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ORIGINAL RESEARCH–OTOLOGY AND NEUROTOLOGY

TriVerse versus molecular resonance–harvested grafts in single-stage Baha surgery

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ABSTRACT

OBJECTIVES: To assess complications occurring in patients with a bone-anchored cochlear stimulator (Baha) following split-thickness skin graft harvested with two surgical modalities: the TriVerse (TV) system and the molecular resonance generator (MR).

STUDY DESIGN: Prospective, randomized, two-group (TV and MR) study of 24 patients who underwent Baha surgery.

SETTING: Tertiary care institution.

SUBJECTS AND METHODS: All patients (5 children, age range 6-14 yrs, median 8.3 yrs, and 16 adults, age range 30-73 yrs, median 60 yrs) underwent the one-stage procedure. The skin flap was harvested by use of the TV in 12 cases (2 children, 10 adults) and the MR generator in 12 (3 children, 9 adults). The main outcome measures were wound healing time, number of follow-up visits, degree of soft tissue reactions around the abutment, and need for revision surgery were examined.

RESULTS: There was a clear difference between the TV- and MR-harvested skin graft groups in relation to severity of skin reactions and complete healing time. The TV group required from three to seven (median 4) visits as outpatients during the initial observation period until healing was complete. The MR group required only one to three (median 2) visits. Complete healing time was significantly lower in the MR group (range 7-12 days, median 10 days) compared to the TV group (range 15-28 days, median 16 days). In the TV group, two patients required in-office revision of the skin graft because of partial necrosis.

CONCLUSIONS: In our experience, the MR-harvested split-thickness skin graft is superior to the TV technique.

The Baha system (Cochlear Bone Anchored Solutions AB, Mölnycke, Sweden) is an effective and well established surgical treatment for hearing rehabilitation. Initially indicated for mixed/conductive hearing losses,[1] the Baha system is now also used to treat single-sided deafness (SSD), such as after unilateral sudden hearing loss, or after acoustic neuroma (AN) removal.[2-5]

The bone-anchored cochlear stimulator is coupled to the temporal bone via a titanium abutment implanted into the bone. The titanium implant is a percutaneous abutment, and since the Baha procedure is generally well tolerated, wound complications are the most common postoperative problems. These complications may vary from mild local skin reactions—usually resolved after local wound care—to more significant problems, such as skin overgrowth, loss of skin flap, or implant extrusion.[4,6-9]

Appropriate and meticulous surgical technique,[10] scrupulous care of soft tissue, and wound care during and after surgery are the key factors for achieving long-term success after Baha surgery. While accurate surgical technique is universally considered mandatory, different methods of harvesting the skin graft are reported,[6,9-12] with different results. In addition, skin incision, soft tissue dissection, and skin-graft harvesting can be obtained with different surgical tools (i.e., cold-knife, dermatome, monopolar cautery, bipolar cautery, etc.). "Cold" techniques (i.e., scalpel, dermatome) provide the advantage of avoiding thermal damage to soft tissue but have the drawback of producing bleeding, which may obscure surgical planes and slow the procedure, whereas "hot" techniques (i.e., monopolar, bipolar cautery) may allow simultaneous hemostasis with ease of dissection but induce thermal injury, which may increase the risk of flap necrosis.

Improvements in surgical technology can help otolaryngologists in obtaining better results via fast, simple, and bloodless procedures. In this light, we evaluated two different technologies as applied to Baha surgery: the TriVerse (TV) system (Tyco Healthcare Corp., Boulder, CO) and the Molecular Resonance (MR) generator (Telea Engineering, Vicenza, Italy). We assessed and analyzed complications that occurred in Baha patients in regard to wound healing after split-thickness skin graft harvested with the TV system and with the MR generator.

