



RESEARCH ARTICLE

EVALUATION REGARDING THE IMPACT OF QUALITY OF LIFE IN THE FUNCTIONAL RESULT AUDIOLOGIC IN PATIENTS IMPLANTED WITH SYSTEM BAHAR[®] IN THE NAVAL HOSPITAL OF HIGH SPECIALTY

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ABSTRACT

Objective: Evaluate the impact of quality of life in the functional result audiologic in patients implanted with system BAHAR[®].

Material and methods: The study included 19 patients implanted with BAHAR percutaneous and transcutaneous system in its varieties BP100, BP110, BAHAR4 and BAHAR5. To measure the quality of life, the Glasgow Benefit Inventory was used. The audiological result was performed with pure tone audiometry at frequencies 500, 1000, 2000 and 3000Hz. Before and after the implant. Applying the tests: Student's T for related samples, Spearman, Chi 2

Results: The change in the degree of hearing loss was significant in the 3 cases with moderate-severe hearing loss, 100% changed to mild; 12 with severe hearing loss, 9 (75.0%) were mild and 3 (25.0%) were normal; 4 cases with profound hearing loss 3 (75.0%) were mild and 1 (25.0%) were normal (p = 0.0001, chi square). The pure tone averages decreased 45.7% the bone-to-air GAP was reduced by 57.5%. There was no significant relationship between the degree of post-operative hearing, the etiology or type of hearing loss and the quality of life. Postoperative pure tones correlated positively with the dimensions of the Glasgow quality of life scale.

Conclusions: Our study demonstrates a high audiometric gain similar with different implant systems BAHAR, which is compatible with significant improvement in quality of life of patients.

INTRODUCTION

Hearing loss is called the functional deficit that occurs when a subject loses hearing capacity, to a greater or lesser degree. Approximately 12,000 children (1-3 per 1000) are born with hearing defects in the United States each year. It is estimated that approximately 278 million people worldwide have moderate or severe hearing loss; And is higher among Latin Americans, African Americans, and people from low-income families (Flint et al., 2015).

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Conductive hearing loss is usually caused by a dysfunction in the transmission of sound through the external ear, medium or by abnormal transduction of sound energy in neuronal activity in the inner ear and the eighth nerve. It is the most common type of hearing loss in children and atresia or stenosis of the external auditory canal being common causes (Ricci 2011). The perforation of the tympanic membrane, discontinuity or fixation of the ossicular chain, otitis media, otosclerosis and cholesteatoma are the most frequent causes of conductive hearing loss in the adult population (Cass et al., 2010). The use of the bone pathway as a way of auditory rehabilitation was described by Tjellstron and Hakansson, applying a system of osteointegration to the temporal bone conceived by Branemark in 1966, who recognized the potential of growth of the bone tissue in contact with the surface of a Implant of titanium,

metal that has been shown to incite to osseointegration instead of reaction to foreign body, which makes titanium the ideal material for Osseointegration (Brånemark et al., 2001; Tjellström et al., 1994). The Glasgow Benefit Inventory (GBI) is a quality of life questionnaire designed to measure outcomes after otorhinolaryngologic procedures. It is validated in an extensive series of procedures, is sensitive to changes in health, and is patient oriented. It measures the quality of life in three domains, social, general and physical ("domain" refers to an area of behavior or experience that a group of questions are trying to measure). Of the 18 GBI questions, 12 refer to general improvement in quality of life, 3 to social improvement, and 3 to physical improvement. Each of the questions has five possible answers; A response of 5 reveals a favorable outcome, and 1, poorer outcomes, a response of 3 indicates no change (Robinson et al., 1996; Arunachalam et al., 2001; Claire et al., 2004; Busch et al., 2015). Studies have been carried out worldwide to evaluate the audiological improvement with BAHA system, have confirmed an improvement in sound quality and speech discrimination (Cochlear, 2016; Ricci et al., 2010). In our country, there are no studies comparing quality of life using questionnaires validated according to the audiological result, in patients using BAHA.

