

# Bioinspired hydrogels for craniofacial muscle regeneration



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## Clinical Need

Traumatic and surgical injuries involving penetration, crush, or resection of the skin and skeletal muscle remain one of the greatest challenges to facial reconstruction. These injuries often involve the underlying musculature of the neck and face; however, despite the rather well known capacity of skeletal muscle to repair, regenerate, and remodel following injury, more severe cranio-maxillary-facial injuries, such as those involving the loss of a substantial portion of muscle tissue, are not capable of full regeneration on their own. That is, such injuries are characterized by volumetric muscle loss (VML) injury resulting in permanent cosmetic and functional deficits of either the injured muscle or the muscle unit (i.e., in the presence of synergists).

## Solution

To overcome the limitations associated with current VML treatments, we propose to exploit “bioinspired” hyaluronic acid-based hydrogels. Our key innovation is that our HyA-based hydrogels embody material features for robust muscle regeneration, where our preclinical findings in biologically-relevant rodent models of VML injury demonstrated functional recovery, accompanied by volume reconstitution, muscle regeneration, and native-like vascularization.

## Competitive Advantage

The surgical treatment options for VML have not changed in 30 years and often result in suboptimal or poor functional and aesthetic outcomes. There is no existing treatment to restore functional muscle with normal form, size, and range of motion. Our technology addresses this critical need.

## Target Market

The global market for VML comprises many distinct market segments including craniofacial muscle regeneration. There are approximately \$300,000 craniofacial reconstruction procedures per year worldwide (e.g., cleft lip/palate; 1:700 children). Of the potential craniofacial indications, we chose muscle repair after surgical resection as the first indication for our technology. The market size is difficult to estimate. The frequency of muscle defects resulting from cancer resection is common (e.g. 4–5 cases per week at UCSF), and lip cancer in particular is the most common cancer of the head and neck.

## Regulatory Pathway

Class II medical device via the 510(k) route.

## Intellectual Property

A composition of matter patent (owned by UC) has been issued and is being nationalized in various jurisdictions, and a second patent has been filed jointly between UC and Univ. of Virginia for use of the HyA-based hydrogel for muscle (VLM) regeneration.

## Related Publications

Jha AK, Tharp KM, Ye J, et al. (2015) Enhanced survival and engraftment of transplanted stem cells using growth factor sequestering hydrogels. *Biomaterials* 47(0):1–12. / Jha AK, Tharp KM, Browne S, et al. (2016) Matrix metalloproteinase-13 mediated degradation of hyaluronic acid-based matrices orchestrates stem cell engraftment through vascular integration, *Biomaterials* 89:136–147.