ISAKOS CONGRESS 2025

MUNICH GERMANY
June 8–11

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Total Meniscus Replacement

In Vivo Safety and Performance of a Novel Fibre-Reinforced Total Meniscus Replacement: *A 3-Month Study in Sheep*

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Disclosures

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My disclosure is:

Paid employee of and own stock options in Orthonika Ltd.

Introduction

Motivation for Synthetic Meniscus Replacement

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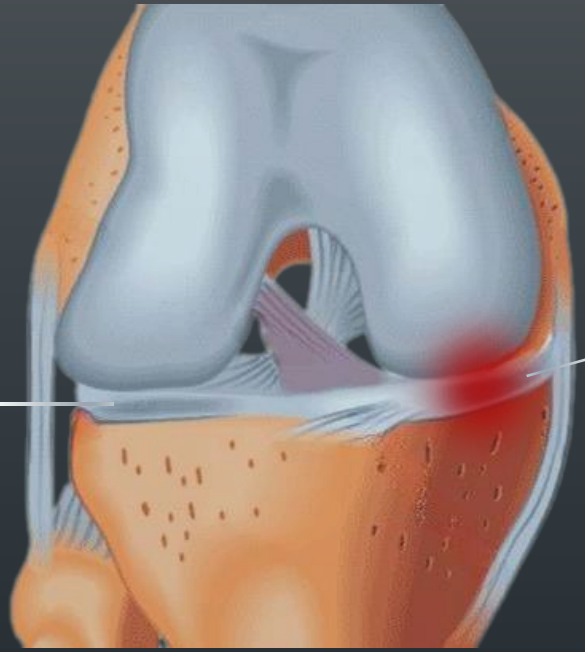
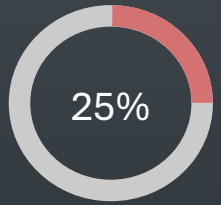
Meniscectomy is one of the most common orthopaedic surgeries worldwide

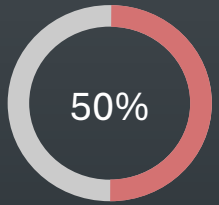
850k surgeries p/a in US [1]



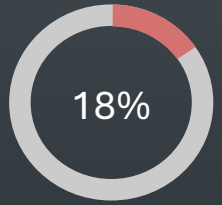
- Only 15% of meniscus tears are repairable [2]
- Meniscal allografts cannot meet demand
- Unsatisfactory outcomes post-meniscectomy:



Persistent Pain [3,4]



Osteoarthritis [5]



Total Knee Replacement [6]

No proven synthetic solution exists for irreparable meniscal injury

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Aim

Evaluation of the safety and performance of a novel anatomical fibre-reinforced polycarbonate urethane (PCU) total medial meniscus implant at 3 months after implantation in an ovine model

Methods

Safety and Performance in 3 Month Ovine Study

Subjects and Implantation Site

- N=7 mature female sheep (North of England mules)
- Right-sided total replacement of medial meniscus of the stifle joint with Orthonika TMR™ implant
- Unoperated, contralateral limb = Control group

Implant Assessments

- Implant integrity, including crack/tear identification, qualitative (visual) wear and deformation
- Implant position and articulation with knee flexion-extension
- Interference screw & strap fixation integrity/accuracy

Clinical Observations

- Lameness assessment at regular time points throughout the study
- Pain (Sheep Grimace Scale) at regular time points throughout the study

Histology

- Macroscopic and microscopic (Modified Mankin Score) cartilage condition [7]
- Integration/Ingrowth of tissue at implant sites (Toluidine Blue & H&E)

