

ORIGINAL RESEARCH

KNEE // IMAGING

Use of a Small-Bore Needle Arthroscope to Diagnose Intra-Articular Knee Pathology: Comparison With Magnetic Resonance Imaging

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AUTHORS:

Carl A. Deirmengian, MD, Joshua S. Dines, MD, Joseph V. Vernace MD Michael S. Schwartz MD MBA, R. Alexander Creighton MD James N. Gladstone MD

AUTHOR AFFILIATION | DISCLOSURES

Dr. Deirmengian reports that he receives equity, patents, and is an advisory board member for Trice Medical, which is directly related to this article. Dr. Dines, Dr. Vernace, and Dr. Schwartz report that they receive equity and are advisory board members for Trice Medical. Dr. Gladstone reports that he is a consultant and advisory board member for Trice Medical. Dr. Creighton reports no actual or potential conflict of interest in relation to this article.

Dr. Deirmengian is Associate Professor of Orthopedic Surgery, The Rothman Institute, Philadelphia, Pennsylvania. Dr. Dines is an Associate Attending, Sports Medicine and Shoulder Service, Hospital for Special Surgery, New York, New York. Dr. Vernace is an Orthopedic Surgeon, Main Line Orthopaedics, Bryn Mawr, Pennsylvania. Dr. Schwartz is President, OrthoTexas, Plano, Texas. Dr. Creighton is Professor of Orthopedics, University of North Carolina, Chapel Hill, North Carolina. Dr. Gladstone is Associate Professor of Orthopedic Surgery, Mount Sinai Hospital, New York, New York.

Address correspondence to: Joshua S. Dines, MD, Sports Medicine and Shoulder Service, Hospital for Special Surgery, 523 East 72nd Street, 6th Floor, New York, NY 10021 (tel, 516-482-3929; email, dinesj@hss.edu).

ABSTRACT

The use of arthroscopy for purely diagnostic purposes has been largely supplanted by noninvasive technologies, such as magnetic resonance imaging (MRI). The mi-eye^{+TM} (Trice Medical) technology is a small-bore needle unit for in-office arthroscopy. We conducted a pilot study comparing the mi-eye^{+TM} unit with MRI, using surgical arthroscopy as a gold-standard reference. We hypothesized that the mi-eye^{+TM} needle arthroscope, which can be used in an office setting, would be equivalent to MRI for the diagnosis of intra-articular pathology of the knee.

This prospective, multicenter, observational study was approved by the Institutional Review Board. There were 106 patients (53 males, 53 females) in the study. MRIs were interpreted by musculoskeletally trained radiologists. The study was conducted in the operating room using the mi-eye^{+TM} device. The mi-eye^{+TM} device findings were compared with the MRI findings within individual pathologies, and a “per-patient” analysis was performed to compare the arthroscopic findings with those of the mi-eye^{+TM} and the MRI. Additionally, we identified all mi-eye^{+TM} findings and MRI findings that exactly matched the surgical arthroscopy findings.

The mi-eye^{+TM} demonstrated complete accuracy of all pathologies for 97 (91.5%) of the 106 patients included in the study, whereas MRI demonstrated complete accuracy for 65 patients (61.3%) ($P < .0001$). All discrepancies between mi-eye^{+TM} and arthroscopy were false-negative mi-eye^{+TM} results, as the mi-eye^{+TM} did not reveal some aspect of the knee's pathology for 9 patients. The mi-eye^{+TM} was more sensitive than MRI in identifying meniscal tears (92.6% vs 77.8%; $P = .0035$) and more specific in diagnosing these tears (100% vs 41.7%; $P < .0001$).

The mi-eye^{+TM} device proved to be more sensitive and specific than MRI for intra-articular findings at time of knee arthroscopy. Certainly there are contraindications to using the mi-eye^{+TM}, and our results do not obviate the need for MRI, but our study did demonstrate that the mi-eye^{+TM} needle arthroscope can safely provide excellent visualization of intra-articular knee pathology.

Surgical arthroscopy is the gold standard for the diagnosis of intra-articular knee pathologies. Nevertheless, the use of arthroscopy for purely diagnostic purposes has been largely supplanted by noninvasive technologies, such as magnetic resonance imaging (MRI). Although MRI is considered the standard diagnostic tool for acute and chronic soft-tissue injuries of the knee, its use is not without contraindication and some potential inconveniences. Contraindications to MRI are well documented. In terms of inconvenience, MRI usually requires a separate visit followed by another visit to the prescribing physician. In addition, required interpretation by a radiologist may lead to a delay in care and increase in cost.

In the early 1990s, in-office needle arthroscopy was described as a viable means of diagnosing pathologies and obtaining synovial biopsies from the knee.¹⁻³ Initial results were good, and the procedures had very low complication rates. Nevertheless, in-office arthroscopy of the knee is not yet widely performed, likely given concerns about the technical difficulties of in-office arthroscopy, the potential for patient discomfort, and the cumbersomeness of in-office arthroscopy units. However, significant advances have been made in the resolution capability of small-bore needle arthroscopy, resulting in much less painful procedures. Additionally, the early hardware designs, which mimicked operating room setups using towers, fluid irrigation systems, and larger arthroscopes, have been replaced with small-needle arthroscopes that use syringes for irrigation and tablet computers for visualization (**Figures 1A, 1B**).