The present study is unique in its type because it has a captive population, which could be evaluated satisfactorily without problems with follow-up or direct interview. This is an important measure because it reflects the patient's trustworthy benefit compared to objective audiological data.

MATERIALS AND METHODS

A study was carried out that included the first 19 consecutive patients who underwent BAHA placement at the High Specialty Naval Hospital, from May 2014 to September 2016. Only 3 surgeons skilled in BAHA placement performed all the operations. All participants were interviewed in a personal Medico - Patient interview, the questionnaire based on GBI, three months after implant use. The pre-and post-operative audiometry studies of the electronic file were collected from the archive of the Audiology service of the Hospital General Naval de Alta Especialidad. The following data were included: pre-and post-operative pure tone average with thresholds for airway and Bone, pre and post operative GAP, and auditory gain calculation, all at frequencies of 500, 1000, 2000 and 3000 Hz (Lustig, 2001).

RESULTS

We studied 19 patients. Eight female patients (42.1%) and 11 male patients (57.9%) were included, with a mean age of 39.9 +/- 20.9 years (range 7-65). The youngest patient was 7 years old, and the oldest patient was 65 years of age (39 years of age). All participants had audiometry prior to surgical procedure, and were evaluated after a minimum of 3 months after the activation of BAHA to allow time to become accustomed to the implant. The pathologies in which BAHA was indicated are shown in Table 1. The main diagnosis was sequelae of chronic otitis media preceded by congenital microtia-atresia, which were the two main groups, followed by otosclerosis and posterior fossa tumors. Airway thresholds oscillated at 69.9 +/- 22.1, and bone conduction threshold 5-42 dB (median threshold, 22 dB).Speech discrimination (SD 50) ranged from 5 to 60 dB (mean value, 26 dB). In 3 cases, preoperative hearing loss was moderate-severe, severe 12, and profound 4. In 15 the BAHA Attract system was used and in 4 the Connect; In 9 the processor was BAHA 4, in 5 the BAHA5, in 4 the BP110 and in one the BP100.

Auditory changes in subjects

The change in the degree of hearing loss was significant: as observed (Table 2) of the 3 cases with moderate-severe preoperative hearing loss, 3 (100%) were mild; Of the 12 with severe hearing loss, 9 (75.0%) became mild and 3 (25.0%) were normal; Finally, of the 4 cases with profound hearing loss 3 (75.0%) completed the mild and 1 (25.0%) in normal (p = 0.0001, chi square). In general, pure tone and air-bone GAP averages were significantly modified: pure tones decreased 45.7% from 69.9 +/- 22.1 in the preoperative period to 37.9 +/- 13.9 in the postoperative period with a P = 0.0001, Student t for related samples); Similarly, bone-air GAP were reduced by 57.5%, decreasing from 38.8 +/- 12.4 in the preoperative period to 16.5 +/- 11.3 in the post-operative period (p = 0.0001, Student's t for related samples). The mean hearing gain was 26.6 +/- 15.2 dB. According to the change in hearing loss levels, see (Chart 1) the reductions in pure tone averages and (Chart 2) those corresponding to bone-to-air GAP. The magnitude of the processor changes was analyzed separately. Beginning with BAHA4 in 6 adults: As shown (Table 3), with BAHA4 the mean pure tone was reduced by 34.6% or 56.9 to 37.2 (p = 0.015);