Methods

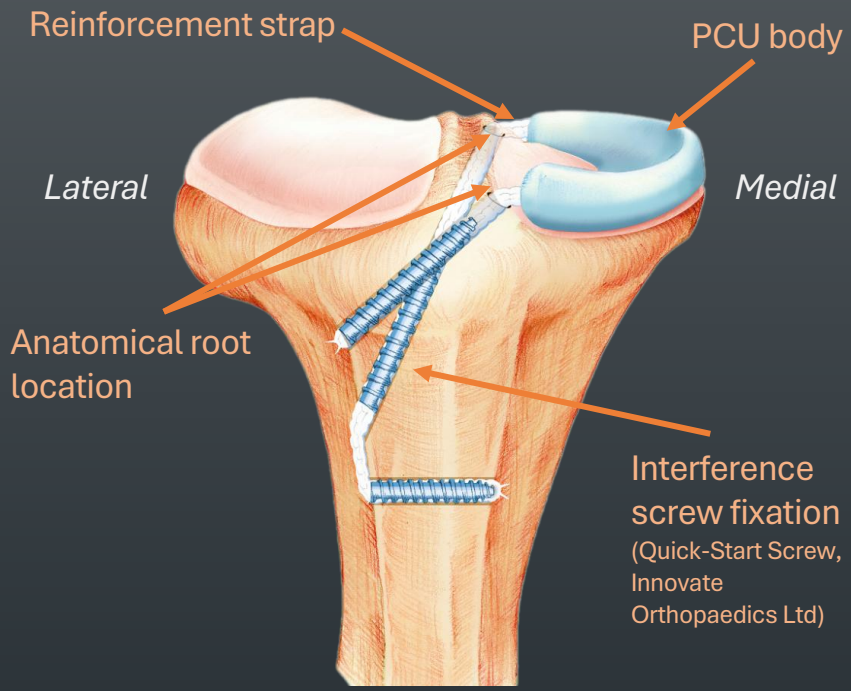
Implant and Surgical Technique

Orthonika TMR™ Design

- Fibre-reinforced polycarbonate urethane total medial meniscus replacement
- One size anatomically-shaped right medial meniscus replacement for the stifle joint
- Restoration of anatomical root location
- Interference screw fixation (Quick-Start Screw, Innovate Orthopaedics Ltd)

Surgical Technique for Implanted Group

- Total meniscectomy of the right medial meniscus
- Implant introduction via epicondylar osteotomy approach
- Transosseous tunnels drilled with meniscal root repair guides
- Screw-strap interference in cortical bone exiting at the anterolateral tibia with additional transverse tunnel for double fixation of posterior strap

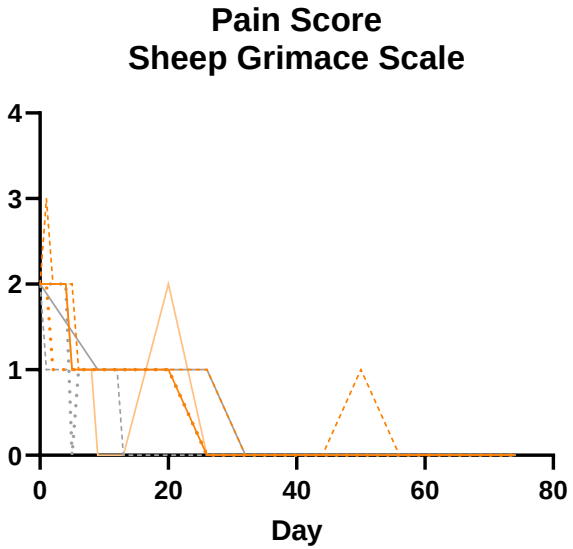


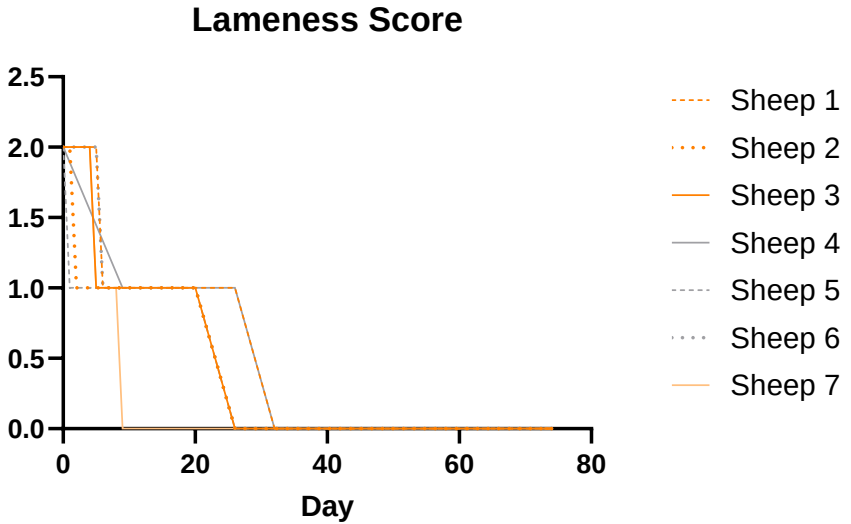
Schematic of the Orthonika Total Meniscus Replacement in situ replacing the entire medial meniscus in the right stifle

