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ORIGINAL ARTICLE

Treatment of Severe to Profound Mixed Hearing Loss With the BAHA Cordelle II☆

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KEYWORDS
BAHA Cordelle;
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Abstract
Goals: Evaluation of the audiological outcome and subjective satisfaction of BAHA Cordelle II in the treatment of patients with severe to profound bilateral mixed hearing loss.
Material and method: Retrospective study of 12 patients suffering a severe to profound bilateral sensorineural hearing loss, using pure tone audiometry (PTA), speech audiometry and subjective evaluation before and after the implantation of a BAHA Cordelle II (Cochlear®).
Results: The average gain in conversational frequencies (0.5 to 4 kHz) with BAHA in free field was 43, 51, 47, and 44 dB, respectively. We observed a GAP over closure in 10 of the 12 patients. Speech audiometry improved from 85% at 83 dB of maximum discrimination to 96% at 62 dB. The subjective evaluation questionnaires showed great satisfaction with a slight decrease in noisy or windy environments. The great majority of our patients used the BAHA device throughout the entire day.
Conclusions: The BAHA Cordelle II (Cochlear®) is a good option in the treatment of severe to profound bilateral mixed hearing loss. Its best advantages are a low risk of labyrinthization, high result predictability, easy and step-by-step surgery, no need for general anaesthesia, and the GAP over closure in all frequencies. Active middle ear devices represent another alternative, but specific indications have not been defined yet because of low universal experience. When the intelligibility of the patient is poor, cochlear implantation should be considered.

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PALABRAS CLAVE
BAHA Cordelle;
Implante osteointegrado;
Hipoacusia severa mixta

Tratamiento de las hipoacusias mixtas severas a profundas con el BAHA Cordelle II

Resumen
Objetivo: Evaluar el rendimiento auditivo del BAHA Cordelle II en el tratamiento de pacientes afectados de hipoacusias mixtas de severas a profundas bilaterales.
Material y método: Estudio retrospectivo de 12 pacientes afectados de hipoacusia mixta de severa a profunda, con audiometría tonal liminar, logoaudiometría y encuesta subjetiva antes y después de la implantación de un BAHA Cordelle II (Cochlear®).
Resultados: La ganancia promedio con el BAHA en campo libre de todos los pacientes en las frecuencias conversacionales (0,5 a 4 khz) fue de 43, 51, 47 y 44 dB, respectivamente. Se obtuvo un sobrecierre del umbral diferencial auditivo (UDA) en todas las frecuencias en 10 de los 12 pacientes. La logoaudiometría pasó de un 85% de discriminación máxima promedio a 83 dB a un 96% a 62 dB. Los cuestionarios subjetivos mostraron un alto grado de satisfacción del uso del BAHA, si bien su rendimiento disminuyó en ambiente ruidoso y con el viento. La inmensa mayoría de usuarios utilizan el BAHA a lo largo de todo el día.
Conclusiones: El BAHA Cordelle II (Cochlear®).es una buena alternativa en el tratamiento de los pacientes afectados de una hipoacusia mixta de severa a profunda bilateral. Su mínimo riesgo de laberintización, su alta previsibilidad de resultados, su cirugía fácil y muy reglada, la anestesia habitualmente local y el cierre del UDA en casi todas frecuencias son sus mayores ventajas. Los dispositivos activos de oído medio representan otra alternativa más compleja, aunque sus indicaciones específicas no están aún bien definidas por la falta de experiencia mundial. Cuando la inteligibilidad del paciente es muy pobre se debe considerar, como mejor alternativa, la indicación de un implante coclear.

Introduction

After over 30 years of experience, the effectiveness, efficiency and usefulness of the bone-anchored hearing aid (BAHA) osseointegrated hearing implants in the treatment of patients affected by pure or mixed transmissive hypoacusis with good cochlear reserve are beyond any doubt. They are generally used in patients suffering from surgical cavities or from chronic otitis media causing uncontrollable otorrhea that precludes tolerance of conventional hearing aids, or else from external ear malformations (mainly external auditory canal atresia) where there is no physical space to accommodate the instrument. These patients are usually affected by moderate to severe mixed bilateral hearing loss with good cochlear reserve. These cases can benefit from the implantation of a BAHA Divino or Intenso®—a proven option already a classic in otology.[1,2]

These good results, together with the design and manufacture of more powerful models, with a greater capacity to amplify the acoustic signal into sound vibration, have led to the implementation of indications for BAHA; indications known as unconventional or less common. The BAHA model Cordelle II[3,4] responds to this description. In this model, unlike in its predecessors, the processor is within a bodily pouch. This has a cable connected to the retroauricular osseointegrated implant (Fig. 1). It is bulkier and less aesthetically pleasing than the Divino or Intenso® models, or the modern BP100, but these drawbacks are partly compensated by its higher power,[5,6] which may be indicated in cases of mixed hypoacusis with bone conduction thresholds near 60 dB.

