A Prospective, Blinded, Multicenter Clinical Trial to Compare the Efficacy, Accuracy, and Safety of In-Office Diagnostic Arthroscopy With Magnetic Resonance Imaging and Surgical Diagnostic Arthroscopy

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Purpose: The purpose of this study was to compare the efficacy, accuracy, and safety of in-office diagnostic arthroscopy with magnetic resonance imaging (MRI) and surgical diagnostic arthroscopy. **Methods:** A prospective, blinded, multicenter, clinical trial was performed on 110 patients, ages 18 to 75 years, who presented with knee pain. The study period was April 2012 to April 2013. Each patient underwent a physical examination, an MRI, in-office diagnostic imaging, and a diagnostic arthroscopic examination in the operating room. The attending physician completed clinical report forms comparing the in-office arthroscopic examination and surgical diagnostic arthroscopy findings on each patient. Two blinded experts, unaffiliated with the clinical care of the study's subjects, reviewed the in-office arthroscopic images and MRI images using the surgical diagnostic arthroscopy images as the "control" group comparison. Patients were consecutive, and no patients were excluded from the study. **Results:** In this study, the accuracy, sensitivity, and specificity of in-office arthroscopy was equivalent to surgical diagnostic arthroscopy and more accurate than MRI. When comparing in-office arthroscopy with surgical diagnostic arthroscopy, all kappa statistics were between 0.766 and 0.902. For MRI compared with surgical diagnostic arthroscopy, kappa values ranged from a low of 0.130 (considered "slight" agreement) to a high of 0.535 (considered "moderate" agreement). The comparison of MRI to in-office arthroscopy showed very similar results as the comparison of MRI with surgical diagnostic arthroscopy, ranging from a low kappa of 0.112 (slight agreement) to a high of 0.546 (moderate agreement). There were no patient-related or device-related complications related to the use of in-office arthroscopy. **Conclusions:** Needle-based diagnostic imaging that can be used in the office setting is statistically equivalent to surgical diagnostic arthroscopy with regard to the diagnosis of intra-articular, nonligamentous knee joint pathology. In-office diagnostic imaging can provide a more detailed and accurate diagnostic assessment of intra-articular knee pathology than MRI. Based on the study results, in-office diagnostic imaging provides a safe, accurate, real-time, minimally invasive diagnostic modality to evaluate intra-articular pathology without the need for surgical diagnostic arthroscopy or high-cost imaging. **Level of Evidence:** Level II, comparative prospective trial.

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Physical examination and magnetic resonance imaging (MRI) are the diagnostic tools most commonly used to assess an orthopaedic patient's underlying joint pain. MRI without contrast is a noninvasive diagnostic technique used in conjunction with clinical evaluation to assess a knee injury or persistent symptomatic pathologies.[1,2] As health care costs continue to increase dramatically, insurers seek to control expenditures by limiting the number of high-cost imaging procedures.[3-6] In fact, many health care centers have identified expensive imaging procedures as one of the leading contributors to their soaring health care costs.[7]

Despite the fact that MRIs are routinely used to evaluate a patient's intra-articular anatomy, they are not always accurate.[3-6,8-21] Arthroscopy has long been the gold standard used to evaluate a patient's joint that has failed nonoperative treatment and presents with persistent pain.[5] However, surgical arthroscopy is an invasive and costly procedure with known potential complications.[22] Currently, there is no minimally invasive, in-office option that can provide intra-articular visualization with the same accuracy and specificity as a surgical diagnostic arthroscopy.

MRI of the knee joint has been referred to as a noninvasive alternative to diagnostic arthroscopy. However, the accuracy of MRI is dependent upon the injury.[9,10,12-14] Routinely, MRIs have been used to help diagnose meniscus or ligament injuries in patients, in conjunction with a physical examination. However, MRIs do not always accurately detect meniscal tears and often fail to correlate with a patient's physical examination in the knee and other joints as well.[16-19] Furthermore, studies have reported that MRIs are not an accurate tool in diagnosing the degree of osteoarthritis or articular cartilage damage.[9,10,23]

An in-office diagnostic imaging system has the potential to enable office-based pre- and postoperative diagnostic imaging assessments.[24,25] One such imaging system in current use is the VisionScope Imaging (VSI) system (VisionScope Technologies, Littleton, MA). It has a 1.4-mm diameter semirigid/fiber-lens endoscope and sterile single-use light sheath and does not require general anesthesia, irrigation fluid, sterilization between procedures, or biohazard processing. The system uses true high-definition imaging in a needle-based system, enabling the user to obtain direct visualization and immediate clinical insight in an office examination room. To date, there are limited options to perform accurate, real-time intra-articular diagnostic imaging in the office and few, if any, alternatives to high-cost MRI scans.

