Grant number 1026421

SBIR Phase II: Customizable meniscus implant prepared by dielectrophoretic biofabrication

BC Genesis, LLC

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Institute for Regenerative Medicine

Commercial Impact:

The problem: Knee joint failure due to irreparable meniscal tears progressing to severe osteoarthritis and significant negative impact on quality of life

The market:

- Estimated 1.5 million people damage meniscus each year (worldwide)
- US market: approximately 225,000 patients/year undergo arthroscopic meniscal repair, averaging $25,000 each.
- Estimated potential need for meniscus implants (worldwide) in targeted population (Adults 18 – 75 years) **is more than $4.5 billion**

Current management of meniscus failure

- Repair of torn meniscus: success rate is variable due to poor healing capabilities of the meniscal tissue
- Partial or full meniscectomy (meniscus removal), resulting in joint degradation and progression to osteoarthritis
- Meniscal replacement

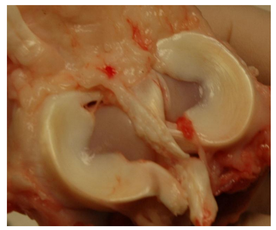
Current treatment options for meniscus replacement are limited

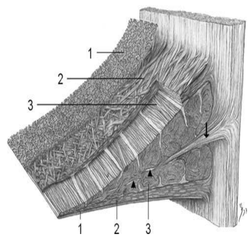
- Cadaveric transplantation of a harvested meniscus. This is the only proven existing solution to treat total meniscus failure.
- Collagen based scaffolds. Success is variable.

The Product and Value Proposition

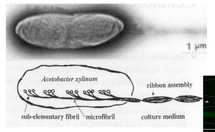
Advantages of bacterial cellulose

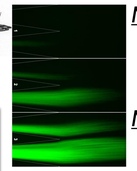
- Implant is not biodegradable and is not dependent upon cellular colonization
- Track record of biocompatibity (surgical mesh, vascular stents) supports hypothesis that implant can remain embedded indefinitely
- Ability to manage cellulose fiber design allows us to design an implant that will mimic the architecture and biomechanics of native menisci
- Our implant will support biointegration along the external wall (adjacent to the joint capsule) and osseintegration of the biosynthetic meniscal horns.
- The bacterial cellulose implant elicits minimal inflammatory response; this will mitigate joint degeneration and progression of osteoarthritis which is a common sequel to invasive joint surgery.

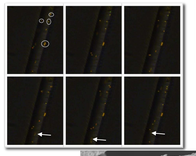


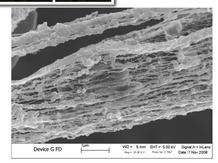


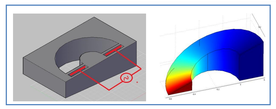
Lineage











NSF SBIR 0912617 Phase I investigated Dielectrophoretic Biofabrication

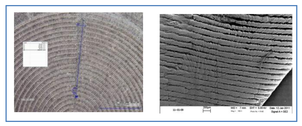
- In collaboration with Dr. Rafael Davalos, Virginia Tech, a new biofabrication process was developed. The morphology of the nano-cellulose network produced is regulated by controlling the motion of the bacteria within an electric field.

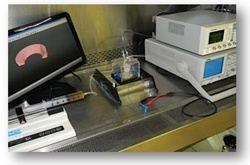
NSF SBIR 1026421 Phase II

- Detailed studies to optimize strength of electric field to control movement of bacteria within channels, in collaboration with Virginia Tech
- Design of microweaver bioreactor, in collaboration with Virginia Tech
- Biofabrication of meniscus prototype
- Biomechanical evaluation of prototype
- Preparation for biocompatibility and proof of concept animal studies
- Initiation of regulatory pathway and selection of partner for commercialization

Intellectual Property

- USPTO Patent Application No.: 20100297239; Date Filed: 12/22/2009 Priority 12/22/2008; Osseointegrative meniscus and cartilage implants based on β-glucan nanocomposite produced by fermentation process
- PCT International Application No: PCT/US2009/046407; Date Filed: 6/5/2009 Priority 6/5/2008; (exclusive license for cartilage and bone) Electromagnetic Controlled Biofabrication for Manufacturing of Mimetic Biocompatible Materials
- PCT International Application No: PCT/US2010/50460; Date Filed: 9/28/2010 Priority 9/28/2009; (exclusive license) Bioprinting of 3D (Three Dimensional) Bacterial Cellulose (BC) Scaffold for Tissue Engineering





The Company and Team

Paul Gatenholm, PhD, CSO, President

- *Global Biomaterial Scientist: >200 peer review papers, >15 international patents*
- *Entrepreneur: 3 successful start-ups*
- *Adjunct Professor at Biomedical Engineering and Sciences at Virginia Tech and Wake Forest University (WFU) ; WFU for Regenerative Medicine*

Laurie O´Rourke, DVM, PhD, CTO

- *15 years experience in translation of laboratory work into accepted products at Novartis and Ciba-Geigy*
- *Veterinary Pathologist (Diplomate ACVP & ECVCP) ; previously Associate Professor, Virginia Tech*

Erik Gatenholm, CEO and Founder

Cristin Ferguson, MD, PhD, WFU: Preclinical Consultant

Joel Berry, PhD, University of Alabama, Birmingham: Bioreactor & Process Design: