ISAKOS CONGRESS 2025 | MUNICH GERMANY June 8–11

Safety and Efficacy of a Novel Polyglycolic Acid Meniscal Scaffold for Irreparable Meniscal Tear in Human Clinical Trial

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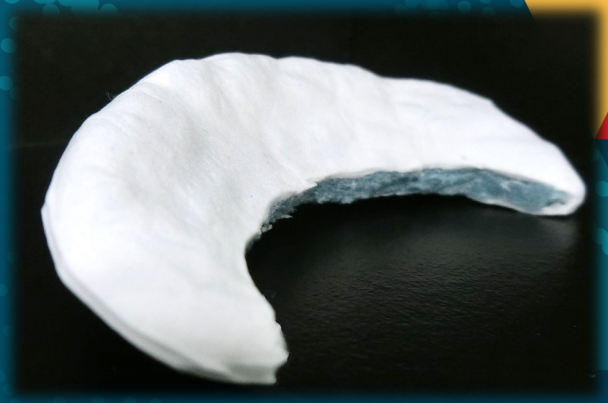
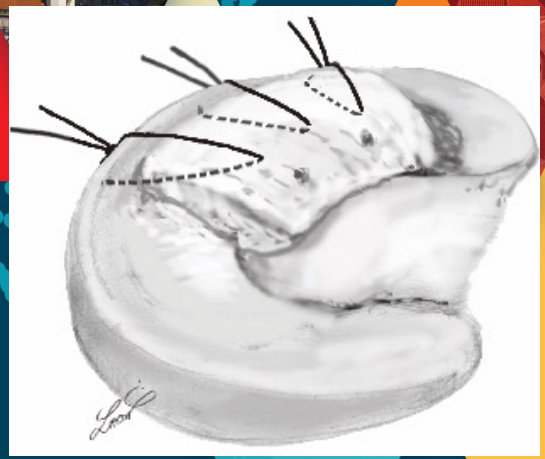




Faculty Disclosure Information

- This clinical trial was supported by Gunze Medical.

How to Treat Meniscal Injury

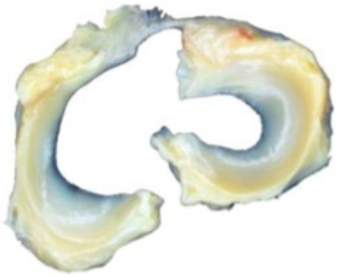
EU

Suture

Meniscectomy

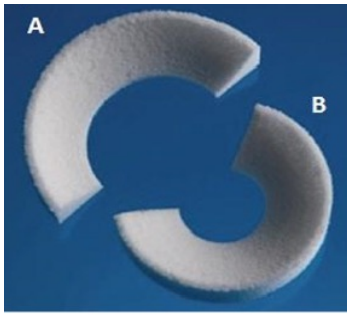
JAPAN

Allograft



Artificial meniscal scaffold

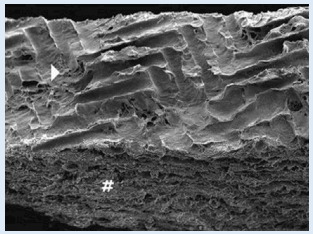
Bioabsorbable meniscal scaffold



Meniscal Scaffold in the World

CMI® **Ivy Sports Medicine**, Germany

Type I collagen from bovine Achilles tendon **natural** polymer



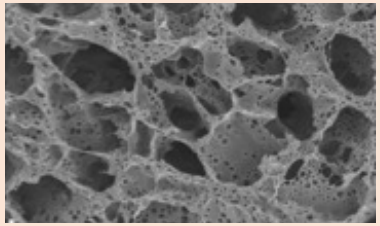
Good replacement but, difficult of handling and suture fixation

Filardo G et al ;Int Orthop 2015

Dr. Kevin R. Stone

Actifit® **Orteq**, England

Polyurethane **synthetic** polymer



Good handling and fixation, but hard to replace native tissue

Verdon R et al ;Knee Surg SportsTraumatol Arthrosc 2012
Schuttler KF et al ;Knee Surg SportsTraumatol Arthrosc 2016

