

Five year results with a new bioreplaceable implant for MTP joints (RegJoint)

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Introduction: Rheumatoid and osteoarthritis can cause severe destruction of the metatarsophalangeal (MTP) joints. The treatment by surgical replacement with joint prostheses manufactured from flexible silicone or other materials lack good long term results. Arthrodesis is not in favour by the patients. Resection arthroplasty (RIAP) is mainly performed but weakens the function. These problems of the current treatments have lead researchers to look for new solutions.

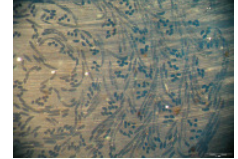
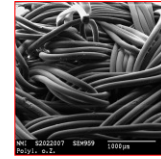
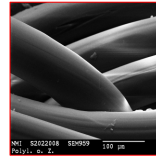
Objectives: Aim of this prospective randomised study is to see if the bioreplaceable scaffold spacer „RegJoint implant“ (Scaffdex, Finland) will show as good or better results respective pain and function than the resection arthroplasty in MTP joints.

Material:

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

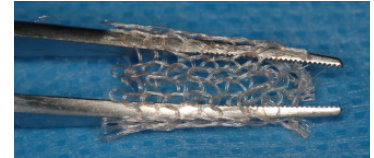
Manufacturing

- melt-spinning of the polymer to a 4-ply multifilament fibre
- knitting a tubular single jersey
- rolling
- sterilisation by γ -irradiation



open Porosity

small pores between fibers \varnothing ca. 50 μ m
big pores between mesh \varnothing ca. 400 - 700 μ m

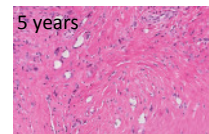
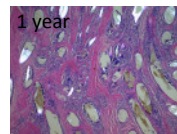
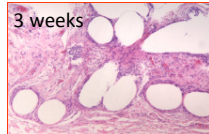


Sizes

- \varnothing 8-24 mm,
- Thickness 3.6-5.0 mm

Ingrowth of fibrous tissue

replacement expected within 2-3 years
example: revision of finger joints
no foot joints needed to be revised

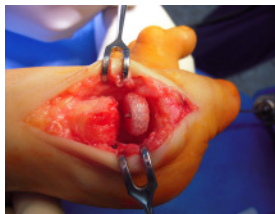


MCP II 5 years histology:
Tens fibrous tissue
Relics of particles
Some histiozytary reaction in surrounding tissue

Operation technique

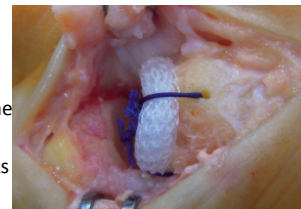
Hallux valgus

Fixation of implant with K-wire for 4 weeks
Then starting exercises



Hallux rigidus with straight toe

Suture through the bone with Vicryl (No2)
Hallux splint for 4 weeks
Then starting exercises



Results:

RegJoint MTP I



1 year

3 years

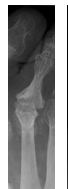
5 years



1 to 5 years unchanged very good function of the fibrous "neojoint"

Morbus Köhler II

Case 1:
5 years painfree



preop

postop

3 months

5 years

Morbus Köhler II

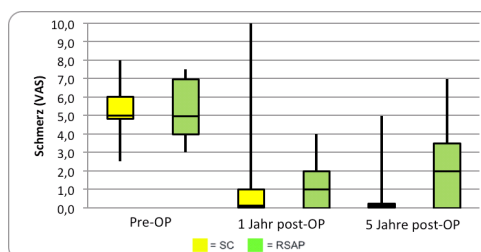
Case 2:
5 years painfree



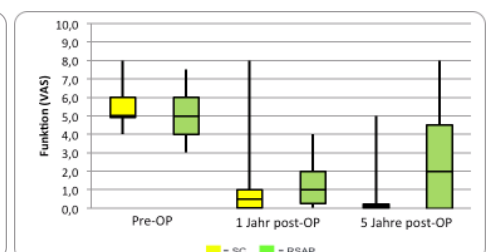
Number of joints	Joint	RegJoint	RIAP
	MTP I	26	24
	MTP II-V	17	41
	Sum	43	65

AOFAS Score	preop	3mo	1y	2y	5y
RegJoint	59	80	85	87	90
Resection-arthroplasty	47	76	75	70	70

Pain (VAS)



Function (VAS)



Summary:

- Better AOFAS Score for RegJoint in comparison to Resection arthroplasty with high significance after 5 years
- Better pain relief
- Mainly excellent function with RegJoint tip toeing possible, Extension / Flexion: 30/0/10
- Sometimes initial cup shaped bone resorption later then increased calcification
- Good cosmetic result
- 100 percent follow up
- No complications in 5 years



Resectionsarthroplasty:

1 successful change to RegJoint because of persistant pain

Conclusion:

The scaffold implant RegJoint is a good option for surgery on destructed MTP joints. Especially patients with hallux rigidus and Koehler's disease profit from this surgery. The implant received the CE certificate. Only long term assessment though will show if the achieved benefit for the patient will last.

References:

Mai S. et al. Ein- bis Zwei-Jahreserfahrungen mit einem neuen biodegradierbaren Implantat für kleine Gelenke, Orthopädische Praxis 43, 4, 2007
Tihonen et al. Comparison of bioreplaceable interposition arthroplasty with metatarsal head resection of the rheumatoid forefoot. Foot and ankle international/Vol. 31, No. 6 June 2010