A Comparison of Operative Techniques and Clinical Outcomes for BAHA Implantation

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INTRODUCTION

Initially introduced in the 1970's, bone-anchored hearing aids (BAHAs) have become a widely accepted treatment in certain individuals with conductive or mixed hearing loss as well as those with single-sided deafness. [1-5] The device transmits sound from a processor though an osseointegrated titanium implant embedded in the temporal bone, and stimulates the cochlea through bone conduction.[5-7] BAHAs have provided significant benefits for individuals who are not candidates for surgery or hearing aids, and have shown improvements in auditory gain of 10 to 25 dB when compared to traditional bone conduction hearing aids.[5,8-11]

Multiple variations for placement of the percutaneous BAHA have been developed, and unfortunately continue to be beleaguered by soft tissue complications including skin flap necrosis, flap infection, skin growth over the abutment, failure of osseointegration, and extrusion of the titanium implant.[13-19] In order to avoid the adverse skin complications and aesthetic concerns associated with the percutaneous BAHA, a new magnetic bone conduction hearing implant system has been developed (Figure 1).[20,21]

This project's purpose is to compare multiple techniques for BAHA implantation in regard to postoperative complications, operative time, and duration between surgery and first use of the BAHA. We compared operative outcomes of both percutaneous and magnetic BAHA implantation techniques.

MATERIALS & METHODS

After Institutional Review Board (IRB) approval was obtained, a retrospective study was conducted of all patients receiving implantation of a BAHA from August 2008 to October 2014 by a single surgeon. The system implanted in each case was either the percutaneous Baha® Connect or magnetic Baha® Attract (Cochlear Ltd., Sydney, Australia).

Medical records were obtained, and data was collected including: patient age, gender, side operated, abutment length, operative time, duration until first use of the BAHA, operative technique, and postoperative complications. A complication was defined as an instance that would require additional postoperative care, including steroid or antibiotic treatment, debridement, surgical revision, or implant removal. Soft tissue complications were further classified according to the Holgers classification system (Table 1). Two cases in the time series reviewed were excluded because of insufficient data.

Data was entered into a database spreadsheet (Excel, Microsoft Corp., Redmond, WA). Statistical analysis was performed on the collected data using analysis of variance (ANOVA), tukey pairwise comparison, chi-square, and paired t-test. Statistical significance was determined using a level of $p < 0.05$.

RESULTS

A total of 88 patients (43 female, 45 male) were included in data analysis. A total of 80 complications were documented, and these complications were classified based on the Holgers criteria (Tables 1 & 2). A significant difference in total postoperative complications existed between the six techniques used (ANOVA; $p<0.01$) (Table 3). Moreover, regarding operative time, a significant difference existed between the six techniques employed (ANOVA; $p<0.01$). The average duration of time until fitting of the BAHA processor between the various techniques trended towards but did not reach statistical significance (ANOVA; $p=0.16$).

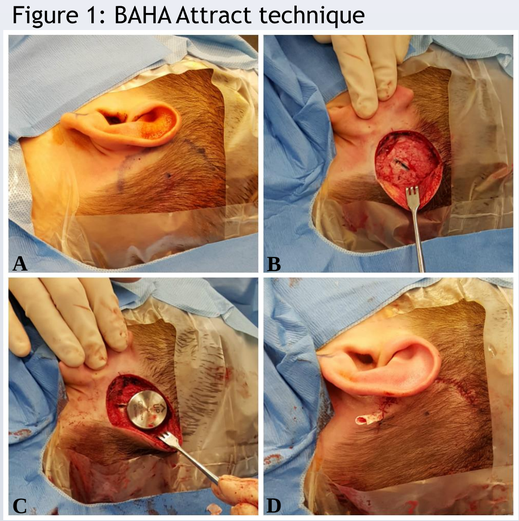
Table 1. Holgers Classification System for Skin Reactions at BAHA Implantation Site

Grade	Description
0	Reaction free skin around the abutment
1	Redness with slight swelling around the abutment
2	Redness, moistness, and moderate swelling
3	Redness, moistness, and moderate swelling with tissue granulation around the abutment
4	Overt signs of infection resulting in removal of the implant

Table 2. Soft Tissue Complications by Technique Employed

Holgers Classification	1	2	3	4	Total Complications	Total cases	Cases without complications (%)
Dermatome	2	1	2	1	6	6	50
Linear	5	0	9	5	19	25	44
Biopsy Punch (BP)	3	3	5	1	12	6	33.3
Linear with BP	7	0	12	1	20	15	26.7
U-shaped Flap	7	6	8	1	22	23	43.5
Attract	1	0	0	0	1	13	92.3
Total					80	88	47.7

Figure 1: BAHA Attract technique



(A) An 18 gauge needle dipped in methylene blue is used to mark the temporal bone where the implant will be placed. A 3cm semi-circle is then marked as the incision site.
(B) The flap is taken down to periosteum with soft tissue reduced.
(C) The implant is drilled in place with magnet secured in proper position.
(D) A drain is placed and the flap is sutured primarily with layered closure.

