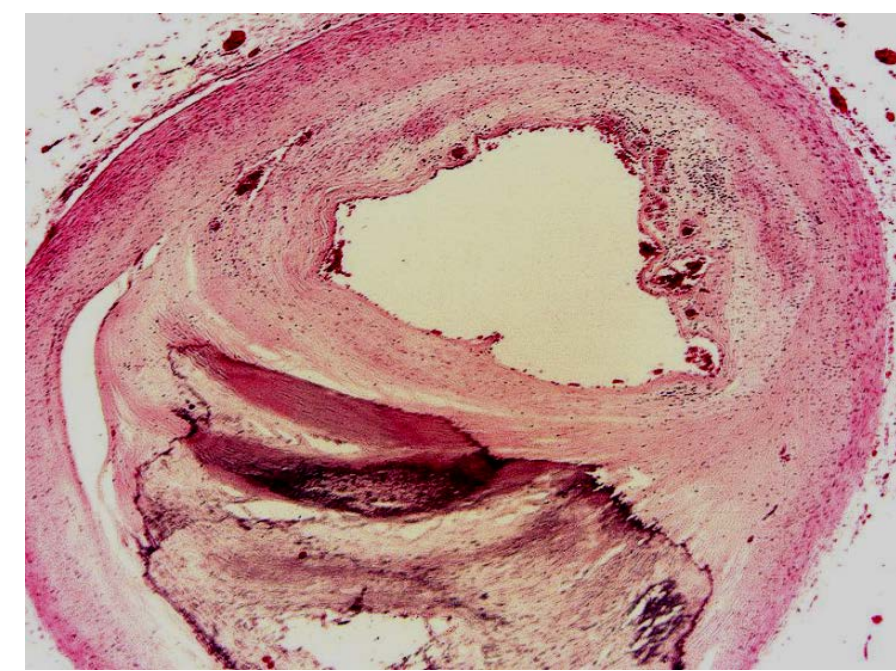


LCL-GRAFT™: Innovative Vascular Grafts for Coronary Bypass and Peripheral Vascular Surgery

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Unmet Clinical Need



Major Problem: Atherosclerosis

Atherosclerosis of the *coronary vessels* in the heart leads to ischemic heart disease, myocardial infarction
Atherosclerosis of *peripheral vasculature* leads to ischemia and loss of extremities

Current methods/approaches to the problem/disease

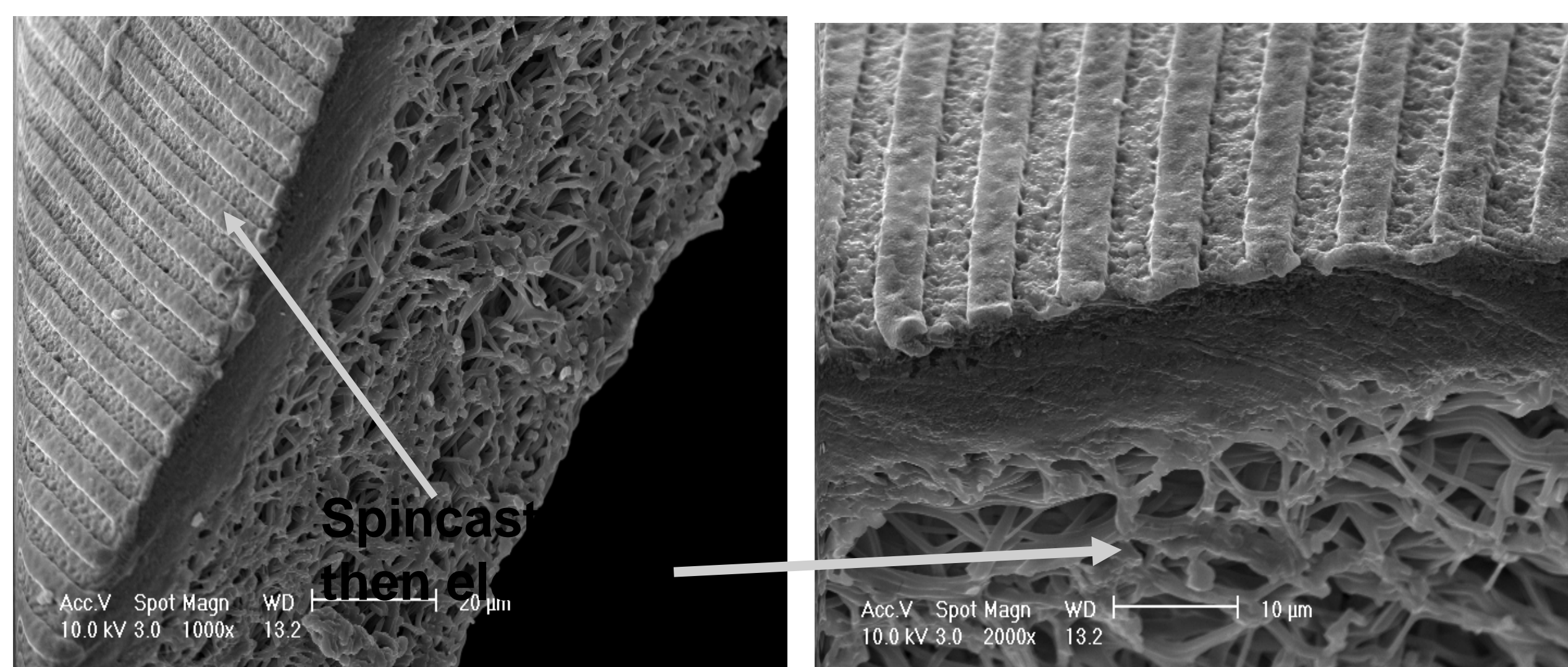
Repair or Replacing Damaged Blood Vessels