These neurosensory losses always have an associated transmissive component of a diverse nature and the patients consequently suffer severe to profound hearing losses, that is, they are patients with very disabling hearing loss. In these patients, the indication for the BAHA Cordelle II does not arise from the conventional problem of hearing aid intolerance due to otorrhea or lack of space (which may coexist), but from a more keen reason, namely that the conventional hearing aid offers them low performance. Patients usually suffer from surgical cavities or chronic otitis media (COM) with an associated sensorineural loss or else labyrinthization or obliterating otosclerosis with poor cochlear reserve. This application was described by the Dutch group of Van der Pouw[5] (1998) that demonstrated the usefulness of the Cordelle BAHA in 7 patients with a moderate to severe sensorineural component in their hypoacusis, compared with less powerful BAHA models such as the *Superbass* BAHA.

The aim of this work is to present the joint initial experience of 2 tertiary hospitals with this unconventional indication of the BAHA Cordelle II model.

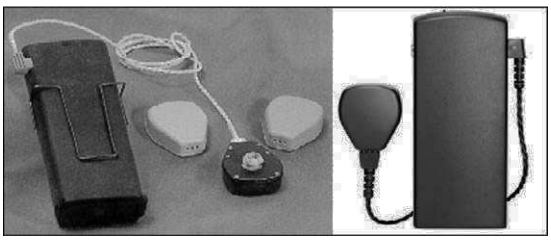

Figure 1 BAHA Cordelle II osseointegrated device.

Table 1 Epidemiological Data From Our Series.

Name	Gender	Age	Months_fu	PD	Cause_h	Ear_i	TH	TH_ni	Incision	Complications	Days_a
MC, JM	M	64	24	g	bTC+SNHL	Left	Mixed	Mixed	DER	PN	102
RV, C	M	65	19	h	bTC+SNHL	Right	Mixed	Mixed	FLAP	no	60
GD, J	M	54	16	h	bTC+SNHL	Right	Mixed	Mixed	LIN	SO	60
VL, J	F	63	15	h	bCOM+SNHL	Right	Mixed	Co.	DER	no	60
GS, S	F	24	8	h	bCOM+SNHL	Right	Mixed	Mixed	DER	no	50
PT, J	M	68	13	h	Otosclerosis	Left	Co.	Mixed	FLAP	PN	74
MEG	F	65	264	g	bCOM+SNHL	Right	Mixed	Co.	DER	no	60
EMB	F	58	24	h	bCOM+SNHL	Right	Mixed	Mixed	DER	PN	65
MPR	F	72	120	h	bCOM+SNHL	Right	Mixed	Co.	DER	SO	60
FMG	M	77	7	h	COM—TC+SNHL	Left	Mixed	Co.	LIN	no	60
MRS	F	80	6	h	bCOM+SNHL	Right	Mixed	Mixed	LIN	no	60
JMVN	M	51	13	g	TC—COM+SNHL	Right	Mixed	Mixed	LIN	no	60

Age: age at implantation; Cause_h: cause of hearing loss (TC: tympanoplasty cavity; bTC: bilateral tympanoplasty cavity; COM: chronic otitis media; bCOM: bilateral chronic otitis media; SNHL: sensorineural hearing loss); Days_a: number of days elapsed between surgery and the adaptation of the processor; DER: dermatome; Ear_i: ear implanted; F: female; FLAP: ''U'' flap; LIN: linear incision; M: male; Months_fu: months of follow-up; PD: previous device (g: glasses with bone vibrator; h: headset); PN: Partial flap necrosis; SO: skin overgrowth; TH: type of hearing loss in implanted ear; TH_ni: type of hearing loss in non-implanted ear (co.: cophosis).

Patients, Material and Method

This was a retrospective study that included patients implanted at 2 tertiary hospitals by senior surgeons with experience in osseointegrated devices.

