Technology Summary: Artificial Blood Vessels/Vascular Grafts

Opportunity Statement

Artificial blood vessels for use as vascular grafts should ideally be composed of viable tissue, be able to contract in response to hemodynamic forces and chemical stimuli and be able to secrete normal blood vessel products. These blood vessels should also allow complete healing without any immunologic reaction and remodeling according to the needs of the environment. Finally, the vessels/grafts should have high and long-term patency rates, high burst strength, low compliance mismatch, lack of thrombogenicity, resistance to infections and off-the-shelf availability.[1]

Over the years, there have been countless attempts to meet this long list of criteria with no one solution meeting all of the objectives. Thus, surgeons have had to settle for the best available alternative rather than the ideal solution.

There is a need for artificial blood vessels for use as vascular grafts that have the potential to meet all of the criteria included above.

Limitations of Existing Technologies

Most early approaches to the tissue engineering of blood vessels focused on the use of natural polymers, such as collagen, or biodegradable synthetic polymers, such as polyglycolic acid. These materials were formed in a tubular shape, seeded with smooth muscle cells or endothelial cells, constituting the vessel tissue, cultivated for a given period of time in vitro so as to have a certain degree of mechanical strength and then implanted into the body. Recent advances in stem cells have led to the implantation of a tubular porous support matrix seeded with stem cells without in vitro cultivation. This approach still does not overcome the fact that the scaffold itself should have sufficient mechanical strength to withstand in vivo forces. In other words, since an artificial blood vessel is an artificial organ that substitutes a damaged vessel in the body and restores blood flow, the vessel construct should have burst strength that is high enough to withstand the blood pressure in the body, and should be made of a highly elastic material that is able to expand and contract with the beating heart, like natural vessels. Currently available artificial blood vessels, achieved through tissue engineering technologies using stem

[1] Kakisis John, D., et al. Artificial blood vessel: The Holy Grail of peripheral vascular surgery, *Journal of Vascular Surgery,* Volume 41, Issue 2, February 2005, pp. 249-354

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cells, have been limited in the clinical applications to the vena cava and the pulmonary artery, which are at relatively low pressure.

Conventional prosthetic vascular grafts made of expanded polytetrafluoroethylene and polyethylene terephthalate satisfy the above requirements, but cannot be used in practice as tissue-engineered artificial blood vessels for inducing regeneration of the body blood tissue because the materials are non-degradable in the body. **No tissue-engineered artificial blood vessels that can endure the high-pressure environment of arterial flow previously have been developed.**

360ip Partner's Solution

360ip's Partner has developed a technology-based solution that can withstand this high-pressure environment and, consequently, which has the potential to meet each of the criteria included in the Opportunity Statement above. Specifically, the artificial blood vessels/vascular grafts developed by 360ip's Partner have the following advantages:

- Composed of viable tissue that is able to contract in response to hemodynamic forces and chemical stimuli.
- High interconnectivity between pores and an optimal mechanical strength.
- High cell seeding and proliferation efficiencies.
- High and long-term patency rates, high burst strength, low compliance mismatch, lack of thrombogenicity, resistance to infections and off-the-shelf availability.
- Provides appropriate biodegradation time so that it can be used in manufacturing bio-degradable porous polymeric scaffolds suitable for regeneration of soft tissues such as skin and blood vessels, and medical materials such as medical matrix and wound coverings.

Patents

The solution has a foundation of patents and patent applications within multiple jurisdictions.

Current Status

360ip's Partner solution is currently undergoing preclinical trials with completion due in early 2011. An initial study using dogs has been completed and the results are available to interested parties under a Non-disclosure Agreement.

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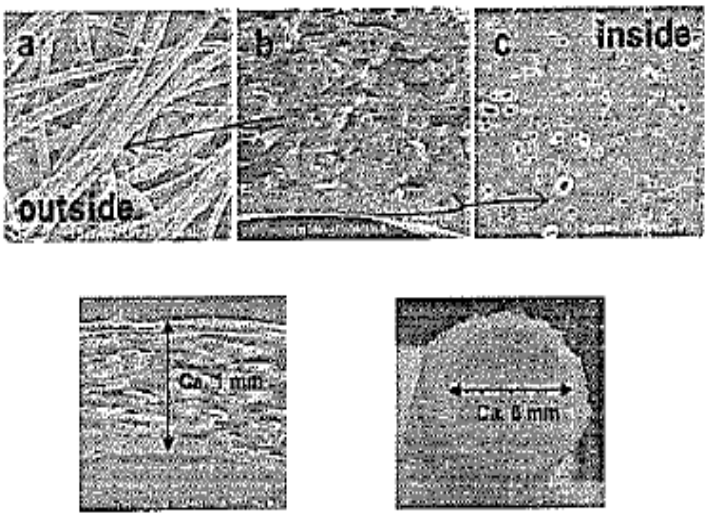

360ip is seeking interested parties for the licensing, further development and commercialization of this technology-based solution.

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