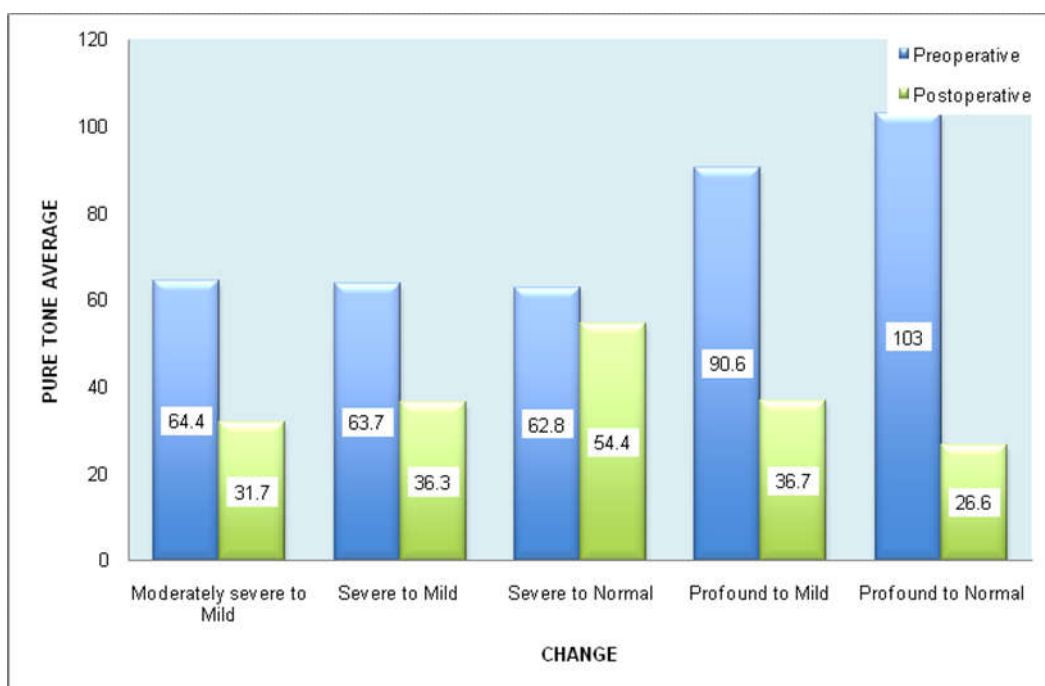
Table 1. Primary pathologies of patients with Bone Anchored Hearing Aids

	Frequency (n=19)
Sequelae of Otitis Media Chronic	47.4% (9)
Microtia-atresia	5 (26.3)
Otosclerosis	3 (15.8)
Tumors of posterior fossa	2 (10.5)

Table 2. Frequency of the degree of preoperative hearing loss in relation to the postoperative result

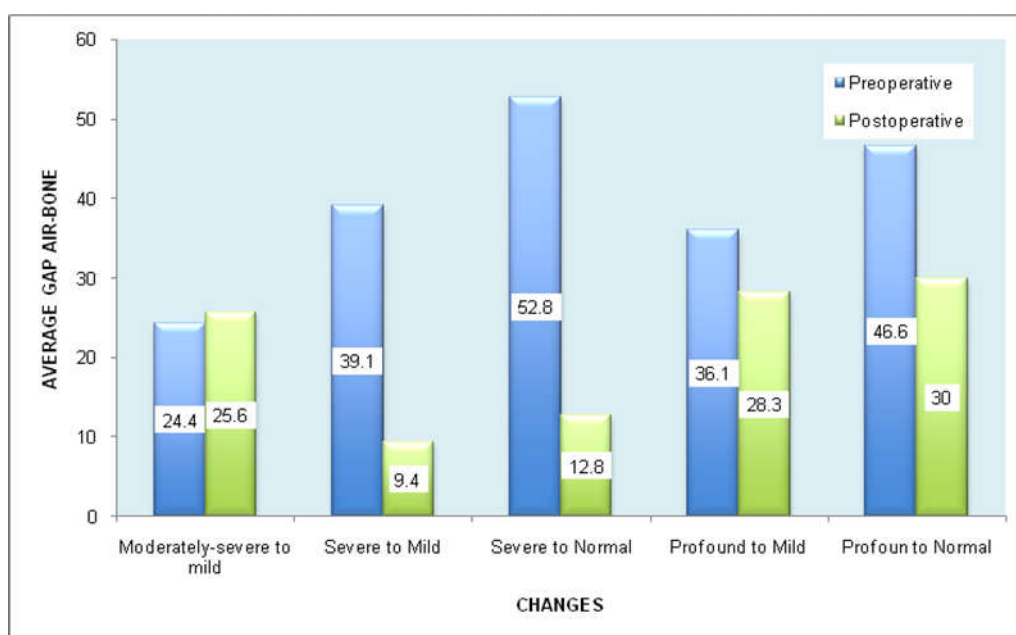
Degree of Preoperative Hearing Loss	P=0.0001*	Degree of Postoperative Hearing Loss		
		Mild (n=15)	Normal (n=4)	
Moderately-severe		100% (3)	0	100% (3)
Severe		75.0% (9)	25.0% (3)	100% (12)
Profound		75.0% (3)	25.0% (1)	100% (4)

