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Original Article

Outcomes of Cochlear Implantation in Patients with Far-Advanced Otosclerosis Who Had Previously Undergone Stapes Surgery

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BACKGROUND: The aim was to assess the hearing outcomes in cochlear implant patients with far-advanced otosclerosis who had previously undergone stapes surgery.

METHODS: We studied 17 implanted patients with far-advanced otosclerosis who had previously undergone stapes surgery. They comprised 15 women and 2 men, aged 37-73 years; the duration of hearing impairment was 9-42 years. Pure-tone audiometry (0.125-8 kHz) was performed preoperatively and at 1, 6, and 12 months postoperatively. Free-field speech audiometry was conducted before and 12 months after surgery, and word recognition scores were assessed.

RESULTS: Average preoperative hearing thresholds were 108 dB HL for air conduction and were at the limit of the audiometer for bone conduction. Word recognition scores before surgery averaged 7.4% (at 70 dB) and increased significantly to 66.2% about 12 months after surgery. Adverse surgical events were rare.

CONCLUSION: Patients with far-advanced otosclerosis and who have previously undergone stapes surgery are likely to experience a deterioration in hearing and receive insufficient benefits from hearing aids. Cochlear implantation can improve their hearing and provide good speech understanding.

KEYWORDS: Otosclerosis, far-advanced otosclerosis, cochlear implant, partial deafness treatment

INTRODUCTION

According to House and Sheehy,[1] diagnosis of far-advanced otosclerosis (FAO) is made when the patient has air-conduction threshold of 85 dB HL or worse and has nonmeasurable bone-conduction thresholds (due to output limits of the audiometer). When House and Sheehy formulated their criteria in the early 1960s, their aim was to "bring the patient from essentially no hearing to some hearing with a hearing aid" (ibid, p.1067). Since then, significant advances in surgical techniques and technological solutions for hearing improvement have been made, so the aims have been expanded.[2-5] Some authors propose that diagnosis of FAO should be made based on more than hearing thresholds. Calmels et al[6] proposed speech discrimination scores worse than 30% at 70 dB and, based on high-resolution computed tomography (CT), the presence of an otosclerotic lesion on the temporal bone. Merkus et al[4] suggested the criteria of low speech discrimination score and the presence of sensorineural hearing loss. Dumas et al[7] proposed a word recognition score (WRS) worse than 50% at 60 dB and profound sensorineural hearing loss.

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The debate about the criteria for FAO is ongoing, but the importance of cochlea ossification in FAO remains unquestioned, even though further issues arise from it. Generally, otosclerosis starts in a fissula ante fenestram; it can eventually reach the footplate and result in conductive hearing loss. Importantly, however, otosclerotic foci may also begin to affect the otic capsule, appearing in the cochlear endosteum and spreading to the scala tympani.[8,9] Ossification most often affects the initial section of the scala tympani. We are then dealing with sensorineural or mixed hearing loss, which produces serious deficits in speech perception and oral communication.

Patients with FAO can be offered 3 treatment options: (1) hearing aids, (2) stapedotomy, and (3) cochlear implantation (CI).[10-12] However, the benefits from hearing aids may be unsatisfactory, and so other surgical alternatives need to be considered. Current indications for stapedotomy have been greatly expanded,[13,14] but surgical correction of the conductive component alone may be insufficient. On the side of the ledger, although CI can yield excellent results, it is more complicated, risky, and expensive.[3,4] In addition, for patients with otosclerosis, another significant problem is tinnitus.[12,15]

Tange[16] has pointed out that when the inner ear is affected by otosclerosis, hearing loss can continue to progress, even when stapedotomy has perfectly closed the air–bone gap. This particular observation aroused our interest because many of the patients we have seen have had 1 or more stapes surgeries because of otosclerosis. However, the benefits of stapedotomy on their hearing have steadily declined as the spongifying process advanced and ultimately ceased to be satisfactory. For such patients, the only solution is CI. In order to minimize the risk of damaging the cochlea when opening the scala tympani, it is recommended to follow the surgical procedure of "Skarżyński's[17-19] 6 steps." This method allows the structure of the inner ear to be fully preserved. The most important stage of this method, which will also work with ossified cochlea, is access to the scala tympani through a round window. By using round window access and selecting an appropriate electrode, we keep the distal section of the scala tympani intact. Despite the use of such a method, in advanced otosclerosis, facial nerve stimulation may appear after CI. This is explained, among other things, by bone remodeling in the area of the facial nerve canal. The spongiotic bone structure results in higher conductivity for the electrical impulse.[20,21] This problem can be resolved by changing the fitting strategy and decreasing the stimulation level of some electrodes.

