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Original Research

Loss of chondroprotection of medial collagen meniscus implant (CMI) at 20-year follow-up☆

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ABSTRACT

Objective: The mid-term results of the collagen meniscus implant (CMI) procedure for the replacement of partial meniscus defects have already been described. However, there is a paucity of long-term comparative studies. This study aimed to compare the clinical outcomes, failures, and osteoarthritis progression of patients who underwent partial medial meniscectomy and medial CMI implantation.

Methods: Thirty-six nonconsecutive patients with medial meniscus injuries that underwent medial CMI (MCMI) implantation or partial medial meniscectomy (PMM) between 1997 and 2000 were included in a prospective study with an intermediate 10-year follow-up examination and a final follow-up examination at 20-year follow-up. Outcome measures at the 20-year follow-up included the Lysholm score, visual analogue scale (VAS) for pain, International Knee Documentation Committee (IKDC) knee form , and Tegner activity level. Bilateral weight-bearing radiographs were also performed to evaluate hip-knee-angle (HKA) and the medial joint line height (JL). Data regarding complications and failures were also collected.

Results: At the 20-year follow-up, 31 patients (83% follow-up rate) with a mean age of 60.7 ± 8.9 years were included in the final analysis (21.1 ± 1.2 years follow-up). Four reoperations and one failure per group were reported. When comparing the clinical results of the two groups, no difference was found considering the Lysholm score, Knee Injury and Osteoarthritis Outcome Score (KOOS), Tegner, and the IKDC. Moreover, 20 patients underwent radiographic examination (10 MCMI, 10 MM), and no statistically significant difference was reported concerning the JL, HKA, and the presence and incidence of osteoarthritis between the two groups.

Conclusion: The CMI implant for partial medial meniscectomy provided good long-term results and a low failure rate. However, differently from the 10 years follow-up, the clinical and the radiological outcomes were not superior compared to the medial meniscectomy group. The present study's result suggests that using a medial scaffold is not chondroprotective.

Level of evidence: III, Prospective case–control study.

What are the new findings?

- The medial collagen meniscus implant could provide superior clinical and radiological results compared to meniscectomy for up to 10 years.
- After this period, there is no clinical benefit or any evidence of chondroprotection.
- This information could help define the indications for this procedure and when discussing the patient's expectations for the procedure.

☆ The investigation was performed at II Clinica, Istituto Ortopedico Rizzoli, IRCCS, Bologna, Italy.

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INTRODUCTION

In the last decades, several clinical and biomechanical studies demonstrated the crucial role of the meniscus for long-term knee function and it is now fully appreciated that even partial meniscectomy increases the probability of developing osteoarthritis and accelerates the degeneration in joints with pre-existing chondropathy [1,2]. There has been an increased interest in meniscal substitution techniques to preserve knee function after meniscectomy. Moreover, the reduced availability of meniscus allograft, storage-related problems, the costs, and the potential infectious disease transmission has led the orthopaedic community to develop alternative meniscus scaffold to replace partial meniscus defect [3]. However, even though the experience with meniscal scaffolds started more than 20 years ago [4], their use is still limited and, in the literature, there is a lack of long-term comparative studies [5]. For this reason, it is still unclear if the meniscus scaffold could provide superior results compared to meniscectomy in terms of clinical function and chondroprotection at very long-term follow-up.

The purposes of this study were to compare the clinical and radiological outcomes of a cohort of medial CMI with a control group of patients who underwent medial meniscectomy at more than 20 years of follow-up, to evaluate a possible duration of the clinical benefit of the chondroprotective effect of the scaffold. The hypothesis was that similar to the intermediate follow-up, the medial CMI could provide a superior outcome and reduced joint space narrowing compared to medial meniscectomy also at a long-term follow-up.

MATERIALS AND METHODS

Ethics

The study was conducted according to the principles of the Declaration of Helsinki. Approval of the study was obtained from the local institutional review board (IRB) of the (General Protocol n. 000P360). Informed consent complied with European Union laws and was signed by the patient before enrolment.