Prof. Rene. Verdonk

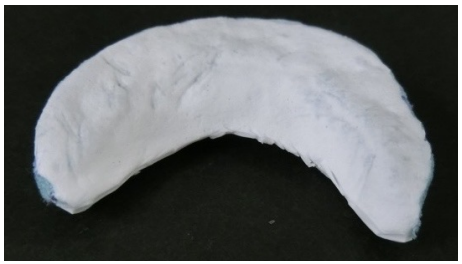
Prof. Phillipe. Beaufils

No similar scaffold in Japan

Novel Meniscal Scaffold

Background:
Meniscal tear treated with partial meniscectomy induces knee osteoarthritis. Therefore, attempts to restoring normal knee kinematics and biomechanical forces are essential.
Because prosthetic replacement of the meniscus has proven ineffective, we had established meniscal scaffold made by Polyglycolic acid (PGA) coated with polylactic acid/caprolactone, (PGA scaffold) that supports ingrowth of new tissue and eventual regeneration of the lost meniscus.

Purpose: To evaluate the effect of a novel meniscal scaffold for the treatment of irreparable meniscal injury in human.



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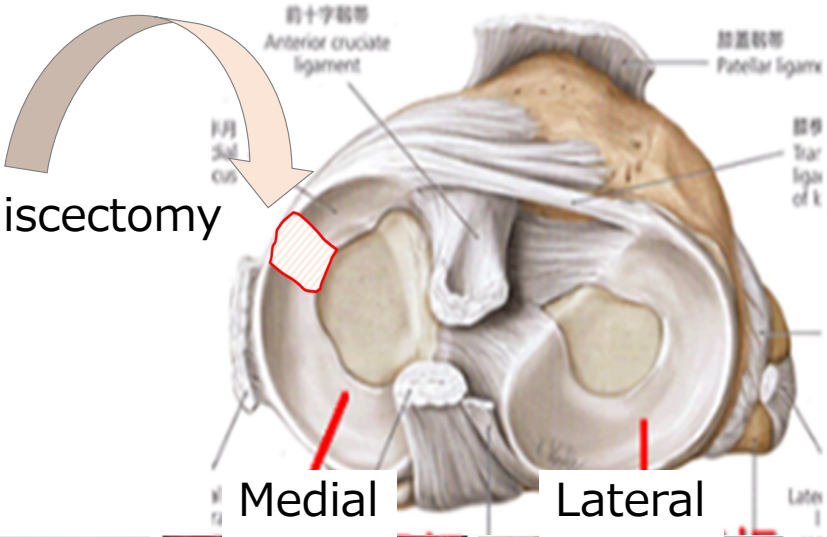
Meniscal Regeneration with PGA Scaffold in Mini Pig