The aim of the study was to assess the hearing outcomes of cochlear implant patients with FAO who had previously undergone stapes surgery.

MAIN POINTS

- In far-advanced otosclerosis, hearing aids are often not enough to compensate for the hearing loss. If the disease is progressive and severe, a CI should be considered.
- Patients with far-advanced otosclerosis have good speech discrimination after CI implantation.
- With cochlear implantation, patients with otosclerosis who have previously undergone stapes surgery can achieve good hearing results.

MATERIAL AND METHODS

Ethical Considerations

The protocol of this retrospective study was approved by the Bioethics Committee of Institute of Physiology and Pathology of Hearing approval (Approval No: IFPS:KB/6/2022) and conformed with the Declaration of Helsinki. All patients gave informed consent to be part of the study.

Eligibility Criteria

The eligibility criteria were as follows: age above 18, had previously undergone stapes surgery in the ear qualified for CI, insufficient benefits from hearing aids, diminished speech discrimination (WRS less than 50%), hearing thresholds for air conduction of 85 dB HL (or worse), and for bone conduction close to the limits of the audiometer.

Audiometric Assessment

Pure-tone and speech audiometry (headphones and free-field) were conducted. Pure-tone and speech audiometry (0.125-8 kHz) were performed preoperatively and tone audiometry was performed at 1, 6, and 12 months postoperatively. If there was no response at a given frequency, the threshold was taken to be the audiometer maximum. Patients did not wear any hearing aids during the tests. Speech reception thresholds were measured with the Demenko & Pruszewicz Polish Mono-syllabic Word Test.

Free-field speech audiometry was conducted, using the same word test, to assess whether hearing aids might be an adequate prosthesis in preference to an invasive cochlear implant. During the test, the patient sat above 1 m from a loudspeaker and wore a hearing aid in the ear to be operated on. Words were presented at 70 dB over the loudspeaker, and the patient's task was to repeat as many words as possible. The resulting WRS represents the percent of correctly identified words. Free-field speech audiometry was conducted before and 12 months after surgery. During postoperative testing, the patient had their cochlear implant on (whereas preoperatively the patient wore a hearing aid). The postoperative examination was performed in silence and in noise of 10 dB signal- to-noise ratio.

All measurements were conducted in the same soundproof cabin by an experienced technician, using the same diagnostic audiometer, the Madsen Itera II (GN Otometrics, Denmark) with calibrated earphones (DH-39P, Telephonics, NY, USA) for pure-tone audiometry and a loudspeaker (Indiana Line Nano 2) for free-field speech audiometry.

Patients

There were 17 patients (15 women and 2 men) aged 37-73 years. The mean age was 52.5 years (SD 11.1). The average duration of hearing impairment was 23.5 years.

Statistical Analysis

Categorical variables were calculated as percentages. Descriptive statistics (range, mean, and SD) were used to describe quantitative variables. A Wilcoxon signed-rank test was performed to compare WRS obtained before and after surgery. Statistical significance was specified as a *P*-value less than .05. Data analysis was conducted using Statistical Package for the Social Sciences (SPSS) version 24.0 (IBM SPSS Corp.; Armonk, NY, USA).

RESULTS

Patient Characteristics

All 17 patients had a history of ear surgery. All had undergone stapes surgery (stapedotomy, stapedectomy, and restapedotomy); 2 patients had also had a myringoossiculoplasty, and 2 patients had an ossicular chain mobilization. Most had vertigo/dizziness and tinnitus. Details are given in Table 1.

Surgery

All patients had ultra-high-resolution CT before CI. The CT scans from one of the patients are shown in Figure 1a and b.

In 11 patients, surgery was performed using a minimally invasive surgical approach through the round window, called the 6-step Skarzynski procedure.[17,18] If ossification of the basal turn was found, additional drilling was performed until the lumen of the scala was identified. In the remaining 6 patients, a round window extended approach was performed due to overgrowth of the round window niche. In cases where the scala tympani was overgrown in the region of the round window, the bony layer was removed until the fluid space of the scala tympani was reached.