* Statistical significance, x2



P = 0.001,

Graphic 1. Reduction of averages of pure tones according to change in the levels of hearing loss



Graphic 2. Reduction of bone-air GAP according to change in the levels of hearing loss

Table 3. Comparison of averages of pure tone and air-bone GAP before and after surgery with BAHA4 adults

	Pre	Post	N	p
Pair 1 Pure tone average	56.94433±18.239	37.22133±8.276	6	0.01*
Pair 2 Bone-air GAP	29.99933±10.380	11.37750±6.874		0.01*

*Statistical significance

The bone-air GAP had a percentage change of 62.2% from 29.9 to 11.3 (p = 0.018). These changes had their correlate with the fact that of the 6 patients 1 had moderate-severe hearing loss in the preoperative period and went on to mild hearing loss, the other 5 were with severe hearing loss and the 5 passed to mild according to the distribution Binomial the expected probability was that of 6 patients 50% went down to mild,

however the observed proportion was 83.3% (p = 0.001). With the BP 110 processor the pure tone averages fell 58.0% (p = 0.08) and those corresponding to the bone-air GAP decreased 62.9% (p = 0.004) as can be analyzed from Table 4. In this case, the correlate was that of the 4 patients 2 had severe hearing loss and both became mild, the other 2 were with profound hearing loss and 1 of them went to mild and the other

Table 4. Comparison of averages of pure tone and air-bone GAP before and after surgery with BAHA BP110 adults

		Pre	Post	N	p
Pair 1	Pure tone average	80.33325±33.572	33.31500±8.728	4	0.08*
Pair 2	Bone-air GAP	41.64975±4.883	15.41650±10.573		0.004*

* Statistical significance

Table 5. Comparison of averages of pure tone and bone-to-air GAP before and after surgery with BAHAS adults

		Pre	Post	N	p
Pair 1	Pure tone average	81.99900±16.765	33.66500±10.231	5	0.013*
Pair 2	Bone-air GAP	36.99940±15.723	26.66620±15.723		0.44*

* Statistical significance

Table 6. Comparison of averages of pure tone and air-bone GAP before and after surgery with BAHA4 children

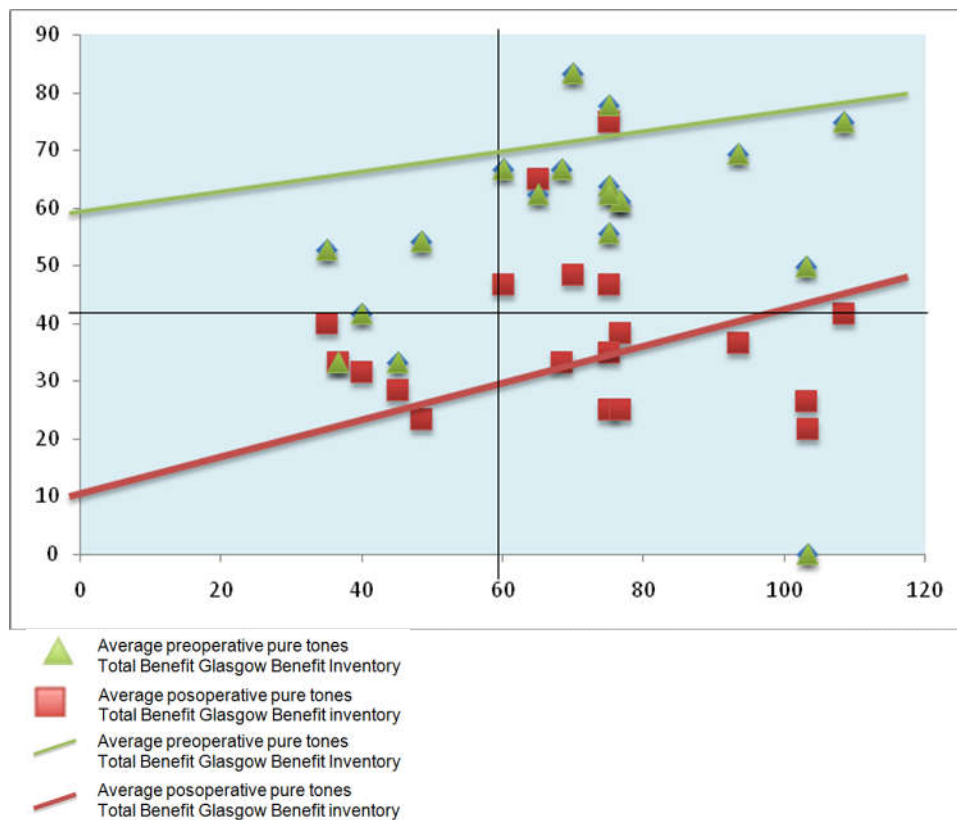
		Pre	Post	N	p
Pair 1	Pure tone average	69.44333±5.092	57.77767±21.752	3	0.42
Pair 2	Bone-air GAP	54.44300±7.877	11.11000±1.922		0.015

