Medical devices

Development of novel treatment method for meniscal injury with defect, using a atelo collagen-based meniscal substitute

Principal Investigator

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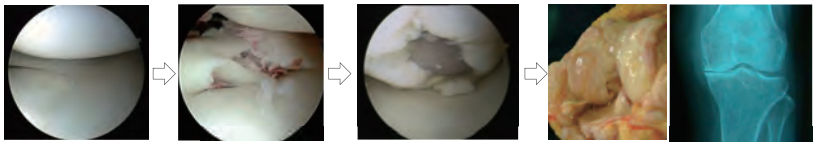
Project Outline

Background

✓ High risk of knee osteoarthritis with meniscal injury



Normal meniscus | Meniscus injury | Cartilage lesion

Fairbank T. J. JBJS 1948
Tapper E. M. *et al.* JBJS 1969
Henning C. E. *et al.* Clin Sports Med 1985

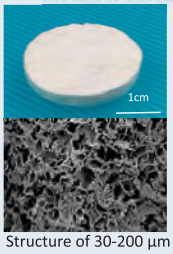
Meniscus has low hearing potential

✓ Low blood flow
✓ Exposure to mechanical stress

Need to develop substitute to promote meniscal regeneration

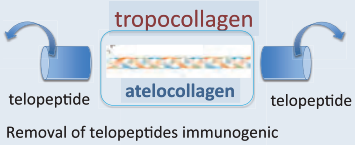
Novel knee meniscus substitute

Atelocollagen meniscus (ACM) (KOKEN, JAPAN)



Structure of 30-200 μm Interconnected pore

✓ **Material:** Bovine type-1 atelocollagen
✓ **Biomechanical properties:** Approx. same stiffness as meniscus



Removal of telopeptides immunogenic

Pre-clinical study

- Created 3x8mm defect at the anterior segment of the medial meniscus of miniature pigs.
- Applied ACM to the defect and fixed with a suture.
- Evaluate at 6 months after surgery

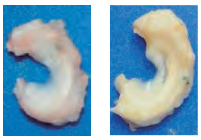
Three groups

i. ACM group (n = 4)
ii. Defect group (n = 4)
iii. Normal group (n = 2)

(1) Macroscopic evaluation

➢ Meniscus

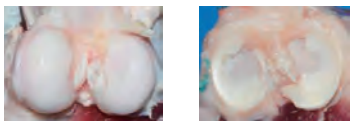
ACM | Defect



Favorable repair to defect site in ACM group

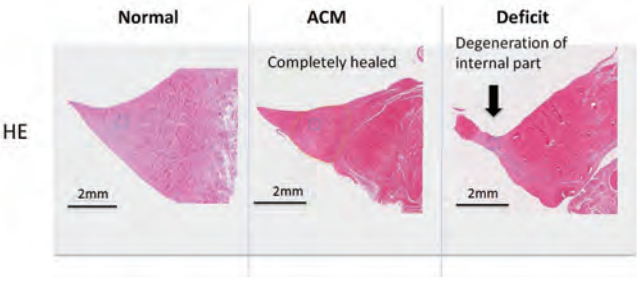
ACM safety

➢ Cartilage | ➢ Synovial



No cartilage injury or reactive inflammation

(2) Histological evaluation



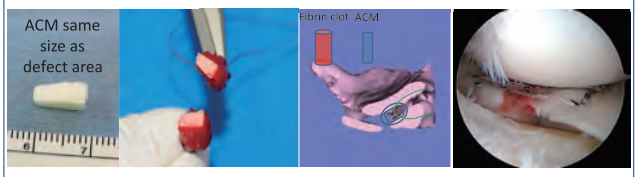
Clinical studies

Eleven patients enrolled, surgery performed

Case: 29-yr-old male, complex tear in right knee medial meniscus

T2-weighted MRI (Front view, Lateral view) | 3D MRI (Lateral view) | Arthroscopie

Complex tear and defect found in middle segment of medial meniscus

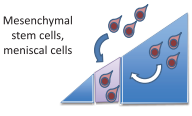


1 y after surgery: no clear adverse events

ACM efficacy

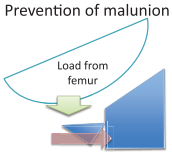
(1) Scaffold for migrating cells

✓ Regeneration with meniscoid tissue
✓ Predominance of fibrochondrocytes



(2) Compensation of the meniscal function

✓ Prevention of malunion



Development roadmap

Item	2017	2018	2019	2020	2021～
1. Evaluation of *in vitro* biological function	←				→
2. Graft study using animals		←			→
3. Clinical study: Advanced medical treatment B			interim evaluation	Final report	△ Preparation Clinical Trial
4. Preparation for clinical trial				Regulatory strategy consultation	