# **ORIGINAL ARTICLE**

# Use of Platelet Gel For Skin Defects After BAHA Implantation

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Objective: To test the use of autologous platelet gel for repairing skin defects following BAHA surgery.

**Background:** Application of autologous platelet gel was shown to be successful for treating skin defects in diabetic patients as well as in orthopedic surgery.

**Materials and Methods:** Two of a cohort of 33 patients, who have undergone BAHA placement by using different skin incisions, presented with a skin defect around the titanium abutment. Autologous platelet gel was prepared as a complex concentrate at the ImmunoHematologic Laboratory of the same University Hospital. The procedure included blood withdrawal from the same patient, to which thrombin, Ca-gluconate 10% and ethanol 96% were added. The protocol consisted in 1 application per week, for six weeks, to be eventually repeated in case of unsatisfactory results.

Main Outcome Measures: Objective photo-documentation was carried out during the protocol period.

Results: In both cases, complete resolution of the skin defects was achieved after the first cycle of application.

**Conclusion:** Although success in BAHA implantation resides on an appropriate osteointegration process, other issues may arise which could jeopardize the final outcome and/or postpone the device activation, such as skin health conditions around the abutment. The use of autologous platelet gel has shown to produce a definitive healing of the defect area, and it allowed avoiding delayed activation or explantation.

Submitted : 12 August 2009

Accepted : 12 November 2009

#### Introduction

Since the first clinical report on Bone-Anchored Hearing Aids (BAHA) in 1981 <sup>[1]</sup>, this system has become a well-established and successful method for auditory rehabilitation of conductive and mixed hearing loss, as well as profound unilateral sensorineural hearing loss, i.e. single sided deafness (SSD). Initial concerns for a percutaneous abutment have largely been compensated by reproducible success rate, high patient satisfaction and lack of serious complications.

The key point in BAHA surgery is the realization of a correct process of osteointegration between titanium screw and patient's skull, a biological, time-dependent

process. Casistics from the major BAHA Centres indicate the possibility of rare, still possible complications, which are often involving the skin around the abutment, such as granulations, skin overgrowth and flap necrosis <sup>[2-6]</sup>. Bone and soft tissue complications seem, however, not to be completely separate, because loss of BAHA abutment has also been related to a poor post-operative skin healing <sup>[2]</sup>.

In the field of wound healing, new-generation treatments, such as platelet (PLT) gel, have recently been introduced in the therapeutic repertoire, for treating soft tissue ulcers in diabetic patients <sup>[7]</sup>, for tissue reconstruction in facial plastic surgery <sup>[8]</sup> and Ophthalmology <sup>[9]</sup>. This latter application has been

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based on the possibility that PLT-derived factors, such as PLT-growth factors and fibroblast growth factors, may also up-regulate growth of dense-tissue cells, such as chondrocytes, osteoblasts and periosteal cells <sup>[10]</sup>.

The present report regards a proposal of treatment of skin defects occurring around the abutment after BAHA surgery, which has been applied to two patients and allowed to achieve a perfect healing so as to successfully activate the implant.

#### **Material and Methods**

Since February 2005, 33 subjects (13 males, 20 females, aging between 16 and 74 years) received a BAHA system at a tertiary referral Centre (University Hospital).

Surgical technique regarding skin incision changed over time, being first performed via a manual Ushaped flap in 5 patients, subsequently via a Dermatome in 18 patients and via a simple linear incision in the last 10 patients.

In two out of the "Dermatome" group of BAHA implantees, alteration of the skin healing process around the abutment was early observed, ending up with the exposure of bare bone which delayed activation of the device and/or jeopardize the whole rehabilitative procedure. After initial attempts with local medications, including iodine solutions and silver nitrate cauterization, the possibility to use applications of autologous platelet gel was considered.

The platelet gel is a complex concentrate produced at the ImmunoHaematology and Transfusion Unit of the same University, according to a standardized protocol <sup>[11]</sup>. The procedure includes blood withdrawal from the same patient, ultracentrifugation in order to isolate the platelets, addition of thrombin, 0.22 mol/L Ca++-gluconate and ethanol 96%, and storage of the final substance at -4° C for 30 minutes.

The procedure followed was in accordance with the ethical standards of the Committee on Human Experimentation of Medical Faculty, Sapienza University and with the Helsinki Declaration (JAMA 2000;284:3043-3049). The patients signed an informed consent before undergoing the whole

procedure. Before application, the substance was put at room temperature and the patient asked to lie in supine position with the head turned towards the unaffected side. After disinfection and debridement of the wound edges, the platelet gel was poured from a syringe, at room temperature, on the site to be treated, and left in place for 10 minutes. The protocol consists in cycles of one application per week, for 6 weeks. An additional cycle is planned in case of incomplete wound healing.

## Case 1

A 57-years old diabetic, Caucasian man, presenting with profound unilateral sensorineural hearing loss following subtotal petrosectomy for petrous bone cholesteatoma surgery, was planned for BAHA rehabilitation as a SSD case. A Dermatome pedicled flap was used. Since the first post-operative days, granulation tissue was observed around the abutment, thus requiring daily medications with iodine solutions and packing with Connectivine<sup>®</sup> gauzes. Despite this intense care, a large defect remained, which ended up in the exposure of the underlying bone and forced to postpone implant activation. PTL-gel application was hence planned and carried out, allowing a satisfactory result after 1 cycle (Figure 1a-b).

