Salvage of Contaminated Cranial Bone Flap Autografts using OsteoCleanse™ - Pilot Study Case Reports

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Purpose:
Current salvage options for contaminated or at-risk cranial bone flap autografts (Autografts) are inadequate due to economic, cosmetic, graft incorporation, and biocompatibility reasons. This pilot study was undertaken to determine clinical outcomes using OsteoCleanse™ to salvage contaminated Autografts for reimplantation.

Materials/Methods:
Contaminated and at-risk Autografts unacceptable for reimplantation were sent to LifeNet Health (LNH) for processing. Three Autografts were cleaned with LNH’s OsteoCleanse™ which uses our proprietary Allowash® process followed by terminal gamma irradiation at 18 - 25 kGy minimum absorbed dose administered at low temperatures (-20° to -50° C). Swab cultures were collected pre- and post- Allowash® and tested in LNH’s QC Laboratory for contaminating agent(s) using both thioglycolate and trypticase soy broth media in a 2 temperature/14 day culture protocol.

Results:
Case 1: A craniectomy was performed on a 43 year old male and, after the patient recovered, the Autograft (stored at -80° C) was reimplanted. One week post-surgery, the patient presented with clinical symptoms of infection, the Autograft was removed and the patient treated to address the infection. The recovered Autograft was sent to LNH where it was subjected to OsteoCleanse™. Swab cultures taken during surgery and pre-processing identified *Enterobacter cloacae* as the infecting organism. Post-Allowash® swab cultures were negative. The Autograft was reimplanted and 2 years post-cleaning there has been no recurrence of the infection.

Case 2: A decompressive craniectomy was performed on a 20 year old male at an outside facility and the Autograft was stored at the facility. The patient recovered well and cranioplasty was scheduled at the reporting facility. The Autograft was transported to the reporting facility on dry ice but arrived at room temperature and was deemed unsafe for implantation. The Autograft was stored at -80° C until transport to LNH where it underwent OsteoCleanse™ (Figure 1). Swab cultures taken pre-processing identified *Staphylococcus epidermidis*. Post-Allowash® swab cultures were negative. The Autograft was reimplanted and 2 years post-cleaning.

Case 3: A craniectomy was performed during excision of a tumor from an immune-compromised 11 year old male. The Autograft was cleaned at LNH using OsteoCleanse™ to prevent complications upon reimplantation. Swab cultures taken pre-processing identified *Staphylococcus aureus* and *Streptococcus viridans* as contaminating agents. Post-processing swab cultures were negative. No complications have been reported one year after reimplantation.

Conclusions:
OsteoCleanse™ was shown to be effective at salvaging otherwise non-implantable Autografts based on clinical outcomes in a pilot study involving three cases: a post-surgical infection, a transport failure, and an immune-compromised patient. Current salvage options for contaminated or at-risk Autografts can be expanded to include OsteoCleanse™.

Figure 1. Autograft Cranial Flap before (left) and after (right) OsteoCleanse™ - Case 2.