2022 TERMIS
EU-Chapter
Kraków
28.06-1.07.2022

Where are all the electrospun medical devices?

Case studies of product development from an industry perspective

John Duckworth PhD

30 June 2022

ELECTROSPINNING® COMPANY

About The Electrospinning Company

We bring our ideas and biomaterial expertise to collaborate in an open and transparent way on product development






Biomaterial Platform

- Electrospinning technology and associated engineering
- ISO 13485 certification since 2015
- Medical Device and Regenerative Medicine Markets

Company

- Contract design, development, manufacturing services
- Proprietary biomaterials for partnering and licensing
- Strategic relationship with Confluent Medical technologies
- Located on Harwell Innovation Campus (near Oxford, UK)

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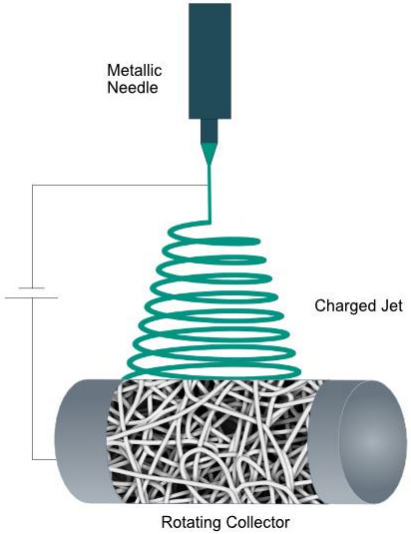
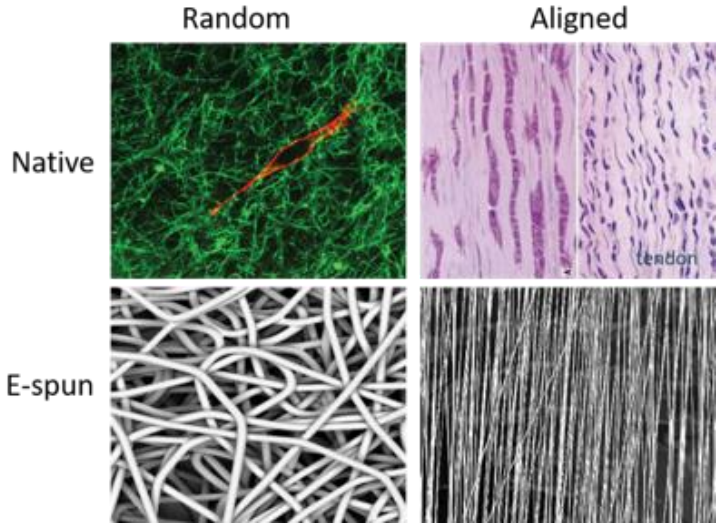
Electrospinning Technology



A medical grade synthetic or natural polymer solution is exposed to an electric field and stretched into thin micro-to submicron fibres and collected



Electrospun fibres of aligned or random orientation can mimic the structure of native extracellular matrix

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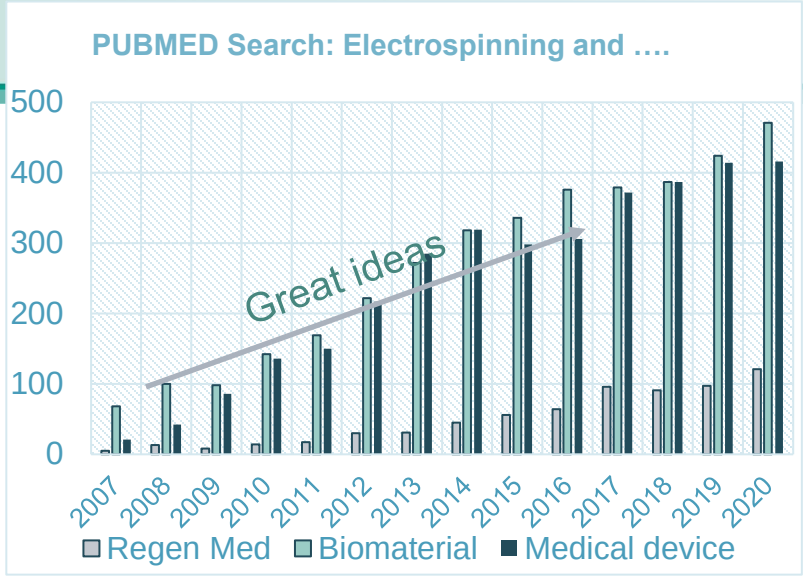
Electrospinning innovation just entering clinical markets