Repair: vessels will restenose

Replacement grafts have significant issues:

- Limited availability of autologous “biologic grafts”
- Tissue engineered grafts - too long a wait (~ 6 months)
- Thrombogenicity of synthetic grafts b/c of lack of endothelial cell lining and/or limited endothelial cell retention

Solution: LCL – Graft



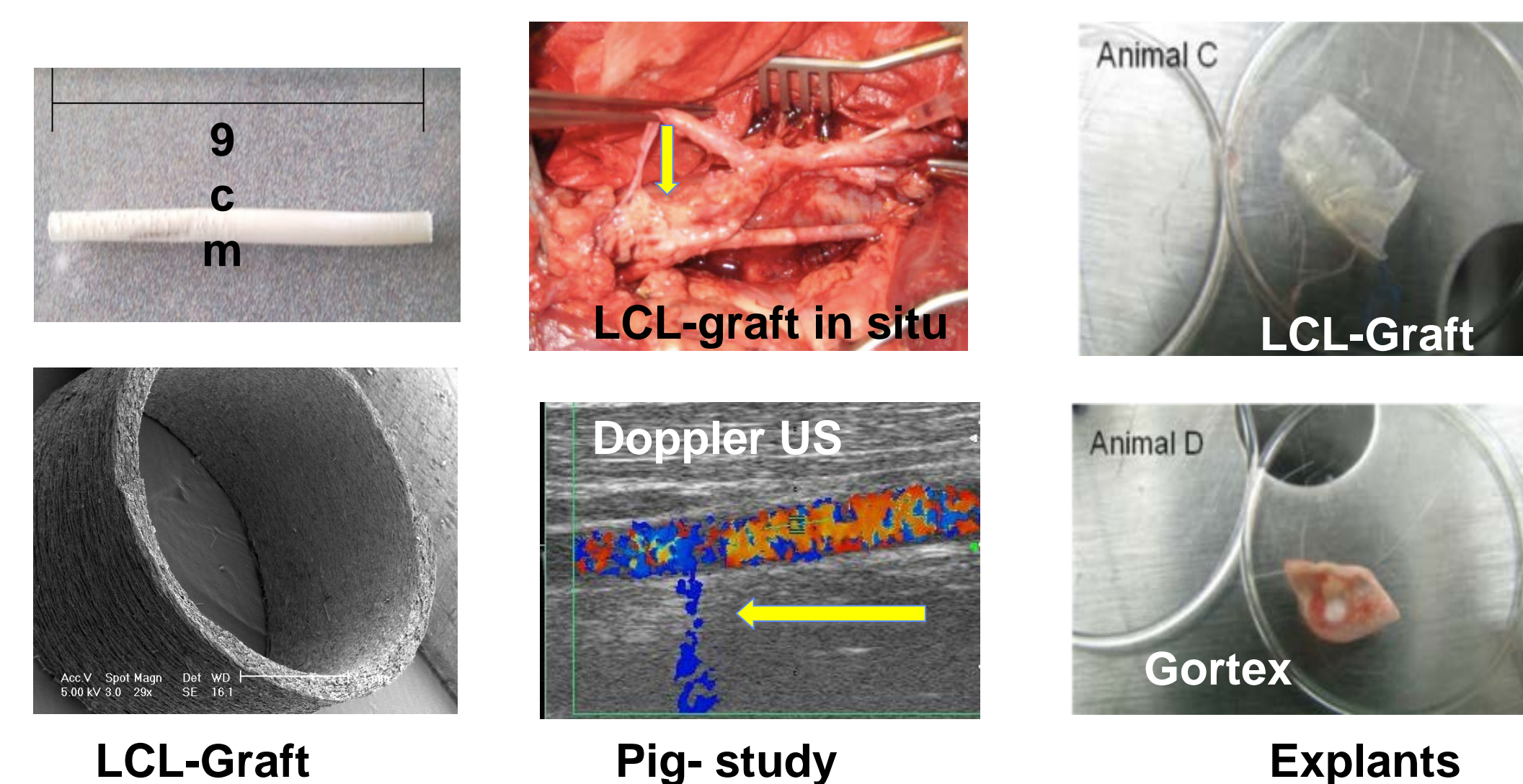
Novel technology/ New IP : To realize both microgrooved (guided cell alignment.) and micro-fibrous structure (maintain the elastic properties) of LCL- vascular graft.

