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Biomechanical Comparison Of Novel Meniscus Cap Repair Technique With Simple Meniscus Suture And Collagen Matrix Meniscus Suture Techniques For Complex Tears Of The Medial Meniscus

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Disclosures:

I have IP PCT for Meniscus Cap implant.

Biomechanical Comparison Of Novel Meniscus Cap Repair Technique With Simple Meniscus Suture And Collagen Matrix Meniscus Suture Techniques For Complex Tears Of The Medial Meniscus

- The objective of this study was to determine the biomechanical properties, strength, stiffness, and mode of failure of the three meniscus repair techniques (simple suture, repair with collagen membrane and repair with Meniscus Cap implant) for the complex tear of the medial menisci in comparison to the intact meniscus in the control group. It is hypothesized that the use of the newly developed Meniscus Cap implant would result in the improved fixation and primary stability to facilitate the repair of the complex meniscus tear. The PCL skeleton incorporated into the collagen membrane contributes to the stability of the repaired construct in a far greater extent than just the collagen membrane.

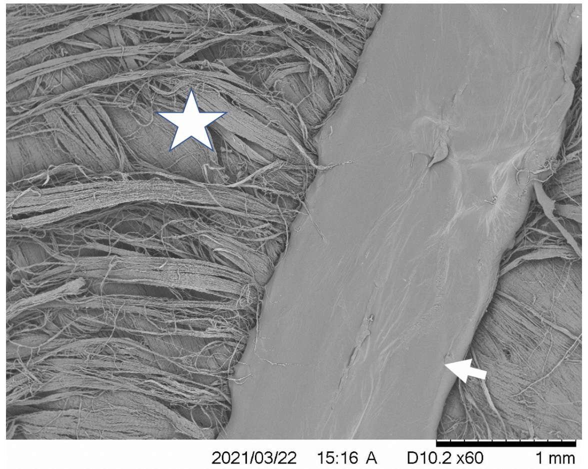

Fig. 1. A- macroscopic view of the Meniscus Cap implant comprising a set of two plates in the shape of the meniscus, each in the form of a composed layer of collagen membrane (*)- 2773,2 mm^2 and bracing polymer (polycaprolactone- PCL (white arrow) - 862,5 mm^2 , connected by a flexible hinge along the inner curvature of implant (black arrow), B- skeleton scanning electron microscopy (SEM) images and diameter of PCL fiber of Meniscus Cap scaffold.

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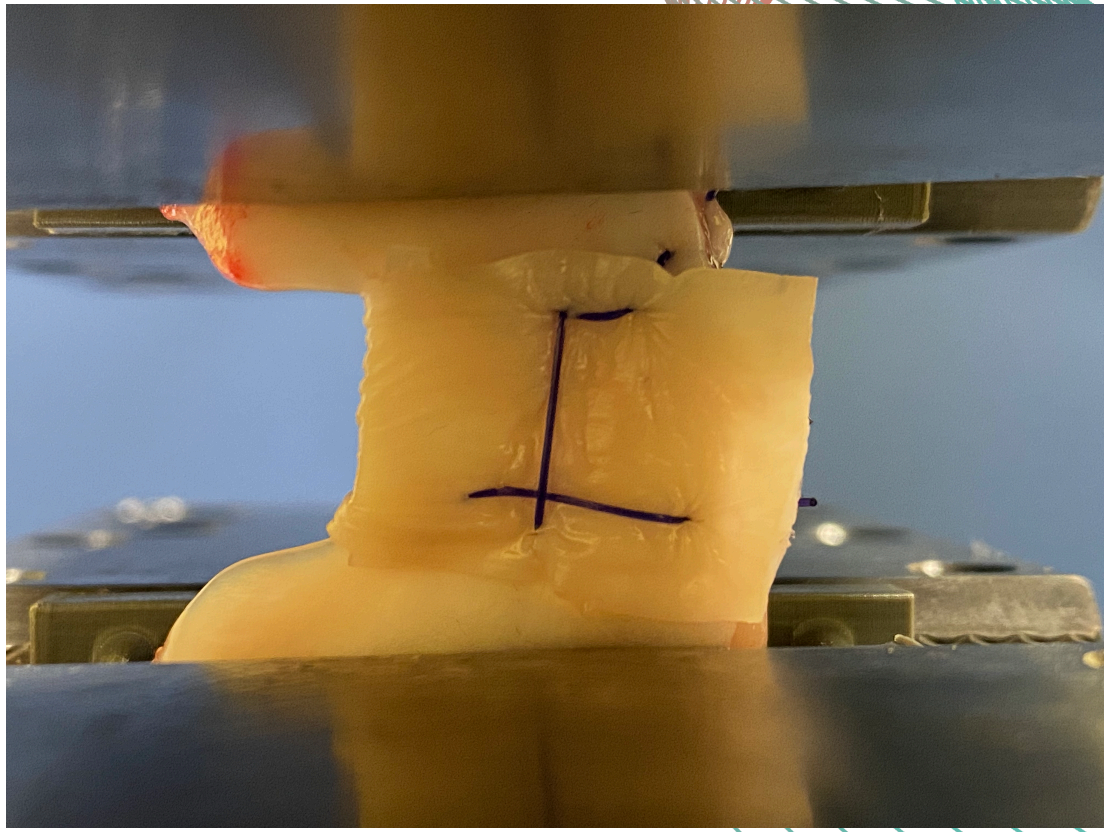
- **Methods:**
- Complex tears were created in 60 fresh porcine menisci. 20 intact menisci were tested as the control group (CG). Repairs were performed using a new Meniscus Cap bioresorbable implant technique (MC, N20) or an inside-out simple suture technique (SS, N20) and collagen matrix meniscus wrapping technique (CMW, N20). The menisci were tested for cyclic loading and load to failure. The displacement, response to cyclic loading (500 cycles) were recorded and load-to-failure testing was then performed at a rate of 3.15 mm/s. The mode of failure were recorded.

