during the operation, which was considered the first multi-channel cochlear implant operation[8]. The term "cochlear implant" appeared for the first time in the paper.

Graeme Clark, an Australian otologist, elaborated on the limitations of the practicability of single channel cochlear implant in his graduate thesis in 1969. He adopted a systematic and scientific approach to develop multi-channel cochlear implant, which includes developing speech processing strategies, optimizing electrode arrays and developing a safe and reliable implantable receiver stimulator. In 1981, Clark[9] completed a multi-channel cochlear implant, which became the first commercial multi-channel cochlear implant. Clark et al. reported their main achievements in the study. First, they performed cochlear fenestration through a circular window niche. The electrode array was implanted in the anterograde direction of the circular window niche fenestration, causing little damage to the cochlear structure. Second, the dissolution of platinum wire electrode caused by biphasic pulse stimulation was the least. In 1985, FDA approved the use of multi-channel cochlear implants made in Australia in adult patients, and in 1990, it was approved for use in children aged 2 years and under.

2.3. History of domestic research

In the 1970s, Peking Union Medical College Hospital carried out animal experiments on cochlear electrical stimulation, and cooperated with Beijing University of Technology and other research institutions to develop a single channel cochlear implant. In 1979, the first-generation single channel cochlear implant was successfully developed in Peking Union Medical College Hospital. In 1980, the first cochlear implant in China was completed, making the deaf hear. In the late 1980s, socket multi-channel cochlear implant was developed. From the 1980s to the early 1990s, several training courses on cochlear implantation were held in China. In 1984, the Ophthalmology and Otolaryngology Hospital affiliated to Shanghai Fudan University successfully developed a domestic single channel pulse cochlear implant. Up to the early 1990s, nearly 1,000 patients in Beijing, Shanghai, Xi'an and other places had been implanted with domestic cochlear implants. Many patients have obtained certain electric hearing, which can assist lip reading for language communication.

The practical stage of multi-channel cochlear implant in China began in the mid-1990s. In May 1995, Beijing Union Medical College Hospital[10] completed the first multi-channel cochlear implant in China, and the patients gained good open hearing and speech ability after surgery. Since then, Peking Union Medical College Hospital has successfully completed thousands of cochlear implants, including many complex and difficult cases. In 1996, Beijing Tongren Hospital implanted the first multi-channel

cochlear implant for children in China.

In 1997, the "multi-channel programmed cochlear implant" developed by the Eye, Ear, Nose and Throat Hospital affiliated to Shanghai Fudan University was granted the national invention patent. In 2004, Shanghai Listent Medical TECH Co., Ltd transferred its technology and began its industrialization. In 2011, the domestic artificial cochlear REZ-I was granted the product registration certificate Hangzhou Norcom was established in 2006. Its cochlear implant system with independent property rights obtained the registration certificate for adult and child patients issued by the China Food and Drug Administration in August 2011 and August 2013 respectively. In 2011, the Morningstar cochlear implant system was officially marketed Shenyang Aiyisheng Cochlear System began clinical validation in 2011. At present, domestic cochlear implants have been used in clinical practice, and their further development still has a long way to go.

2.4. Basic research on cochlear implant technology-speech strategies

In the late 1970s and early 1980s, studies showed that electrode interference could be minimized through asynchronous stimulation and dislocation stimulation. Another finding is that asynchronous stimulation with a pulse rate greater than 1 kHz can significantly improve the effective speech comprehension of the implant. The University of California, San Francisco, and Triangle College jointly used this concept to test and implement this speech processing scheme, and applied for a patent, which is called continuous interleave sampling (CIS). CIS scheme makes great progress in speech recognition of implant. In the late 1970s, the University of Utah developed the first commercial multi-channel cochlear implant. Its speech processor divided the voice into four different channels, and then compressed the analog signal output from each channel to adapt to the narrow dynamic range of electrical stimulation. This speech processing scheme is called compressed analog (CA).