Results

Animal Health

- All N=7 sheep were fully weight bearing with mild lameness and pain at 1-week post-op
- No lameness or pain at 3 months
- No evidence of comorbidity





Results

Implant Integrity at 3 months

All implants were well positioned on the tibial plateau with smooth articulation throughout flexion-extension cycles

Articulating Body

- Implant integrity confirmed for all n=7 implants
- No evidence of tears or cracks
- Minor evidence of localised wear
- Mean implant deformation expected for tibiofemoral conformance:
  - 1.6 mm in AP direction (< 10 %)
  - 0.2 mm in ML direction (~ 1 %)
  - 1.2 mm in SI direction

Fixation

- Interference screws fixation was secure and fully integrated
- No fixation strap slippage

Strap

- Minor fretting at proximal tunnel apertures in n=6 posterior tunnels and n=2 anterior tunnels

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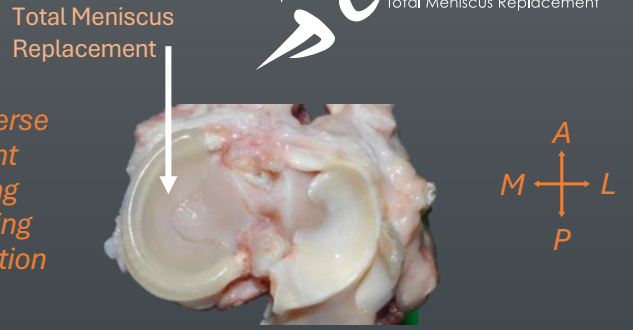
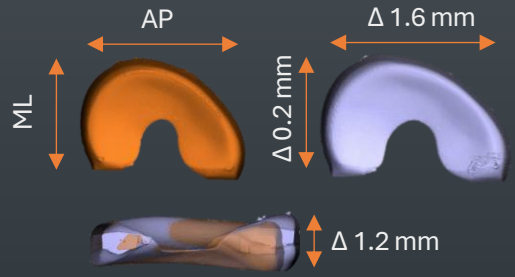
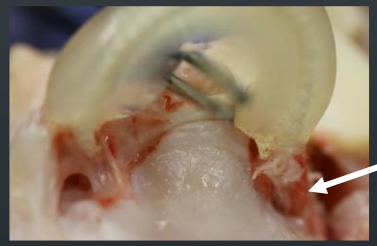


Post-mortem transverse plane view of the right tibial plateau showing the good size matching and anatomical location of the implant



Example implant dimensional change post-mortem in transverse (top) and sagittal (bottom) planes



View of implant underside in situ, showing the partial fretting on inferior strap coincident with the posterior bone tunnel

Results

Cartilage Condition at 3 months

Median Modified Mankin scores reported for the tibial cartilage. Compared with Mann Whitney, Control vs. Implanted (α = 0.05)

Microscopic Cartilage

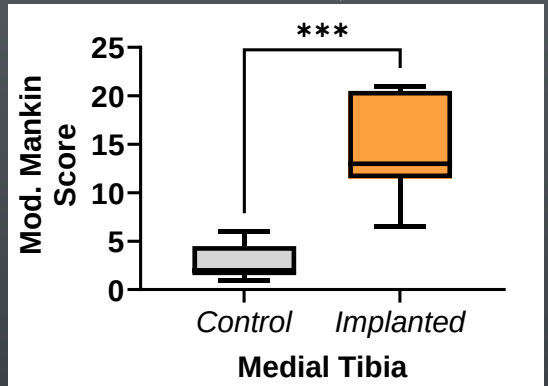
- *Control group:* Changes reflective of the usual spontaneous changes common in this age of sheep
- *Implanted group:* Consistent with compressive and tribological effects of surgery and implantation