Methods

This was a prospective, randomized, two-group (TV and MR), single-blinded study, performed from March 8, 2007, to March 9, 2008, at a tertiary care otologic institution. The study protocol was approved by the ethics committee from the first author's institution, and written informed consent

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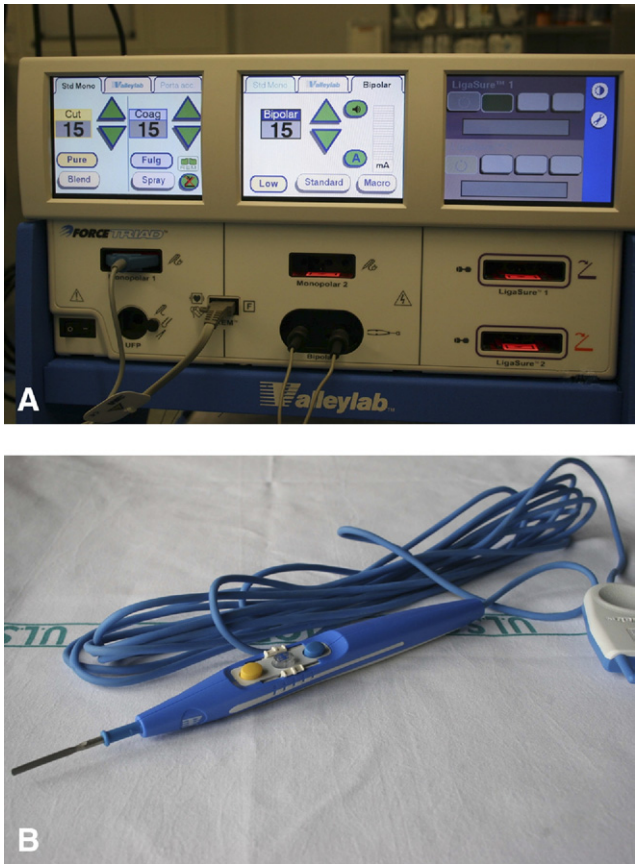

Figure 1 (**A**) The Force Triad generator workstation. (**B**) The TriVerse monopolar disposable electrode. The middle button allows activation of the "Valleylab mode," providing impedance-controlled simultaneous cut and coagulation.

was obtained from each patient (from parents or caregivers in the case of children) before admission. Twenty-seven patients were evaluated at our clinic and considered appropriate candidates for Baha. Of these, 25 patients agreed to participate in this study and were scheduled for Baha surgery. Twelve patients were male and 13 were female, with an equal male-to-female ratio distribution between the TV and MR groups. All patients (5 children, age range 6-14 yrs, mean 8 yrs, median 8.3 yrs, and 19 adults, age range 30-73 yrs, mean 58.4 yrs, median 60 yrs) underwent the single-stage Baha procedure. All cases were performed with the patient under local anesthesia, except in children (5 patients) or in patients unwilling to go under local anesthesia. Two adult patients were treated under general anesthesia because they were classified for such by the anesthesiologist. All patients were operated on by the same attending surgeon (R. D. E.), who was blinded to the type of medical device (i.e., TV or MR) to be applied until entering the operating room. Patients were randomly assigned to the TV or the MR arm of the study, and randomization was obtained via a computer-generated random number table. The allocated procedures were placed in a numbered envelope to be opened by the scrub nurse the day of surgery. Therefore, the allocation sequence was concealed until surgery took place.

In 13 cases (2 children, 11 adults), the skin flap was harvested by use of the TV system; in the other 12 (3 children, 9 adults), it was harvested by use of the MR generator. The standard U-shaped graft technique, previously described in the literature,[9,10] was applied in all cases, with a superiorly based skin graft. All grafts were harvested through a U-shaped skin incision. The dermatome was not used in any patient. In all cases, a 3.5 × 4.5 cm skin flap was obtained (the Baha model template was applied on intact skin prior to incision to define correct position and incision margins). In the TV system group, the Force Triad generator (Valleylab, Tyco Healthcare Corp.) (Fig 1A) and the Force TriVerse FT 3000 with the EDGE Safety Sleeve insulated blade (mod E1544B-4) (Fig 1B) electrode were used, with a power setting of 10 W. The cutaneous incision was made with a #15 blade, then the TV pencil was applied to harvest the graft, remove the subcutaneous and muscular tissues down to the periosteum, undermine the soft tissue at the incision edges, and to obtain appropriate hemostasis. Soft tissues were undermined for 2 cm from incision edges. Extreme care was taken to preserve the underlying periosteum intact. In the MR group (n = 12), surgery was performed with the Vesalius MC generator (Telea Engineering) (Fig 2A) and the nonstick forceps (model 2606240) (Fig 2B) following the same procedure described above. In all cases, the skin graft was thinned free-hand with a #11 blade scalpel down to the hair follicles. Hair follicles were scraped away as well. All soft tissue work and the subsequent drilling and abutment placement procedure were performed under magnification using ×2.5 surgical loupes. The drilling and abutment placement procedures were performed as