The mi-eye^{+TM} technology (Trice Medical) is a small-bore needle unit for in-office arthroscopy with digital optics that does not need an irrigation tower. We conducted a pilot study of the sensitivity and specificity of the mi-eye^{+TM} unit in comparison with MRI, using surgical arthroscopy as a gold-standard reference. We hypothesized that the mi-eye^{+TM} needle arthroscope, which can be used in an office setting, would be equivalent to the standard of care (MRI) for the diagnosis of intra-articular pathology of the knee.

METHODS

Central regulatory approval for this prospective, multicenter, observational study was obtained from the Western Institutional Review Board for 3 of the sites, and 1 institution required and was granted internal Institutional Review Board approval.

The study was performed by 4 sports medicine orthopedic surgeons experienced in using the mi-eye^{+TM} in-office arthroscope. Patients were enrolled from December 2015 through June 2016. Inclusion criteria were an indication for an arthroscopic procedure of the knee based on history, physical examination, and MRI findings. Patients were excluded from the study if there were any contraindications to completing an MRI. Acute hemarthroses of the knee or active systemic infections were also excluded. Once a patient was identified as

meeting the criteria for participation, informed consent was obtained. Of the 113 patients who enrolled, 7 did not have a complete study dataset available, leaving 106 patients (53 males, 53 females) in the study. Mean age was 47 years (range, 18–82 years).

A test result form was used to record mi-eye^{+TM}, surgical arthroscopy, and MRI results. This form required a “positive” or “negative” result for all of several diagnoses: medial and lateral meniscal tears, intra-articular loose body, osteoarthritis (OA), osteochondritis dissecans (OCD), and tears of the anterior and posterior cruciate ligaments (ACL, PCL). MRI was performed at a variety of imaging facilities, but the images were interpreted by musculoskeletally trained radiologists.

The study was conducted in the operating room. After the patient was appropriately anesthetized, and the extremity prepared and draped, the mi-eye^{+TM} procedure was performed immediately prior to surgical arthroscopy. A tourniquet was not used. At surgeon discretion, medial, lateral, or both approaches were used with the mi-eye^{+TM}, and diagnostic arthroscopy was performed. During the procedure, the mi-eye^{+TM} was advanced into the knee. Once in the synovial compartment, the external 14-gauge needle was retracted, exposing the unit’s optics. Visualization was improved by injecting normal saline through the lure lock in the mi-eye^{+TM} needle arthroscope. An average of 20 mL of saline was used, though the amount varied with surgeon discretion. Subsequently, the surgeon visualized structures in the knee and documented all findings.

At the end of the mi-eye^{+TM} procedure, the scheduled surgical arthroscopy was performed. After the surgical procedure, if there were no issues or complications, the patient was discharged from the study. No follow-up was required for the study, as arthroscopic findings served as the conclusive diagnosis for each patient, and no interventions were being studied. There were no complications related to use of the mi-eye^{+TM}.

The mi-eye^{+TM} device findings were compared with the MRI findings within individual pathologies, and a “per-patient” analysis was performed to compare the arthroscopic findings with those of the mi-eye^{+TM} and the MRI. Additionally, we identified all mi-eye^{+TM} findings and MRI findings that exactly matched the surgical arthroscopy findings. When a test had no false-positive or false-negative findings in comparison with surgical arthroscopy, it was identified as having complete accuracy for all intra-articular knee pathologies. For these methods, the 95% confidence interval was determined based on binomial distribution.

RESULTS

The mi-eye^{+TM} demonstrated complete accuracy of all pathologies for 97 (91.5%) of the 106 patients included in the study, whereas MRI demonstrated complete accuracy for 65 patients (61.3%) ($P < .0001$). All discrepancies between mi-eye^{+TM} and surgical arthroscopy were false-negative mi-eye^{+TM} results, as the mi-eye^{+TM} did not reveal some aspect of the knee’s pathology for 9 patients. On the other hand, MRI demonstrated both false-negative and false-positive results, failing to reveal some aspect of the knee’s pathology for 31 patients, and potentially overcalling some aspect of the knee’s pathology among 18 patients.

The pathology most frequently identified in the study was a meniscal tear. The mi-eye^{+TM} was more sensitive than MRI in identifying meniscal tears (92.6% vs 77.8%; $P = .0035$) and more specific in diagnosing these tears (100% vs 87.5%; $P < .0002$). The difference in specificity resulted from the false MRI diagnosis of a meniscal tear among 24 patients, who were found to have no tear by both mi-eye^{+TM} and surgical arthroscopy.