In the early 1980s, the University of Melbourne, Australia successfully developed a Nucleus cochlear implant device with 22 intracochlear annular electrodes. The design idea of Nucleus speech processor is to extract important speech features, such as fundamental frequency and formant, and then transmit them to the corresponding electrode by encoding Nucleus processor is characterized by biphasic pulse, bipolar stimulation, time-sharing stimulation of different electrodes and stimulation frequency not exceeding 500 Hz. The speech processing scheme has evolved from the original one that only extracts the information of the fundamental frequency and the second formant (F0F2) to the WSP processor (F0F1F2) with the first formant, the multi peak processor with F0F1F2 and three high-frequency peaks, and the current one that only extracts the information of any six highest energy frequencies in 22 analysis bands.

The CIS speech processor developed by American Wilson et al.[11] from the perspective of information content, CIS and CA processors are basically the same, but CIS has the advantage of avoiding the problem of electric field interference caused by simultaneously stimulating multiple electrodes. Although CIS and Nucleus both use biphasic pulse interval stimulation, they have the following two differences: First, each electrode of CIS uses a high-frequency (800–2,000 Hz) pulse train for constant speed and continuous stimulation, even in silence, but its pulse amplitude drops to the threshold level. Second, the analysis frequency band of CIS is consistent with the number of stimulating electrodes. At present, CIS speech processing scheme is adopted and improved by most cochlear implant companies in the world, such as AB's S series scheme, Nucleus's ACE scheme and MEDEL's fast CIS scheme.

2.5. Artificial cochlear technology and deafness gene research

According to literature, about 60% of deafness patients are related to genetic factors[12]. About 30% of deafness caused by genetic factors are syndromic deafness, and 70% of non-syndromic deafness. In

patients with syndrome type deafness, autosomal recessive inheritance accounts for 75%–80%, autosomal dominant inheritance accounts for 20%, 2%–5% is X-linked inheritance, and 1% is maternal inheritance of mitochondrial mutation. With the development of deafness gene research, gene diagnosis is gradually used to help patients with cochlear implants to perform preoperative evaluation.

At present, there are about 400 kinds of syndromic deafness reported[13], and the more common ones in clinic are Waardenburg syndrome, Van der Hoeve syndrome, Usher syndrome, CHARGE syndrome, Alport syndrome, etc. Syndromic deafness involves many systems and many pathogenic genes. With the progress of medical science and technology, more and more deaf patients hope to improve their hearing through the treatment of patients with syndrome. Gene diagnosis can help doctors evaluate whether cochlear implantation benefits patients.

GJB2 gene mutation in non-syndromic deafness is the most common deafening gene in the Chinese population. The carrying rate of normal people is 11.71%, and 20% of deaf patients are deaf due to this gene mutation, which belongs to autosomal recessive inheritance[13]. This gene defect only causes the presynaptic structure abnormality of inner ear hair cells, so the rehabilitation effect after cochlear implantation is good SLC26A4 gene mutation is the second major deafness gene in China. The carrier rate of normal people is 3%, which causes autosomal recessive DNFB4 and Pendred syndrome. Vestibular aqueduct enlargement (with or without Mondini malformation) is the most common malformation in the inner ear, accounting for 78.2%. Most patients have severe or extremely severe neurological hearing loss, and a few have delayed hearing loss of varying degrees. Trauma and cold can induce or aggravate hearing loss. Early gene detection found that the hearing loss caused by this gene mutation can slow down the occurrence of deafness and protect speech development by preventing the inducement. According to the literature, the speech recognition rate of patients with large vestibular aqueduct syndrome caused by this gene mutation after cochlear implantation is significantly higher than that of patients without this gene mutation[14].