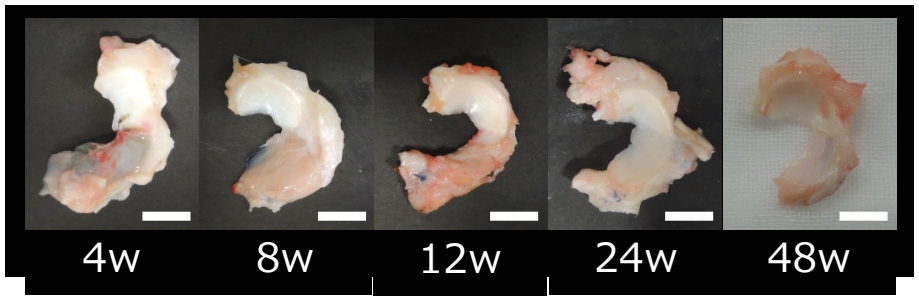
<*Method*>

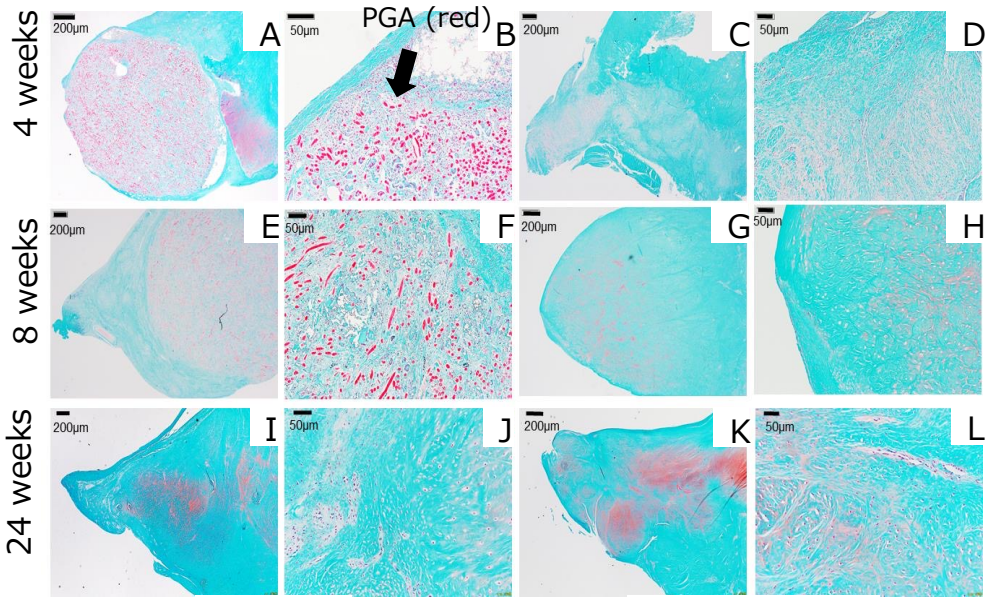
Partial meniscectomy



Otsuki et al. Am J Sports Med 2019.

<Results>



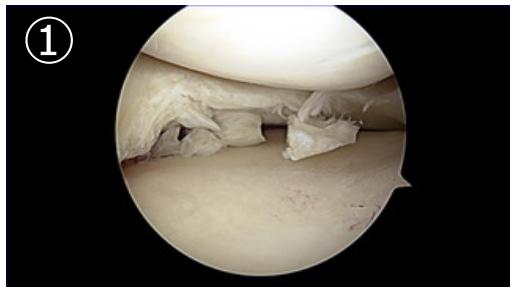


Human Clinical Trial and its Surgical Technique

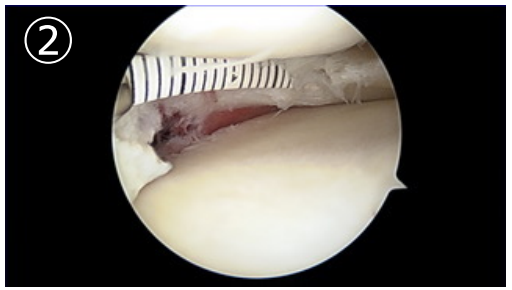
Clinical Trial	
Age	41.5 (31 - 59)
Sex	Male : 4、Female : 2
Height (m)	1.67 (1.60 – 1.72)
Weight (kg)	65.2 (52 – 76)
BMI (kg/m^2)	23.3 (18.6 – 29.4)

Xp findings	
FTA (°)	175.3 (173 - 177)
HKA (°)	0 – 3° varus
Mechanical axis (%)	42.5 (31 – 51)

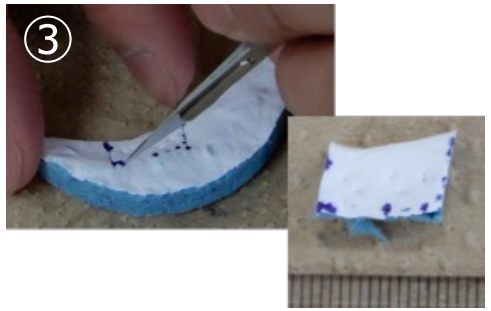
➢ Surgical Technique



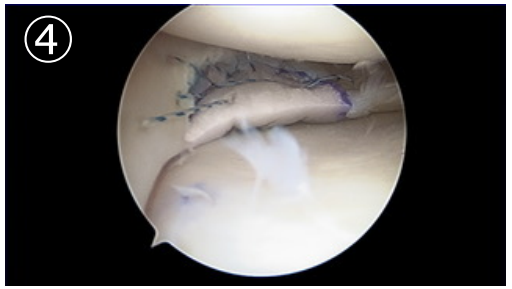
Partial meniscectomy of degenerated meniscus



