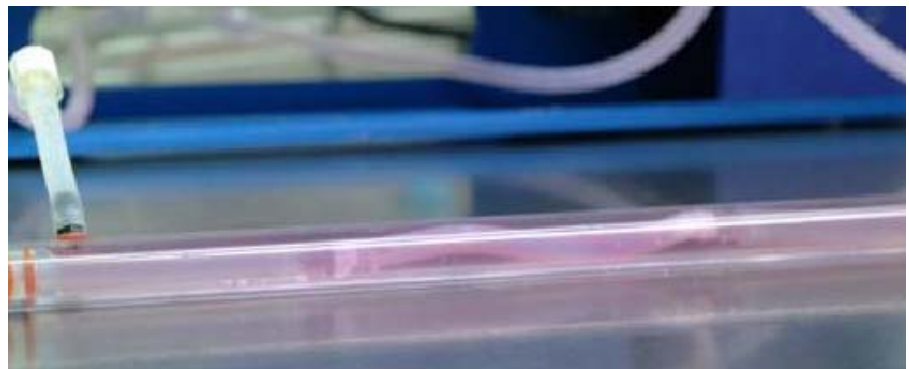


Tissue Genesis Inc. Vascular Program Overview



Tissue Genesis, Inc. (TGI™) is focused on creating biomedical instrumentation that solves military and civilian medical problems. Toward that end, TGI developed an automated cell perfusion platform, the Bio-Optimization System™ (BOS®), to pressure sod vascular grafts to provide rapid and complete endothelial cell linings for peripheral and ultimately coronary applications. The next generation of instrumentation, the Automated Cell Isolation and Sodding System™ (ACISS™), is under development to provide an operating room (OR) compatible, portable solution for rapidly endothelializing grafts in a clinically and commercially viable platform. The ACISS will also serve as a platform technology capable of integrating rapid autologous cell recovery with a variety of regenerative medicine applications including cardiac repair, wound healing, burn recovery, and soft tissue repair. TGI is actively seeking partnerships and collaborations to help advance the study and use of adipose derived autologous cells for important regenerative medicine and therapeutic applications.



Close-up showing redesigned vascular biochamber with 10 cm long graft with 3 mm bore during a five minute sustained pressure sodding with the BOS.

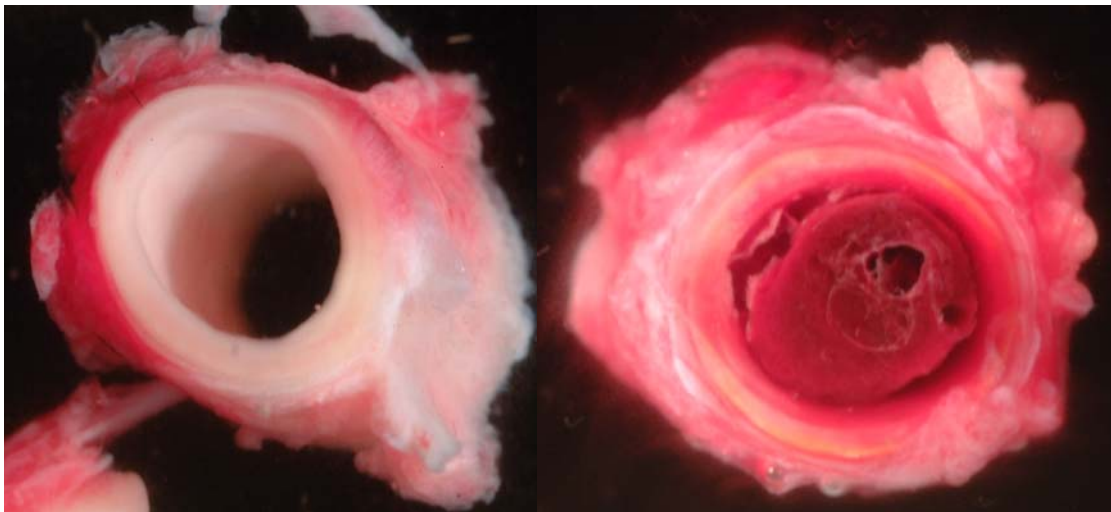
BOS perfusion cartridge with tubular vascular biochamber.