The purpose of this study was to compare the efficacy, accuracy, and safety of the VSI system (used in the operating room prior to surgery) with MRI and surgical diagnostic arthroscopy. Our hypothesis is that the VSI system will be more accurate than MRI and comparable to surgical arthroscopy for the diagnosis of intra-articular pathology in the knee.

Methods

A prospective, blinded, multicenter study was performed on patients who had been scheduled for a routine surgical diagnostic arthroscopy at one of 6 participating clinical sites over a 12-month period from April 2012 to April 2013. One surgeon per site participated in the study. After Institutional Review Board approval at each respective institution, patients who presented with knee symptoms (such as pain, effusion, popping, locking) underwent a physical examination and were prescribed a diagnostic 1.5-T MRI for the purpose of confirming the findings in the physical examination. If it was determined that arthroscopic surgery was indicated, the patients were identified as potential study candidates. The study enrolled 110 patients (43% female and 57% male) ranging in age from 19 to 75 years old. Patients were consented by the physician investigator at each site. Study inclusion criteria consisted of suspected meniscal tears or articular cartilage damage. Patients were excluded from the study if they had (1) acute traumatic hemarthosis, (2) a concomitant ligament injury, or (3) an active systemic infection. No patients met these exclusion criteria.

At the time of the surgical diagnostic arthroscopy, physicians first performed a diagnostic imaging evaluation using the VSI system (Fig 1) prior to introducing the surgical arthroscopic and irrigation systems. The VisionScope was inserted into either the medial or lateral compartment first, based upon the location of the patient's symptoms and the physical examination findings.

The VSI exam was performed through a medial or lateral portal. First, the skin was prepped over the standard portal site using betadine and alcohol. Then 2 mg of 1% lidocaine were injected into the subcutaneous tissue, 3 mg into the joint capsule, and 5 mg into the joint. The anesthetic was given 5 minutes to take effect. The VisionScope needle scope was then inserted into the most symptomatic compartment (medial or lateral). The articular cartilage of the femur and tibia was first inspected, and the knee was placed through flexion and extension to allow complete access to the femoral condyle. Next, the anterior, middle, and

Fig 1. VisionScope Imaging System.

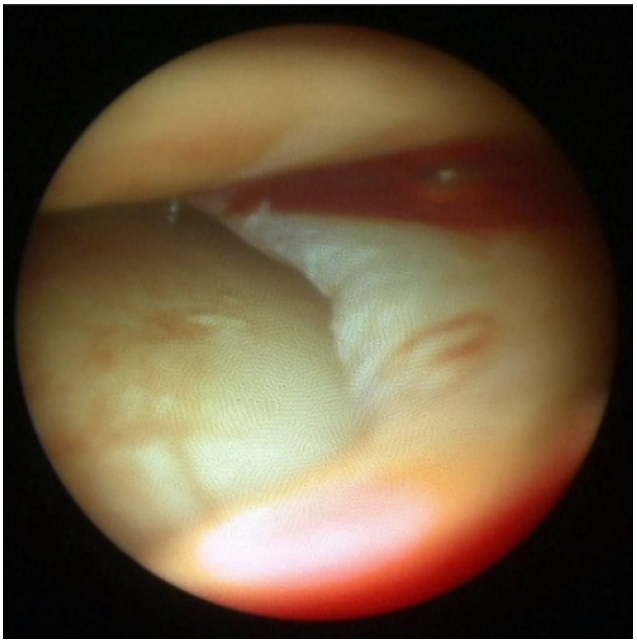

Fig 2. VisionScope Imaging view of lateral meniscus, which is status post partial lateral meniscectomy.

posterior horns of the meniscus were inspected (Figs 2 and 3).