The second most frequent pathology was an intra-articular loose body. The mi-eye^{+TM} was more sensitive than MRI in identifying loose bodies (86.7% vs 20%; $P = .0007$). The specificity of the mi-eye^{+TM} and the specificity of MRI were equivalent in diagnosing loose bodies (100%). **Table 1** and **Table 2** show the complete set of diagnoses and associated diagnostic profiles.

DISCUSSION

The overall accuracy of the mi-eye +™ was superior to that of MRI relative to the arthroscopic gold standard in this pilot study. Other studies have demonstrated the accuracy, feasibility, and cost-efficacy of in-office arthroscopy. However, likely because of the cumbersomeness of in-office arthroscopy equipment and the potential for patient discomfort, the technique is not yet standard in the field. Recent advances in small-bore technology, digital optics, and ergonomics have addressed the difficulties associated with in-office arthroscopy, facilitating a faster and more efficient procedure. Our goal in this study was to evaluate the diagnostic capability of the mi-eye +™ in-office arthroscopy unit, which features a small bore, digital optics, and functionality without an irrigation tower.

This study of 106 patients demonstrated equivalent or better accuracy of the mi-eye +™ relative to MRI when compared with the gold standard of surgical arthroscopy. This was not surprising given that both the mi-eye +™ and surgical arthroscopy are based on direct visualization of intra-articular pathology. The mi-eye +™ unit identified more meniscal tears, intra-articular loose bodies, ACL tears, and OCD lesions than MRI did, and with enough power to demonstrate statistically significant improved sensitivity for meniscal tears and loose bodies. Furthermore, MRI demonstrated false-positive meniscal tears, ACL tears, OCD lesions, and OA, whereas the mi-eye +™ did not demonstrate any false-positive results in comparison with surgical arthroscopy. This study demonstrated statistically significant improved specificity of the mi-eye + compared with MRI in the diagnosis of meniscal tears and OA.

There are several limitations to our study. We refer to it as a pilot study because it was performed in a standard operating room. Before taking the technology to an outpatient setting, we wanted to confirm efficacy and safety in an operating room. However, the techniques used in this study are readily transferable to the outpatient clinic setting and to date have been used in more than 2000 cases.

The specificity of MRI for meniscal tears was unexpectedly low compared with previous studies, which may reflect the multi-institution, multi-surgeon, multi-radiologist involvement in MRI interpretation.⁴⁻¹⁰ MRI was performed at a variety of institutions without a standardized protocol. This lack of standardization of image capture and interpretation may have contributed to the suboptimal performance of MRI, falsely decreasing the potential ideal specificity for meniscal tears. Although this study may have underestimated the specificity of MRI for meniscal tears, we think the mi-eye +™ and MRI results reported here reflect the findings of standard practice, without the standardization usually applied in studies. For example, a study of 139 knee MRI reports at 14 different institutions confirmed arthroscopic findings and concluded that 37% of the operations supported by a significant MRI finding were unjustified.¹¹ The authors attributed the rate of false-positive MRI findings to the wide variety of places where patients had their MRIs performed, and the subsequent variation in quality of imaging and MRI reader skill level.¹¹

Before inserting the mi-eye +™ needle arthroscope, the surgeons had a working diagnosis of the pathology based on their clinical examination and MRI results. Clearly, this introduced a bias. Further studies will be conducted in a prospective, blinded manner to address this limitation.

Although studies of in-office arthroscopy technology date to the 1990s, there is an overall lack of data comparing in-office arthroscopy with MRI. Halbrecht and Jackson² conducted a study of 20 knee patients with both MRI and in-office needle arthroscopy. Overall, MRI was poor in detecting cartilage defects, with sensitivity of 34.6%, using the in-office arthroscopy as the confirmatory diagnosis. Although the authors did not compare in-office diagnoses with surgical arthroscopic findings, they concluded that office arthroscopy is an accurate and cost-efficient alternative to MRI in diagnostic evaluation of knee patients. Xerogeanes and colleagues¹² studied 110 patients in a prospective, blinded, multicenter trial comparing a minimally invasive office-based arthroscopy with MRI, using surgical arthroscopy as the confirmatory diagnosis. They concluded that the office-based arthroscope was statistically equivalent to diagnostic surgical arthroscopy and that it

outperformed MRI in helping make accurate diagnoses. The authors applied a cost analysis to their findings and determined that office-based arthroscopy could result in an annual potential savings of \$177 million for the healthcare system.¹²

Modern imaging sequences on high-Tesla MRI machines provide excellent visualization. Nevertheless, a significant number of patients do not undergo MRI, owing to time constraints, contraindications, body habitus, or anxiety/claustrophobia. Our study results confirmed that doctors treating such patients now have a viable alternative to help diagnose pathology.

CONCLUSION

The mi-eye^{+TM} device proved to be more sensitive and specific than MRI for intra-articular findings at the time of knee arthroscopy. Certainly there are contraindications to using the mi-eye^{+TM}, and our results do not obviate the need for MRI; our study did demonstrate that the mi-eye^{+TM} needle arthroscope can safely provide excellent visualization of intra-articular knee pathology. More studies of the mi-eye^{+TM} device in a clinical setting are warranted.