Measure the defect size



Trimming of Scaffold as same as defect size



Scaffold fixation with inside-out technique

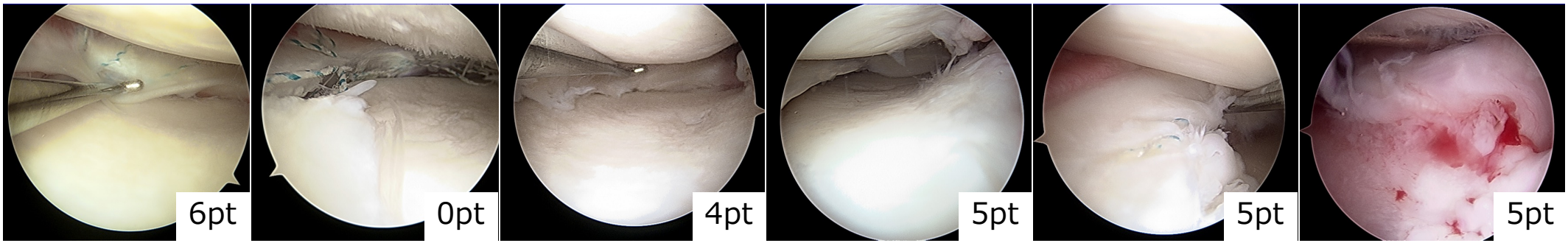
Otsuki et al. Arthroscopy Tech, 2022.

Second-look Arthroscopy (1yr after Implantation)

	Initial				Second-Look			
	Presence	Stability	Smoothness	Total	Presence	Stability	Smoothness	Total
Case 1	1	0	0	1	2	2	2	6
Case 2	1	0	0	1	0	0	0	0
Case 3	0	0	1	1	1	1	2	4
Case 4	1	0	0	1	2	2	1	5
Case 5	0	0	0	0	1	2	2	5
Case 6	0	0	0	0	2	2	1	5
Mean ± SD		0.67 ± 0.52				4.2 ± 2.1		
P value								0.0030

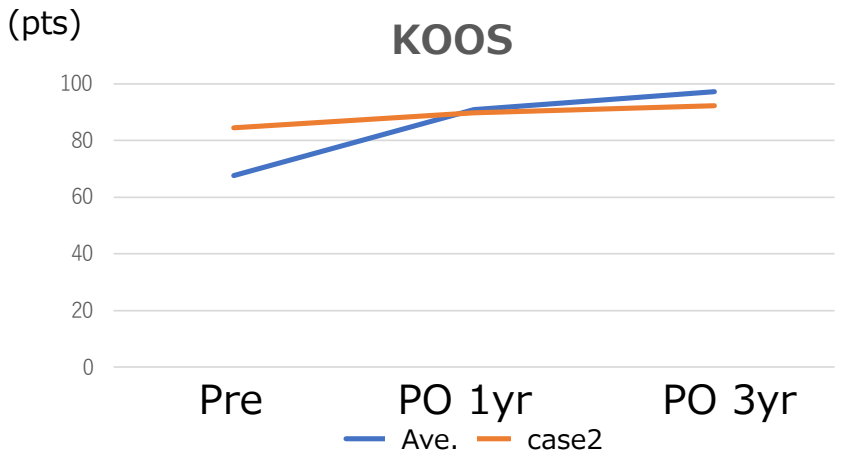
Scoring was referred by Sekiya *et al.* Paired *t* test was used for statistical analysis.