The scope was then directed anterior to the anterior cruciate ligament into the opposite compartment for a similar sequence of inspection. The leg was gently manipulated with minimal varus and valgus stress as needed. Upon completion, the scope was repositioned into the patellofemoral joint while the leg was simultaneously brought into full extension. Approximately 8 to 10 mg of sterile saline was used to insufflate the knee or irrigate any drops of blood as needed. The syringe was then used to aspirate the joint through the system prior to removing the scope. Physicians recorded video and captured still images during the VSI procedure and completed a standardized clinical report form (CRF).

Immediately following the VSI exam, a standard surgical diagnostic arthroscopy was performed, during which physicians also recorded video and captured still images. Upon each investigative site's completion, a copy of the MR images, a completed surgical diagnostic arthroscopy CRF (Exhibit A), a completed VSI CRF (Exhibit B), and the collected images/video from both the VSI and surgical diagnostic arthroscopy were provided for each patient to the study's blinded expert readers. The Chondropenia Severity Score was used to grade the articular cartilage defects.

The study's blinded experts were an orthopaedic sports medicine surgeon and a fellowship-trained musculoskeletal radiologist—both unaffiliated with the study sites and blinded to the radiological readings and surgical notes. The VSI and surgical images were evaluated by the surgeon. The MR images were evaluated by the radiologist. This was to provide a best practice comparison between 2 sets of experts in their respective fields. In addition, the images were reviewed in a randomized order at separate readings. The surgical diagnostic arthroscopy images served as the control comparison between the VSI and MRI images.

Statistical Analysis

An independent statistician completed all statistical analyses. Comparisons were made using several statistical measures: Cohen's kappa coefficient (a measure of agreement between 2 readers), McNemar's test, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). A power analysis was performed to determine study size.

Results

There were 110 consecutive patients included in this study, all of whom had a physical exam, a preoperative MRI, a VSI exam, and a surgical diagnostic arthroscopy. The MRI, VSI, and surgical diagnostic arthroscopy procedures were compared on a total of 7 different anatomical locations within the knee (Table 1). The assessments for each location were performed either by the surgeon, a blinded expert, or both. Statistical analyses were performed separately for the surgeon assessments and the blinded expert reader assessments. All analyses were done twice—once using the surgeon assessments and once using the blinded reader assessments. The primary comparisons with MRI were made using the blinded expert's assessments. The primary comparisons of VSI to surgical diagnostic arthroscopy were made using the surgeon's assessments (based on CRFs).

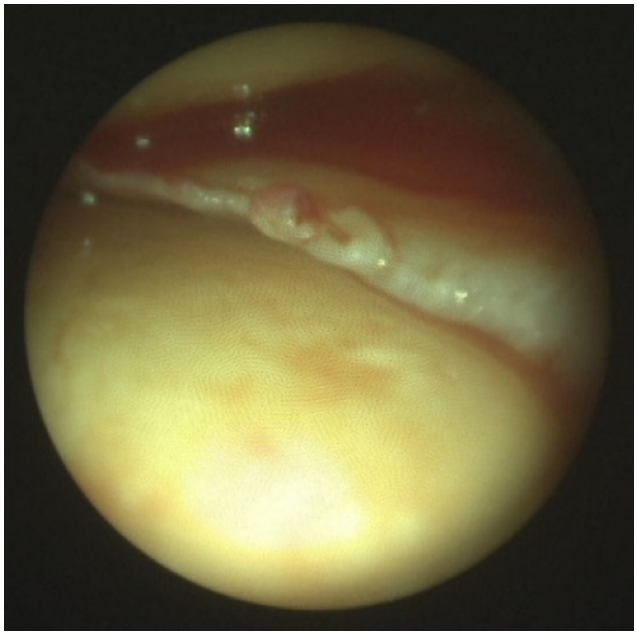

Fig 3. VisionScope Imaging System image of the lateral compartment following partial lateral meniscectomy.

Table 1. Summary of Evaluation Locations and Results

Compartment	Results
Articular cartilage Medial femur Lateral femur Medial tibia Lateral tibia Patella Medial meniscus Lateral meniscus	For all compartments, VSI is comparable to surgical diagnostic arthroscopy. VSI is more accurate at detecting tears than MRI.

MRI, magnetic resonance imaging; VSI, VisionScope Imaging.