### Case 2

A 75-years old Caucasian woman, suffering from bilateral mixed hearing loss due to long-standing chronic middle ear disease, which required multiple operations without functional recovery, was selected for BAHA rehabilitation. A manual U-shaped flap was used. One month after surgery, just before the planned activation of the device, the skin around the abutment began to appear unhealthy, with formation of granulation tissue that was at first treated by using daily local medications. Owing to the lack of efficacy, it was then decided to proceed with PTL-gel application, obtaining a satisfactory healing result after one cycle (Figure 2a-b).

### Discussion

Among the possible complications from BAHA surgery, those involving the skin around the abutment,

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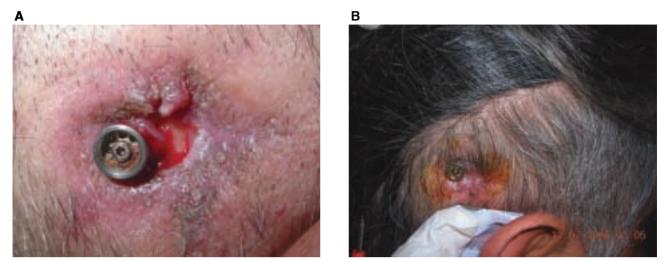


Figure 1. Case 1 patient: a) early post-operative skin defect around the abutment; b) skin healed after platelet gel application protocol is completed

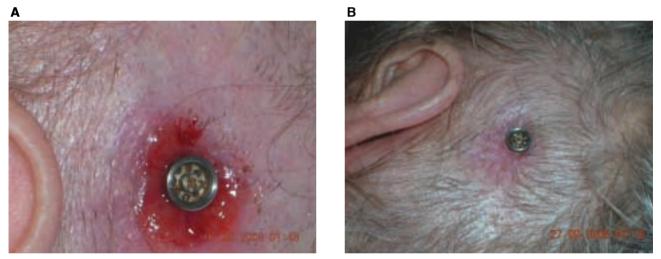


Figure 2. Case 2 patient: a) skin granulations around the abutment occurring one month after surgery; b) skin healed after platelet gel application

such as skin overgrowth or skin necrosis, represent the most frequent ones, and are currently staged according to Holgers <sup>[12]</sup> between Grade 0 (no adverse reaction) and Grade 4 (inflammation/infection resulting in the removal of the abutment). The reason for these minor complications seems to be partly due to the mere contact between skin edges and a foreign body, such as the abutment screw; partly to unfavourable local or general conditions of the patient. In this regard, it must be stressed the importance of thoroughly carrying out the standardized operative steps, mainly the accurate thinning of the skin by reducing the redundant soft tissue <sup>[13,14]</sup>. It may be logical to assume that, when

applying the abutment close or in correspondence with scar tissue from previous surgeries, the risk for such a complication may increase. As a matter of fact, the two patients included in this report had previously undergone ear surgery, i.e. multiple tympanoplasties and subtotal petrosectomy, respectively. In addition, one patient was also diabetic. Although both of them had received a "Dermatome" incision, it would not seem plausible to assume that this type of technique is more likely to favour this complication.

Wound healing is a process that involves different cell types, growth factors and other proteins, which interact with each other leading to a fast, efficient repair of the lesion <sup>[11]</sup>. Platelets play a primary role in tissue repair/regeneration not only because of their haemostatic properties, but also because of their capability to release a series of growth factors involved in the repair of the lesion. For this reason, the use of blood components, especially from the same individual (autologous), has been rapidly extended to various clinical settings.

As already mentioned, among the various blood components available for topical use, platelet gel has drawn particular interest since it could generate growth factors able to stimulate tissue regeneration and repair. As a matter of fact, due to its high platelet concentration, platelet gel contains a large amount of growth factors released by activated platelets, such as platelet-derived growth factor, tumor growth factor-(, vascular endothelial growth factor, insuline-like growth factor and basic fibroblast growth factor, obtained by degranulation of the platelets. Once secreted, these factors bind to their respective receptor and activate cells in the surrounding tissues, thus contributing to the repairing process of a lesion.

Many studies have also shown that platelet gel is able to induce proliferation of fibroblasts, endothelial cells and also osteoblasts, a predominant cell type present in the skull, where BAHA titanium screw is going to be implanted.

In BAHA surgery, the possibility of a skin defect can be due to the interface with a foreign, though biocompatible, body, which in addition needs to be integrated within the skull. This double integrative process may be at risk in case of general (diabetes, etc.) or local (previous surgery) negative factors.

Also the process of osteointegration involves growth factors (TGF- $\alpha$ , IL-1 and IL-2) for a good response to the inflammation at the unsterile site of contact between bone and titanium. This is the reason why, in this specific type of surgery, platelet gel could be very helpful, as demonstrated in the two patients object of the present report.

It is possible to conclude that skin defects, which could hypothetically jeopardize the final outcome in BAHA

surgery, may be successfully treated by local application of PLT-gel. This laboratory product should therefore be considered a useful implementation in the armamentarium of Centres involved in this hearing rehabilitative procedure.

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