Biomechanical tests



Load to Failure [N]

Cyclic Loading displacement [mm]

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- Material:
- *Specimen preparation*
- A total of 80 specimens were harvested intact from young adult pigs by resecting the tissue at the meniscoscapular junction
- Complex tears were then formed in 60 of the menisci with a No. 11 surgical blade in the mid-body section equidistant from the anterior and posterior horns. The radial tears extended from the central margin to 1 mm from the peripheral meniscus rim. The vertical tears was created perpendicular to the radial tear extended for 10 mm and crossed with the radial tear in a half way. For reproducibility of the radial and vertical tears pattern a template was prepared to define the position of the meniscal transection [Fig 2.A, 2.B]. The horizontal tear was created at both sides of the radial tear and the depth of the horizontal tear was 5 mm. The tear was a defect in 3 planes, through the 3 vascular involvement zones (1-3) of the meniscus and was thus designated a complex tear [Fig.2.C].
- and the two insertional ligaments [fig.3.A]

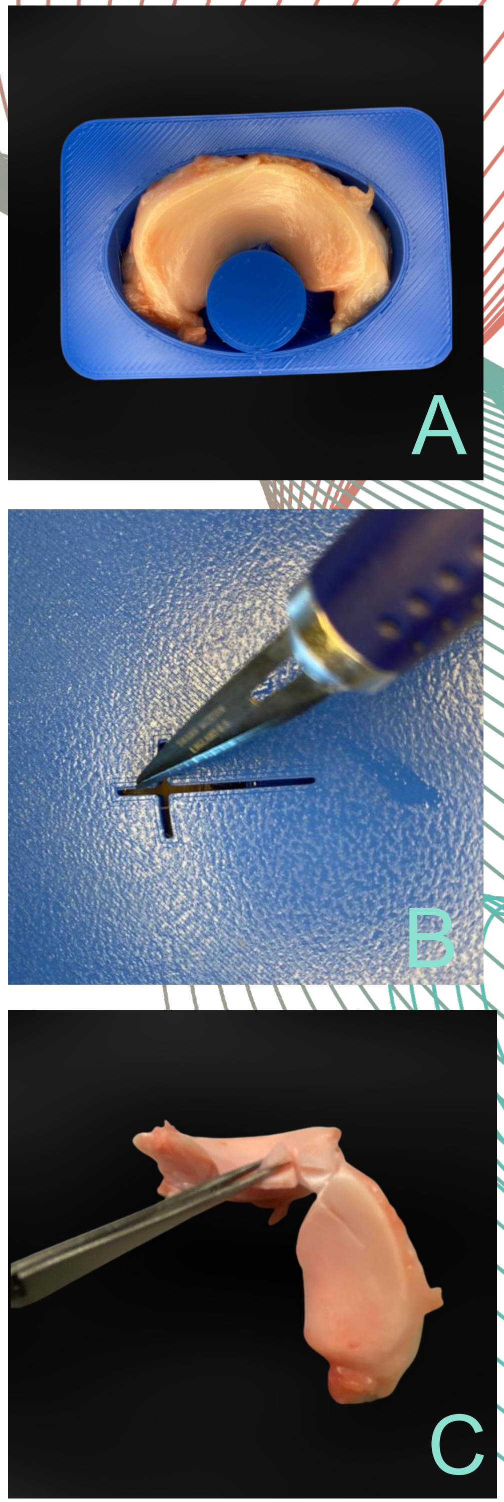

Fig.2A. Meniscal samples: medial meniscus placed in template
Fig. 2B Template of radial and vertical tears created with #11 Surgical Blade,
Fig. 2C. Cross section of the complex meniscus tear created in 3 planes across zones 1-3 denoting crossing the varying vasculature of the meniscus,