Table 3. Comparison of Patients Undergoing BAHA Implantation Using Various Techniques

Characteristic	Dermatome	Linear	Biopsy Punch (BP)	Linear with BP	U-shaped Flap	Attract	P-value
	n=6	n=25	n=6	n=15	n=23	n=13	
Mean Age (years)	54.8	55.8	60.5	58.9	59.3	56	0.94
Location (% right-sided)	50	44	66.7	46.7	47.8	38.5	0.92
Gender (% male)	33.3	56	83.3	60	34.8	53.8	0.26
Complications (Total)	6	19	12	20	22	1	<0.01
Avg. Surgical Time (min.)	67	54	30	51	41	62	<0.01
Avg. Time to 1st Use (days)	90	91	97	88	92	59	0.16

DISCUSSION

In this study, we compared the complication rates and operative times among six different techniques for BAHA implantation performed by a single surgeon. As shown in Table 3, a total of 80 complications occurred among the 88 procedures performed. Although many patients experienced multiple complications, only 47.7% of the entire population experienced no soft tissue reactions postoperatively. Moreover, among the percutaneous surgeries, the rate of cases performed without complications was best for the dermatome technique, having only half the cases experiencing adverse soft-tissue reactions.

In contrast to the high rate of soft-tissue complications among percutaneous BAHA implantations in this and other series, use of the magnetic Attract system resulted in significantly less overall complications in our series. Indeed only one complication occurred in the Attract group, and was classified as a Holgers class 1 complication. In addition, 92.3% of the Attract cases did not experience any complications. These results are supported by the study by Briggs et al. in that only 4 cases of mild skin erythema were noted in their series of 27 implanted patients, and no major complications occurred.[21] The erythema noted in each case is likely due to the pressure on the soft-tissues from the magnet. Although a cause for irritation from the pressure exerted, it seems to carry less risk for bacterial seeding and chronic inflammation of the soft tissues than a percutaneous implant.

Analysis of our data demonstrated another advantage of the Attract system in comparison to percutaneous techniques for BAHA implantation, in that time to fitting the processor was shortest for the Attract population (average time to fitting processor: percutaneous 88-97 days; Attract 59 days). Thus, patients have to wait a significantly less amount of time until first use of their BAHA with the Attract system.

Despite the improvement in soft-tissue reactions, the Attract technique took significantly longer to perform than one of the percutaneous techniques (avg. time of 62 min. for Attract and 30 min. for biopsy punch). Given the potential reduction in healthcare cost associated with decreased OR time, this finding can have substantial impact. Moreover, a similar finding was made by Gordon and Coelho in demonstrating that the biopsy punch technique could be performed in significantly less time that the linear incision technique.[11] Thus, when comparing the Attract and biopsy punch techniques, the decreased operative time for the biopsy punch technique must be weighed against its significantly greater risk of soft-tissue reactions.

CONCLUSION

Bone-anchored hearing aids (BAHAs) play an important role in treating patients with hearing loss who are not suitable candidates for surgery or conventional hearing aids. Multiple techniques have been developed throughout the years in an attempt to decrease operative time and minimize complication rates. Through retrospective review of ninety patients over a six year time period, we found significant differences in operative outcomes among various techniques for BAHA implantation. Based on statistical analysis of our data, the Attract system consumes greater operative time, but is associated with less postoperative complications than percutaneous techniques and its processor may be fitted significantly sooner.

REFERENCES

1. Woolford TJ, Morris DP, Saeed SR, Rothera MP. The implant-site split-skin graft technique for the bone-anchored hearing aid. Clin Otolaryngol. 1999;24:177-180.

2. Mudry A. Bone-Anchored Hearing Aids (BAHA): Skin healing process for skin flap technique versus linear incision technique in the first three months after the implantation. Rev Laryngol Otol Rhinol. 2009; 130: 281-284.

3. Allis TJ, Owen BD, Chen B, Jones DT, Moore GF. Longer length Baha™ abutments decrease wound complications and revision surgery. Laryngoscope. 2014;124(4):989-92.