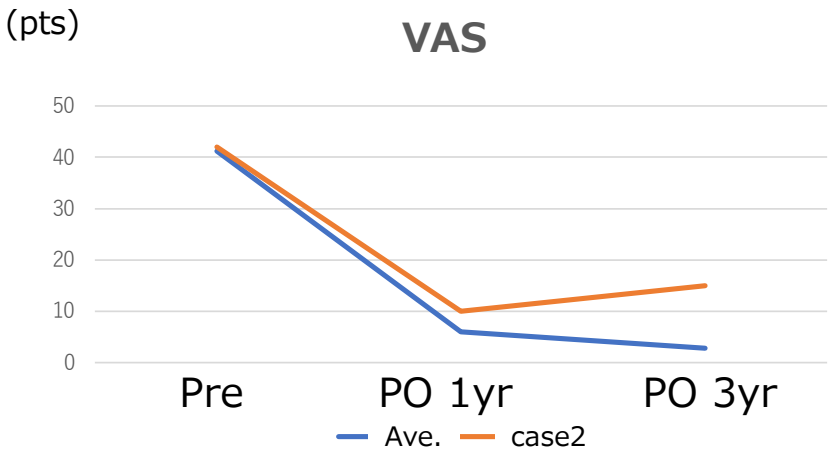
Case 6: lateral

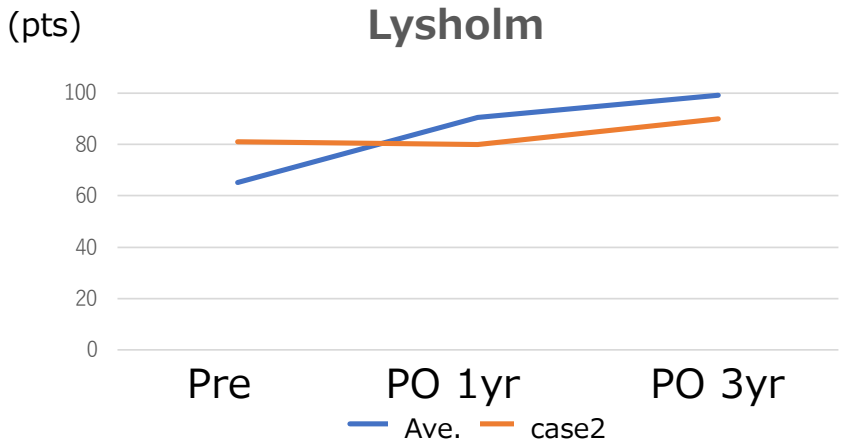


Case 1 | Case 2 | Case 3 | Case 4 | Case 5 | Case 6

Clinical outcome



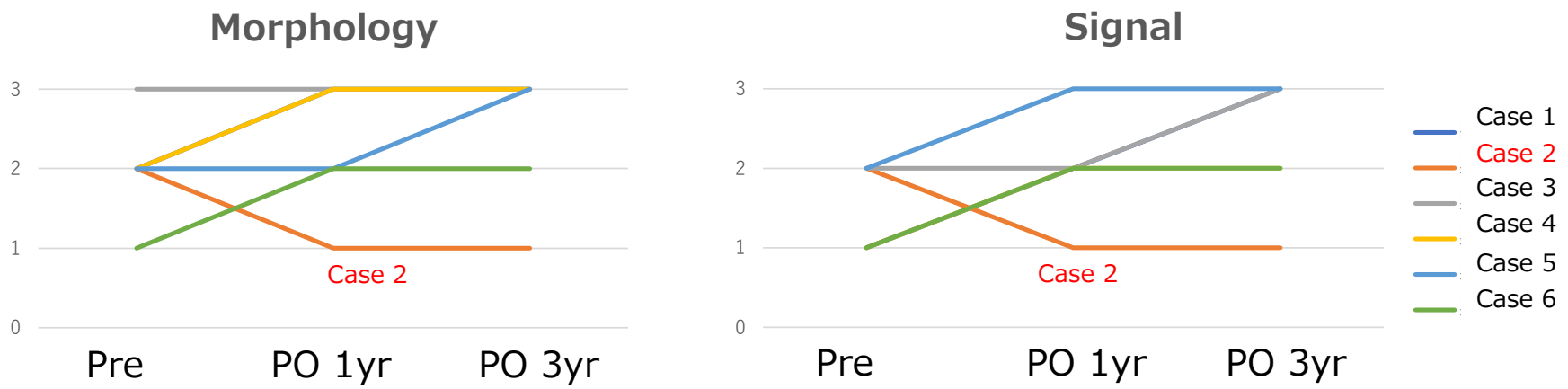




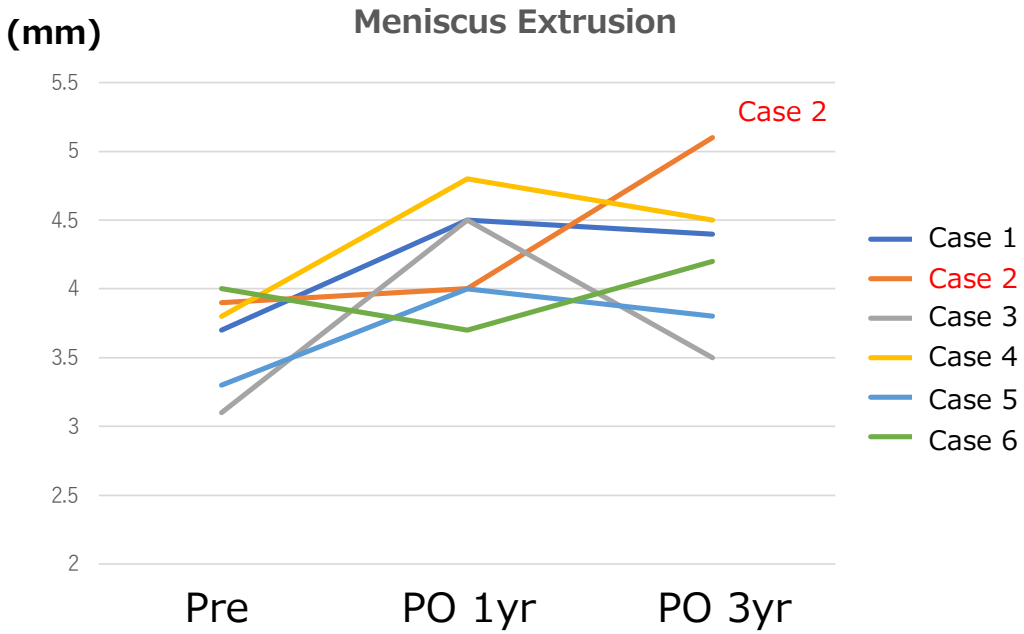
- All cases were improved clinical outcomes, however, case 2, which was scaffold absorption was lower.
- Importantly, VAS in Case2 got deteriorated at postoperative 3 year.

Size and Signal after Implantation (MRI)