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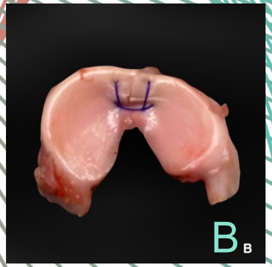
- <u>Intervention groups and suture techniques</u>
- For all specimens, the sutures were tied manually, in an open fashion.
- The “SS” group - The hybrid meniscal suture configuration was performed as provided in Figure 3 (Fig. 3B). First, 2-0 absorbable meniscal sutures (PDS No 2.0) were performed using the inside-out technique, with vertical mattress suture configuration serving to reduce both vertical (and clinical cases any horizontal component of the) tears. These vertical sutures function as a “rip stop” style reinforcement for the 2 horizontal mattress sutures that follow, tied with the inside-out technique, perpendicular to, and over the top of, the vertical mattress sutures at the radial tear area. One horizontal suture was placed on the femoral surface of the meniscus and another on the tibial surface.
- The “CMW” group – The tear area was wrapped with a wet collagen matrix (Evolution®; Osteobiol-Tecnoss, Italy) before suturing. The suture configuration was as described for the “SS” group (Fig. 3C).
- The “MC” group - The tear area will be covered with wet Meniscus Cap (Meniscus Cap Spólka z o.o., Poland) before suturing. The suture configuration was as described for the “SS” group (Fig. 3D).

Intact Menisci

(CG, N20)

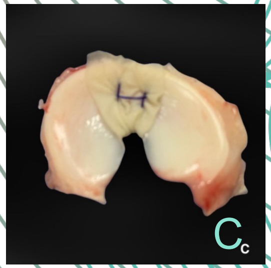
Simple Sutures

(SS, N20)



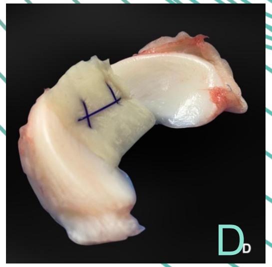
Collagen Matrix Wrapping

(CMW, N20)



Meniscus Cap

(MC, N20)



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- **Results**
- In order to carry out the analysis of variance with the Shapiro-Wilka test (*SW*), the hypothesis assuming normal distribution of the ultimate failure load (*FL*) test results was verified. The *SW* result for each examined population with *n* equal to 20, was >.9489, thus proving the hypothesis that test results in each population follow a normal distribution. In the next step, the Brown-Forsythe (*BF*) test was used in order to test the equality of group variance. The *p* value was >.05, thus allowing the assumption that the hypothesis assuming the equality of result variance was met.
- Successful confirmation of the initial hypotheses allowed to carry out the analysis of variance employing the post-hoc Tukey test. The result variance between individual populations were statistically relevant, excluding the SS and CMW group pairing. The p_{FL} parameter values for each pairing in the compared populations are recorded in Tab. 1.

Table 1 *pFL* value

	CG	CM	CMW	SS
CG		**.000148**	**.000148**	**.000148**
CM	**.000148**		**.001428**	**.000328**
CMW	**.000148**	**.001428**		.947836
SS	**.000148**	**.000328**	.947836	

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- Confirming the hypothesis of statistically relevant differences in the test results for the average values of *FL* for the majority of the analyzed populations allows for their comparison. Table 2 and Figure 4 show the average ultimate failure load value F_L for the given population together with minimum value, maximum value and I II and III quartile value for this group.