Hearing Thresholds

Hearing thresholds (0.125-8 kHz) before and 12 months after CI implantation are shown in Figure 2. They are extremely poor, especially for bone conduction.

Table 2 shows average hearing thresholds for air and bone conduction measured before surgery and 1, 6, and 12 months after surgery. For air conduction, pre-operative thresholds were 108 dB HL on average and for bone conduction the thresholds were at the limits of the audiometer. In contralateral ears hearing thresholds were better.

Speech Discrimination

Before implantation, speech audiometry conducted without a hearing aid began at 20 dB sound pressure level (SPL), but at this level, no patient recognized a single word. For patients to recognize any words, it was found that a level of at least 100 dB SPL was required. At such levels, patients had an average WRS of 5.9% (SD = 14.5) with a range between 0% and 45%. The best result was 45%, 1 patient scored 40%, another patient scored 10%, and the other 14 patients did not recognize any words (WRS of 0%).

The other test performed before surgery was free-field audiometry using a well-fitted hearing aid, and here the results were somewhat better. WRSs were between 0% and 50%, with 7.4% on average (SD = 16.1). The best result was 50%; other patients achieved scores of 40%, 30%, and 5%, but the other 13 did not recognize any words (WRS of 0%).

About 12 months after surgery, the free-field audiometry results were significantly better. In quiet, the minimum score among the 17 patients was 15% and the maximum was 95%; the mean score was 66.2% (SD = 27.9%). The difference between pre- and post-WRSs in quiet was statistically significant ($Z = 3.63$; $P < .001$). In 10 dB noise, the minimum score was 0% and the maximum was 95%; the mean score was 42.3% (SD = 26.9%). The results achieved before and 12 months after implantation are shown in Figure 3.

Table 1. Demographics and Clinical Characteristics of the Patients

		Patients with Advanced Otosclerosis (n = 17)
Age	Range	37-73
	Mean (SD)	52.5 (11.1)
Gender	Female	15 (88.2%)
	Male	2 (11.8%)
Operated ear	Right	8 (47.1%)
	Left	9 (52.9%)
Duration of hearing impairment (years)	Range	9-42
	Mean (SD)	23.5 (8.2)
Vertigo/dizziness	Yes	11 (64.7%)
	No	6 (35.3%)
Tinnitus in the operated ear	Yes	13 (76.5%)
	No	4 (23.5%)
Tinnitus in the contralateral ear	Yes	11 (64.7%)
	No	6 (35.3%)
Previous surgeries in the operated ear	Yes	17 (100%)
	Stapedotomy	13 (76.5%)
	Restapedotomy	3 (17.6%)
	Stapedectomy	1 (5.9%)
	Myringoossiculoplasty	2 (11.8%)
	Ossicular chain mobilization	2 (11.8%)
Previous surgeries in the contralateral ear	Yes	8 (47.1%)
	No	9 (52.9%)
Computed tomography	Yes	17 (100%)
	No	–
Surgical approach	Posterior tympanotomy, extended round window	6 (35.3%)
	Posterior tympanotomy, round window	11 (64.7%)
Implant model	Med-El	17 (100%)
Processor	Concerto	2 (11.8%)
	Sonata	13 (76.4%)
	Synchrony	2 (11.8%)
Electrode	Standard	2 (11.8%)
	Medium	1 (5.9%)
	FlexSoft	2 (11.8%)
	Flex 28	5 (29.4%)
	Flex 26	4 (23.5%)
	Flex 24	3 (17.6%)
Surgical adverse events	Incomplete electrode insertion	2 (11.8%)
	Facial nerve stimulation	1 (5.9%)
	Cerebrospinal fluid gusher	1 (5.9%)