Patient selection criteria

Since the procedure was considered experimental at the time of surgery, the number of subjects included in the scaffold group was the maximum allowed by the local ethical committee Thirty-six patients with medial meniscal injuries were included in the present prospective study. Between October 1997 and March 2000, the patients enrolled underwent either partial medial meniscectomy (PMM group) or medial CMI implantation (MCMI group) by a single experienced surgeon. Due to the experimental nature of the study, the allocation to the study group was not randomized. Instead, the patients received information concerning the CMI according to the available literature and chose the treatment group the day before surgery. The included patients represented a prospective cohort whose 10-year outcomes had already been published [6]. Patients were contacted and recalled for further evaluation at a minimum of 20 years of follow-up. The inclusion and exclusion criteria for the study are presented in Table 1.

Outcome measurement

Patients were evaluated at 3, 6, 12, and 24 months after surgery. The patients underwent a clinical and a radiological evaluation preoperatively and at 10 and 20 years of follow-up. The clinical evaluation included the 100-mm visual analogue scale (VAS) for knee pain (assessed during rest and activity) [7], the International Knee Documentation Committee (IKDC) form [8], the Lysholm knee score, and Tegner activity level questionnaires [9]. Additionally, at the 20-year evaluation, the patients completed the Knee Injury Osteoarthritis (KOOS) questionnaire [10]. Patients willing to return for on-site evaluation underwent a standard clinical examination of the operated and contralateral knees and long-standing radiographs.

Table 1
Inclusion and exclusion criteria for the present study.

Inclusion and exclusion criteria
Inclusion criteria
Irreparable acute meniscal tears requiring partial meniscectomy or chronic prior loss of meniscal tissue greater than 25%
Intact anterior and posterior meniscus horns
Intact rim over the entire circumference of the meniscus
Anterior cruciate ligament (ACL) deficiency stabilized at the time of the index surgery
Age between 18 and 60 years
Contralateral healthy knee
Exclusion Criteria
Concomitant posterior cruciate ligament (PCL) insufficiency
Diagnosis of outerbridge grade IV
Axial malalignment of the lower limb greater than 5°
Documented allergy to collagen or chondroitin-sulphate of animal origin
Systemic or local infection
History of anaphylactoid reaction
Administration of corticosteroid or immunosuppressive agents within 30 days of surgery
Osteonecrosis of the involved knee
History of rheumatoid arthritis, inflammatory arthritis, or autoimmune disease
Neurological conditions that would preclude the patient's rehabilitation
Pregnancy

ACL: anterior cruciate ligament; PCL: posterior cruciate ligament.

A musculoskeletal radiologist, blinded to patient's surgical procedure, evaluated the following radiological parameters: the Kellgren–Lawrence grade of the medial compartment [11], the difference between the joint line heights of the medial compartment of the contralateral and operated knee (ΔJLheights), the hip-knee angle (HKA) and the difference between the HKA of the affected and the contralateral limb (ΔHKA). The radiographic measurements were performed using an electronic digital system (PACS; Kodak, Rochester, New York), Patients were questioned, and data was collected about whether they had undergone any additional unplanned surgeries on the operated knee during the follow-up period and if they were currently undergoing knee injection therapies. Patients with partial or total scaffold removal, unicompartmental knee arthroplasty (UKA), or total knee arthroplasty (TKA) were considered failures.

Surgical technique and rehabilitation

The surgical technique for arthroscopic CMI implantation has been previously described [6,12]. Briefly, a standard diagnostic arthroscopy was performed to confirm that patient fulfilled the inclusion criteria for the study. During arthroscopy, the stability of the meniscus horns was checked, and all the unstable meniscus tissue should be debrided. Moreover, the meniscus deficiency area should be trimmed square and then measured with the appropriate instrumentation. Afterwards, the CMI implant is cut with a scalpel to fit into the defect in the meniscus. The CMI implant is inserted into the knee joint through an enlarged lateral arthroscopic portal and placed in the correct position using an arthroscopic probe. Standard all-inside sutures or in–out suturing techniques are placed every 5 mm of the scaffold. After the CMI implant is sutured into place, any associated procedures such as an ACL reconstruction with single-bundle plus lateral extra-articular tenodesis technique [13], or microfracture of grade III outerbridge [14] cartilage lesion are performed according to Steadman et al. [15]. Patients with partial meniscectomy underwent a standard physical therapy program, including full weight-bearing, unrestricted range of motion, quadriceps and hamstring strengthening, and resumption of activity as tolerated at four weeks post-surgery. In the medial CMI group, a knee brace was applied for six

weeks. A continuous passive motion was performed 4 times per day, from 0° to 60° during the first two weeks and then it was increased to 90° from the second to the fourth week. Complete range of movement (ROM) is allowed starting from the 6th week. The patient is asked to avoid weight-bearing for three weeks. After this period, progressive weight-bearing is encouraged and, at six weeks, full and unrestricted weight-bearing is permitted. Return to sport and cutting activity is permitted six months after surgery [6].