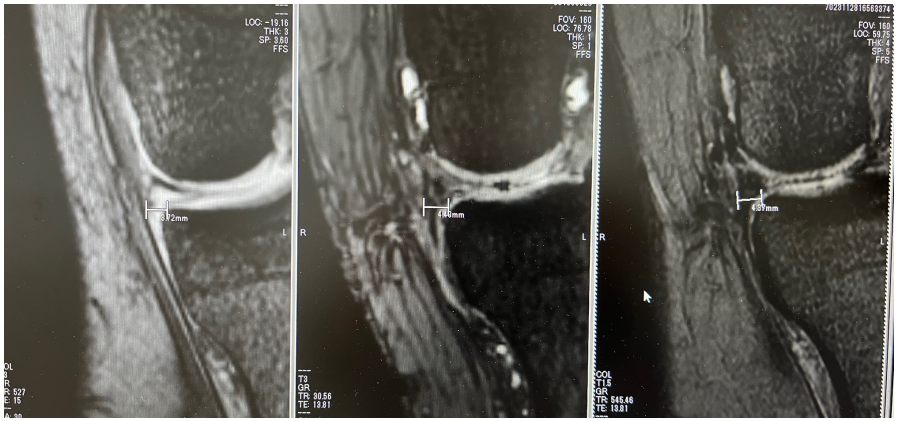
Modified Genovese Score	Grade I	Grade II	Grade III
Morphology and size	Totally resorbed implant or markedly small	Small implant with regular and/or irregular morphology. Slightly hyperintense	Implant with identical shape and size to the normal meniscus
Signal intensity	Markedly hyperintense or no signal at implant area	Slightly hyperintense	Isointense relative to the normal meniscus (no signal)



Meniscus extrusion (MRI)