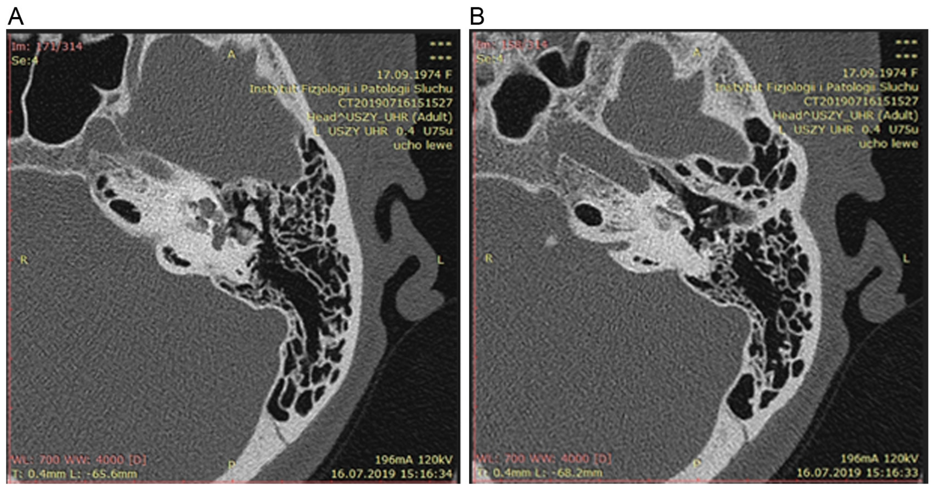

Figure 1. (A) Coronal scan showing the foci of otospongiosis in the otic capsule and the shadow of a prosthesis used during a stapedotomy performed at another otorhinolaryngology center. (B) Axial scan shows sclerotization of the scala tympani in the basal turn.

Surgical Adverse Events

Surgical adverse events were encountered in 4 ears. These involved incomplete electrode insertion (n = 2), a cerebrospinal fluid gusher (n = 1), and facial nerve stimulation (n = 1). Incomplete electrode insertion was caused by obstructions within the cochlea. The gusher ceased after electrode insertion and securing the electrode with periosteum and tissue glue. After surgery, this patient remained in the observation room, and a bed regimen was ordered. Apart from transient vertigo for the first 2 days after surgery, there were no additional complications linked to the gusher. Facial nerve stimulation occurred 9 months after surgery; the problem was resolved by programming new settings and decreasing stimulation levels for electrodes 1-9.

DISCUSSION

The aim of the study was to evaluate the hearing outcomes of cochlear implant patients with FAO who had previously undergone stapes surgery. The hearing of all 17 patients had deteriorated due to otosclerosis, and a CI became the only practical option.

The patients met the criteria for FAO, in terms of both poor hearing thresholds and low levels of speech discrimination. The average hearing threshold before surgery was about 108 dB HL for air conduction and was practically unmeasurable for bone conduction. Before surgery, WRS with hearing aids was only 7.4% on average, and in 76% of the patients it was 0, and in the other patients it was no more than 50%. Our patients had a long history of hearing impairment, averaging 23.5 years. Against this backdrop, 1 year after surgery, the patients had completely satisfactory speech discrimination. The WRS was on average 66.2% for quiet and 42.3% for noise. Such results are comparable to or better than those found by other authors. For example, 12 months after CI implantation, Dumas et al[7] saw an average WRS in FAO patients of 53% for monosyllabic words, 68% for disyllabic words, and 76% for sentences and speech material presented at 60 dB. Much better figures were presented by Kabbara et al[3] who studied 3 groups of patients with FAO: those receiving (1) a primary stapedotomy, (2) a primary CI, and (3) a secondary CI (after a previous history of stapedotomy). About 12 years after surgery, their