Statistical analysis

The normal distribution of the data was verified through the Shapiro–Wilk test. The normally distributed continuous variables were expressed as mean ± SD, the non-normally distributed variables were presented as median (IQR), and the categorical variables were expressed as number and percentage. Only the Tegner score was reported as median and range. A 2-way analysis of variance for repeated measures was performed to assess the between-group differences of continuous variables, while the Mann–Whitney test was used to compare each group with the other. The Pearson's chi-square test was performed to assess the differences in categorical variables. Differences between the groups were considered statistically significant if $P < 0.05$. For the post-hoc multiple comparisons, P values were adjusted using the Bonferroni post hoc correction. The statistical analysis was performed in MedCalc (MedCalc Software Ltd, Ostend, Belgium, version 19).

RESULTS

Overall, five patients (17%) were lost during the evaluation process. Therefore, at the 20-year follow-up, 31 patients (83%) with a mean age of 60.7 ± 8.9 years were included in the final analysis at 21.1 ± 1.2 years of follow-up (Fig. 1). As previously reported, there was no difference in age, previous surgeries, and clinical scores at the baseline between the two groups of patients [6].

Over the entire follow-up period, 4 patients underwent reoperations (two per group). In the PMM group, one patient underwent high tibial osteotomy (HTO) and another underwent arthroscopic debridement followed by UKA. Similarly, in the MCMI group, one patient required HTO, while another patient underwent arthroscopic cartilage debridement and subsequent TKA. According to the failure criteria, one patient was considered a failure and the survival rate of the CMI was 93%.

The Lysholm and the Tegner score showed continuing and similar improvement in knee function between the two groups over the 20 years after surgery. Similarly, at the 20-year follow-up, there was no difference between the two study groups in all the domains of the KOOS (Fig. 2). Differently from the 10 years evaluation, at the 20-year follow-up there was no statistically significant difference between the two groups in terms of VAS. The PROMs are reported in details in Table 2.In the PMM group, four patients (25%) are receiving injections due to knee-related symptoms, while in the MCMI only one (7%) is undergoing this therapy. This difference was not statistically significant. Finally, the satisfaction rate was similar among the two study groups.

At the 20-year follow-up, four patients were excluded from the imaging evaluation due to subsequent surgeries and seven patients did not complete the radiographic evaluation. Therefore, 20 patients (10 MCMI and 10 PMM) were included the radiographic evaluation. Overall, there was no difference between the two groups in all the measurements and the scores performed (see Table 3 for details). In the PMM group, statistically significant differences were found between the preoperative group and the 10-year follow-up group in the following scores: VAS ($p < 0{,}0001$; Cohen's $d = 2{,}42$), Lysholm ($p < 0{,}0001$; Cohen's $d = 2{,}82$), IKDC ($p < 0{,}0001$; Cohen's $d = 2{,}11$), Tegner ($p < 0{,}001$; Cohen's $d = 2{,}32$).

In the MCMI group, statistically significant differences were found between the preoperative group and the 10-year follow-up group in the following scores: VAS ($p < 0{,}0001$; Cohen's $d = 4{,}68$), Lysholm ($p < 0{,}0001$; Cohen's $d = 4{,}63$), IKDC ($p < 0{,}0001$; Cohen's $d = 3{,}99$), Tegner ($p < 0{,}001$; Cohen's $d = 2{,}57$).

Moreover, as for the VAS score at 10-year follow-up, a statistically significant difference was found between the MCMI and the PMM group ($p < 0{,}00001$; Cohen's $d = 1{,}48$).