The mutation of POU3F4 gene leads to the IP-III type in Mondini malformation, which is X-linked recessive deafness DFNX2. The genetic characteristics are female carriers, male carriers, and severe or extremely severe sensorineural deafness. CT images showed enlargement of the internal auditory canal floor, cochlea connected with the internal auditory canal, and absence of the cochlear axis. Cochlear implantation can help to obtain hearing. Due to structural abnormalities, there will be complications such as electrode insertion into the internal auditory canal, cerebrospinal fluid blowout and cerebrospinal fluid leakage after surgery. The speech recognition rate, hearing and speech rehabilitation ability of DFNX2 deaf patients caused by POU3F4 gene after cochlear implantation are lower than the average level of patients with normal cochlear structure[15].

Mitochondrial 12S rRNA gene mutation is the responsible gene for drug-induced hearing loss[16]. The most common mutation sites in Chinese population include A1555G, C1494T, etc. The mutation rate of C1494T site is 0.16%, and the mutation rate of mitochondrial A1555G site is 1.76%. About 20%–30% of drug-induced hearing loss is related to it. The effect of cochlear implantation in patients with drug-induced deafness caused by this gene mutation is better.

Auditory neuropathy is a group of diseases characterized by normal function of inner ear hair cells (otoacoustic emission (OAE) and/or cochlear microphonic potential (CM) can be elicited), and abnormal function of auditory nerve (abnormal or total disappearance of auditory brainstem response (ABR)). At present, studies have found that 40% of patients with auditory neuropathy are related to genetic factors. Twenty genes related to auditory neuropathy have been reported, including PJVK, DIAPH3, OTOF, SLC17A8, SLC19A2, 12SrRNA related to non-syndromic type, GJB3, OPA1, NF-L, MPZ, PMP22, NDRG1, FXN, TIMM8A, GJB1,

TMEM126A, WFS1, AIFM1[17] genes related to syndromic type. It has also been reported that mitochondrial mutation MTND4 (11778mtDNA) and 12rRNA (T1095C) are related to auditory neuropathy, but data are still needed to verify. According to the location of auditory pathway damage caused by gene mutation, it can be divided into three types: auditory neuropathy (postsynaptic type) (MPZ, PJVK), auditory synaptic disease (synaptic and presynaptic type) (SLC19A2, OTOF, SLC17A8, DIAPH3) and non-specific (mitochondrial related). Based on the principle of cochlear implant, different gene mutation patients have different effects after cochlear implant surgery. OTOF gene mutation is the abnormal expression of Otoferlin protein at the synapse, but the auditory nerve is normal. The effect of this kind of patients after cochlear implantation is better than that of patients with postsynaptic lesions. The identification of the genetic causes of auditory neuropathy combined with intraoperative. EABR examination has a positive guiding significance for the preoperative evaluation and postoperative rehabilitation of cochlear implants.

Cochlear implantation technology is also considered to provide hearing rehabilitation assistance for patients with COCH, MYO7A, TECTA, TMPRSS3, TMC1, ACTG1 and other gene mutations. Because the mutation of TMPRSS3 causes lesions in spiral ganglion cells, it is not recommended to perform cochlear implantation in early evaluation, but there are reports at home and abroad that the effect of cochlear implantation for patients with this gene mutation is good[18]. In addition, it is reported that the effect of cochlear implantation in patients with TIMM8A gene mutation is poor. In addition, many unknown genes have not been found and need further research.

3. Development of cochlear implant technology

At the beginning of the birth of cochlear implants, cochlear implants were limited to deaf patients with bilateral total deafness, hearing aids that were ineffective after speech training, and normal cochlear development and posterior cochlear auditory pathway. With more and more successful experience in surgery, the indications of cochlear implants are gradually broadened.

3.1. Cochlear implantation in special cases

With the further exploration of clinical work, the indications of artificial cochlea have been greatly expanded. In addition to reducing the audiological standard of ordinary cases to 80 dB, other cochlear malformations, ossification of the cochlea, stenosis of the internal auditory canal, abnormalities of the white matter of the brain, and auditory neuropathy in special cases have changed from original contraindications to relative contraindications. At present, clinical experience shows that most of these special patients can achieve satisfactory results after surgery. However, detailed audiological, imaging and electrophysiological (brainstem auditory evoked potential, etc.) assessments are required before surgery, and certain benefits can be obtained from the assessment of patients after surgery.