Table 2 F_L value

	Average Value	*Minimum Value*	*First Quartile*	*Median Value*	*Third Quartile*	*Maximum Value*
CG	1 278.7 ±271.43 N	816.7	1135.4	1278.0	1401.8	1860.2
CM	628.6 ±227.88 N	158.6	460.5	672.8	781.3	997.1
CMW	380.1 ±127.54 N	196.4	364.5	427.0	510.6	634.4
SS	345.1 ±153.96 N	101.7	164.3	239.3	360.8	446.8

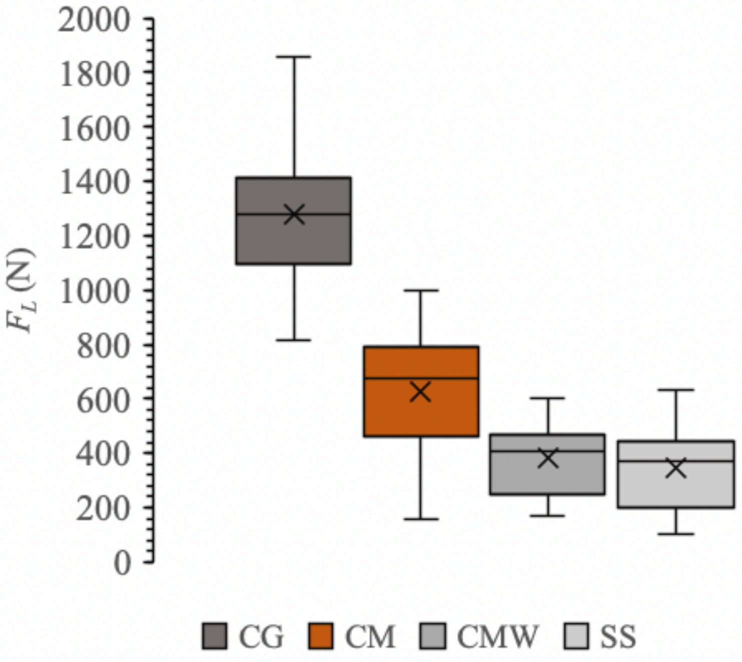

Fig. 4. Box-and-whisker plot of FL

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- Analogously to the description provided earlier, the test results for extension after cycling loading (s) were analyzed in a similar fashion. The *W* parameter value in the SW test, for populations with n=20, were >.9055. Whereas in regards to the *BF* test, the p value was >.29. The test results therefore confirm the hypotheses of the populations following the normal distribution and that group variance is uniform. In the next step, the post hoc Tukey test was carried out. Statistical relevance results p_S for the comparison of average *s* values are provided in Tab. 3. The differences in results between individual populations were statistically significant for the following pairings: CG-CMW, MC-CMW, MC-SS.

Table 3 p_S value

	CG	MC	CMW	SS
CG		.947608	**.004920**	.147288
CM	.947608		**.000923**	**.042321**
CMW	**.004920**	**.000923**		0.558677
SS	.147288	**.042321**	.558677	

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- Confirming the hypothesis of statistically relevant differences for the *s* values in the majority of populations under comparison allows their juxtaposition. Tab. 4 and Fig. 5 provide the average *s* value obtained as a result of the determination of the differences in sample length before and after the testing. Table 2.1 provides analogous information as for the F_L parameter value, enabling the determination of the value differences obtained for the population.

Table 4 *s* value

	Average Value	*Minimum Value*	*First Quartile*	*Median Value*	*Third Quartile*	*Maximum Value*
CG	0.524±0.417	0.026	0.125	0.509	0.657	1.449
CM	0.437±0.342	0.055	0.112	0.448	0.692	1.092
CMW	1.077±0.607	0.116	0.698	1.067	1.303	2.857
SS	1.077±0.569	0.031	0.578	0.848	1.183	2.311