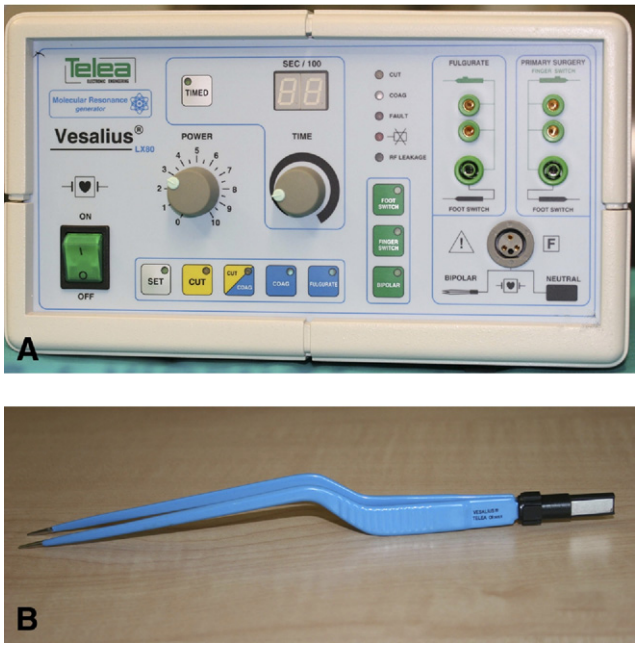

Figure 2 (**A**) The Vesalius molecular resonance generator. (**B**) The Vesalius bipolar forceps with nonstick-tip edges. The 1-mm tips allow precision of dissection along with excellent simultaneous hemostasis.

recommended by the manufacturer[10] in all patients. The only difference was the torque applied: 40 to 50 Nm in adults, 30 to 40 Nm in children. All children received one implant only: no "sleeper" abutment was placed. The same postoperative-care dressing was performed in all cases, as previously described.[10,11] In all patients, a pressure head dressing was applied overnight to prevent hematoma. On postoperative day one, all patients were checked before discharge. The healing cap and antibiotic gauze were removed one week postoperatively, at the first outpatient visit. Patients were reevaluated in the clinic two weeks postoperatively, and then at one-month intervals for eight months. Then, a follow-up examination was scheduled every six months. Skin interface at the implantation site was evaluated by the same surgeon at every follow-up examination, with the use of ×2.5 magnification surgical loupes. Soft tissue reactions around the abutment were assessed and classified according to Holgers et al[13] (Table 1). Implants were loaded eight weeks after surgery in adults and in children. Comparisons of categorical variables were made using the χ^2 test, with a level of significance of $P \leq 0.05$.

Results

Twenty-five patients were implanted between March 2007 and March 2008. Among these patients, two received a bilateral simultaneous implant (2 children), for a total of 27 implants. Etiology of hearing loss is reported in Table 2. The most common reason for implantation was chronic otitis media (COM; 11 patients). Among these 11, two had a chronic draining ear and eight had undergone a canal wall-down procedure with no ossicular chain reconstruction. Among patients with congenital aural atresia (n = 6), two children presented with unilateral hemifacial hyposomia. In one of these patients, a bilateral simultaneous procedure was performed.

Two patients had Down syndrome, and one received a bilateral implant for a severe conductive hearing loss due to failed reconstruction of the ossicular chain after multiple canal wall-up procedures for cholesteatoma. The other child was affected by a moderate-to-severe bilateral hearing loss following multiple attempts to repair a tympanic membrane perforation on the right side and an ossicular chain malformation on the left.

