

## **Report for the Australian and New Zealand Head and Neck Cancer Society Foundation Grant 2023 (Reconstructive Surgery Fund)**

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**Title: In-vivo evaluation of a novel biosynthetic graft for skeletal and soft tissue reconstructive surgery**

Project Details

Description:

Grafts in use in plastic and reconstructive surgery vary in terms of biocompatibility, bioactivity and biodegradability. Most commercially available grafts are non-biodegradable and have a lifelong risk of implant extrusion and infection necessitating removal. While biodegradable implants are a focus of investigation currently, this is often at the expense of reduced biocompatibility. There is currently a dearth of materials with the ideal balance of biocompatibility, bioactivity and biodegradability. Actv-graft is a proprietary bioresorbable, regenerative scaffold that combines bioglass, a bioactive ceramic silica-based glass, and polycaprolactone, a biodegradable polymer. Previous preclinical studies have verified the biocompatibility of actv-graft and its ability to both integrate well into host tissue as well as facilitate tissue growth in subcutaneous and dermal applications in small animal models.

Aims of the project:

1. To establish the feasibility of actv-graft as a material for skeletal and soft tissue facial reconstruction in an ovine model.
2. To assess, from radiological and histological perspectives, the ability of actv-graft to integrate into host tissue and the surrounding host reaction in the facial tissues of the ovine model.

Results:

This study involved the implantation of actv-graft as a soft sheet for volume augmentation in subcutaneous pockets in the nasal dorsum and cheek, and as a semi-rigid thin sheet over a surgically created orbital floor defect in three sheep. The grafts were explanted en bloc with surrounding tissue at three months. The explants were assessed radiologically with pre- and post-surgery macroscopic CT scans and microscopic CT scans, and were then flash-frozen and cryosectioned for histology. The ANZHNCS Foundation Grant 2024 supported the histological analysis of explants via simple histological stains and immunohistochemistry.

Macroscopically, no significant orbital prolapse, enophthalmos, animal distress or other surgical complications were noted at three months. Volume augmentation in the nasal dorsum and cheeks were maintained at three months.

Radiologically, no evidence of soft tissue prolapse in the orbit was noted post-operatively, and this was maintained at 3 months. The cheek and nose grafts also demonstrated volume augmentation on CT scans post-operatively and maintained this augmentation at three months.

Histologically, all grafts demonstrated a rich cellular infiltrate with mild to moderate fibroblastic and inflammatory contents. An interface rich in hyalinized collagen was formed between the graft and surrounding tissues. The relative amounts of type I and type III collagen in the interface varied widely. Immunohistochemical analysis to further characterise the cellular infiltrate inside the grafts remains underway.

#### Summary and Conclusions:

This is the first study of actv-graft in a large animal model and represents a step forward in the preclinical testing of this material for soft tissue and skeletal reconstruction. The preliminary results of this study are promising and support the feasibility of actv-graft as a material for soft tissue and skeletal reconstruction.