According to recent American Heart Association statistics, cardiovascular disease accounted for 39.4% (2.4 million people) of all deaths in 2000 in the United States alone. Over half of these were due to coronary artery disease primarily caused by arteriosclerosis. The standard surgical solution to cardiovascular disease is vascular replacement, or bypass. An estimated 519,000 coronary artery bypass graft procedures were performed in the United States in 2000, including over 5,000 per year performed by the Veterans Health Administration. It is also estimated that 70,000 patients per year who are candidates for coronary artery bypass surgery lack appropriate donor tissues and therefore do not receive treatment.

TGI believes its combined approach of cell source, graft materials and bioreactor design will improve clinical outcomes by providing an autologous endothelial zed graft in a few hours while the patient is in the OR. A sterile graft in a disposable chamber will be able to be stocked in a dry state until needed. Cells are isolated from the patient's own adipose tissue prior to the patient being prepped for the vascular procedure. These cells are combined with an appropriately sized graft within the OR compatible bioreactor while the patient is being prepped for the bypass procedure. This reduced timeline will benefit both pre-scheduled cases as well as patients that present symptomatic in emergency rooms. The ease of operation will allow medical staff without cell culture

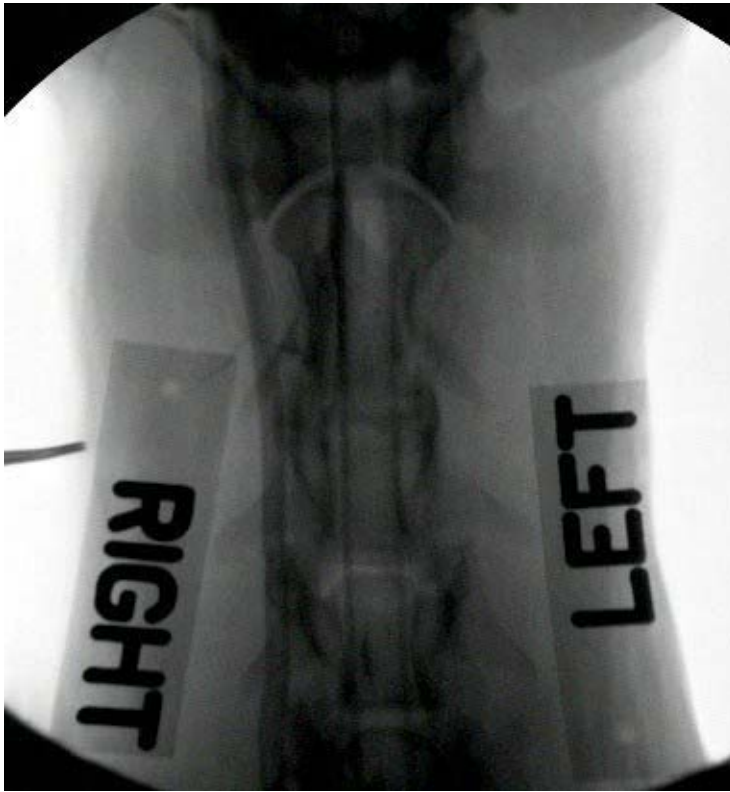
experience to operate the system. This will eliminate the need for highly trained specialized staff and make this system available to surgeons at facilities without research support. The use of adipose-derived autologous cells and endothelial cell sodding with the automated perfusion bioreactor platform allow for rapid endothelialization of bypass grafts and makes their application clinically and commercially relevant.

Tissue Genesis's past accomplishments include developing the BOS for sustained pressure sodding, a rapid method of adhering cells to the lumen of a permeable graft material (patent pending) that allows for rapid re-endothelialization and formation of neo-intima in a small, portable package. TGI is currently developing methodologies to optimize this sodding process and harvest adipose-derived autologous cells for other cell therapies. These cells are a mixed population consisting mostly of microvascular endothelial cells with a subpopulation of adult stem cells that can be differentiated into many different cell types. The benefit of using these cells for cell therapy is that they can be harvested in large numbers from a patient's fat tissue in less than one hour. Initial applications of these cells include rapidly endothelializing both peripheral and coronary vascular grafts, and pilot studies are under way using these cells in wound repair, directed cardiac tissue repair, and endothelialized stents for cardio and peripheral vascular, neurologic, urologic and pulmonary applications.



Mid-graft gross morphology of endothelialized (left) and control (right) ePTFE grafts after three month implantation in a canine carotid segmental replacement model.