Table 1
Skin reaction grades, according to Holgers et al,[13] in the two different treatment groups

	TriVerse (n = 13)		Molecular resonance (n = 12)	
Grade	Observations	%	Observations	%
0	150	87.2	177	97.8
1	18	10.5	3	1.7
2	4	2.3	1	0.5
3	0	0	0	0
4	0	0	0	0
Total	172	100	181	100

Table 2
Etiology of hearing loss in 25 patients implanted with Baha

Cause of hearing loss	n	%
Treacher Collins	2	8
Atresia	6	24
COM	11	44
SSD	6	24
Total	25	100

COM, chronic otitis media; *SSD*, single-sided deafness.

Unilateral hearing loss or single-sided-deafness (SSD) was present in six patients. In two patients, an acoustic neuroma (AN) was previously diagnosed; one patient underwent cyber-knife radiation therapy, while the other refused any treatment for the AN. In the other four patients with SSD, the deafness followed profound sudden sensorineural hearing loss. In a patient with Ménière's disease, we implanted the more severely affected ear (nonfluctuating profound hearing loss).

In three children (4 ears) and two adults, dura was encountered at final drilling, but this did not result in violation of the dural tissue in all cases, even after standard countersink application and drilling. Surgery and postoperative care proceeded for these patients as it did for all uncomplicated patients, with an uneventful recovery.

In one adult patient, moderate-to-severe bleeding coming from an underlying venous intraosseous (intradiploic) lake was encountered. However, this occurred at a drilling depth of 3 mm, and subsequent standard insertion of a 4-mm abutment with a 40 Nm torque was performed, with an uneventful postoperative period.

The follow-up timeframe ranged from eight to 30 months (median 17.2 mo). During follow-up, a total of 353 observations were made in all patients. Observations were tallied on the basis of abutments implanted, so that patients with two implants counted double at each follow-up visit. No skin, scar, or soft tissue proliferation requiring surgical removal was observed in our series. No patient required removal of the abutment during the observation period of this study. In two cases, we observed a partial skin flap necrosis that required in-office revision, with a small pedicled rotation skin flap in one case. Complete healing of the graft was obtained six weeks after initial surgery. The other patient underwent surgical debridement of the eschar in an in-office procedure, and after appropriate local treatment, complete healing "per secundam" was obtained in five weeks. Both cases were adults (54 and 79 yrs of age, respectively) and were part of the TV system arm of the study. These patients were loaded eight weeks after implant placement, as in all other cases.

Complete healing time was significantly lower in the MR group (range 7-12 days, median 10 days) compared to the TV group (range 15-28 days, median 16 days). This difference was statistically significant ($P = 0.002$).

In the TV-system arm of the study, 150 (87.2%) of 172 observations demonstrated a grade 0 skin reaction, while in the MR group, this was evident in 177 (97.8%) of 181 observations. In the MR arm, nine patients out of 12 showed no reaction at the abutment site, two patients had one episode, and one patient presented two episodes during the follow-up timeframe. In the TV group, six patients had no reaction, five presented one episode, one presented two episodes, and one presented three episodes during follow-up. This difference proved to be statistically significant ($P = 0.002$).

Discussion

The Baha system was introduced in 1977 to restore hearing in patients with conductive hearing loss, replacing common bone vibration devices, such as in cases of congenital aural atresia or mastoid cavities.[1,14] In 2002, the Baha was applied to treat unilateral deafness, as after AN removal, unilateral sudden deafness, or Ménière's disease,[3,15] thus broadening its field of application. This increased both the field of interest in the device and the number of surgeons performing the Baha procedure, with a subsequent increased incidence of complications.

Complications in Baha surgery can be divided mainly into bone and soft tissue complications.[7] Bone-related complications are due to failed or lost integration of the implanted titanium abutment within the bone tissue.[16] This may be related to inappropriate surgical technique,[10] trauma, or incomplete insertion.[17] In addition, exposure to direct trauma and pediatric ages are predisposing factors to a possible failure or loss of osseointegration.[16,18-20]

The absence of implant loss in our single-stage series is encouraging, especially in our implanted children. The process of osseointegration for creating a biological bond between titanium oxide and bone is time dependent, and different surgeons have used varied timeframes before loading the implant.[21] In dental surgery, even in the presence of strong applied forces, implant loading ranges from immediate to six months.[21] Based also on our previous personal observation, we loaded our patients after eight weeks. Even though our pediatric series is small, our results compare favorably with the larger series reported by Kohan et al.[18] This may reflect our strict application to a rigorous surgical technique during bone drilling and abutment placement, even if a higher extrusion rate is reported in the pediatric ages.[19,20] However, larger series on early loading in children may evaluate new recommendations on loading timeframes.

