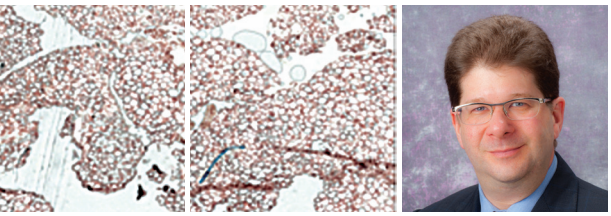
A Device to Preserve Adipose Tissue Grafts for Soft Tissue Reconstruction



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"The ability to easily and inexpensively store tissue on-site will result in significant decrease in patient discomfort and risk, as well as significant decrease in surgeon time spent on the repeat procedure."

https://plasticsurgery.pitt.edu/research/research-labs/adipose-stem-cell-center-ascc

CLINICAL NEED

Soft tissue deformities and volume/ contour deformities from craniofacial trauma, congenital anomalies, and cancer treatment are difficult to correct. Current standard of care includes injectable fillers, implants, and soft tissue flap procedures, which have limitations and often involve operations with significant risk. As such, autologous fat transfer is being explored as a lower risk alternative. However, as optimal results with fat transfer often require at least two treatments, there is a need for an on-site preservation of harvested tissue for subsequent procedures to minimize donor site morbidity and encourage fast recovery.

SOLUTION

A team of researchers at the University of Pittsburgh led by Dr. Peter Rubin has previously validated the use of autologous fat transfer as a minimally invasive therapy for the restoration of craniofacial form. In order to facilitate fat transfer with minimal donor site morbidity, the team has developed a novel device to cryopreserve adipose for storage at the treatment facility, which can directly be used for the subsequent fat transfer(s).

COMPETITIVE ADVANTAGE

With the on-site cryopreservation and storage of the fat tissue, the device is envisioned to reduce patient and clinician burden for tissue harvest. The utilization of the device obviates the need for repeat tissue grafting procedures, and is anticipated to lead to reduction in treatment costs as the fat transfer injections may be performed outside of an operating room in a less acute setting.

ITP SUPPORT

The work supported by the ITP program is focused on the generation of a prototype cryopreservation/storage device that can be used for clinical trials. Towards that end, project plans include prototype development and validation, as well as the development of a regulatory strategy and commercialization plan.

CLINICAL TRANSLATION PATHWAY

Publications:
Optimization and Standardization of the Immunodeficient Mouse Model for Assessing at Grafting Outcomes. Plast Reconstr Surg 2017.

Intellectual Property:
PCT/US2018/049083 Method and Kit for Preservation of Adipose Tissue Grafts

Regulatory Pathway:
Anticipated: Device, 510(k)

Commercialization Strategy:
In development with the MPWRM Commercialization/ Market Needs Core

Product Launch Strategy:
In development with the MPWRM Commercialization/ Market Needs Core

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A DEVICE TO PRESERVE ADIPOSE TISSUE GRAFTS

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DOCTRC DENTAL, ORAL, & CRANIOFACIAL TISSUE REGENERATION CONSORTIUM

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Annual Retreat 2020 | December 8, 2020

UNMET CLINICAL NEED

Autologous fat transfer (AFT) is a surgical procedure that involves harvesting adipose tissue by liposuction techniques and grafting it to another site on the body to correct deformities from trauma, congenital anomalies, and cancer treatment, as well as make aesthetic improvements. AFT has evolved as a common procedure with over 100,000 cases performed in the US alone (2016 data-up 13% from 2015) and an estimated worldwide market of 250,000 cases per year, with continued growth. The major problem with fat grafting is that only 63% of the graft volume, on average, heals and persists long term, meaning that optimal results are obtained with at least two treatments. Therefore, preserving harvested tissue on-site for the next procedure is a major clinical need. There is no current technology that does this. Our proposed solution is minimizing the number of surgeries and maximizing the use of adipose tissue for better patient outcomes. Thus allowing for reduced cost making it relevant for the entire market of AFT cases.

MARKET ANALYSIS

- **Stakeholders**
  - Hospitals or private clinics who provide expensive OR resources and personnel
  - 80,000 cosmetic and 30,000 reconstructive patients undergoing fat graft procedures in the USA. Worldwide market exceeds 200,000 cases/year
  - Physicians spending extra time performing secondary fat grafting procedure
- **Customers**
  - Plastic surgeons (Market entry)
  - ENT
  - General surgeons
  - Orthopedic surgeons
  - Ophthalmologists
  - Dermatologists
  - Oral and maxillofacial surgeons
- Hospitals, private clinics, and private practitioners are purchasers
- **Channels to market**
  - Device sales
    - Through licensed partner
    - Engage sales distributor
  - Marketing/Outreach:
    - First adopters (clinical demonstrations at UPMC)
    - Conference proceedings
    - Conference/trade show demonstrations

INTELLECTUAL PROPERTY

Patent/ IP information (appl/ serial #)	Date filed	Title	Assignee
Serial no.: 62/553,322	9/01/17	A Device to Preserve Adipose Tissue Grafts	Univ of Pittsburgh