Medial Compartment

Articular Cartilage. When comparing VSI to surgical diagnostic arthroscopy for the diagnosis of femoral articular cartilage injuries, the kappa statistic was 0.902, meaning close agreement (95% confidence interval, 0.818, 0.986; Table 2). There was no significant difference between VSI and surgical diagnostic arthroscopy (McNemar's test, 2.131). The sensitivity of VSI compared with surgical diagnostic arthroscopy was 0.961, and the specificity was 0.941 (Table 3). The PPV was 0.942, and the NPV was 0.960 (Table 3).

The blinded expert's interpretation of the MRI findings as compared with surgical diagnostic arthroscopy reported a moderate correlation between the 2 modalities (kappa, 0.522). The sensitivity of MRI compared with surgical diagnostic arthroscopy was 0.758, and the specificity was 0.784 (Table 3). The PPV was 0.855, and the NPV was 0.659 (Table 3).

When comparing VSI with surgical diagnostic arthroscopy of the articular cartilage of the medial tibia, the 2 procedures were in agreement for the variable intact articular cartilage 94% of the time. There were 3 false positives and 3 false negatives. In this comparison, VSI was statistically equivalent in detecting tibial articular cartilage defects (kappa, 0.832; 95% confidence interval, 0.703, 0.962) and identical when comparing accuracy in detecting a cartilage defect ($P = 1$). In this comparison, the sensitivity of VSI was 0.875 and the specificity was 0.957 (PPV = 0.875; NPV = 0.957).

When comparing MRI to surgical diagnostic arthroscopy, statistical agreement was fair (kappa, 0.303). McNemar's test showed a high, statistically significant difference ($P < .0001$) in the percent of agreement with MRI (74.2%) compared with the percent of agreement with surgical diagnostic arthroscopy (49.5%). Using the blinded expert assessments for the MRI to surgical diagnostic arthroscopy comparison, the sensitivity of MRI was 0.408 and the specificity was 0.896. The PPV of MRI was 0.800, indicating a low rate of false positives. However, the NPV was a low 0.597, signaling a high percentage of false negatives (i.e., MRI is missing chondral defects).

Comparing VSI with surgical diagnostic arthroscopy of the tibial articular cartilage using the blinded expert assessments, the kappa was 0.60. MRI compared with VSI and surgical diagnostic arthroscopy (blinded expert assessments) similarly showed a very low kappa (0.330) and a statistically significant difference in the percent of agreements ($P = .0017$).

Medial Meniscus. Comparing VSI with surgical diagnostic arthroscopy, the kappa statistic indicated close agreement, the sensitivity of VSI was 0.944, and the specificity was 0.967. The PPV was 0.986, and the NPV was 0.882. In comparison, using the experts' MRI compared with surgical diagnostic arthroscopy assessments, the kappa statistic indicated moderate agreement. The sensitivity of MRI was 0.813, and the specificity was 0.611. The PPV of MRI was 0.788, while the NPV was 0.647.

Lateral Compartment

Articular Cartilage. When comparing VSI with surgical diagnostic arthroscopy of the femoral articular cartilage, the kappa statistic indicated substantial agreement (Table 2 for all kappa statistics), the sensitivity of VSI was 0.818, and the specificity was 0.948 (PPV = 0.818; NPV = 0.948). In comparison, using the blinded expert's assessments comparing MRI with

Table 2. Summary of Kappa Statistics for Agreement

Location	Reader	Procedure Comparison	Kappa Measure of Agreement
Articular cartilage:			
Femur, medial	Surgeon	VSI vs Arthro	0.902
	Blinded	MRI vs Arthro	0.522
	Blinded	VSI vs MRI	0.546
Femur, lateral	Surgeon	VSI vs Arthro	0.766
	Blinded	MRI vs Arthro	0.443
	Blinded	VSI vs MRI	0.112
Tibia, medial	Surgeon	VSI vs Arthro	0.832
	Blinded	MRI vs Arthro	0.303
	Blinded	VSI vs MRI	0.330
Tibia, lateral	Surgeon	VSI vs Arthro	0.785
	Blinded	MRI vs Arthro	0.245
	Blinded	VSI vs MRI	0.267
Meniscus, medial	Surgeon	VSI vs Arthro	0.888
	Blinded	MRI vs Arthro	0.429
	Blinded	VSI vs MRI	0.429
Meniscus, lateral	Surgeon	VSI vs Arthro	0.836
	Blinded	MRI vs Arthro	0.535
	Blinded	VSI vs MRI	0.479
Patellofemoral joint	Surgeon	VSI vs Arthro	0.795
	Blinded	MRI vs Arthro	0.500
	Blinded	VSI vs MRI	0.528

NOTE. Summary of the computed Kappa statistics, for each location, using the primary reader comparisons described above.