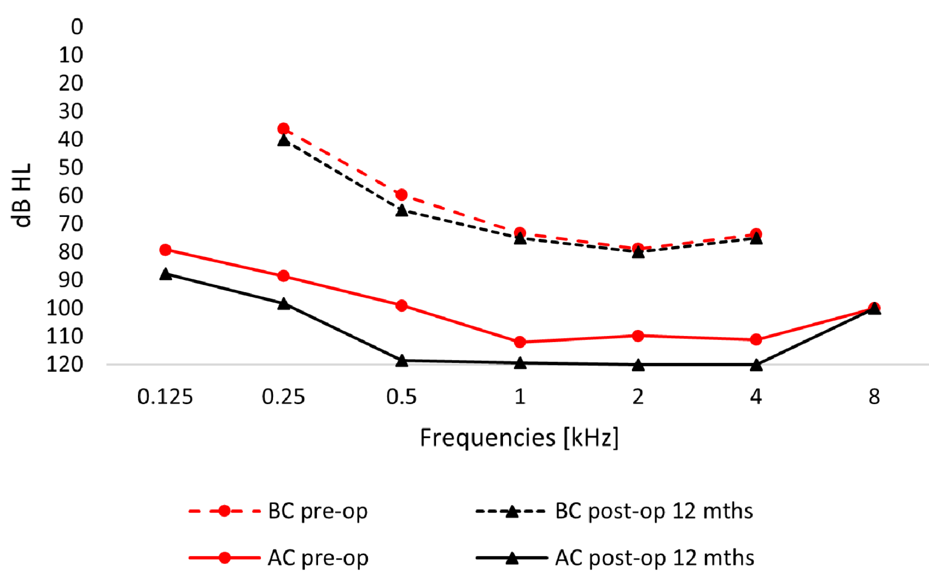

Figure 2. Pre- and 12-month-postoperative hearing thresholds in 17 implanted patients with far-advanced otosclerosis. If there was no audible percept at any frequency, the hearing level was taken to be the maximum audiometer output at that frequency. AC, air conduction; BC, bone conduction, dB HL, decibel hearing level.

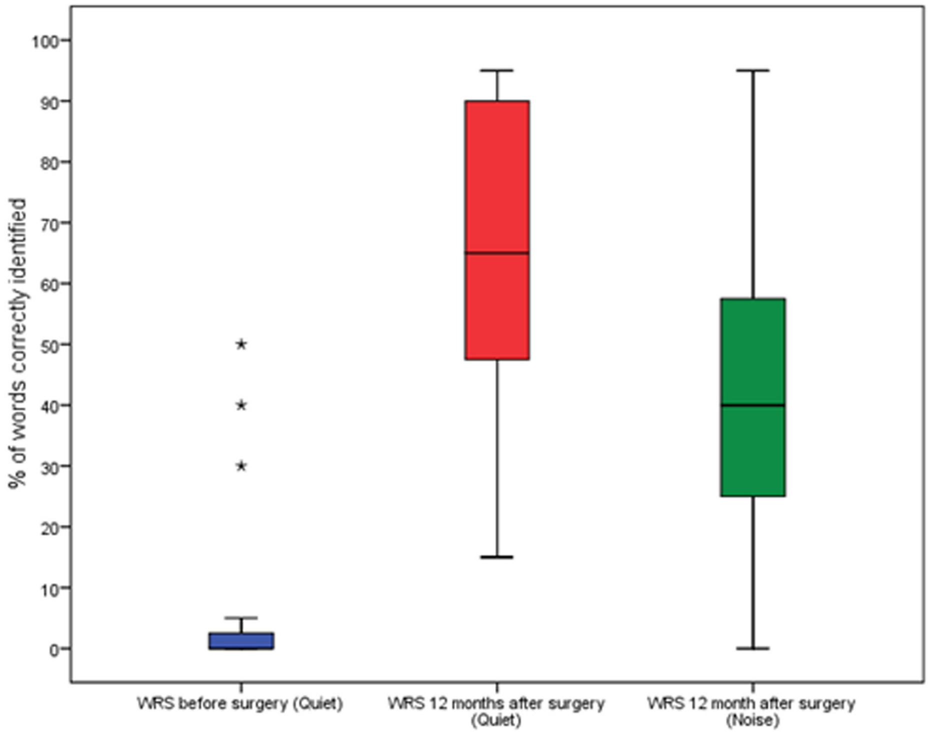

Figure 3. Word recognition scores (%) in quiet (before surgery, blue) and in quiet and noise 12 months after CI implantation (red and green). WRS, word recognition scores.

mean WRSs were, respectively, 51%, 75%, and 72%. Our results and those of Kabbara et al[3] indicate that CI is a very effective treatment for FAO, even if it is not the first treatment option. It is clear that prior stapes surgery does not preclude further CI in patients with long-term otosclerosis.[2,22,23]

In general, we agree with Van Loon etal.[24] that the best measure of success in treating patients with otosclerosis is speech recognition measured in free-field. Word recognition score is a good reflection of an impaired patient's performance in daily life, although we think that the measure could be expanded to include quality of life since disability due to hearing loss is usually long lasting and has severe psychosocial consequences for overall functioning. Such studies have already been conducted in groups of otosclerosis patients undergoing stapedotomy and patients who have undergone CI.[14,25-27]