RESULTS

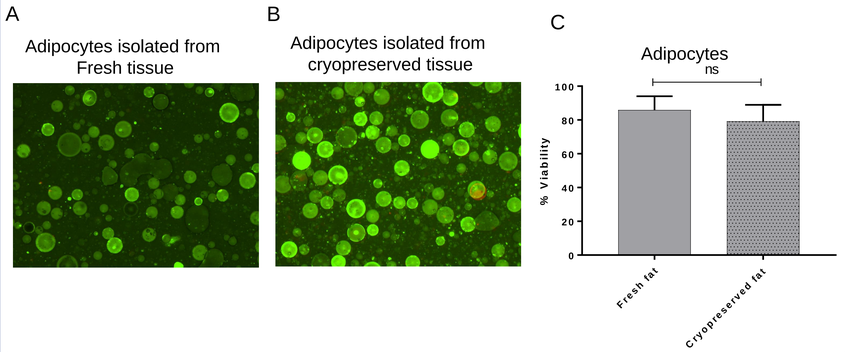


Figure 1. Adipocytes isolated from either fresh fat (A) or cryopreserved fat at day 7 post-cryopreservation (B) were stained with Calcein- Am and propidium iodide. Percentage viability was analyzed by employing Nexcelom cellometer K2 and platted (C). No significant difference in viability between the two different groups was observed.

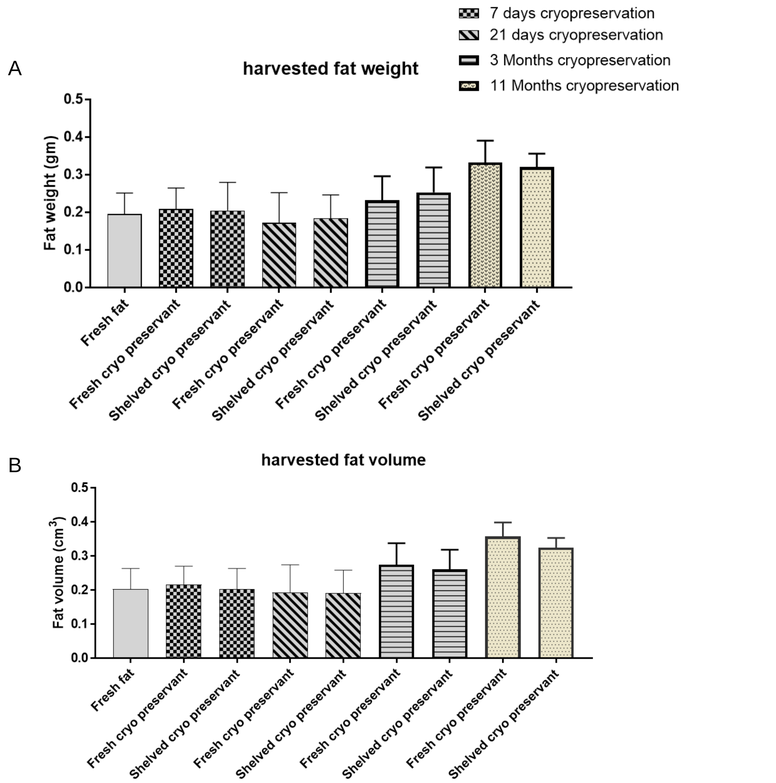
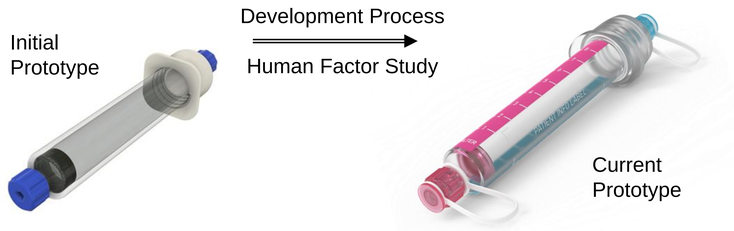


Figure 2. SCID mice were transplanted with either fresh isolated human adipose tissue lipoaspirates or lipoaspirates cryopreserved using freshly formulated cryo preservant or cryo preservant shelved for 3 months at 4 ° C. Fat graft was surgically removed at 9 weeks post transplant. Weight (A) and volume (B) of the graft was measured and plotted.

MANUFACTURING

Development Process:

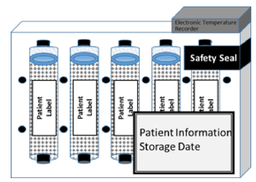
- Initial prototype was developed in partnership with Source Design International LLC.
- Contracted Archimedic in Aug 2020 for the design & development per ISO 13485
- Conducted Human Factors Study:
  9 participants; both Surgeons and Nurses
- Detailed mechanical design, risk analysis, manufacturing specs in process



REGULATORY PATHWAY

LipoStore: Regulatory Compliance

- 510(k) submission for syringe
- Tissue is minimally manipulated, allowing for FDA-approved repeat injections
- Compatible with clinically used cryogenic reagents for safe long-term storage
- Stored on-site in -80C degree freezer
- FDA and GMP-compliant labeling and safety seals
- Storage case logs the temperature for quality control



TIMELINE & FUTURE DIRECTIONS