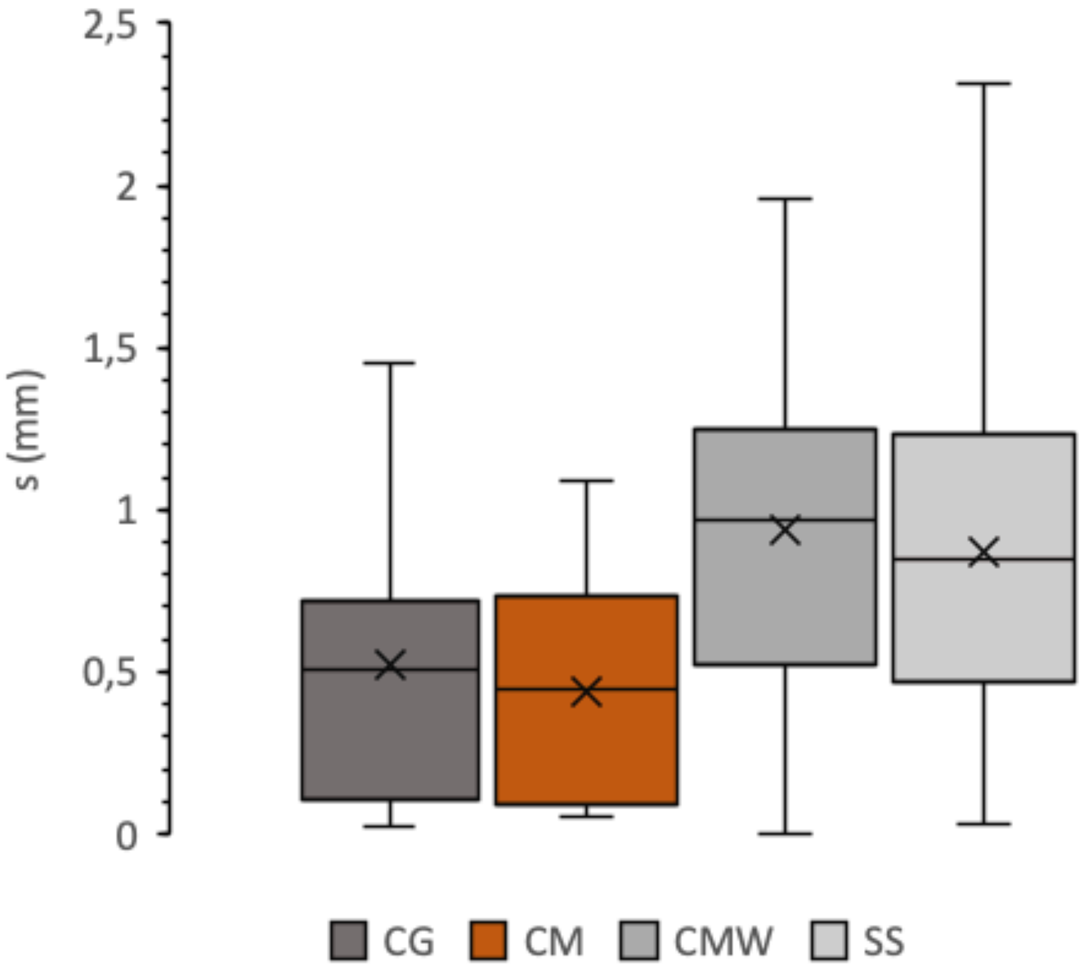

Fig.5. Box-and-whisker plot of s

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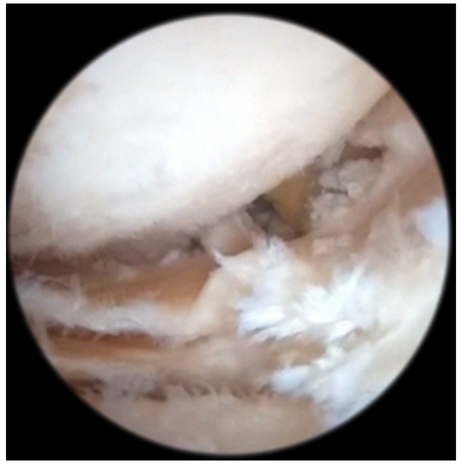
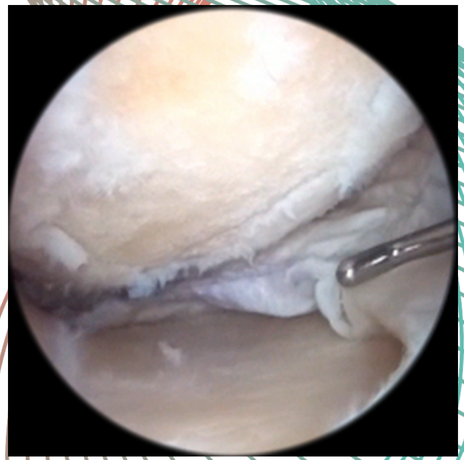
Conclusions:

In a porcine specimen meniscus repair model, the biomechanical properties of a novel Meniscus Cap repair technique were superior to that of the simple suture and collagen matrix wrapping techniques.

Future studies of biomechanical and clinical outcomes in human meniscal repairs with this device are warranted to explore whether this repair method is valuable to clinical practice and patient outcomes.





Meniscus Cap

Clinical Relevance

The results suggest that the Meniscal Cap repair technique may provide sufficient primary stability of the meniscal fixation even in the cases of complex meniscus tears. Future studies of biomechanical and clinical outcomes in human meniscal repairs with this device are warranted to explore whether this repair method is valuable to clinical practice and patient outcomes.

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