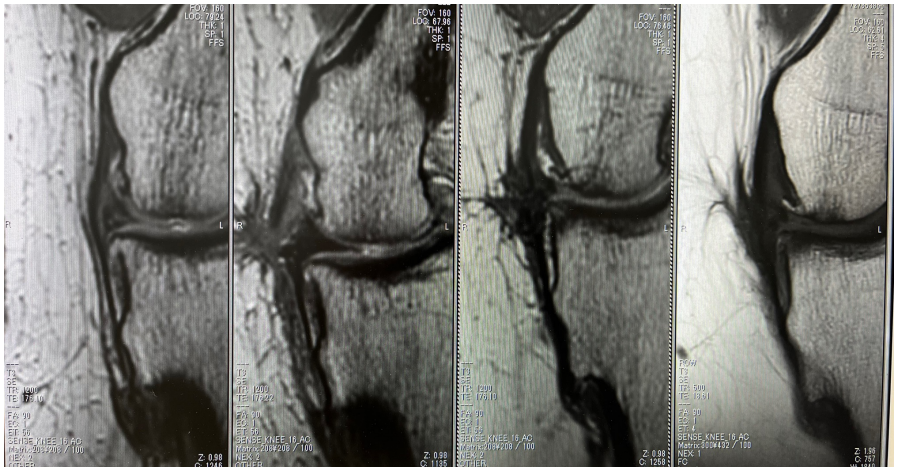


Case 4



Pre PO 1yr PO 3yr

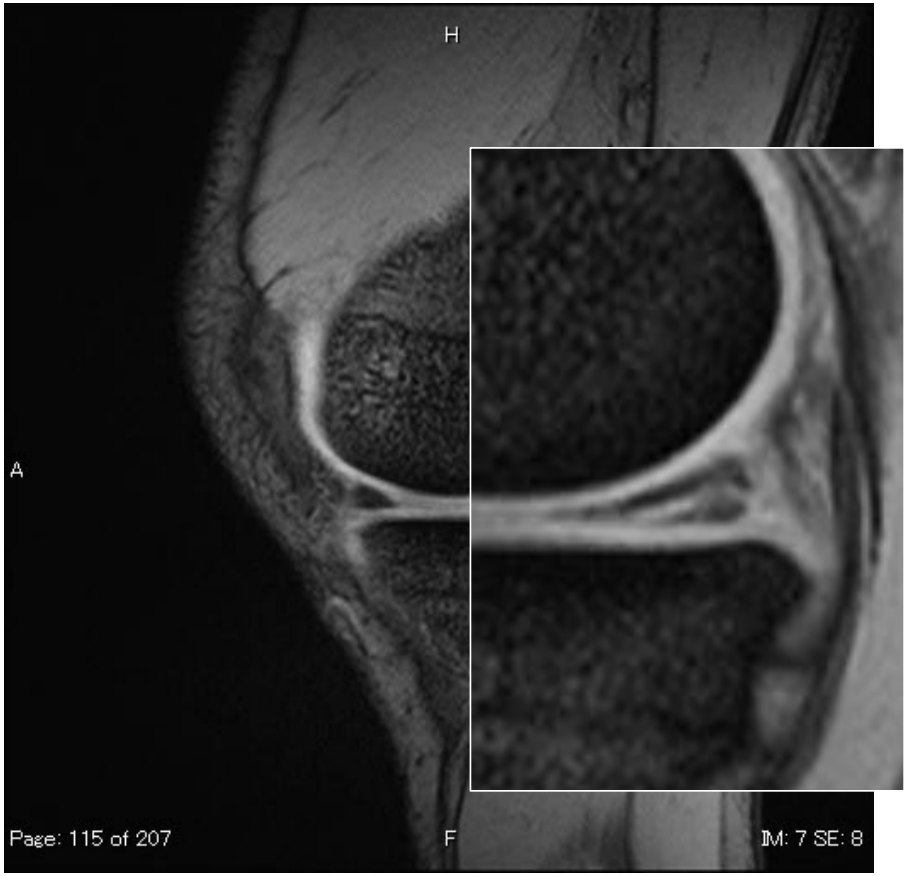
Case 2



Pre PO 1M PO 1yr PO 3yr

Clinical Trial

45yr M



Pre

PO 3yr

Meniscus density was significantly improved at postoperative 3 years.

Conclusion and Future Plan for the Scaffold

- Although it is 3 years follow-up, the clinical outcome was good, with MRI showing near-normal signal change of the implanted meniscus and no relative cartilage degeneration.

- The meniscus scaffold has the potential to be a novel treatment for non-sutured meniscus if strict surgical indications are followed.

Future plan of meniscus scaffold

- ✓Multicenter clinical trial in 2025
- ✓Clinical application in 2028