Of biomaterial research groups have an electrospinning setup

4,444 patents mention Electrospinning in their claims

Product	Approval
Medprin ReDura ™ (dura)	On market (60 countries)
Zeus bioweb™ PTFE for e.g. stent coating	USA and other
ZB Biowick™ orthopaedic	USA, Japan
PK Papyrus coated stent	CE Mark, FDA
Acera Restrata® (wound), Cerafix® (dura mater)	FDA 510(k)
ReBossis® (bone void filler)	FDA 510(k)
Nanofiber solutions Rotium™ (orthopaedic), Pheonix™ (wound)	FDA 510(k)
Tisseos® (dental)	CE mark.
Xeltis Restorex® heart valve	Clinical trials
Afyx Rivelin dental patch/drug delivery	Clinical trials
St Theresa Medical Surgiclot®	Clinical trials

S. Omer, L. Forgách, R. Zelkó, I. Sebe, Scale-up of Electrospinning: Market Overview of Products and Devices for Pharmaceutical and Biomedical Purposes. Pharmaceutics. 13 (2021)

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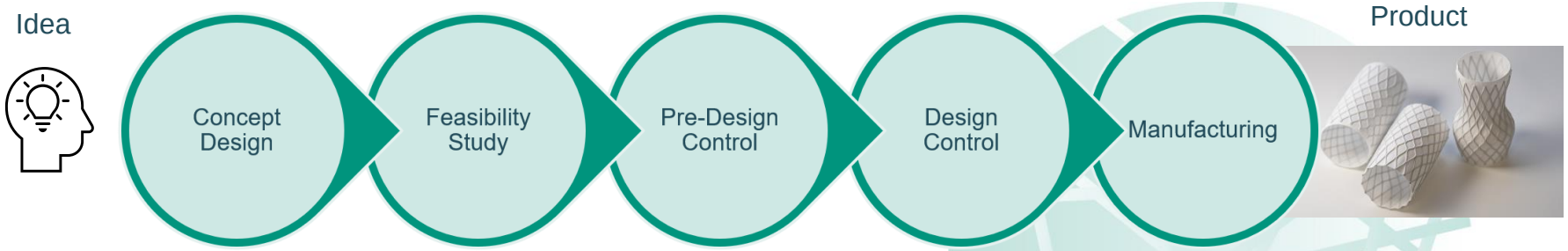
Challenges of translation



- Consistent and Scalable manufacturing process
  - Regulators confident to approve use
  - Predictable cost of goods from efficient and reliable process
  - Would you put this into a person?

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From Design to Manufacturing

Increasing cost

Idea

Concept Design

- Target Product Profile

Feasibility Study

- Proof of concept
- Regulatory plan and risk register

Pre-Design Control

- Product Requirement Specification (PRS)
- Packaging & Sterilisation
- Draft SOP
- Test methods

Design Control

- Verification & Validation
- Product Specification
- SOP
- Design Transfer
- Test method validation

Manufacturing

Product

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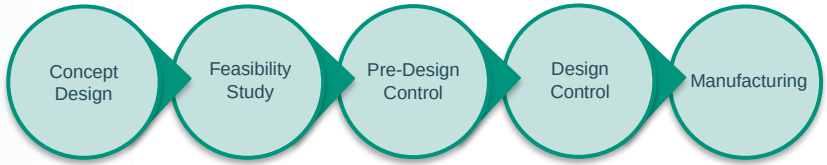
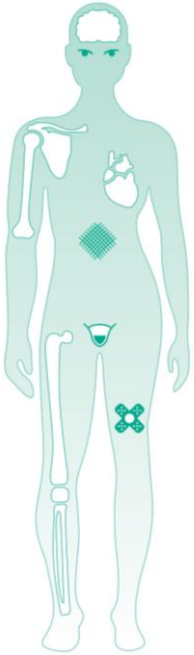
Our projects

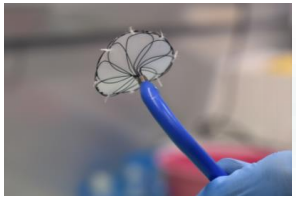
Broad range of therapeutic applications and stages