Macroscopic Cartilage

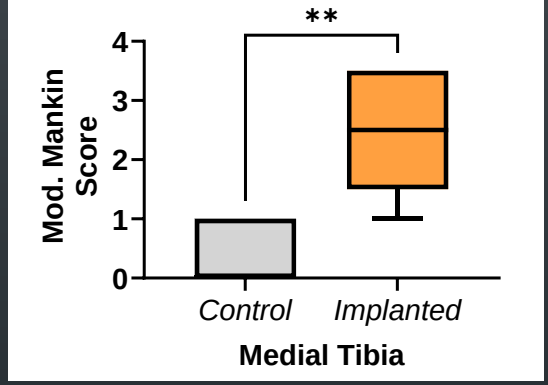
- Mild localised articular cartilage degeneration was noted for implanted stifles compared to non-operated controls

At the 3-month timepoint in the ovine model, our implant demonstrated effects on the tibial cartilage comparable to those observed with other meniscal devices that have progressed to the clinical stage. [8]

Microscopic



Macroscopic



*N=7 per group. Microscopic and macroscopic scores are out of 25 and 4, respectively. Asterisks represent differences between groups (** significant at p <0.01, *** significant at p <0.001).*

Results

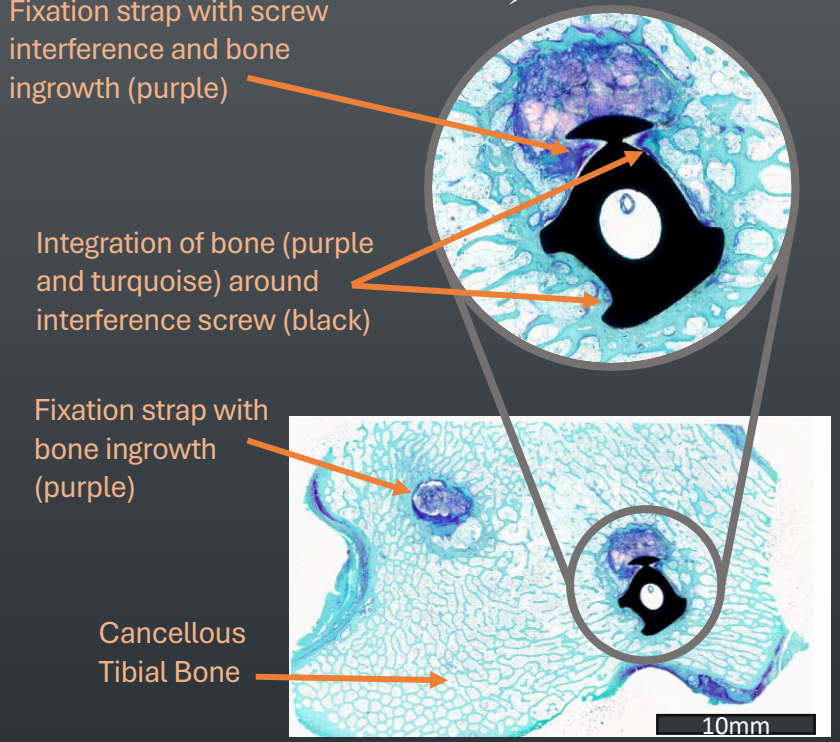
Tissue Integration at 3 months

Tissue Integration

- Complete healing of tissue around reinforcement strap at anterior proximal tunnel aperture, some healing at posterior strap
- Substantial deposition of relatively mature bone, around the implant (n=7)
    - Bony integration to interference screws
    - Tissue ingrowth in transosseous tunnels into strap with an absence of degeneration, necrosis, or haemorrhage

Inflammatory Markers

- No indication of any implant component causing inflammatory irritation, consistent with implantation of inert materials



Transverse cross section showing fixation straps in situ in tibial bone tunnels. Purple staining indicates bone ingrowth into the strap, with bone integration around the screw

Conclusions

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- ✓ Synthetic Total Meniscus Replacement presents a safe, viable solution for the treatment of irreparable meniscus tears
- ✓ The fibre-reinforced polycarbonate urethane TMR can withstand short-term physiological loading in sheep with minimal implant wear, and restore knee biomechanics and function
- ✓ Strap fixation with interference screws provides a suitable, biocompatible method of positioning and securing meniscal implants
- ✓ Longer-term investigations into implant performance versus meniscectomy and meniscal allograft will be performed to establish comparative cartilage data
- ✓ Further modifications at proximal tunnel boundary have since been implemented to minimise risk of strap fretting and therefore potential extrusion over time

References

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