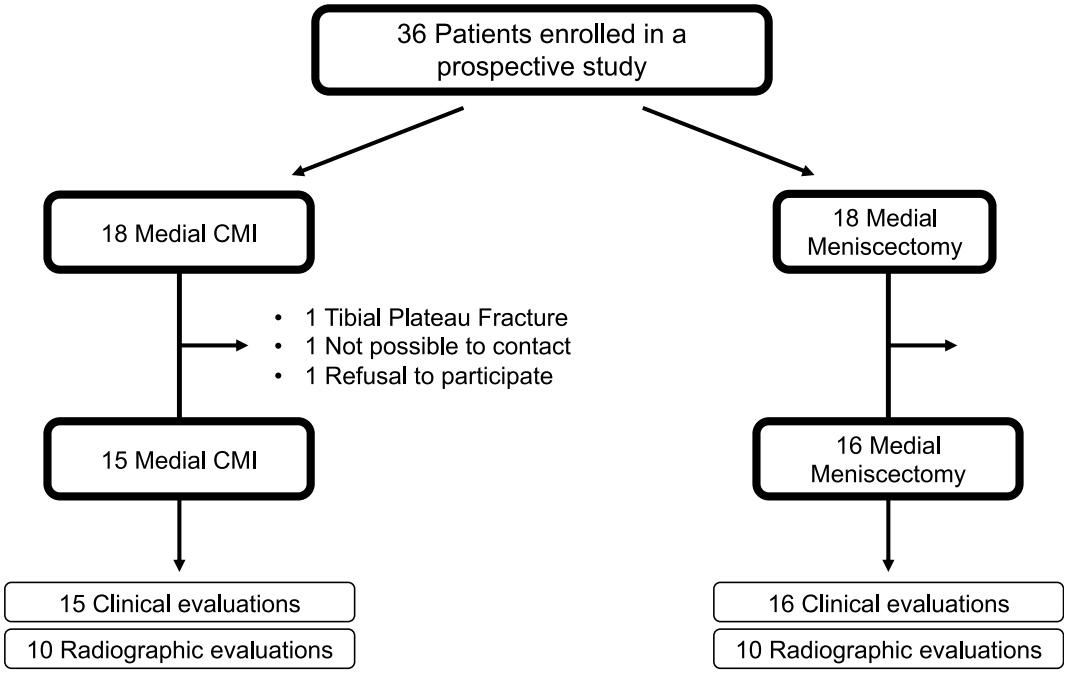

Fig. 1. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) diagram. CMI, collagen meniscus implant.