Academic/Pre-clinical | Clinical (Phase I/II/III) | Commercial

- Sports medicine (3)
- Artificial cornea
- Vascular access device
- Dura repair membrane
- Aortic device
- Breast reconstruction
- Stress urinary incontinence
- Synthetic amniotic membrane



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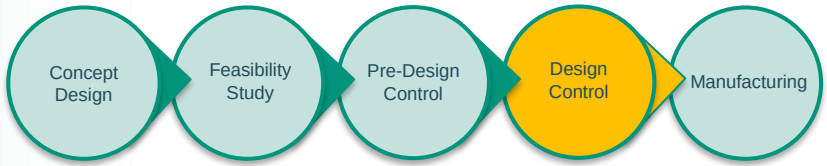
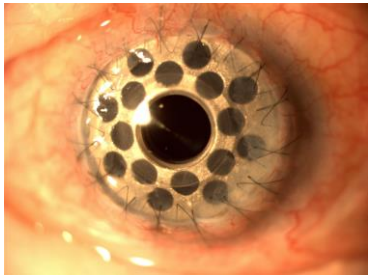
K-Pro



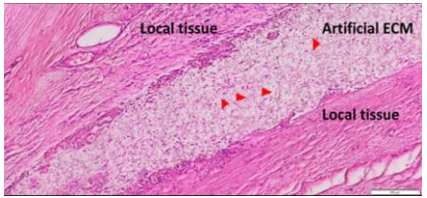
- Synthetic cornea keratoprosthesis
- Optical lens embedded in electrospun skirt
- Tissue integration eliminates need for visible, permanent sutures
- In clinical trials in Israel, France and Canada



*Boston Keratoprosthesis

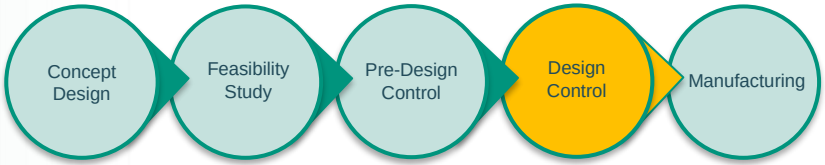
At the feasibility phase, revisited choice of polymer raw material to ensure:

- Consistency as the process scales
- Security of supply chain

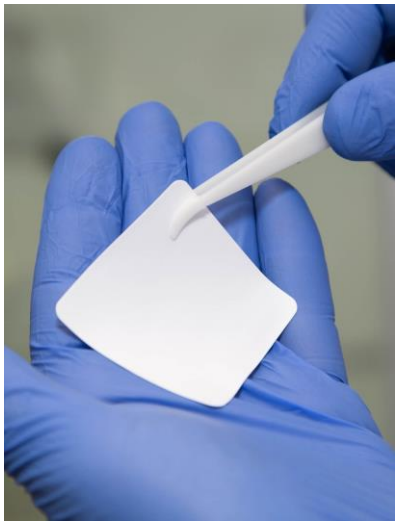


Nurami
medical nanofiber technology

ArtiFascia® Dural Graft



- Company was lean spin-out – Electrospinning Company provided clinical grade development and manufacturing capacity
- Synthetic dura mater surgical patch - sheet of porous biopolymer nanofibres plus adhesive layer
- Tissue integration provides tight and permanent resealing of dura mater after surgery



- Pivotal clinical trials complete
- Finalising Process Validation for regulatory dossier (FDA and EU)
- Planning process scale within regulatory parameters

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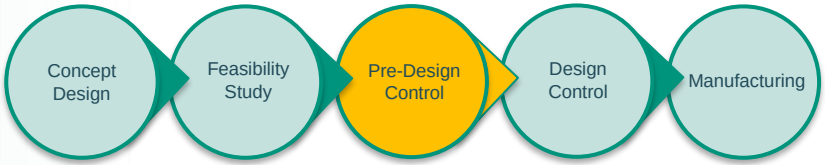
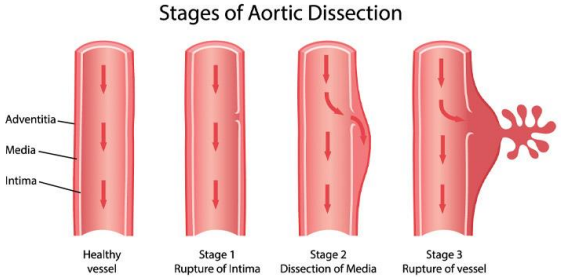
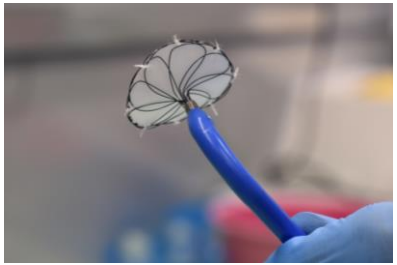
Aortic repair patch