In all cases, the implanted model was a BAHA Cordelle II (Cochlear®). All patients had a minimum follow-up of 6 months. The adaptation of the processor was carried out 2-21/2 months after the placement of the osseointegrated implant. None of the patients presented tolerance problems.

The case studies were of 12 patients, all adults. The epidemiological data and aetiology of hypoacusis are shown in Table 1. As can be seen, 7 patients were affected with bilateral mixed hearing loss (3 bilateral surgical cavities, 3 bilateral COM and a surgical cavity on one side and one COM on the contralateral side, all of them associated to sensorineural hearing loss) and 5 patients were affected with unilateral mixed hypoacusis with one cophosis in the contralateral ear. Of these 5 cases, in 4 occasions the BAHA was implanted on the side of the mixed hearing loss and in one case on the cophosis side to correct the shadow effect of the head. The cophoses were caused by previous surgery (4 tympanoplasties and one stapedectomy). The audiometric characteristics of these patients are shown in Table 2. In all cases, we performed a liminal pure tone audiometry (PTA), speech audiometry without BAHA and speech audiometry with BAHA after 6 months of use, in open field. We always evaluated the gain with BAHA with respect to the better ear. Subjective evaluation was conducted over telephone or during a postoperative visit, following the standardized form.

The data were managed with a standard statistical program (SPSS). The differential hearing threshold (DHT) was calculated by subtracting the bone conduction threshold from the air conduction threshold for each frequency. The mean DHT was calculated by adding the DHTs at each conversational frequency (0.5, 1, 2, and 4 kHz) and dividing by 4. The postoperative air conduction threshold with BAHA Cordelle II was conducted in open field.

Results

Surgery (Table 1)

The incisions used in the 12 cases were: 6 cases with dermatome, 2 cases with ''U'' flap and 4 cases with vertical incision. In all cases, we removed the subcutaneous cellular tissue to the periosteum. The implant used was 4 mm in length in 11 cases, and in one case it was 3 mm. There were no notable intraoperative complications.

Audiometric Evaluation (Tables 2 and 3)

The mean preoperative pure tone thresholds for air conduction in our patients, collected in the better ear, were 85, 85, 85, and 94 dB at frequencies of 500, 1000, 2000, and 4000 Hz respectively, and 45, 47, 60, and 55 dB for bone conduction. The mean postoperative tone thresholds for air conduction in open field were 42, 33, 37, and 50 dB at frequencies of 500, 1000, 2000, and 4000 Hz, respectively. The mean preoperative DHT for all conversational frequencies (AC-BC: calculated by subtracting the preoperative bone conduction threshold from the preoperative air conduction threshold, for conversational frequencies and then averaged) was 36 dB and the postoperative DHT (calculated by subtracting the air conduction threshold in open field with the BAHA Cordelle II minus the preoperative bone conduction) was −10. The mean gain with the BAHA in open field for all frequencies and all patients was 46 dB: broken down by conversational frequencies (0.5 to 4 kHz), it was 43, 51, 47, and 44 dB. An overclosure of the DHT was obtained in all frequencies in 10 of the 12 patients. Only in two cases (patients 6 and 7) was there no overclosure, although the gain was very significant. The logoaudiometry went from 85% mean maximum

Table 2 Preoperative Liminal Tone Audiometry and Maximum Discrimination.

Patient	AC 500	AC 1000	AC 2000	AC 4000	BC 500	BC 1000	BC 2000	BC 4000	m Loss	% Max. Dis.	dB Max. Dis.
1. MC, JM	100	95	105	105	55	60	75	75	101	100	90
2. RV, C	105	100	85	100	50	65	70	55	97	80	100
3. GD, J	100	115	110	120	60	65	75	65	111	90	90
4.VL, J	55	40	55	55	40	30	50	40	51	100	60
5. GS, S	90	100	70	45	55	55	55	15	76	100	70
6. PT, J	35	20	25	80	10	5	25	55	40	100	50
7. MEG	105	115	120	115	30	50	–	50	113	–	90
8. EMB	60	90	80	100	30	40	70	70	82	80	90
9. MPR	100	100	105	105	60	55	65	55	102	90	90
10. FMG	105	85	85	90	60	55	70	70	91	65	90
11. MRS	85	85	95	110	50	50	55	70	93	75	90
12. JMVN	85	75	85	110	50	45	50	60	88	65	90
Average	*85*	*85*	*85*	*94*	*45*	*47*	*60*	*55*	*87*	*85*	*83*