SEM:1st spin-cast, 2ND electro-spun—re. creation of a *hybrid tube by spin-cast and electrospinning—ideal surface and graft compliance*

Envisioned Future Health Care Product:

- Our “product”, the LCL graft will be an off-the-shelf available, non-thrombogenic small diameter vascular graft that can function remain patent for more than 5 years
- Initial focus on larger diameter grafts for AV shunts and/or peripheral arterial surgery of 1cm diameter
- Subsequent products: small diameter coronary grafts ~ 0.3-0.5 cm diameter

Science: LCL graft tested in pig carotid bypass model



Impact on Health Care Costs (USA only):

300,000 peripheral vascular bypass surgeries / year

Cost / operation (no complications) ~ \$ 25,000 if insured, >100,000 if paying “full price”

Conservative estimate only for bypass bypass surgeries

Direct costs \$ 25,000 x 300,000 = 7.5 Billion \$\$\$ / year

100,000 revision surgeries/year

More complications (longer hospital stay) , i.e. costs are higher: \$ 50,000 x 100,000 = 5 Billion \$\$\$

5 Billion \$\$\$ could be saved annually if no revisions were necessary for coronary bypass surgery !

At least another 5 billion \$\$ that could be saved if LCL-Grafts were also used in coronary bypass surgery

Target Market / Patient Population

A/V Dialysis Access Fistula (Shunts): ~ annually 600,000 patients with kidney failure (in the USA alone) will need long term dialysis access fistula

Peripheral Grafts: e.g., Femoral - Popliteal grafts

~ 600,000 annually world wide

80% are saphenous autografts - 66% patency at 5 years

20% are synthetic (entirely PTFE, ~ 1cm) - 33% patency at 5 years

Coronary Bypass Grafts: 300,000 annually in the USA, 300,000 annually in Europe,

75-90 % patency of saphenous and mammary autografts (5 years)

No synthetic grafts (< 5 mm) available (0% patency)

LCL-GRAFT™ Economics

- USA (only peripheral bypass operations): Revenue generated for (conservatively) 300,000 procedures: 300,000 x \$ 5,000 = \$ 500,000,000
- Projected profit if the LCL-GRAFT™ corners the entire market: \$ 500 Million
- No viable competitor

Intellectual Property Landscape

- Invention Disclosure 07-0869D – the graft & method of making it; patent application filed November 25,2009
- Issued patents and pending patent applications at CHOP protecting the graft material
- Coordination of IP protection and commercialization with UPenn and CHOP; Drexel is the lead

Commercialization/Licensing Strategy

APS is licensed to:



Affiliations

- Chair of Bioengineering at Temple University
- School of Biomedical Engineering, Science and Health Systems, Drexel University
- Drexel University College of Medicine
- University of Pennsylvania
- The Children's Hospital of Philadelphia