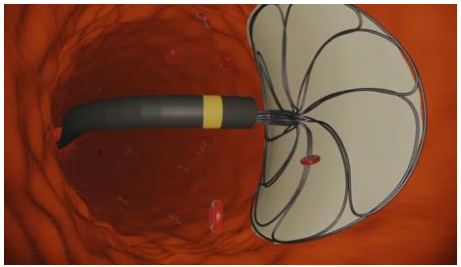


- Biomimetic bioresorbable adhesive patch
- Can cover ruptured aorta and integrate surrounding tissue to reform vessel wall
- Patented microfibrous structure and applicator



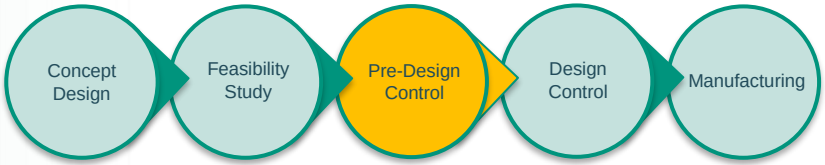
- Company spun out of university
- Had done small animal trials – successful
- We are optimising process to de-risk the regulatory process and minimise future production costs
  - Test methods
  - Accuracy/tolerance in specifications





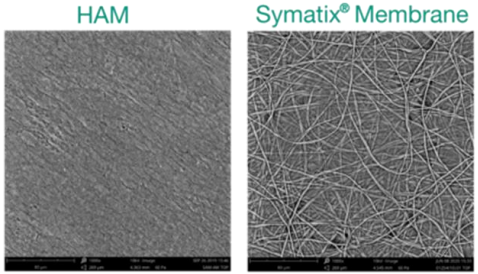
*Aortic (Heart) Aneurysm & Aortic Dissection | Mount Elizabeth Hospitals

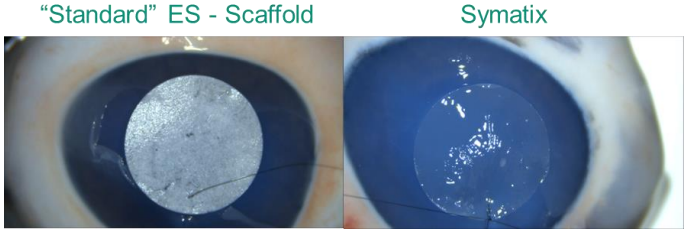
Symatix®: Synthetic Amniotic Membrane



- Electrospun scaffold + biomaterial composite
- Synthetic alternative to human amniotic membrane (HAM)
- Many advantages over harvested human tissue
  - Scalable, storable, tuneable, sterile

- Building on previous experience with academic research project
- Collaborative project with University of Nottingham and hospital
- Concept design has been clinician-led
  - Ensure clinical acceptance
  - Minimise regulatory risk





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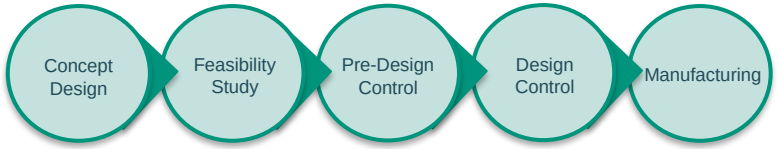
Conclusions

How can my idea become a manufactured product?

- Simplicity of design to de-risk regulatory pathway
  - Drugs
  - Multiple materials
- Previous regulation
  - Are there similar things on the market already you can point to?
  - Have raw materials been used in other products?
- Involving end-users early on
  - No good making a product clinicians hate using
- Preparation! Ask for help early and often!



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Dziękuję bardzo!

Thank you!

Please make sure to see my colleague's presentation at 16:20 in Room S3 A

Dr. Konstantina Kanari - Electrospinning and Metal Stents – A Good Fit?

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