% Max. Dis.: Maximum discrimination in speech audiometry; AC: air conduction; BC: bone conduction; dB Max. Dis.: Decibels at which the maximum discrimination is obtained; m Loss: mean loss of conversational frequencies in preoperative air conduction.

discrimination at 83 dB to 96% at 62 dB. The subjective questionnaire showed a high degree of satisfaction with the use of the Cordelle II BAHA, although its performance declined in noisy and windy environments. The vast majority of carriers used the BAHA all throughout the day (Table 3).

Subjective Evaluation (Table 4)

We used a pre-designed and standardized questionnaire for the subjective assessment of patients who carried a Cordelle II BAHA. This included a visual analogue scale with 1 as a poor result, 2 as regular, 3 as satisfactory and 4 as very satisfactory (Table 4). The overall assessment of all patients was of ''very satisfactory'' in most patients (7%–83%), satisfactory in 4 patients and only one user reported a regular subjective performance. None of the patients described the general performance as poor. Discrimination in noisy and windy environments was the parameter with the lowest score, with 3 patients considering it regular. The average number of usage hours of the patients was 14 (they took it off only to sleep) and only one patient used it just during working hours. There were no cases of rejection or abandonment of the device and they all declared an improvement in their quality of life.

Complications

These patients did not present any specific complications due to the use of a Cordelle II BAHA. The complications observed were the same as in any series of BAHA surgery, regardless of the type of processor. Only 2 cases presented overgrowth of the skin, and a longer pillar had to be placed in

Table 3 Postoperative Liminal Tone Audiometry (Free Field), Gain and Logoaudiometry.

Patient	AC 500	AC 1000	AC 2000	AC 4000	Post. Loss	Pre. DHT	Post. DHT	FG	% Max. Dis.	dB Max. Dis.
1. MC, JM	50	30	50	50	45	40	−16.25	56.25	100	60
2. RV, C	40	25	60	65	47.5	37.5	−12.5	50	100	70
3. GD, J	40	25	35	40	35	45	−31.25	76.25	100	40
4.VL, J	40	25	30	40	33.7	11.25	−6.25	17.5	100	40
5. GS, S	60	20	20	20	30	31.23	−15	46.25	100	40
6. PT, J	35	10	15	45	26	16.25	2.5	13.75	100	50
7. MEG	40	55	45	65	51	81	18	62	100	80
8. EMB	30	50	40	55	43	30	−8	38	100	70
9. MPR	45	50	40	55	47	43	−11	55	100	85
10. FMG	45	45	40	65	48	27	−15	42	70	60
11. MRS	45	40	40	55	45	37	−11	48	100	85
12. JMVN	35	30	35	45	36	37	−15	52	90	70
Average	*42*	*33*	*37*	*50*	*40*	*36*	*−10*	*46*	*96*	*62*

% Max. Dis.: Maximum discrimination in speech audiometry; AC: Air conduction; dB Max. Dis.: decibels at which there was maximum discrimination; DHT: mean differential hearing threshold in conversational frequencies; FG: mean functional gain in conversational frequencies; Pre. DHT: preoperative mean differential hearing threshold (AC-BC: calculated by subtracting the preoperative bone conduction threshold from the preoperative air conduction threshold, for conversational frequencies); Post. DHT: postoperative mean differential hearing threshold (calculated by subtracting the open-field air conduction threshold with the BAHA Cordelle II minus the preoperative bone conduction); Post. loss: postoperative mean loss in conversational frequencies by air conduction.

Table 4 Survey of Personal Satisfaction.

