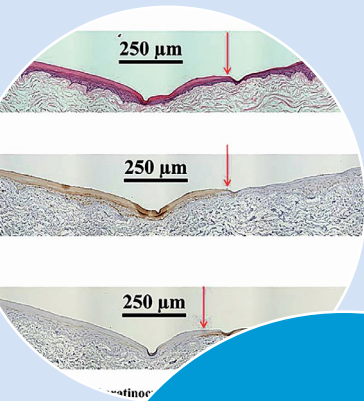


Tissue Engineering Functional Human Lips



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“Our goal is to establish a platform technology to create a paradigm shift in functional reconstruction of composite soft tissues with a mucocutaneous junction, containing a stoma/opening/lumen.”

Clinical Need

The intended product assists in the repair/ regeneration resulting from traumatic avulsion injuries or secondary to cancer ablative surgery involving a sphincter/stoma/lumen/opening that result in loss of volumetric muscle mass and function in the body such as the face (lips, eyelids) and urogenital tract (anal sphincter, vagina).

Solution

The product consists of a pre-fabricated innervated (motor nerve) pre-vascularized pre-laminated (PIPP) composite “designer” soft tissue microvascular free flap, based on latissimus dorsi muscle (LDM), that is composed of autogenous oral-skin-dermis-muscle that can be used in functional reconstruction of human lips. The in vitro produced muco-cutaneous “laminar” is composed of autogenous oral and skin keratinocytes cultured on an acellular dermal matrix, and is placed on LDM using the body as an “in situ bioreactor” to finalize the tissue engineering medical product. The stoma/opening in the PIPP flap is maintained with a proprietary biocompatible obturator.

Competitive Advantage

There are no other competitive products on the market. The gold standard is the radial forearm free flap with the palmaris longus tendon, which creates an immobile, stiff lip, or an allogeneic cadaver graft that requires immunosuppression. The ultimate source of the cells to develop the soft tissue constructs (lips), PIPP, will come from the patient, thus making the construct autochthonous (self to self) and obviates the need for immunosuppression seen with allogeneic grafts.

ITP Support

ITP has supported the creation of an autogenous mucocutaneous construct to use as a laminate for the PIPP flap, development and fabrication of a biocompatible proprietary obturator to maintain the stoma opening, and the development of an athymic rat model for use in preclinical GLP studies. Regulatory guidance and consultation for preparation of an IND submission to the FDA for a first-in-human clinical trial are supported by the program.

Clinical Translation Pathway

Publications: Peramo et al. Tissue Engineering of Lips and Muco-Cutaneous Junctions: In Vitro Development of Tissue Engineered Constructs of Oral Mucosa and Skin for Lip Reconstruction.

[Tissue Eng Part C Methods 2012](#)

Kuo et al. Principles of Soft Tissue Engineering for Craniomaxillofacial Reconstruction. In: Melville J., Shum J., Young S., Wong M. (eds) [Regenerative Strategies for Maxillary and Mandibular Reconstruction](#). Springer, Cham.

IP: US PRV Obturator, Methods of Forming a Prefabricated, Innervated, Pre-Vascularized, Prelaminated (PIPP) Flap Using an Obturator to Maintain a Stoma or Lumen, and Methods of Restoring Damaged or Surgically-Removed Soft Tissue with A PIPP Free or Rotational Flap.

Anticipated regulatory pathway: Combination product through a single IND/BLA pathway

Anticipated commercialization strategy: In development

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