* Statistical significance

Table 7. Statistical descriptors of the Glasgow Benefit Inventory

	N	Minimum	Maximum	Media±S.D.
Total Benefit Glasgow Benefit Inventory	19	0	83.33	56.35±19.15
General subscale Glasgow Benefit Inventory	15	0	87.50	61.94±24.39
Social support Glasgow Benefit Inventory	15	0	83.33	49.62±23.04
Subscale physical health status Galgow Benefit Inventory	19	0	75.00	47.58±22.75
Emotional state Glasgow Children Benefit Inventory	4	52.78	80.56	63.89±11.78
Learning Glasgow Children Benefit Inventory	4	53.57	85.71	63.39±14.97
Vitality Glasgow Children Benefit Inventory	4	47.05	73.52	62.49±11.10

S.D.= Standard deviation



Graphic 3. Correlations superimposed between pure tones pre-operative and Total Benefit in the scale of Quality of Life and pure tones post-operative with Total Benefit of the scale of Quality of Life

to normal. With BAHA5 (Table 5) only the pure tone averages underwent a significant change of almost 60% from 81.9 to 33.6 ($p = 0.013$), but bone OSA only declined 27.9% from 36.9 to 26.6 ($p = 0.44$); However, from the clinical point of view, the change was very significant, since in the preoperative period 2 of the 5 patients had moderate-severe hearing loss, 1 had severe hearing loss and 2 had profound hearing loss. All 5 were mild.

In the case of children with the BAHA4 processor (Table 6), pure tone averages dropped only 16.8% from 69.4 to 57.7 ($p = 0.42$), however bone-to-air GAP averages decreased 79.5% from 54.4 to 11.1 ($p = 0.015$). The 3 cases operated with this processor had severe hearing loss: 2 passed to normal and 1 to mild BP 100 can not be analyzed statistically because it only included 1 child; however, it should be noted that pure tones fell from 48.3 to 23.3 or a reduction of 51.7%; While the air bone GAP decreased from 43.3 to 18.3 for a 57.7% reduction and that this 7.0-year-old boy from the male gender went from severe to normal hearing loss. The results of the quality of life in adults and children, on the Glasgow scale (whose Cronbach alpha reliability coefficient was 0.814 CI95% 0.626-0.933, $p = 0.0001$), showed the descriptive values observed in Table 7 Only pure post-operative tones correlated positively with the Glasgow scale of quality of life but only in adults: with Total Benefit coefficient $\rho = 0.615$ ($p = 0.005$); With General Subscale $\rho = 0.581$ ($p = 0.02$); With Social Support $\rho = 0.745$ ($p = 0.001$) and with Physical Health $\rho = 0.659$ ($p = 0.002$). See Chart 3 for overlapping correlations in which it is observed that when correlating the preoperative pure tone scores with the Total Benefit scores of the Glasgow scale (black circles) the patients who currently scored high in Total Benefit were those who Originally had high scores in pure tones, but correlating them simultaneously with post-operative scores of pure tones, the correlation changes drastically ($\rho = 0.651$, $p = 0.005$), so the correlation indicates that those who lowered the pure tones of the pre t Post-operative (most were below 40 dB) increased in the Total Benefit of the quality of life scale (most were above 60.0 points).