The psychophysical threshold after cochlear implantation is the “gold standard” to objectively reflect the patient’s auditory response, while the electric stimulation auditory evoked potential is the “gold standard” to evaluate the patient’s residual hearing before surgery. In foreign countries, the electric stimulation auditory evoked potential is routinely tested before cochlear implantation. In 2008, Beijing Union Medical College Hospital[19] successfully developed the method of electro stimulating the cochlea before surgery to record the evoked potential responses of ECAP, EABR and EMLR representing different levels of auditory pathway nuclei (spiral ganglion, brain stem and primary auditory cortex), which can simultaneously understand the physiological functions of auditory centers at all levels, and predict the effect of postoperative hearing and speech rehabilitation. Up to now, more than 500 cases of cochlear malformation, auditory neuropathy. The patients with white matter disease and cochlear ossification and other difficult cases were tested for electric hearing before operation, and the appropriate

implants were selected to avoid ineffective implantation. At present, systematic minimally invasive (electrophysiological test across the tympanic promontory or round window niche) research was being conducted.

3.2. Cochlear implantation for unilateral deafness

Single sided deafness (SSD) has been included in the indications of cochlear implants in developed countries such as Europe and America. After cochlear implantation, the patients with unilateral deafness[20] have improved their stereo hearing and sound source localization ability, which can balance the time difference and loudness difference between the two ears, reconstruct good sound quality, and inhibit intractable tinnitus. Considering the bad remodeling of the hearing center of unilateral deafness and the effective control of tinnitus by cochlear implantation, the international trend is to implant cochlear implants as early as possible for unilateral deafness. Among them, those with severe tinnitus and/or obvious risk of deafness on the opposite side are preferred. It has been reported that[21] 85 patients were included in the study in the literature on the relationship between cochlear implantation and tinnitus in unilateral deafness, of which 81 patients (95.3%) had improved tinnitus, and 34.1% had completely suppressed tinnitus. According to foreign reports, unilateral deaf patients with/without severe tinnitus are implanted with cochlear implants. After a period of time, different acoustic and electrical stimulation sources of both ears can be integrated to obtain the hearing benefits of both ears. Through a questionnaire covering language ability, spatial sense of direction and hearing quality, unilateral deaf patients with cochlear implants believe that language ability and spatial sense of direction are significantly improved and tinnitus is significantly improved. However, unilateral deafness cochlear implantation has not been included in the guidelines in China, which needs to be carried out with caution.

3.3. Combined acoustic and electrical stimulation

Electrical acoustic stimulation (EAS) is a combination of cochlear implant and hearing aid, which is used to solve low frequency mild to moderate hearing loss with high frequency extremely severe hearing loss. In essence, acoustic electric combined stimulation belongs to a kind of artificial cochlea, which is different from ordinary artificial cochlea mainly in its special indications and the additional hearing aid components of the sound processor. In 1999, MED-EL (Austria) Company developed the first speech processor device that combines cochlear implants with hearing aids, namely acoustic and electrical combined stimulation, and successfully adjusted and worn it for the first patient. At the same time, the company began to devote itself to the development of supporting electrodes. In 2004, MED-EL of Austria officially released the FLEX electrode dedicated to combined acoustic and electrical stimulation. In the same year, the world's first case of children's combined acoustic and electrical stimulation (EAS) implantation was carried out. Since then, various cochlear implant companies have also developed similar equipment, such as the Hybrid acoustic electric combined stimulation system launched by Australia COCHLEAR in 2011, and the Nucleus 6 sound processor launched in 2015 all have the acoustic electric combined stimulation (Hybrid) mode. In 2012, Beijing Union Medical College Hospital[22] carried out surgical implantation of acoustic and electrical stimulation of cochlear implants for the first time in China.

