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Systems to Facilitate Adult Stem Cell Seeding and Conditioning of Aortic Heart Valve Scaffolds

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Depositing a confluent layer of cells on all surfaces. Providing conditions under which varying attachment
improving cell seeding efficiency and uniformity

A common treatment is replacement with either a mechanical or tissue-derived heart valve.

Existing heart valve replacements provide major improvements in cardiac function and life expectancy, but have significant limitations and eventually require surgical replacement within 15-20 years.

Mechanical: requires life-long anticoagulation therapy and calcification

In pediatric patients, mechanical implants are naturally outgrown and degradation and calcification of tissue-derived implants is accelerated.

A device for uniform cell seeding will be required to facilitate the development of an autologous TEHV in the areas of:
- Depositing a confluent layer of cells on all surfaces.
- Improving cell seeding efficiency and uniformity over manual seeding regardless of user variations.
- Providing conditions under which varying attachment improvements can be evaluated and compared.

Porcine aortic heart valves were decellularized to remove the porcine-specific antigens,2 sterilized using peracetic acid, and stabilized with pentagalloyl glucose to control tissue degradation.

Valve surfaces were incubated in 50% serum in cell culture medium overnight to neutralize any remaining pentagalloyl glucose molecules then coated with Fibronectin or Pronectin to improve cell attachment.

Valves were mounted in individual seeding chambers, seeded with 15 to 24 million porcine aortic endothelial cells (pAECs) or human adipose-derived stem cells (hASCs), and rotated according to multiple regimens. Cell seeded valves were placed in a dynamic heart valve bioreactor under pulmonary or aortic pressures.

Valves were evaluated for initial attachment, retention after bioreactor testing, and viability throughout.

The treated surface was compatible with both cell types.

Device design and protocol enabled a reproducible & semi-automated seeding process. Made progress toward achieving a confluent valvular endothelium layer.

Cells were retained on the scaffold surface under pulmonary pressure conditioning in the bioreactor.

Surface seeding has been successful with two cell types and is quickly progressing toward a translational regenerative TEHV fully seeded with the patient’s own cells.

Porcine aortic heart valves were stented bioprosthetic heart valve.

Aortic Valve

Normal Aortic Valve

Stenotic Aortic Valve

Decelleled TEHV

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Fibronectin Coating

Fibronectin Coated 16,000,000 hADSC Static Day 0

Fibronectin Coated 24,000,000 hADSC Static Day 0

Fibronectin Coated 15,000,000 hADSC Static Day 6

Fibronectin Coated 15,000,000 hADSC Bioreactor 40/20 Day 17

Fibronectin Coated 2,500,000 pAEC Bioreactor 40/25 Day 14

References

2. Sierad, Cardiovascular Engineering and Technology (2010)