Patient	General	In Noise	Verbal	Hours (day)	Days (week)	Quality of Life
1. MC, JM	3	3	4	8	7	Yes
2. RV, C	3	3	4	17	7	Yes
3. GD, J	4	3	4	16	7	Yes
4.VL, J	4	4	4	17	7	Yes
5. GS, S	4	3	4	16	7	Yes
6. PT, J	4	3	3	16	7	Yes
7. MEG	4	4	4	15	7	Yes
8. EMB	4	3	4	14	7	Yes
9. MPR	3	2	4	14	7	Yes
10. FMG	2	2	4	10	7	Yes
11. MRS	3	2	4	15	7	Yes
12. JMVN	4	3	4	16	7	Yes
Average	*3.5*	*2.92*	*3.92*	*14*	*7*	*Yes*

Days/week: number of days per week using the BAHA; General: overall assessment of the usefulness of the BAHA Cordelle II; Hours/day: use of the device in hours per day; In noise: evaluation in noisy environments; Score: 1 (poor) to 4 (very good); Verbal: language comprehension.

one of them. Lastly, there were 3 cases of partial flap necrosis, which were resolved with topical cures and patience. There were no changes in bone conduction thresholds during follow-up, eliminating the possibility of sound trauma by cochlear hyperstimulation.

Discussion

The usual profile of a candidate for a BAHA device is generally that of a patient with open surgical cavities, or affected by benign COM with uncontrollable otorrhea, or finally, those with diseases of the external ear who cannot tolerate conventional hearing aids. They tend to be affected by transmissive or mixed hearing loss, with a good cochlear reserve.[1] These patients may benefit from a Divino, Intenso or the new BP100 BAHA, obtaining excellent results, with closure of the DHT in most cases (85%). There are contrasted results in recent years[1,2] proving that these devices lead to better adaptation to the sound environment and a clear improvement of the quality of life. McLarnon et al.[7] used the standardized questionnaire Glasgow Benedit Inventory (GBI) in 94 patients to demonstrate an overall mean benefit of BAHA system users around +33 (95 CI: 25–42). They also described that the benefit obtained by BAHA users sometimes depended on the underlying disease. According to McLarnon, malformations (atresia of the EAC) were the subgroup with the maximum benefit.

However, there are currently other indications for BAHA devices, which are not commonplace. These have arisen in connection with the development of newer and more powerful processors, capable of stimulating the cochlea despite it being affected, with bone conduction thresholds close to 60 dB.[2–6] These patients usually suffer severe to profound, bilateral and mixed hearing loss due to a transmissive problem of diverse aetiology (post-surgical, otosclerous, tympanosclerous, etc.) associated with sensorineural hearing loss with also very diverse causes (ototoxicity, degenerative, etc.). They are, therefore, highly hypoacusic patients. In our series, the average loss in conversational frequencies was 87 dB. This group generally uses conventional hearing aids or classic devices for bone conduction stimulation that are not osseointegrated (glasses).

In these cases, hearing aids usually offer moderate or poor performance because they have to ''work to the limit'', since they need a high amplification to stimulate a diseased cochlea.[8,9] In addition, extra amplification is required to overcome the resistance or impedance represented by the associated transmissive or ossicular problem.

This high amplification is only achieved with modern digital hearing aids. Despite this, the need for amplification makes the hearing aid work to the limit, creating phenomena such as feedback, distortion and saturation, thus making their tolerance more difficult.[9] Traditional devices for stimulation by bone conduction that are not osseointegrated (glasses, etc.) are the other option often used by this collective. As in the previous case, they offer worse results than osseointegrated devices.[8] Nevertheless, patients do use hearing aids or non-osseointegrated stimulators because they hitherto had no other option to join the world of sound.

The BAHA Cordelle II stimulates bone conduction directly, thus avoiding the middle ear and requiring less amplification for adequate cochlea stimulation. In addition, it has been shown in experimental models of the skull that the saturation level induced is low[3] and is well tolerated by most patients, even though the amplification with these devices is very high.

Flynn et al.,[9] in 10 patients suffering from severe mixed hearing loss, found that BAHA provided better hearing performance than digital hearing aids in terms of language discrimination and sound quality. In fact, they recommend BAHA in cases where the transmissive component of the severe loss is greater than 30 dB.In short, most studies, as well as our own experience, indicate that BAHA is a highly recommendable therapeutic option and should be considered in this profile of hearing loss.[7–10]

From the point of view of complications, despite being so powerful, this device has not added any new complications

to the usual range. We have observed only 2 cases of skin overgrowth and 3 cases of partial flap necrosis, which were resolved with standard measures. It is very important to note that there were no changes in bone conduction thresholds during follow-up in any case, thus eliminating the possibility of sound trauma by cochlear hyperstimulation. The series by Ricci et al.[2] reported a similar rate of complications. It can be concluded that the BAHA Cordelle II does not increase the complication rate implicit in all BAHA.