Arthro, arthroscopy; MRI, magnetic resonance imaging; VSI, VisionScope Imaging.

Table 3. Summary of Diagnostic Performance

Location	Reader	Procedure	Sensitivity	Specificity	PPV	NPV
Articular cartilage:						
Femur, medial	Surgeon	VSI	0.961	0.941	0.942	0.960
	Blinded	MRI	0.758	0.784	0.855	0.659
Femur, lateral	Surgeon	VSI	0.818	0.948	0.818	0.948
	Blinded	MRI	0.575	0.855	0.742	0.734
Tibia, medial	Surgeon	VSI	0.875	0.957	0.875	0.957
	Blinded	MRI	0.408	0.896	0.800	0.597
Tibia, lateral	Surgeon	VSI	0.826	0.957	0.950	0.849
	Blinded	MRI	0.388	0.864	0.760	0.559
Meniscus, medial	Surgeon	VSI	0.944	0.967	0.986	0.882
	Blinded	MRI	0.813	0.611	0.788	0.647
Meniscus, lateral	Surgeon	VSI	0.905	0.931	0.905	0.931
	Blinded	MRI	0.667	0.864	0.690	0.851
Patellofemoral joint	Surgeon	VSI	0.788	0.981	0.963	0.879
	Blinded	MRI	0.696	0.844	0.886	0.614

NOTE. Summary of the performance statistics (sensitivity, specificity, positive and negative predictive values) computed for each location, using the surgical diagnostic arthroscopy results as the gold standard control comparison.

MRI, magnetic resonance imaging; NPV, negative predictive value; PPV, positive predictive value; VSI, VisionScope Imaging.

surgical diagnostic arthroscopy, the kappa statistic reported moderate agreement (Table 2 for all kappa statistics); the sensitivity of MRI was 0.575, and specificity was 0.855 (PPV = 0.742; NPV = 0.734).

Comparing VSI with surgical diagnostic arthroscopy of the lateral tibial articular cartilage, the kappa statistic indicated substantial agreement. The sensitivity of VSI was 0.826, and the specificity was 0.957 (PPV = 0.950; NPV = 0.849).

Using the blinded expert assessments for the MRI to surgical diagnostic arthroscopy comparison, the kappa statistic indicated fair agreement. The sensitivity of MRI was 0.388, and the specificity was 0.864. The PPV of MRI was 0.760, and the NPV was 0.559, both notably lower than VSI.

Lateral Meniscus

Comparing VSI with surgical diagnostic arthroscopy, the kappa statistic indicated close agreement, the sensitivity of VSI was 0.905, and the specificity was 0.931. The PPV was 0.905, and the NPV was 0.931. In comparison, using the experts' MRI compared with arthroscopy assessments, the kappa statistic indicated moderate agreement, the sensitivity of MRI was 0.667, and the specificity was 0.864. The PPV of MRI was 0.690, and the NPV was 0.851.

Patellofemoral Joint. Comparing VSI with surgical diagnostic arthroscopy, the kappa statistic indicated close agreement, with the sensitivity of VSI 0.788 and the specificity 0.981. The PPV was 0.963, and the NPV was 0.879. In comparison, using the experts' assessments for the MRI to surgical diagnostic arthroscopy comparison, the kappa statistic indicated moderate agreement, with the sensitivity of MRI 0.696 and the specificity 0.844. The PPV of MRI was 0.886, and the NPV was 0.614.

Discussion

When evaluating for meniscal or chondral injury in the knee, needle-based arthroscopic technology that can be used in the office has the potential to be more accurate than MRI and equivalent to arthroscopic evaluation. In this study, the accuracy, sensitivity, and specificity of the VSI system were equivalent to surgical diagnostic arthroscopy and more accurate than MRI in the assessment of menisci, articular cartilage, and the patellofemoral joint in the knee. There were no patient- or device-related complications related to the use of the VSI system.

