



# Tissue Engineering Functional Human Lips

## Clinical Need

Tissue engineering and regenerative medicine face several barriers preventing translation of in vitro technology to the clinical arena: (1) the inability to create composite soft tissue structures that contain striated muscle, skin, and mucosa with a mucocutaneous junction (lip) and (2) difficulty in developing an in vivo perfusion system (blood vessels) to supply nutrition for large segments of tissue created in vitro. Lack of tissue perfusion is a major limitation of survival of implanted in vitro produced complex composite soft tissue implants.

## Solution

A team of researchers at the University of Michigan led by Dr. Stephen E. Feinberg has developed a tissue engineering approach in conjunction with the surgical technique of prelamination, to create an innervated pre-vascularized prelaminated composite soft tissue microvascular free flap based on the latissimus dorsi muscle for use in functional reconstruction of human lips.

## Competitive Advantage

This approach addresses the issues of creating autogenous complex composite soft tissue structures with an adequate perfusion system. In addition, this approach provides a platform technology for fabrication of autogenous mucocutaneous junctions in the body such as the anus, vagina, and eyelid that circumvents the need for immunosuppression required from allografts.

**Stephen E. Feinberg, DDS, MS, PhD**  
*University of Michigan*

*"The success gained from the proposed first-in-human Phase I multicenter clinical trial to tissue engineer functional human lips will establish a platform technology that will create a paradigm shift on how the surgeon may reconstruct composite soft tissues that have a mucocutaneous junction, i.e., lips, vagina, eyelids, and anal sphincter. It will also validate a method to fabricate autogenous composite soft tissue grafts that will supplant procedures requiring lifetime immunosuppression."*

## How the ITP Program Supports this Project

With the overall objective of using mucocutaneous constructs to restore soft tissue, support from the ITP program will be used for preparatory and follow-through events surrounding IND discussions with the FDA for initiation of a first-in-human clinical trial.

## Clinical Translation Pathway

### Publications:

- Bayar GR, Kuo S, Marcelo CL, Feinberg SE. In Vitro Development of a Mucocutaneous Junction for Lip Reconstruction. *J Oral Maxillofac Surg*. 2016 Nov;74(11):2317-2326.  
(<https://www.ncbi.nlm.nih.gov/pubmed/27160362>)
- Peramo A, Marcelo CL, Feinberg SE. Tissue engineering of lips and mucocutaneous junctions: in vitro development of tissue engineered constructs of oral mucosa and skin for lip reconstruction. *Tissue Eng Part C*. 2012;18(4):273.  
(<https://www.ncbi.nlm.nih.gov/pubmed/22067042>)

### Intellectual Property:

- US 7,887,829: Mucosal cell composites and methods (<https://patents.google.com/patent/US7887829B1>)
- US 8,835,169: Compositions, methods and systems for preparation of a stem cell-enriched cell population (<https://patents.google.com/patent/US8835169B2/>)

### Commercialization Strategy:

In development with the MPWRM Commercialization/Market Needs Core

### Regulatory Pathway:

In development with the MPWRM Regulatory Core

### Product Launch Strategy:

In development with the MPWRM Commercialization/Market Needs Core