Audiometric and Subjective Results

The audiometric tonal results obtained were very satisfactory in all users, with closure of the DHT in almost all patients (10/12) in the average of all conversational frequencies. The average gain in air conduction was of 46 dB at conversational frequencies. The gain curve, like in all BAHA, reached a maximum at the frequency of 1000 Hz and then decreased slowly for higher and lower frequencies. Our results are comparable to those from other series such as that by Bosman et al.[3] with 25 patients suffering from severe mixed hearing loss with a minimum DHT of 30 dB. In this series, the differences in air conduction thresholds with and without BAHA Cordelle II in open field were 45.3, 45.8, 47.5, and 43.5 dB at 500, 1000, 2000, and 4000 Hz, respectively.

These results with the Cordelle II BAHA, compared with the results from other BAHA models (Divino, Intenso) are especially good, with DHT overclosure being obtained in most of them. In our experience, the Cordelle II model is the BAHA model that offers the best results.

The speech audiometry also showed improvement not only in the maximum discrimination percentage (it went from 85% to 96%) but also in the decibels required for 100% discrimination (from 83 to 62 dB).

In addition, the subjective evaluation in 11 of the 12 cases was good or very good in general, and especially in quiet environments or in one-on-one conversations. However, as usually happens with most hearing aids, it was worse in noisy or windy environments.[4] All of our patients used the BAHA Cordelle II regularly for over 8 hours each day. The English group of Ho[4] with 50 cases reported a very positive subjective feeling in 66% with the same characteristics as in our group. In addition, 80% used the BAHA Cordelle II over 8 hours each day with a high overall satisfaction. It must be noted that this BAHA group was formed of older patients with poor cochlear reserves, and verbal discrimination was therefore more difficult to rehabilitate. Users should be made aware of this limitation.

It must also be noted that these devices are not a guaranteed, universal solution. There are some patients who perceive the sound amplified by the BAHA as very metallic and unpleasant in the preoperative test with headset, and therefore prefer to continue using their conventional hearing aids. It is recommended that candidates carry out the preoperative test correctly and in different noise environments. Only in this way can a successful result be ensured.

Taking into account all the results, both in our series and in other publications, we can say that the BAHA Cordelle II is an option that should be taken into account for the treatment of patients with severe to profound mixed hearing loss.

Therapeutic Options[10–15]

The debate should also take into account other treatment options for patients suffering from severe to profound bilateral mixed hearing loss. These are mainly[9,10] conventional reconstructive otological surgery, conventional hearing aids and the latest active devices for the middle ear that are fully or partially implantable (Carina, MET, Vibrant SoundBridge, etc.).

Reconstructive surgery is undoubtedly the least indicated and least used option. Ossicular reconstruction in open surgical cavities is complex and the results are not stable over time. At the same time, we must bear in mind that sometimes it is not possible to ever ''dry'' the cavity. In the case of otosclerosis with very mixed losses, which are partially labyrinthized or obliterated, the results with traditional surgery are worse than for standard otosclerosis; there is also the increased risk of labyrinthization. Furthermore, all these surgeries do not solve the sensorineural problem, so despite obtaining good results with surgical closure of the DHT, patients are left with a significant hearing loss that forces them to use other hearing aids. In short, from instability of the results, from scarce foresight or from by the risk of labyrinthization, reconstructive surgery is an unattractive option in this group of patients.

Conventional hearing aids are currently the most common option. This is the safest option, it involves no risk of labyrinthization and the results are predictable, albeit generally not excellent. The disadvantages of this option are the moderate performance achieved, the possibility of feedback and the inconvenience of EAC occlusion. In addition, patients with chronic otorrhea can use them only temporarily or not at all.

Active devices that are totally/partially implantable in the middle ear (Carina®, MET®, MED-EL Vibrand SoundBridge®, etc.) represent the most innovative option for these patients.[11–15] These devices are attached directly to the middle ear structures, thereby avoiding some of the problems of conventional hearing aids: acoustic feedback, occlusion effect, discomfort in the EAC; the Carina also provides the functional and aesthetic advantage of being totally implantable.[10] Most implanted patients refer clear benefits over users of conventional hearing aids; better intelligibility, especially in noisy environments, better sound quality and a more natural own voice with better sound.[13,15]

They can be employed both on the ossicular chain in closed cavities in ears with non-surgical ossicular problems, and in radical open cavities either directly on the round window or even on the platen (occasionally, the cavity has to be obliterated) or in malformations. They can also be used in partially labyrinthized or obliterating otosclerosis, without options for classic stapedial surgery.