DISCUSSION

After the introduction of osseointegration and its application to hearing devices by Hakansson, bone-anchored hearing systems have become the standard of care for patients with conductive or mixed hearing loss and the inability to tolerate a conventional hearing aid. Systems with an external transducer anchored to an osseointegrated one have been applied since 1977 and consecutively have been successfully applied in more than 120,000 patients worldwide since then. The quality of life questionnaires were designed and validated to quantify the benefit that patients obtain from different otorhinolaryngological interventions, with this benefit being understood as the changes that occur in the health status as a result of a health action. There are several studies for this evaluation of which are Glasgow Benefit Inventory (GBI) and Glasgow Children's Benefit Inventory (GCBI), (Arunachalam, 2001; Sánchez-Camón, 2007). These instruments had a high reliability (Cronbach's $\alpha = 0.814$) with the 24 reagents for GCBI, there was no reagent that diminished its reliability, it was also found that the GBI (Glasgow Benefit Inventory) instrument showed a high reliability (Cronbach's $\alpha =$

0.739) with the 18 reagents with statistically significant correlations among all the reagents.

The three GBI domains applicable to BAHA were analyzed separately. The results indicate that the overall benefit is maximal, followed by social and physical benefits. This pattern is similar to the results of other otological procedures with good results. The average overall benefit score for BAHA users was 56.35 (minimum 0 and maximum 83.33) compared to what is described by Mc Larnon 2004, who reported an overall benefit of +33 [95% CI 25-42] (Claire, 2004). It was found that BAHA produces a greater improvement in quality of life than middle ear surgery, but only slightly less than cochlear implants. Therefore, the use of BAHA can be justified in terms of safety (ie, no risk of serious side effects such as facial nerve palsy associated with other middle ear procedures), and the costs are much lower than with a cochlear implant.

Las dos principales patologías para colocación de BAHA en nuestra población, son similares a los reportados por Arunachalam, 2001 y Busch, 2015 (Arunachalam, 2001; Busch et al., 2015). La mejoría auditiva que tuvieron los pacientes implantados en tonos puros con media de 70dB (35 - 108) fue en promedio de 38 dB (21.6-75), la cual es mayor a la reportada por Lustig, et al., 2001 reportaron una ganancia promedio de 32 + - 19 dB HL en 40 pacientes después de la implantación de un dispositivo con un transductor externo (Lustig, 2001). Los datos comparables de este tipo son presentados por Ricci et al., 2010, que reportaron una ganancia funcional de 28,5 + - 17,3 dB HL (Ricci et al., 2010). The most significant changes were found in patients with profound hearing loss achieved an improvement in mild hearing loss (Graph 1); improvement in air-bone GAP was greater in patients who previously had severe hearing loss.

Regarding the Glasgow questionnaire our results clearly show that the use of BAHA is related to an improvement in the quality of life, as is also seen in other studies, the mean of the total score obtained in our study was 56.35, which is compared Positively with the results obtained in another very similar study by Arunachalam et al. (2007). All of our patients scored above 25 on the overall subscale, and in almost all total score numbers were greater than twenty. Bone anchored devices are relatively expensive equipment; It is important to evaluate the quality of life in BAHA users and to identify the group of patients who are most likely to obtain maximum benefit from their use. This in turn manages to be of help in the decision making related to the group of patients who must have preference for the placement of BAHA.