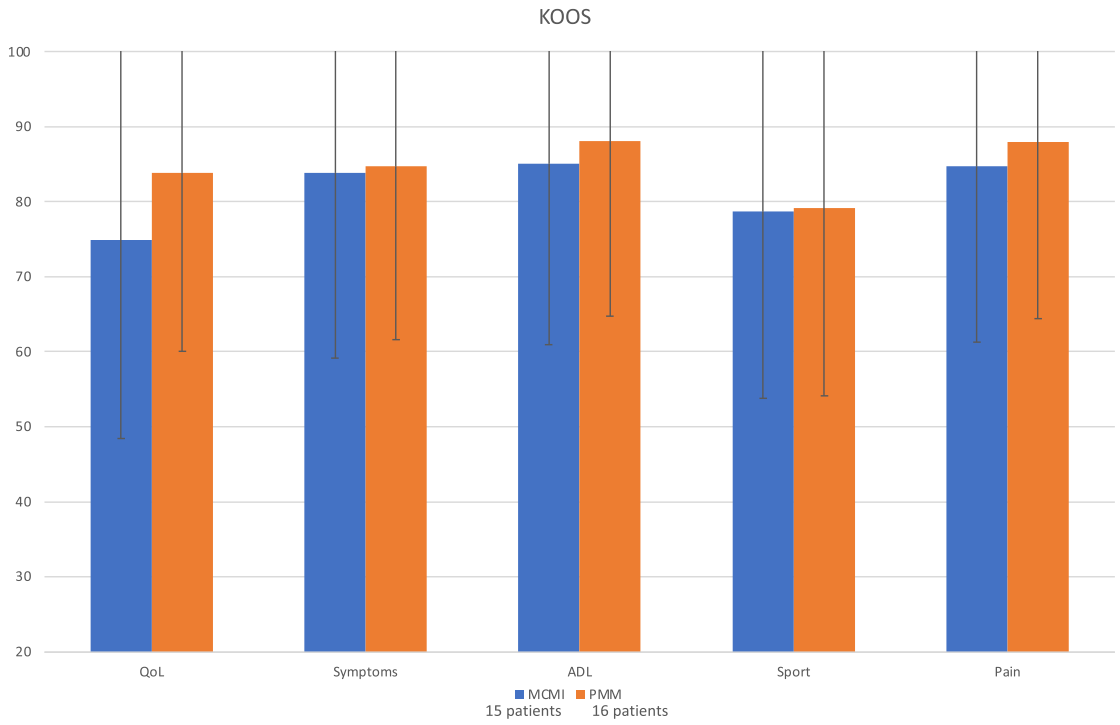

Fig. 2. Graphic representation of the KOOS score at 20-year follow-up evaluation. QoL (quality of life), ADL (activity of daily living), MCMI (Medial CMI group), PMM (Partial Medial Meniscectomy group).

Table 2
Details of the PROMS.

PROMs						
	MCMI (15 patients)			PMM (16 patients)		
	preoperative	10 years FU	20 years FU	preoperative	10 years FU	20 years FU
VAS	5.9 ± 1.1	1.2 ± 0.9[a]	2.3 ± 2.5	7.1 ± 1.3	3.3 ± 1.8[a,b]	2.5 ± 2.3
Lysholm	50.9 ± 11.3	93.7 ± 6.6[a]	81.8 ± 21.7	45.3 ± 13.9	86.6 ± 15.4[a]	84.6 ± 21.1
IKDC	41.2 ± 14.9	87.5 ± 6.9[a]	75.0 ± 19.6	40.4 ± 14.5	75.2 ± 18.3[a]	75.2 ± 22.7
Tegner	1 (1–4)	5 (4–6)[a]	4 (1–6)	1 (0–5)	5 (1–6)[a]	4 (1–6)

PROMS: patient reported outcomes; MCMI, medial collagen meniscus implant; PMM: partial medial meniscectomy; VAS: visual analogue scale; IKDC: International Knee Documentation Committee Questionnaire.
[a] Statistically significant differences ($p < 0.05$) between preoperative and 10 years follow-up.
[b] Statistically significant differences ($p < 0.05$) between the two group at the same follow-up.

Table 3
Radiographic evaluation of the patients. MCMI; Medial Collagen Meniscus Implant. PMM, Partial Medial Meniscectomy; HKA, hip-knee angle; ΔHKA, the difference between the HKA of the affected and the contralateral limb; ΔJLheights, the difference between the joint line heights of the medial compartment of the healthy and operated knee.SD, standard deviation. p as p-value.

RADIOGRAPHIC MEASUREMENT			
	Group	Mean ± SD	P
HKA (°)	MCMI	182.7 ± 3.4	0.270
	PMM	184.0 ± 3.3	
ΔHKA (°)	MCMI	0.4 ± 2.3	0.601
	PMM	1.3 ± 2.4	
Δ JL HEIGHT (mm)	MCMI	1.2 ± 1.9	0.669
	PMM	0.9 ± 1.7	

KELLGREEN-LAWRENCE			
Grade	MCMI	PMM	P = 0.825
0	0	0	
1	2	3	
2	5	3	
3	2	3	
4	1	1	

MCMI: medial collagen meniscus implant; PMM: partial medial meniscectomy; HKA: hip-knee angle; ΔHKA: the difference between the HKA of the affected and the contralateral limb; ΔJLheights: the difference between the joint line heights of the medial compartment of the healthy and operated knee; SD: standard deviation; P as P-value.