TGI conducted canine chronic implantation studies using a carotid segmental replacement model. The grafts consisted of 7 cm lengths of 4 mm ID ePTFE. Two animals received a sodded graft randomly placed with a contralateral unsodded control graft. The animals were maintained on anticoagulants (aspirin and persantibe) for the first six weeks of the study to reduce acute thrombosis events. This is a typical anticoagulation regimen and is similar to human anti-coagulant therapy. At six weeks the anticoagulants were discontinued and the animals monitored for graft patency. By the three month explant date, both control grafts had clotted. Ultrasound evaluations of the grafts illustrated unobstructed flow through the sodded grafts and complete occlusion of the control grafts. The grafts were evaluated by angiography and the patency of the sodded grafts was confirmed. At explant the sodded grafts exhibited an intimal lining that was thrombus free and exhibited characteristics identical to a native endothelial cell lining observed on native blood vessels.

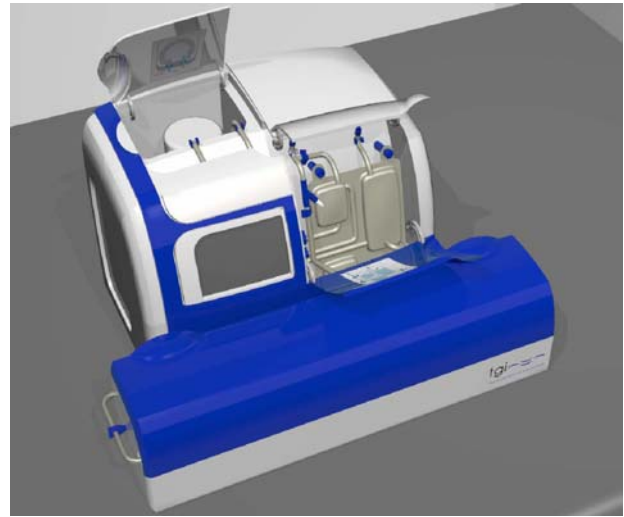


Angiograph showing the non-patent control ePTFE graft labeled left and the patent sodded graft labeled right, three months after carotid implantation of autologous adipose-derived cells sodded onto the ePTFE graft in the OR for five minutes prior to implantation.

Automated Cell Isolation and Sodding System

TGI has completed extensive design specifications for the ACISS. The ACISS processes a patient's own adipose tissue producing a cell product for clinical use in an OR setting. This cell product can be used immediately as a cell suspension or can be further processed and deposited onto a suitable scaffold such as a tubular vascular graft or a two dimensional sheet/patch. The ACISS has an unprecedented automation level for the clinical procedure of rapidly separating a desired fraction of the patient's cells from adipose tissue by filtering, washing, heating, macerating, separating, resuspending, and, if desired, pressure sodding the cells onto a permeable scaffold. The ACISS consists of a durable small-footprint OR compatible instrument with a stand-alone front display panel, pumps, centrifuge, heater, pressure and flow sensors, and valves that mates with a disposable. The disposable will be a sterile, one-time-use element that will contain fluid reservoirs, filters, centrifuge bowl, biochamber, and waste reservoir.

The first intended use of the ACISS is to harvest and deposit cells on the lumen of a vascular graft for immediate implantation of an autologous endothelialized graft in the OR. TGI is working with Food and Drug Administration consultants to prepare a 510K strategy for use of the ACISS as an accessory for applying a biological coating to an approved graft material. However, the company believes the strength of the ACISS is the rapid OR deployment of the fat-derived cells, which consist of a mixed population of microvascular endothelial cells and adult stem cells, with tremendous potential for a myriad of cell therapy applications. TGI has initiated pilot studies for several applications of these cells other than vascular tissue engineering, including wound healing, cardiac tissue repair, and burn treatments.



Fully integrated ACISS for sodding of vascular grafts within the OR environment.

About Tissue Genesis Inc.

Tissue Genesis Inc. was incorporated in Hawaii in 2001 to meet the growing needs of the traditional and emerging biotechnology markets including tissue engineering, cell therapy, and drug discovery. The company, led by Anton Krucky, brings together a unique platform cell culture and tissue engineering technology, a strategic alliance with Becton Dickinson, and two novel tissue engineering constructs to serve the vascular and musculoskeletal clinical markets. The company’s vision is to bring together these related research activities into a portfolio with the view of developing them to their full market potential. Tissue Genesis is in the business of helping people and solving medical problems in the field of regenerative medicine. The TGI Vascular Program is under the direction of Paul Kosnik, PhD. and Stuart K. Williams, PhD.

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