5 Years Experience
with a Biodegradable Implant
for Small Joints
Hand and Foot

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Data of Vitos Orthopädische Klinik Kassel
Medical Director Prof. W. Siebert
International Study supported by the European Commission QLK6-CT-2002-02700
Many implants without publication and without midterm results most of them not on the market
**Scaffolds (SC)**

- **Material:** Poly-L/D-lactide copolymer with L/D-monomer ratio of 96/4, P(L/D)LA 96/4

- **Manufacturing**
  - melt-spinning of the polymer to a 4-ply multifilament fibre
  - knitting a tubular single jersey
  - rolling
  - sterilisation by $\gamma$-irradiation

- **Sizes**
  - $\varnothing$ 8-24 mm,
  - Thickness 3.6-5.0 mm
Scaffolds

- **open Porosity**
  small pores between fibers Ø ca. 50 µm
  big pores between mash Ø ca. 400 - 700 µm

- **Ingrowth** of fibrous tissue

MCP II 5 years histology
- tens fibrous tissue
- Relics of particles
- Histiozytary reaction in surrounding tissue

3 weeks

1 year

5 years
Study design

– Prospective randomised
  • MCP II-V: SC compared to Swanson
  • CMC I: SC compared to tendon-suspension-resection-arthroplasty
  • MTP I-V: SC compared to resectionarthroplasty (RA) and arthrodesis

– Prospective observation
  • PIP and DIP

Onset Vitos Orthopädische Klinik Kassel

– hands April 2004
– feet December 2004

Hypothesis:
Results at least as good as standard treatment
Better long term results
# Data of Vitos OKK

<table>
<thead>
<tr>
<th>Joint</th>
<th>Scaffold</th>
<th>Swanson</th>
<th>RIAP</th>
<th>Arthrodesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMC I</td>
<td>33</td>
<td></td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>MCP II-V</td>
<td>16</td>
<td>26</td>
<td></td>
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<tr>
<td>PIP</td>
<td>36</td>
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<td></td>
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<tr>
<td>DIP</td>
<td>15</td>
<td></td>
<td></td>
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<tr>
<td>MTP I</td>
<td>26</td>
<td></td>
<td>24</td>
<td>1</td>
</tr>
<tr>
<td>MTP II-V</td>
<td>17</td>
<td></td>
<td>41</td>
<td></td>
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<tr>
<td>Sum</td>
<td>143</td>
<td></td>
<td></td>
<td>143 Scaffolds (new name: RegJoints)</td>
</tr>
</tbody>
</table>
Scaffold intraoperative in situ

CMC I
Fixation with anchor or transossary sutures

MTP I
Fixation with K-wire
CMC I Arthroplasty with SC
Results: Hands

CMC I

- **Pain:**
  same in both groups (VAS)

- **Function:**
  SC significantly faster improvement (VAS)

- **Strength and grip test:**
  SC significantly better

- **Radiology:**
  signifikantely wider space with SC

- **No complications** in both groups
CMC I Scaffold

preop  3 months  5 years

B.R., w, 64J
Results: Hands

MCP

• Pain:
  same improvement (VAS)

• Function:
  SC significantly faster improvement (VAS)

• strength and flexion:
  SC significantly better, grip test same

• Complications
  – 2 Infections with Swanson
  – 1 revision of SC to SC due to suspicion of infection
  – 2 revision of SC to Swanson because of instability
MCP II Scaffold

preop 1 year 3 years 5 years 5 years
Results: Interphalangeal Joints

- **PIP**
  - Improvement of pain (VAS) and Function (VAS)
  - ROM often limited
  - Tendency to deviation
  - Due to instability: 1 change to Swanson, 2x arthrodesis
  - Due to bad flexion: 1 change to Swanson
  - Early explantation: 1 due to fistula with psoriasis,
    1 due to infected hematema (K-wire ex)

- **DIP**
  - Strengthful flexion
  - Extension deficiency and tendency to deviation
  - 2 secondary arthrodesis

- **Radiology** 
  - MCP, PIP, DIP
  - Initial cup shaped bone resorption
  - Later increasing sclerosis
Case 1: PIP II

3 months

Case 2: PIP IV+V

5 years:
- free of pain,
- collateral ligaments stable,
- ROM 0/30/60,
- satisfied

Revision 1 year postop because of instability

H.C., f., 62 y

R.E., f., 67 y
DIP II

preop postop 4 mo 1 year 3 years

5 years: ROM 0/20/60, painfree

N.H. w, 75J
Case 1: DIP II

preop | postop | 4 Mo | 1 Jahr

Case 2: DIP II + PIP III

5 Jahre

3 Jahre

5 Jahre

N.H. w, 75J
**Results: Feet**

<table>
<thead>
<tr>
<th>AOFAS Score</th>
<th>3 mo</th>
<th>1y</th>
<th>2y</th>
<th>5y</th>
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</thead>
<tbody>
<tr>
<td>Scaffold</td>
<td>80</td>
<td>84</td>
<td>87</td>
<td>89</td>
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<tr>
<td>Resection-arthropl.</td>
<td>76</td>
<td>76</td>
<td>70</td>
<td></td>
</tr>
</tbody>
</table>

Scaffold:
- better Score of SC in comparison to RA (s.o.)
- Good pain relief
- Good cosmetic result
- Mainly excellent function
tip toeing possible, Extension / Flexion: 30/0/10
- Sometimes initial cup formed bone resorption
  later increase calcification
- No Complications in 5 years

Resectionsarthroplasty:
1 successful change to SC because of persistant pain
Results: Feet

Scaffold MTP I

1 to 5 years unchanged very good Function
Case 1: preop

Case 2: 5 years postop

Morbus Köhler II

both patients 5 years postop painfree and very good function

3 mo 5 years 5 years

N.E., w.68J

O.I., w. 55J
# Results of SC-Implantations

<table>
<thead>
<tr>
<th>Joint</th>
<th>Pain relief</th>
<th>ROM</th>
<th>Stability</th>
<th>strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMC I</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>MCP II-V</td>
<td>+++</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>PIP</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
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<td>++</td>
<td>+</td>
<td>+</td>
<td>++</td>
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<td>MTP I-V</td>
<td>+++</td>
<td>++</td>
<td>++</td>
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</table>
Resumée

The biodegradable PLDLA Scaffold Spacer is a promising implant for destroyed small joints of hands and feet.

**Fingerjoints:** CMC I and MCP II-V destruction without subluxation seem to be good indications. PIP und DIP-joints achieve good pain relief but sometimes a disappointing function.

**Toejoints:** especially hallux rigidus and osteonecrosis of MT-head seem to be ideal indications.

Long term results are not available.
Literatursauswahl


• Tiihonen R. et. al. Comparison of bioreplaceable interposition arthroplasty with metatarsal head resection of the rheumatoid forefoot. Foot & ankle international/Vol. 31, Nol 6 June 2010
Greetings from Kassel in the Heart of Germany

Bergpark Kassel