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Nanofibrillar Collagen Scaffold Implantation Enhances Lymphatic Regeneration in Conjunction with Lymphatic venous Anastomosis or Vascularized Lymph Node Transfer

Danielle H Rochlin MD1, Michael Paukshto PhD2, Dung H Nguyen MD1

1 Division of Plastic and Reconstructive Surgery, Stanford University School of Medicine, Stanford, CA, USA

2 Fibralign Corporation, Union City, CA, USA

drochlin@stanford.edu

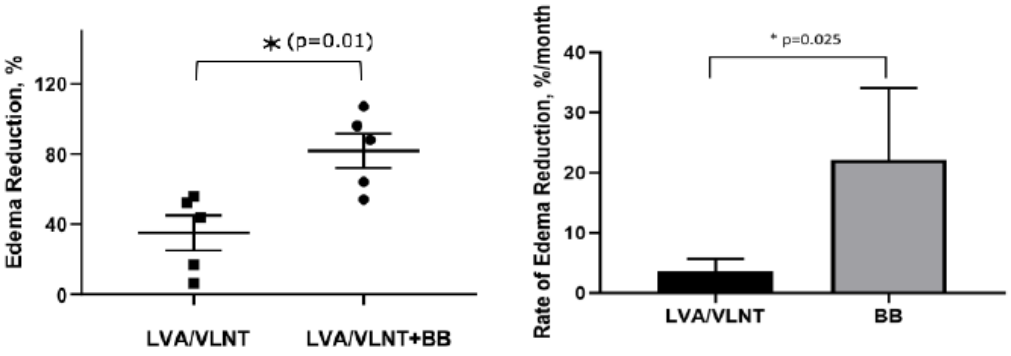
Background: Reported rates of volume reduction following lymphatic venous anastomosis (LVA) and vascularized lymph node transfer (VLNT) in lymphedema patients typically do not exceed 50-60%. The purpose of this study was to investigate a hypothesized synergistic effect of adding a nanofibrillar collagen scaffold as an additional modality to improve outcomes in lymphedema patients.

Methods: A retrospective cohort study was performed of patients who underwent LVA or VLNT followed by collagen nanofibrillar scaffold (BioBridge™; Fibralign Corporation, Union City, CA) implantation. Procedures were performed by a single surgeon from 2016 to 2018. Volumetric analysis was performed by comparing the relative amount of excess volume in milliliters (mL) between affected and healthy limbs before and after treatment with BioBridge (BB). Unpaired t-tests were used to compare the mean volume reduction between groups.

Results: Five patients underwent LVA/VLNT with secondary BioBridge implantation on average 9 months later. All patients were female with an average age of 48.3 years. Three upper and two lower extremities were treated. Compared to pre-procedure baseline, LVA/VLNT yielded a mean of 35% 22.2% edema reduction over an average of 9.2 months. Compared to LVA/VLNT alone, collagen scaffold implantation led to a statistically significant increase in mean edema reduction (81.8% 22.2%, p=0.0103) over the total study period (average 13.0 months). The addition of BioBridge enhances the average rate of edema reduction to 22.1%/month versus 3.6%/month (p=0.025). Post-operative lymphatic mapping with ICG-SPY confirmed the presence of dynamic ICG uptake along the BioBridge.

Conclusions: Nanofibrillar collagen scaffold implantation enhances lymphatic regeneration and augments edema reduction compared to LVA/VLNT alone. A large randomized study is necessary to prospectively evaluate the impact of this promising adjunct treatment.

Figure 1. Effect of adjunct nanofibrillar collagen scaffold implantation on edema reduction



	Total time (months), mean ± SD	Edema reduction (%), mean ± SD	p-value
LVA/VLNT	9.2 ± 4.0	35.0 ± 22.2	-
LVA/VLNT + BB	13.0 ± 3.8	81.8 ± 22.2	0.0103

LVA, lymphaticovenous anastomosis; VLNT, vascularized lymph node transfer; BB, BioBridge implantation; SD, standard deviation.