One of the possible complications of CI is stimulation of the facial nerve, and among our 17 implanted patients, this happened once. The problem was resolved by changing the fitting strategy and decreasing the stimulation level of some electrodes.[28] In this context, Van Horn et al[20] systematically reviewed 37 articles on 5694 patients who had hearing loss of various etiologies and found that the overall rate of aberrant facial nerve stimulation was 5.6%, although the range was very wide (0.68%-43%). Interestingly, in an additional meta-analysis, the author showed that CI recipients with otosclerosis were much more likely to have aberrant facial nerve stimulation compared to patients with different hearing loss etiologies (odds ratio of 13.7). The likely mechanisms underlying facial nerve stimulation in CI are electrode array characteristics, bony changes within the cochlea following implantation, and predisposition to bony disease during the preimplantation period.[20] Likewise, Tuset et al[21] listed several factors leading to aberrant stimulation: higher conductivity of spongiotic bone, elevated excitation level of the auditory nerve, and lower threshold for facial nerve excitation. The authors suggested that, based on preoperative CT scans, the likelihood of facial nerve stimulation could be predicted by looking for otosclerotic foci close to the facial nerve canal.

Table 2. Average Hearing Thresholds of 17 Patients Before and After Cochlear Implantation

		Minimum	Maximum	M	SD
AC operated ear	Pre	82.5	120.0	108.0	12.8
	1 month	108.8	120.0	118.8	3.0
	6 months	113.8	120.0	119.3	1.6
	12 months	117.5	120.0	119.5	1.0
BC operated ear	Pre	62.5	73.8	71.4	4.4
	1 month	73.8	73.8	73.8	0.0
	6 months	73.8	73.8	73.8	0.0
	12 months	73.8	73.8	73.8	0.0
AC contralateral ear	Pre	57.5	120.0	85.7	19.7
	1 month	65.0	120.0	86.5	18.2
	6 months	61.3	120.0	87.9	19.7
	12 months	67.5	120.0	89.6	19.0
BC contralateral ear	Pre	35.0	73.8	58.8	14.3
	1 month	35.0	73.8	59.5	14.1
	6 months	30.0	73.8	59.8	14.1
	12 months	33.8	73.8	60.6	13.3

Thresholds averaged over 0.5, 1, 2, and 4 kHz.
AC, air conduction; BC, bone conduction; M, mean.

In our study, CT scans were performed on all 17 patients. Although a CT scan is considered the imaging technique of choice for the diagnosis of otosclerosis,[29] its sensitivity is not ideal. Maxwell et al[30] found that, in otosclerotic patients undergoing primary stapedotomy, CT sensitivity was only 47.1%. Wegner et al[31] in their review of 8 patients with otosclerosis, reported CT sensitivities between 60% and 95%. The authors considered that preoperative CT may not be necessary to confirm a diagnosis of otosclerosis and should instead be reserved for patients with additional abnormalities. Our view is that, in patients with FAO, CT findings are very useful for showing extensive otosclerotic foci with cochlear involvement.

In our study group, a gusher was encountered in 1 ear. Generally, gushers occur in 1%-5% of cases during CI.[32] It is known that inner ear malformations increase the risk of a gusher during CI.[33]

Incomplete insertion of the electrode array occurred in 2 ears in our study. This complication may be due to bony dysplasia, labyrinthis ossificans, and anomalies in the inner ear, but it may also occur when there is no apparent evidence of obstruction.[34]

To sum up, the results we obtained in patients with FAO were satisfactory. One year after surgery, patients had good speech discrimination, with an average WRS of 66.2%. Adverse surgical events were rare. One case of gusher and one of facial nerve stimulation were effectively managed, and there were no further negative consequences.
Cochlear implantation in FAO provides satisfactory results. Patients who have previously undergone stapes surgery but whose hearing has deteriorated over time may achieve good hearing outcomes through cochlear implantation.

Ethics Committee Approval: This study was approved by the Ethics Committee of Institute of Physiology and Pathology of Hearing (Approval No: IFPS:KB/6/2022).

Informed Consent: Informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

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