DISCUSSION

The most important finding of the present study is that patients who underwent CMI could experience at least a 10-year period of relative clinical benefit when compared with medial meniscectomy. However, after 20 years there was no difference in the clinical results between the two treatments. Likewise, unlike the intermediate follow-up, the CMI did not show a chondroprotective effect compared with medial meniscectomy. These findings have high clinical relevance, as it is well known that the loss of meniscus tissue could predispose early cartilage degeneration and decreased clinical function over time [16]. For this reason, meniscus replacement options have been extensively studied in the past years by orthopaedic surgeons but evidence of clinical benefit or chondroprotection still need to be defined in the long term. The results of the current study further expand the meniscus substitution literature with ultra-long-term data regarding clinical outcomes and osteoarthritis progression after medial meniscus scaffold. A previous large randomized controlled trial of 311 patients treated with medial CMI or medial meniscectomy was the first comparative study that reported superior clinical outcomes of the scaffold. Over the 6-year follow-up period, in the chronic arm of the study, patients who underwent medial CMI showed a higher Tegner and significantly fewer unplanned reoperations compared with the control group. Bulgheroni et al. [17] compared patients who underwent medial meniscectomy or medial CMI in the setting of ACL reconstruction at 10 years of follow-up. They found that patients in the scaffold group experienced less pain and reduced anteroposterior translation compared to the control group. At the same follow-up time, Monllau [18] et al. reported statistically significant improvement and stable clinical scores in a cohort of 22 patients who underwent medial CMI implantation. Interestingly, the vast majority of patients did not show any further joint space narrowing at the radiographic evaluation. In our series, the CMI group showed statistically significant less medial joint space narrowing than the medial meniscectomy group at the 10-year follow-up. Interestingly, those findings were not confirmed at the 20-year evaluation, reflecting a greater overall progression of joint space narrowing in the scaffold group in the last timeframe. Our results support recent biomechanical and clinical studies that have demonstrated that the current meniscus substitution techniques provide satisfactory clinical results but fail to restore the native knee stress distribution and joint homeostasis [19,20]. Studies have shown that the CMI underwent a progressive integration with the host tissue matrix which is correlated with structural changes and progressive reduction of the scaffold size within the first two years after surgery [3,21] Moreover, recent long-term studies reported a continuous remodelling of the scaffold with decreased signal intensity over time and a complete CMI reabsorption in 15–20% of patients [18,22]. The durability of the clinical and radiological results has been reported to be a main issue in the meniscus substitution literature. Also for MAT, there is no conclusive evidence of chondroprotection, and the presence of degenerative morphological changes in allograft are frequently encountered [23]. The present study has several limitations to be considered while interpreting the results. The first one is the low sample size of the study. Second, this was a non-randomized trial and the patients were not blinded to their treatment allocation. The reason for both those limitations is that when this research was designed, only reports on animals and one clinical feasibility trial on humans were published [4] therefore, the patients decided the treatment group allocation. Third, we included a heterogeneous group of patients regarding the number of previous surgery, time from meniscectomy to the scaffold, age at surgery and axial alignment. Lastly, at the 20-year follow-up, the patients did not perform an MRI and therefore it is not possible to evaluate if there is a correlation between the cartilage status, scaffold morphology, and clinical symptoms. Nevertheless, this study has several strengths that are important to highlight. This is the first comparative study at 20 years of follow-up comparing the clinical outcomes, complications, and osteoarthritis progression of two groups of patients treated with medial meniscectomy and medial meniscus scaffold. Moreover, a follow-up rate of 83% at more than 20 years of follow-up could be considered excellent. Based on our study, the medial CMI could provide superior clinical results compared with meniscectomy for up to 10 years. However, there is no clinical benefit after this period and little evidence of chondroprotection. These results could help the clinician to further define the role of the medial CMI in joint-preserving surgery.

CONCLUSION

The CMI implant for partial medial meniscectomy provided good long-term results and a low failure rate. However, differently from the 10 years follow-up, the clinical and the radiological outcomes were not superior compared with the medial meniscectomy group.

Funding

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Ethical approval

This study was approved by the local Institutional Review Board (General Protocol n. 000P360).

Informed consent

All the patients included in the study signed an informed consent.

Authors' contributions

All listed authors have contributed substantially to this work: GA,PA, SDP,GDF and AP collected data, performed statistical analysis, literature review, and primary manuscript preparation. SZ, and AG performed the surgeries, assisted with interpretation of the results, initial drafting of the manuscript, as well as editing and final manuscript preparation. All authors read and approved the final manuscript.

Declaration of competing interest

SZ is a consultant from Smith and Nephew and Depuy-Attune, is a board member of the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS), and editor-in-chief of the Journal of Experimental Orthopedics (JEO).

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