EAS indications: It is applicable to partial deafness with good low frequency residual hearing and medium high frequency extremely severe hearing loss. Specific indication selection criteria are as follows: Due to the gain limitation of hearing aids, the audiological standard for EAS implantation is that the hearing threshold within 1,000 Hz does not exceed 65 dB, and the hearing is stable without progressive aggravation. The standard of preoperative speech evaluation is that the optimal monosyllabic recognition rate of hearing aids is less than 60% (sound intensity 65 dB SPL). Have a history of hearing aid wearing, can wear ear mold for a long time,

and there is no adverse reaction in the external auditory canal. Postoperative debugging of combined acoustic and electrical stimulation. On the basis of the routine process of cochlear implant debugging, hearing aid debugging is added. This requires to evaluate the frequency and degree of residual hearing before debugging, find the dividing frequency of acoustic stimulation and electrical stimulation, and then debug separately. For patients who choose long electrodes, if the low-frequency hearing is good after surgery, some channels in the front end can be closed, only hearing aids are used to compensate low-frequency hearing, and other channels provide medium and high frequency sound signals through electrical stimulation.

3.4. Bilateral cochlear implantation

Human beings rely on binaural hearing to obtain information. It is reported that binaural hearing can obtain better speech recognition and sound source localization in noisy environments. For patients with severe or extremely severe neurological deafness, different bilateral intervention modes are selected according to bilateral residual hearing: It includes bimodal listening with cochlear implants and hearing aids, sequential bilateral cochlear implants, and simultaneous bilateral cochlear implants literature report[23]. For children with congenital sensorineural hearing loss, bilateral cochlear implants before the age of 3 still have the opportunity to achieve better hearing and speech rehabilitation than unilateral cochlear implants in the "critical learning period".

In 1996, ENT Hospital in Werzburg, Germany, carried out bilateral cochlear implants to meet the requirements of an adult patient for bilateral hearing reconstruction Beijing Union Medical College Hospital[24,25] also carried out research on bilateral cochlear implants. The results show that bilateral cochlear implants can improve speech recognition ability, sound source localization ability and music appreciation ability, especially in noisy environments. Other literature[26] shows that speech recognition of bilateral implantation is about 15% higher than that of unilateral implantation in quiet environment, speech recognition under noise can be improved by 20%–30%, and sound source positioning error can be reduced to 4.7°. In music appreciation, the instrument recognition rate of bilateral implants was closer to that of normal people, 18.8% higher than that of unilateral implants. In recent years, with the development of the times and the improvement of children's parents' awareness, more and more deaf children and even some adult deaf patients choose to implant bilateral cochlear implants.

Bilateral cochlear implants can be divided into simultaneous bilateral implantation and staged bilateral implantation. The operation process is the same as that of unilateral cochlear implantation. When children are implanted with bilateral cochlear implants at the same time, the operation time and blood loss should be strictly controlled. Research shows that the integration of bilateral cochlear implants at the same time is the best. The advantages of hearing after bilateral cochlear implants are due to the cephalometric effect, central redundancy effect and binaural noise suppression effect. However, staged bilateral implantation can also obtain considerable binaural hearing advantages after debugging, adaptation and integration. Some experts believe that the interval should not exceed three years. However, more and more staged implantation cases show that bilateral implantation is effective even if the interval is longer. Some cases report that bilateral implantation interval is more than 20 years, and binaural hearing gain is obtained after adaptation, but the brain needs a longer time to adapt and integrate.

3.5. Senile deafness and cochlear prosthesis

In 2014, data from the National Bureau of Statistics showed that 212 million people aged 60 and above in China, and epidemiological reports showed that 11.04% of the elderly aged 60 and above had hearing impairment. At the same time, emotional disorder and social activity limitation[27] affect the quality of life of the elderly. Cochlear implantation technology can help hearing impaired patients recover

their hearing. However, there are two issues that are most concerned by the elderly deaf patients when carrying out cochlear implantation, the first is whether it is safe and the second is whether it is effective.