Soft tissue complications may vary in their manifestations and rates. Skin reactions range from 4.5 percent[3] to 7.5 percent[2] in the literature, but the surgeon's increasing expertise over time can play a role. Tjellström et al reported a decrease in soft tissue complication rate, from 6.8 percent down to 3.5 percent, after 10 years of Baha surgery,[12] and this compares favorably with the overall complication rate of 2.2 percent in our series. Technology may greatly influence the outcome when dealing with soft tissue handling.

It is claimed that the Force TV in the Valleylab mode provides a combination of monopolar hemostasis and dissection at low power setting, resulting in less char and less thermal spread. Furthermore, it is claimed that this closed-loop coagulation provides hemostasis by sensing tissue changes during activation and adjusting the output to obtain a controlled hemostatic effect.[22]

MR technology is based on the generation of electron energy quanta (EEQ) by means of high-frequency electron waves, characterized by a precisely and well defined major wave at 4 MHz, followed by well defined 8-, 12-, and 16-MHz waves with decreasing amplitudes. These calibrated EEQ, delivered to tissue, place molecular bonds into resonance (the MR), with bond breakage at minimally raised temperature.[23]

In our series, we observed a higher rate of partial flap necrosis in the TV system group (n = 12), with two patients requiring flap revision, whereas no patient reported such complication in the MR group (n = 13). Standard monopolar cautery induces temperatures as high as 600°C, while it is claimed that that rise in tissue temperature induced by MR is as low as 47°C.[22] This results in reduced thermal spread within soft tissue, with subsequent reduced thermal damage and better recovery after surgery. We performed a meticulous and consistent harvesting of the skin flap in both arms of the study, and thinning of the flap was always made with the cold steel blade in order to avoid any thermal injury. Most likely, the different temperatures induced on the surrounding tissue by these technologies have played a role. Additional evidence of this includes the different recovery time after surgery in the MR patients, who experienced faster wound healing.

No patient in this study was treated with the dermatome. The reason for this was based on a personal observation: in previous patients who were treated with Baha plus dermatome, a long-lasting crusting of the flap was observed, requiring debridement of the flap and multiple examinations after surgery.

The remains of hair insufficiently removed during surgery may cause foreign body reactions in hair shafts on the underside of a split-skin graft, thus leading to increased incidence and severity of skin reactions around the titanium shaft.[9] In our series, the overall favorable outcome and the absence of skin proliferation in both groups in the long term are consistent with the fact that free-hand thinning of the skin flap, along with scraping all hair follicles, was performed in our patients, as strongly recommended by Stalfors and Tjellström.[9]

Further possible advantages of using MR in Baha surgery can be seen in the reduced need for follow-up examinations. A faster recovery period means earlier return to

normal activities. This could benefit patients by reducing time spent in the hospital, encouraging better compliance to after-surgery care, and by possibly reducing economic impact.

Cost is always an issue when new technologies are introduced to an established surgical procedure. The additional cost for the TV procedure was the TriVerse disposable pencil, which cost $35.00, while the Vesalius MR forceps cost $500.00, but can be reused up to 500 times, thereby resulting in an additional cost of $1.00 per procedure. Future studies on cost analysis may evaluate the financial impact of this new procedure.

Conclusion

This prospective, single-blinded, randomized study of MR versus TV in Baha surgery has demonstrated a statistically significant improvement in postoperative recovery. MR resulted in reduced postoperative morbidity and faster healing after Baha surgery.

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Author Contributions

Riccardo D'Eredita, study conception and design, acquisition of data, data analysis and interpretation, article draft, final approval; **Mario Cenzi,** acquisition of data.

Disclosures

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