A Novel Polycarbonate-Urethane Meniscus Implant for the Treatment of Middle-Aged Patients: Overview and First Experience in Israel


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Background

- The medial meniscus plays an important role in the knee joint.
- Meniscus dysfunction due to tear is a common knee injury which leads to degenerative arthritis, attributed to load distribution changes (Allen, 1984; Englund, 2004; McDermott, 2006)

- In these cases, there is clearly a need to protect the articular cartilage by either repairing or replacing the meniscus.

Messner (1998)

Meniscus replacement still represents an unsolved problem in orthopedics

- **Allograft** menisci suffer from problems related to:
  - Availability
  - Size matching
  - Cost
  - Risk of disease transmission.
  - Remodeling after implantation, causing shrinkage and reduced mechanical strength

- **Temporary scaffolds** for meniscal tissue engineering lack durability under knee loading conditions and also vary in the body response to the implant and the quality of the tissue formed.

In both solutions, target populations are **limited to young patients** (<40)


To develop a non-anchored synthetic meniscus implant, that will be able:

1. To relieve pain, and
2. To restore the meniscus function
Main Target Population

Chronic patients, post partial-meniscectomy or with meniscal tear with cartilage degeneration in their medial compartment

Regenerative approach:
- Repair
- Meniscectomy
- Biodegradable solutions, allografts

NUsurface®

TKR

UKA

20 years
35 years
45 years
65 years
MRI Analyses

Implant Design

Improvements:
- Geometry
- Structure
- Sizing

Mechanical Tests

Computational Models

Sheep Study

Improvements:
- Indications
- Surgical Technique
- Sizing

First-in-Man Series / Verona
Prof. Zorzi & Dr. Condello
18 patients, longest FU: 4 years

Multi Center Study / IT, IL, BL, DE
Zorzi, Condello, Arbel, Agar, Beer, Rozen, Israeli, Ben-Haim, P. Verdonk, R. Verdonk, Angele, Zellner, Weiler
90 patients, longest FU: > 1 year, Ongoing

Current Design
In-Vitro Static Tests in Human Cadavers

- More than 30 cadaveric knees
- Pressure distributions measurements under load
- More than 1500 pressure measurements

Linder-Ganz et al., 2010, J Biomech Eng
In-Vitro **Dynamic** Tests in Human Cadavers

The effect of the following parameters on Implant Stability were tested:

1. **Implant size**
2. **Surgical technique**
3. **Knee laxity / MCL condition**
4. **Different loading conditions**

The 6 Degree-of-Freedom Robot

C-arm during simulation (upper), and example of coronal fluoroscopy view (lower)

1. Correct size, indication and surgical technique will assure device stability
2. Too small implant and/or severe ACL Injury may lead to dislocation
Fatigue Test

The fatigue machine

Cyclic loading (1200N, 2Hz, 15 MM cycles), in 37°C

6 specimens, smaller size (worst case scenario)

Weight, shape and functionality were evaluated in each specimen, every million cycles

Results:

- **PCU and fibers were not affected** in respect to form and fiber-matrix bonding
- **No significant dimensional changes**
- **Pressure distributions remained similar** to those measured prior to the test
Finite Element Analyses

- Medial load of 1200N
- Contact pressure and internal stresses/strains were evaluated

- Contact pressures were similar to those measured under an intact natural meniscus (5-8 MPa)
- Strain/stress values in both the PCU and the reinforcement fibers remain within the allowed limits

Elsner et al., 2010, J Biomech Eng
Sheep Study: Macroscopic Results, 6 months post-op

Contradistinctively, it has been shown recently that a total medial meniscectomy in sheep, leads to extensive destruction of articular cartilage within ~3.5 months (Kelly et al. 2007).
Device Location & Surgical Technique
Multi-Center, Prospective, Non-randomized, Clinical Study

The study is taking place in 4 countries:

**Israel**
- Ichilov: Dr. R. Arbel
- Dr. N. Blumberg
- Assaf Harofe: Dr. G. Agar
- Dr. Y. Beer
- Emek Medical Center: Dr. N. Rozen
- Dr. S. Israeli

**Italy**
- Verona: Prof. C. Zorzi
- Dr. V. Condello

**Belgium**
- Ghent: Prof. R. Verdonk
- Dr. P. Verdonk

**Germany**
- Regensburg: Prof. P. Angele
- Berlin: Dr. A. Weiller
Selected Intra-op Images

Posterior horn before implantation

The device located in the posterior horn “pocket”
Continuous Fluoroscopy of the NUsurface®
All KOOS scores at 12 Mo are significantly ($p<0.05$) better than baseline.
KOOS – NUsurface® MCT

67%*

160%*

KOOS Pain  KOOS Symptoms  KOOS Activity  KOOS Sport  KOOS QoL

n = 53  n = 70  n = 83
Take Home Message

• A new meniscus implant was presented

• First clinical experience show improvement in all measures, 12 months post-op

• Clinical follow-up of the device is underway
Thanks for your attention