In the study of 188 CI patients by Mosnier et al.[28] and Büchsenschutz et al.[29], the postoperative complications of different age subgroups have no significant difference and do not increase with age. However, patients with diabetes, cardiovascular disease and other chronic diseases will increase the incidence of such complications.

Peripheral and central hearing loss occurred in senile deafness, which had no significant effect on hearing and speech rehabilitation after cochlear implantation. The retrospective analysis of Sanchez Cuadrado et al.[30] found that pure tone hearing threshold and speech resolution were significantly improved in patients over 70 years old and under 70 years old after cochlear implantation, and there was no significant difference in quality of life. Poissant et al.[31] followed up the elderly deaf patients, who reported that the hearing impairment was significantly reduced, the sense of loneliness and depression were generally reduced, self-satisfaction was increased, and the quality of life was significantly improved through cochlear implantation, and there were no other new psychological problems caused by implantation. Senile deafness is also accompanied by cognitive decline. Cosetti et al.[32] showed that the continuous improvement of speech perception after cochlear implantation may be related to the remodeling mechanism of the central nervous system of the brain.

4. Development trend of cochlear implants

4.1. Robot assisted cochlear implantation

Medical robot technology has broken through the technical bottleneck and achieved great success in the field of minimally invasive surgery. Cochlear implantation surgery is mainly divided into two stages: electric drill approach and electrode implantation. They have different requirements for robot technology. The electric drill approach emphasizes positioning accuracy and operation stability, and electrode implantation emphasizes precision.

The United States, France, Switzerland and others took the lead in carrying out research on ear robot technology. The KUKA6 DOF industrial robot of the University of Hanover uses the marker points fixed on the patient and robot benchmarks for spatial registration and motion tracking, opens the facial recess, and designs a program for automatically inserting electrodes into the cochlea to conduct reliability and repeatability studies on specimens[33]. Johns Hopkins University completed image-guided electrode implantation with the help of Da Vinci robot system and ear endoscope system, and Vandenberg University took the lead in conducting surgical trials in clinical practice. Weber and Caversaccio team[34] applied the HEARO developed by the University of Bern in Switzerland in 2017®. The robot completed a clinical trial of artificial cochlear implantation, and the French Sterkers team developed the world's first ear robot system (RobOtol) with clinical access®.

Domestic robot research mainly focuses on the theoretical level Beijing University of Aeronautics and Astronautics has developed a 4-DOF passive biplane device[35], which is located according to image data and uses a fixed electric drill channel to limit the drill bit within the planned path to eliminate the operator's hand tremor. The electrode implanting robot[36] designed by China University of Metrology and Metrology based on 6-SPS parallel mechanism pulls out the preset electrode guide wire through the repulsive mobile structure to solve the problems of implanting the pre bent electrode that requires the cooperation of both hands, inconvenient position adjustment and difficult positioning accuracy. Shanghai Jiao Tong University studied the quantitative accuracy of optical navigation system based on reference mark through different surface registration algorithms. The Ninth People's Hospital affiliated to Shanghai Jiaotong University School of Medicine reported[37] the first application of RobOtol in China

in 2020® cochlear implantation assisted by system robot.

The application of new technology is bound to have certain risks. The Vandenberg University team used the frame assisted system to localize the facial nerve during the operation[38]. The ear surgery robot involves many frontier theories and key technologies of science and engineering. The bottleneck of the research and development process lies in the micro mechanical devices, especially the force feedback components. The research and development of surgical robot for cochlear implantation still needs multidisciplinary cooperation, including surgical instrument design, imaging positioning, intraoperative navigation, intraoperative and postoperative evaluation of hearing and speech, etc. It is urgent to make breakthroughs in key technologies and theories to develop a robot system that meets clinical needs.

