Transferring Research Knowledge to Clinical Practice
Challenges and Chances

Prof. Dr. med. habil. Katrin Engelmann, Dr. Marcus Binner
May 21, 2019

Chemnitz Seminar “MEMS Technologies and Applications”
Hurdles towards Clinical Translation

Hurdles
- Patent vs. Publication?
- Timing
- Company Foundation & Administration
- Market Analysis
- Financing (Clinical) Studies

Basic Research
Applied Research
Clinical Trials
Official Approval

Health Insurance

Doctors
Clinics
Patients
Example: AmnioClip-plus (AC+)

Project aim: suture-free amnion membrane transplantation

Benefits: ambulant treatment, no operation, repeatable

Indication: corneal surface damage (scars, chemical burn, infectious keratitis...)

recently: dry eye – “Office Eye Syndrome” (GER: 12 Mio. patients)
“Bottlenecks”
Patents
Usage Studies (Research)
Consistent Quality Management
License by DGFG
Official Approval for German Healthcare applications (PEI)

Time besides clinical routine
• Intense discussions with Paul-Ehrlich-Institute
• Preliminary approval with restrictions: Effect of AM orientation should be studied in clinical surrounding (risk management for production)
• Klinikum Chemnitz: study completed (2017)
• Beneficial: in parallel AM approval for general wound healing applications
• DGFG for assembly and distribution

• Nowadays: Official approval for dry eye disease!
• DGFG is allowed to distribute the AC+ to German clinics
A long pathway until medical approval...

Timeline AmnioClip-plus

2004
Idea & Research

2005-2015
Patent & company foundation, PEI

Competition
2012 US patent “PROKERA®”

2016
PEI approval with restrictions
Clinical study Chemnitz

Competition
2017 US approval “PROKERA®”

2017-2019
DGFG support
PEI approval
DGFG final processing, storage and documentation

Distribution to German clinics

Transferring Research Knowledge to Clinical Practice | Dr. Marcus Binner | info@tissuemguard.de

May 21, 2019
Example: TissueGUARD project

Leibniz-Institute of Polymer Research Dresden

- one of the largest polymer research facility in GER
- application oriented fundamental research
- synthesis, characterization, theory, processing & testing of novel materials
- 2017: 480 employees & > 950 publications per year

- knowledge transfer project for medical applications
- innovative solutions for hydrogel applications
- materials for artificial cornea production, storage and transportation

Dresden Old Town
The Cornea is the „Window of the Eye“.

Corneal Curvature affects the Visual Acuity.

The Endothelium is responsible for the Visual Transparency.

While the Corneal Epithelium has regenerative potential, The Endothelium is non-regenerative.
Corneal Endothelial Damage & Cure

Turbid Vision
Damaged Endothelium

www.coavision.wordpress.com 2018


Cornea after DSEK/DMEK

DMEK operation
Stripping
Loading
Injection

DGFG 2017
Miracles in Sight 2018

Augenklinik Saar – Sulzbach 2016

DMEK Graft
DMEK Injector

Miracles in Sight 2018
The Obstacle

12.7 Million people worldwide suffering from corneal blindness.


Only 1 out of 70 Patients receives a corneal transplant.

Artificially produced tissues will cover the global demand.
Ex vivo tissue production

Donated cornea  Cell isolation  Cell culture & proliferation  Cell sheet engineering

Recover function with artificial tissue

How to collect and transfer the engineered tissue?

Artificial DMEK Graft?
Enzymatically cleavable hydrogels for tissue production

hydrogel casting – mix 2-3 solutions

- Cell culture
- Enzyme*

hydrogel network

hydrogel dissolved


*Possible enzymes, e.g.: Thrombin, FXa, Tobacco etch virus protease, Caspase-3, Enterokinase

The Principle


May 21, 2019
Can it be translated to clinics?

Prof. Dr. Alfonso L. Sabater
Dr. Enrique Salero
Angela Gomez

Elizabeth Fout-Caraza, MHSA
William Brian Buras Sr., CEBT
Next Steps & Challenges

“Bottlenecks”
Patent transfer
Labspace
GMP production
Certification
Clinical Trials
Approval of new therapies

Follow-up financing!

cell culture products

customized hydrogel precursors
“Klinisches Ökosystem”

Aim: Create methods/how-to’s as template for bio-/medtech & pharma start-up’s

- **Government Entities**
  - Early negotiations

- **Health Care System**
  - Health insurances

- **Investors**
  - Selective choice

- **Clinics**
  - Estimate Demand

- **Key Opinion Leaders**
  - Get in contact, LOI’s

Decrease hurdles, improve market entry.
“Klinisches Ökosystem”

The clinical ecosystem program to conduct market entry process

**Innovation Assistant**
Communication with clinicians, searching for new projects

“Template” to guide from idea towards market entry

Manage contacts to KOL’s, clinics, government entities, investors

**Use Cases**
Document and present examples of successful knowledge transfer projects

Valuable tool to arise interest, e.g. of investors

Direct feedback to Innovation Assistant

**Digital Clinic**
Develop new therapy algorithms with regards to government regulations

University degree program to implement “application-oriented thinking” to clinicians

Strengthen regional economy as innovation leader.
The project TissueGUARD is part of the EXIST program and is funded by the German Federal Ministry for Economic Affairs and Energy (BMWi) and the European Social Fund (ESF) as well as the Leibniz Institute of Polymer Research Dresden (IPF) Germany.

Dr. Marcus Binner

Web: www.tissueguard.de
E-Mail: info@tissueguard.de
Phone: +49 (0) 351 4658 1265
Mobile: +49 (0) 1577 4703321
Mail: Trienter Strasse 16, Dresden, Saxony 01217, Germany

Please scan QR code for my contact details.

THANK YOU FOR YOUR ATTENTION.