The experience accumulated worldwide with these devices is becoming considerable. Over 3500 SoundBridge® and 300 MET®[15] devices have been implanted worldwide since 1996. In 2006, Colletti implanted a Vibrant SoundBridge® in a round window with favourable results. Nakajima et al.[14] have shown that it is possible to obtain correct cochlea stimulation through the round window, especially when a fascia is interposed between the transducer and the round membrane.

Martin et al.[11] published a European multicentre study of 11 cases in which the Carina® was used directly on the round window, with a 2-year follow-up. The preliminary results were satisfactory, with mean open-field gains of 29±5 dB, ranging between 22 and 42 dB, and most patients using the device daily. There were 2 cases of severe postoperative infection, which required explanation. Fraysse et al.[13] published a series of 25 cases of implantation of the Vibrant SoundBridge® device with satisfactory results, although their indications were purely sensorineural hearing loss.

Wagner et al.[10] suggest that these devices may be indicated in cases of poor performance of conventional hearing aids and sensorineural losses of 30 to 60 dB associated to DHT of 30 to 40 dB.

However, it is noteworthy that the implantation surgery for all such devices is complex, special and detailed, only suitable for experienced hands. The results obtained so far seem to be good or very good, although the series are short in number of cases. It is also essential to mention that these devices have notable drawbacks, including their high cost, lack of long-term monitoring that demonstrates the absence of cochlear damage (especially in the basilar membrane by overstimulation) and lack of universal, contrasted results. Our experience includes only 4 cases, one with an excellent result, 2 with good results (although the benefit was temporary) and one failure, due to labyrinthization after 10 days.

It could be concluded that active, middle ear devices seem to be the option with the best future, although they are currently under study. They are not the first option and a prior use of conventional hearing aids is still advisable.

In summary, taking into account all the options discussed, the Cordelle BAHA is currently an option that should be taken into account, It might be considered the option of choice because the risk of labyrinthization is low, the predictability of results is maximum (patients can carry out preoperative tests with the headset), results are good and it has very few limitations, although its cost is quite high.

Cordelle BAHA or Cochlear Implant?

On some occasions, the cochlear reserve of the Cordelle BAHA candidate is so poor that it raises questions about which device may provide better discrimination, the Cordelle BAHA itself or a cochlear implant. On this point, there are 2 different management situations to be considered, depending on whether the cause of the sensorineural hearing loss evolves or not.

Obviously, if the cause is moderately or rapidly evolving, it is reasonable to propose a cochlear implant, since the BAHA will stop being useful in a relatively short period of time and will have to be replaced, resulting in skin problems and higher costs.

In the event that the cause of the hearing loss evolves slowly or not at all, the Cordelle BAHA may be a good option. In this situation, the controversy focuses on establishing the cut-off point from which the cochlear implant is preferred to the Cordelle BAHA. Probably, the most important factor in deciding the best option is language discrimination. The worse the discrimination is, the greater the options for a cochlear implant and the less for the Cordelle BAHA are.

The Dutch group of Nijmehgen[16] has the widest experience in this aspect. This group has published that the parameter that best reflects this decision is the phoneme recognition rate at 65 dB SPL in silence. Verhaegen et al.[16] reported that when this parameter (PS65) was less than 40% (or else when the bone conduction thresholds were higher than 70 dB HL), the cochlear implant was better than the Cordelle BAHA. In our experience, when the maximum discrimination of patients with Cordelle BAHA is less than 60%–70%, cochlear implantation is the best hearing aid. In cases near the limit, the patient's subjective evaluation and preoperative verbal audiometry with the BAHA Cordelle II are of great aid in the decision.

Conclusions

The BAHA Cordelle II is a very good alternative for the treatment of severe to profound mixed bilateral hearing losses, especially in elderly patients at high surgical risk or who require surgery with the possibility of labyrinthization or who are unstable but have high auditory requirements not covered by conventional hearing aids. Active middle ear devices represent another alternative, although there is still a lack of experience to define their indications. Their preliminary results paint a good future. Patient discrimination should be considered in the algorithm of option decision. If this is poor, a cochlear implant should be considered.

Conflict of Interests

The authors have no conflicts of interest to declare.

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