4.2. Fully implanted artificial cochlea

The commercially approved cochlear implant consists of two parts: In vivo and in vitro External part exposed to air will be affected by ambient temperature, humidity, electromagnetic and physical external forces. Unilateral deafness patients often consider the appearance and psychological effects, and reject cochlear implants. There are also certain conditions (swimming, sleeping) when the external part must be removed, resulting in the inability to continue to provide artificial hearing. The fully implanted cochlear implant can realize the all-weather service mode, with the same appearance as ordinary people, and can avoid psychological trauma. Although clinical trials of fully implanted cochlear implants have been carried out abroad, there are still some technologies that need to be tackled, including sound wave transmission, battery power supply and component failure treatment. The fully implanted cochlear implant requires internal energy supply. The battery is required to have the characteristics of rapid recharging, continuous power consumption greater than 24 hours, less heat generation, no leakage, etc. At present, the battery technology cannot meet these requirements. The problem of external acoustic wave entry should be considered for fully implanted cochlear implants. Some researchers buried microphones under the skin of the external auditory canal or mastoid process, and some designed eardrums as microphones. Some studies believe that the human inner ear is a natural battery array, which can generate voltage to drive, but the voltage generated is far less than the energy consumption of cochlear implants. MIT developed a low-power chip[39], which provides a new idea. The chip includes an ultra-low power wireless transmitter and a gradually rechargeable power conversion circuit. The transmitter can be powered after 40 s to 4 minutes of charging. In addition, an implantable microphone made of piezoelectric polymer polyvinylidene polymer[40] has been developed, which provides a direction for external sound waves to enter the body, but its signal-to-noise ratio is low. With the progress of technology, mature fully implanted cochlear implant products will bring more convenient help to patients in the future.

4.3. Artificial cochlea and tinnitus

House and Brackmann[41] began to study the relationship between cochlear implant and tinnitus at the end of the 20th century, and affirmed its positive role. Aschendorff et al.[42] Vermeire and Van de Heyning[43] analyzed 20 subjects and found that the tinnitus on the implanted side of patients with bilateral tinnitus was relieved or disappeared after cochlear implantation, and it was also unexpectedly found that the tinnitus on the opposite side was relieved. Tinnitus reduction in the short term after cochlear implantation may be caused by acoustic masking effect and electric stimulation of auditory nerve. Tinnitus reduction after half a year compared with that before operation may be related to the remodeling of cerebral central nerve. In some patients, tinnitus can be partly improved or completely disappeared no matter whether the machine is turned on or off after cochlear implantation. Some researchers have successfully treated tinnitus in patients with sudden deafness through cochlear implants, and proposed that tinnitus should be considered as a new indication of cochlear implants, but it must be carefully

considered. A large number of basic theoretical research and clinical electrophysiological tests are also needed, and clinical effect evaluation and how to reduce risks are also carried out.

4.4. Optical cochlear prosthesis

Conventional cochlear implants rely on current stimulation. Some researchers have also tried to use laser instead of current stimulation to treat neural deafness, which is called optical cochlear implant[44]. According to the characteristics of laser, an energy tool for precise stimulation can be developed to stimulate different areas of the cochlear spiral ganglion at fixed points. At present, animal experiments have successfully used the optical cochlea to stimulate the auditory nerve to obtain stable action potential, but a lot of research work is still needed from auditory evoked potential to practical hearing.

5. Outlook

The development of cochlear implant technology has gone through a complicated and bumpy process. Many scientists from various disciplines have made joint efforts and achieved success. At present, it is in the stage of vigorous development. However, there are still many problems to be further studied, such as music appreciation, speech recognition in noisy environment, full implant, price, etc. Up to now, the number of patients receiving cochlear implants in China is about 70,000, more than 90% of whom are children, while the proportion in foreign countries is about 50%. This proportion is also a feature of cochlear implants in China. In recent years, relief projects funded by the state and local governments at all levels, as well as donation projects funded by various charities and individuals, have enabled more hearing-impaired children to recover. With the improvement of people's economic conditions and the gradual development of domestic cochlear implant technology, more and more adult deaf and elderly deaf patients will be implanted with cochlear implants. The improvement of the market will certainly promote the rapid development of cochlear implant technology.

Conflict of interest

The authors declare no conflict of interest.

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