The ability to diagnose intra-articular pathology in patients with persistent knee pain can be challenging, particularly in the areas of articular cartilage damage and in patients who have had previous surgery. Many studies in the literature report on the diagnostic difficulties and accuracy of MRIs in patients with intra-articular pathology.[9-13] Navali et al.[20] reported on 120 patients with knee injuries, with an average age of 29 years, and the accuracy of MRI as compared with physical examination. That study found that MRI was accurate 77.5% of the time in diagnosing medial meniscus tears and accurate 85.8% of the time in diagnosing lateral meniscus tears. However, that study also found that MRI was not as accurate when used in the diagnosis of concurrent or complicated injuries. In a separate study, Bernthal et al.[21] found that MRI was not an effective or efficient predictor of reparability of meniscal tears with the current arthroscopic criteria.

Similar results were found regarding the accuracy of MRI in diagnosing meniscal tears in older patients. According to this study, the accuracy of MRI for diagnosing meniscal tears in older patients is high and similar to that in younger patients, when only definitive findings are considered a tear. This is in contrast to the

findings of Subhas et al.,[26] who reported on the accuracy and frequency with which abnormal MRI findings correlate with degeneration, fraying, and tears during subsequent arthroscopy. They reported the results of 92 patients, age 50 years and older, who had undergone a knee MRI followed by knee arthroscopy within 6 months. MRI is not always an accurate tool at assessing pathologies depending on previous injuries, concurrent injuries, and complicated knee pathology. Due to such difficulties in diagnosing intra-articular knee injuries, surgical diagnostic arthroscopy is the current "gold standard" for diagnosing intra-articular pathologies, in conjunction with a physical examination. However, combined with the rise in the number of ambulatory surgical centers, there has been an increase in the use of surgical arthroscopic procedures.[27] This has placed an increased cost on the health care delivery system. Needle-based in-office arthroscopy has already been shown to decrease costs substantially compared with the current diagnostic and treatment paradigm.[5,6] This is the first study to report the accuracy, efficacy, and safety of needle-based arthroscopy that can be used in the office compared with traditional diagnostic and treatment paradigms.

In the present study that compared the VisionScope needle-based diagnostic imaging (VSI) to surgical diagnostic arthroscopy, all kappa statistics were very high, indicating that there was no significant difference between the 2 modalities. Looking across all evaluation locations, VSI and surgical diagnostic arthroscopy were in substantial to near perfect agreement, with performance statistics consistently and uniformly high between the 2 modalities. In contrast, MRI's comparison to surgical diagnostic arthroscopy reported kappa values ranging from fair-to-moderate agreement, and the comparison of MRI to VSI reported similar results. Looking across all evaluation locations, MRI had a lower agreement and lower performance statistic values compared with both surgical diagnostic arthroscopy and in-office diagnostic arthroscopy.

Complications

There were no complications reported in any patient.

Limitations

This was a prospective, multicenter, blinded study designed to investigate the efficacy, accuracy, and safety of in-office diagnostic imaging. As such, there are relatively few limitations to the study. Both the MR images and VisionScope images were interpreted after the surgeon had performed a physical examination, and therefore there was no bias toward either imaging modality. One possible limitation is that there was not a standardized MRI protocol or magnet strength for the study, due to the multicenter nature of the patient enrollment. That said, all scans were reviewed by the same blinded radiologists. Another possible limitation is that the VisionScope procedure was performed in the operating room rather than the office. That said, the exact location would not affect the images obtained or the actual patient or device assessment of the technology. Lastly, the study design did not allow potential complications due to the VSI examination of the surgical arthroscopy to be separated. That said, no patient in the study reported any complications, and therefore no complications could be attributed to the VSI examination.

Conclusions

Needle-based diagnostic imaging that can be used in the office setting is statistically equivalent to surgical diagnostic arthroscopy with regard to the diagnosis of intra-articular, nonligamentous knee joint pathology. In-office diagnostic imaging can provide a more detailed and accurate diagnostic assessment of intra-articular knee pathology than MRI. Based on the study results, in-office diagnostic imaging provides a safe, accurate, real-time, minimally invasive diagnostic modality to evaluate intra-articular pathology without the need for surgical diagnostic arthroscopy or high-cost imaging.

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