4. Asma A, Ubaidah MA, Hasan SS, et al. Surgical outcome of bone anchored hearing aid (baha) implant surgery: a 10 years experience. Indian J Otolaryngol Head Neck Surg. 2013;65(3):251-4.

5. Wilson DF, Kim HH. A minimally invasive technique for the implantation of bone-anchored hearing devices. Otolaryngol Head Neck Surg. 2013;149(3):473-7.

6. Mylanus EAM, Beynon AJ, Snik AFM, Cremers CWRJ. Percutaneous titanium implantation in the skull for the bone-anchored hearing aid. J Invest Surg 1994;7:327-32.

7. Wilkinson EP, Luxford WM, Slattery WH, De la cruz A, House JW, Fayad JN. Single vertical incision for Baha implant surgery: preliminary results. Otolaryngol Head Neck Surg. 2009;140(4):573-8.

8. Hol MK, Snik AF, Mylanus EA, et al. Does the bone-anchored hearing aid have a complimentary effect on audiological and subjective outcomes in patients with unilateral conductive hearing loss? *Audiol Neurootol*. 2005;10:159-168.

9. Badran K, Bunstone D, Arya AK, et al. Patient satisfaction with the bone-anchored hearing aid: a 14-year experience. *Otol Neurotol*. 2006;27:659-666.

10. Kunst SJ, Hol MK, Mylanus EA, et al. Subjective benefit after BAHA system application in patients with congenital unilateral conductive hearing impairment. *Otol Neurotol*. 2008;29:353-358.

11. Gordon SA, Coelho DH. Minimally invasive surgery for osseointegrated auditory implants: A comparison of linear versus punch techniques. Otolaryngol Head Neck Surg. 2015;152:1089-1093.

12. Tjellstrom A, Lindstrom J, Hallen, O, et al. Osseointegrated titanium implants in the temporal bone. A clinical study on bone-anchored hearing aids. *Am J Otol*. 1981;2:304-310.

13. Holgers KM, Bjursten LM, Thomsen P, et al. Experience with percutaneous titanium implants in the head and neck: a clinical and histological study. *J Invest Surg*. 1989;2:7-16.

14. Snyder MC, Moore GF, Johnson PJ. The use of full-thickness skin grafts for the skin-abutment interface around bone-anchored hearing aids. *Otol Neurotol*. 2003;24:255-258.

15. Lekakis GK, Najuko A, Gluckman PG. Wound related complications following full thickness skin graft versus split thickness skin graft on patients with bone anchored hearing aids. Clin Otolaryngol. 2005;30:324-327.

16. Shirazi MA, Marzo SJ, Leonetti JP. Perioperative complications with the bone-anchored hearing aid. *Otolaryngol Head Neck Surg*. 2006;134:236-239.

17. House JW, Kutz JW, Jr. Bone-anchored hearing aids: incidence and management of post-operative complications. *Otol Neurotol*. 2007;28:213-217.

18. Stalfors J, Tjellstrom A. Skin reactions after BAHA surgery: a comparison between the U-graft technique and the BAHA dermatome. Otol Neurotol. 2008;29:1109-1114.

19. Van Rompaey V, Claes G, Verstraeten N, et al. Skin reactions following BAHA surgery using the skin flap dermatome technique. Eur Arch Otorhinolaryngol. 2011;268:373-376.

20. İşeri M, Orhan KS, Kara A, et al. A new transcutaneous bone anchored hearing device – the Baha® Attract System: the first experience in Turkey. Kulak Burun Bogaz Ihtis Derg. 2014; 24:59-64.

21. Briggs R, Van Hasselt A, Luntz M, Goycoolea M, Wigren S, Weber P, Smeds H, Flynn, M, Cowan R. Clinical performance of a new magnetic bone conduction hearing implant system: Results from a prospective, multicenter, clinical investigation. Otol Neurotol. 2015;36:834-841.

22. Mylanus EAM, Cremers CWRJ. A one-stage surgical procedure for placement of percutaneous implants for the bone-anchored hearing aid. J Laryngol Otol 1994;108:1031-5.

23. de Wolf MJF, Hol MKS, Huygen PLM, et al. Clinical Outcome of the Simplified Surgical Technique for BAHA Implantation. Otol Neurotol. 2008;29:1100-1108.

24. Fontaine N, Hemar P, Schultz P, Charpiot A, Debry C. BAHA implant: implantation technique and complications. Eur Ann Otorhinolaryngol Head Neck Dis. 2014;131(1):69-74.