Conclusion

In conclusion, for patients in whom the therapeutic procedures do not aim to improve survival, as is the case of patients operated in order to provide them with a better hearing, the quality of life results become essential, especially if in several Studies show that there is no significant relationship between audiological outcomes and quality of life outcomes as might be expected. This fact emphasizes the need to carry out an evaluation not only of objective measurements of hearing but also of the quality of life perceived by the patient through questionnaires intended for this purpose. Our study, with a high response rate (96%) that provides validity to the results

obtained, shows a significant improvement in the quality of life of patients receiving BAHA, information that is very useful when giving advice Preoperative to patients and otolaryngologists in daily clinical practice.

REFERENCES

- Arunachalam, S., Perumkulam, David Kilby, David Meikle, Tom Davison, y Ian J. M. Johnson. «Bone-Anchored Hearing Aid Quality of Life Assessed by Glasgow Benefit Inventory.» *The Laryngoscope* 111 (2001): 1260-1263.
- Brånemark, P.I., Rickard Brånemark, Björn Rydevik, y Robert R. Myers. «Osseointegration in skeletal reconstruction and rehabilitation: A review.» *Journal of Rehabilitation Research and Development (Department of Veterans Affairs)* 38, n° 2 (Abril 2001): 175-181.
- Busch, Susan, Thomas Gier, Thomas Lenarz, y Hannes Maier. «Comparison of Audiologic Results and Patient Satisfaction for Two Osseointegrated Bone Conduction Devices: Results of a Prospective Study.» *Otology & Neurotology* 0, n° 0 (2015): 1-7.
- Cass, Stephen P., y Pamela A. Mudd. «Bone-anchored hearing devices: indications, outcomes, and the linear surgical technique.» *Operative Techniques in Otolaryngology (Elsevier)* 21, n° 3 (septiembre 2010): 197-206.
- Claire M. McLarnon, Tom Davison,. «Bone-Anchored Hearing Aid: Comparison of Benefit by Patient Subgroups.» *Laryngoscope* 114 (2004): 942-944.
- Cochlear AG. Julio de 2016. <http://www.cochlear.com/wps/wcm/connect/intl/for-professionals/baha-bone-conduction-implants> (último acceso: 2 de Agosto de 2016).
- Flint, Paul W., y otros. Cummings Otolaryngology HEAD AND NECK SURGERY. 6. III vols. Canada: Elsevier, 2015. p 2051-2070.
- Gurgel, Richard K., Robert K. Jackler, Robert A. Dobie, y Gerald R. Popelka. «A New Standardized Format for Reporting Hearing Outcome in Clinical Trials.» *Otolaryngology-Head and Neck Surgery (American Academy of Otolaryngology—Head and Neck Surgery Foundation)* 5, n° 147 (julio 2012): 803-807
- Lustig, Lawrence R., et al. «Hearing rehabilitation using the BAHA bone-anchored hearing aid: results in 40 patients.» *Otology & Neurotology* 22 (3 2001): 328-334.
- Ricci, G., Della Volpe, A., Faralli, M., Longari, F., Gullà, M., Mansi, N., & Frenguelli, A. «Results and complications of the Baha system (bone-anchored hearing aid).» *European Archives of Oto-Rhino-Laryngology* 267, n° 10 (2010): 1539-1545.
- Ricci, Giampietro, y otros. «Bone-anchored hearing aids (Baha) in congenital aural atresia: Personal experience.» *International Journal of Pediatric Otorhinolaryngology (Elsevier BV)* 75, n° 3 (Enero 2011): 342-346.
- Robinson, K., Gatehouse, S. and Browning, G. Measuring Patient Benefit from Otorhinolaryngological Surgery and Therapy. *Annals of Otology, Rhinology & Laryngology*, 105 (1996): 415-422.
- Sánchez-Camón, Isabel, Luis Lassaletta, Alejandro Castro, y Javier Gavilán. «Calidad de vida de los pacientes con BAHA.» *Acta Otorrinolaringológica Española (Elsevier BV)* 58, n° 7 (2007): 316-320.
- Tjellström, Andres, y Gösta Granström. «Long-term follow-up with the bone-anchored hearing aid: a review of the first 100 patients between 1977 and 1985.» *Ear, nose, & throat journal* 73, n° 2 (1994): 112-114
