

An acellular biologic scaffold treatment for volumetric muscle loss: results of a 13-patient cohort study

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Abstract: Volumetric muscle loss (VML) is a severe and debilitating clinical problem. Current standard of care includes physical therapy or orthotics, which do not correct underlying strength deficits, and surgical tendon transfers or muscle transfers, which involve donor site morbidity and fall short of restoring function. The results of a 13-patient cohort study are described herein and involve a regenerative medicine approach for VML treatment. Acellular bioscaffolds composed of mammalian extracellular matrix (ECM) were implanted and combined with aggressive and early physical therapy following treatment. Immunolabeling of ultrasound-guided biopsies, and magnetic resonance imaging and computed tomography imaging were performed to analyse the presence of stem/progenitor cells and formation of new skeletal muscle. Force production, range-of-motion and functional task performance were analysed by physical therapists. Electrodiagnostic evaluation was used to analyse presence of innervated skeletal muscle. This study is registered with ClinicalTrials.gov, numbers NCT01292876. In vivo remodelling of ECM bioscaffolds was associated with mobilisation of perivascular stem cells; formation of new, vascularised, innervated islands of skeletal muscle within the implantation site; increased force production; and improved functional task performance when compared with pre-operative performance. Compared with pre-operative performance, by 6 months after ECM implantation, patients showed an average improvement of 37.3% ($P < 0.05$) in strength and 27.1% improvement in range-of-motion tasks ($P < 0.05$). Implantation of acellular bioscaffolds derived from ECM can improve strength and function, and promotes site-appropriate remodelling of VML defects. These findings provide early evidence of bioscaffolding as a viable treatment of VML.