

# Prospective Multi-Center Clinical Trial to Compare Efficacy, Accuracy and Safety of the VisionScope® Imaging System Compared to MRI and Diagnostic Arthroscopy

Xerogeanes, JW, MD<sup>1</sup>, Safran, MR, MD<sup>2</sup>, Huber, SB, MD<sup>3</sup>, Mandelbaum, BR, MD<sup>4</sup>, Robertson, W, MD<sup>5</sup>, Gambardella, RA, MD<sup>6</sup>

Emory Orthopaedic Center<sup>1</sup>, Stanford Sports Medicine Center<sup>2</sup>, Mansfield Orthopaedics/Copley Hospital<sup>3</sup>, Santa Monica Orthopaedic Group (SMOG)<sup>4</sup>, University of Texas Southwestern Medical Center<sup>5</sup>, Kerlan-Jobe Orthopaedic Clinic<sup>6</sup>

Each author certifies that he has no financial disclosures relevant to this work.

## BACKGROUND

- Arthroscopic surgery is the gold standard for diagnosing intra-articular pathology.
- MRI is commonly used as a diagnostic modality to assess intra-articular pathology in patients with persistent pain.
- There is no non-surgical option that can provide detailed information about the intra-articular pathology of a joint.
- VisionScope Imaging (VSI) is an **office-based** diagnostic modality that provides comprehensive real-time images and video of a joint.

## PURPOSE

To conduct a prospective, multi-center, IRB-approved, blinded clinical trial for the purpose of comparing the efficacy, accuracy and safety of the VisionScope Imaging system to MRI and diagnostic arthroscopic surgery.

## METHODS

- Study participants were recruited at one of six participating clinical sites between July 2012 and May 2013.
- Inclusion criteria: suspected meniscal tears or chondral defects.
- Exclusion criteria: acute traumatic hemarthroses, concomitant ligament injury or active systemic infection.
- Each patient had an MRI and a comprehensive physical exam prior to determine their qualification for surgical diagnostic arthroscopy.
- Once enrolled, each patient underwent an MRI, VSI exam and surgical diagnostic arthroscopy.
- The attending surgeon completed standard clinical report forms comparing VSI findings to the diagnostic arthroscopy findings on each patient.
- Two blinded experts, unaffiliated with the study, reviewed the VSI, MRI and arthroscopy images.
- Diagnostic arthroscopy served as the control comparator between VSI and MRI findings.

## RESULTS

- 110 patients participated in the study.
- The accuracy, sensitivity and specificity of VSI was equivalent to surgical diagnostic arthroscopy and more accurate than MRI (Table 1).
- When comparing VSI to arthroscopy, the two were in near perfect agreement with Kappa values ranging from 0.766 to a high of 0.902.
- When comparing MRI to arthroscopy the two were in slight-to-moderate agreement with Kappa values ranging from 0.130 to a high of 0.535.
- When comparing MRI to VSI, the two were in slight-to-moderate agreement with Kappa values ranging from 0.112 to a high of 0.546.
- Kappa statistics indicate a clear pattern that VSI and arthroscopy are consistently in very close agreement, while MRI does not agree with either.

Table 1: Summary of Diagnostics Performance

Summary of the performance statistics: sensitivity, specificity, positive and negative predictive values computed for each location, using the arthroscopy results as the 'gold standard.'

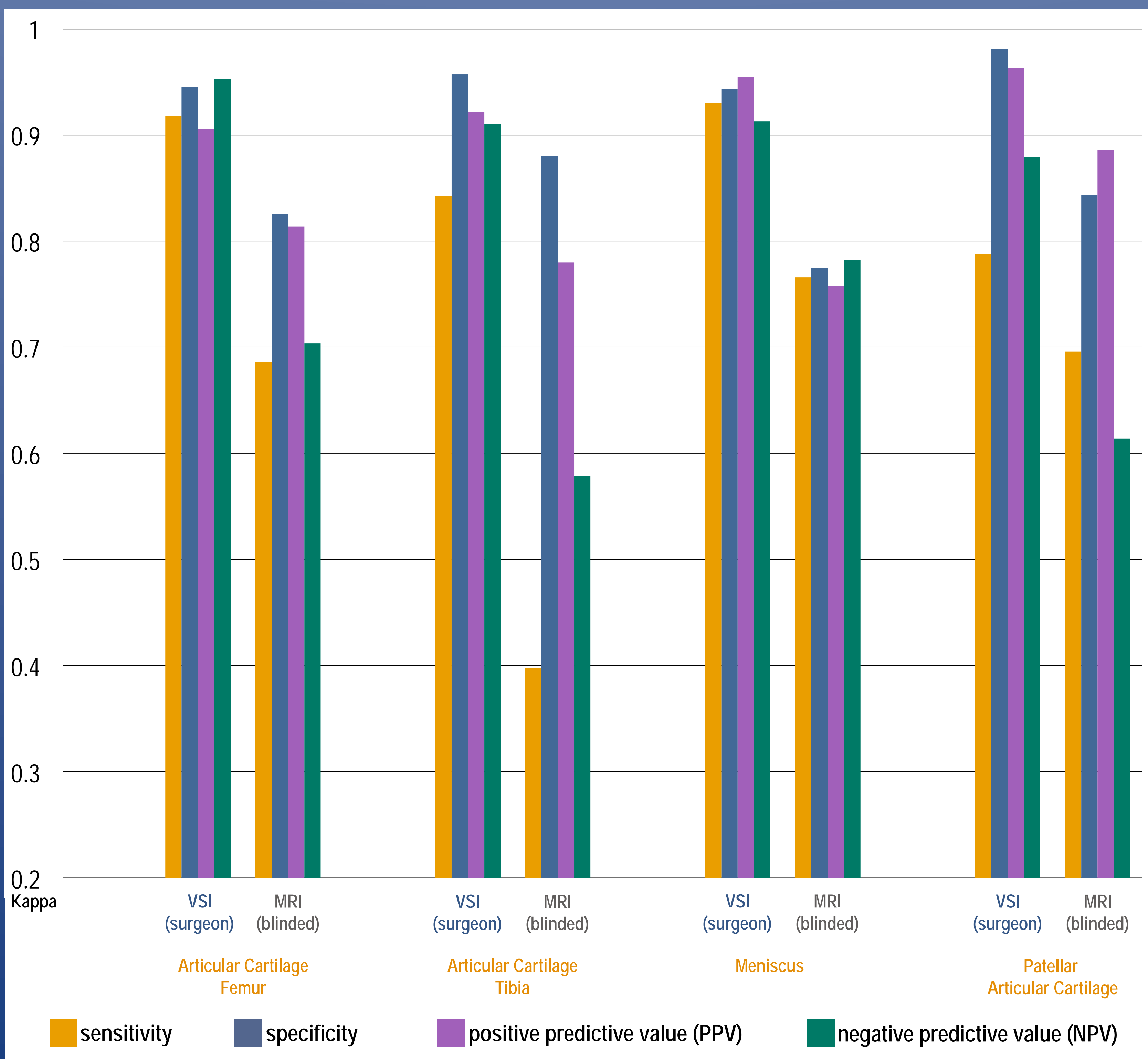


Figure 1. Chondral defect diagnosed by VSI

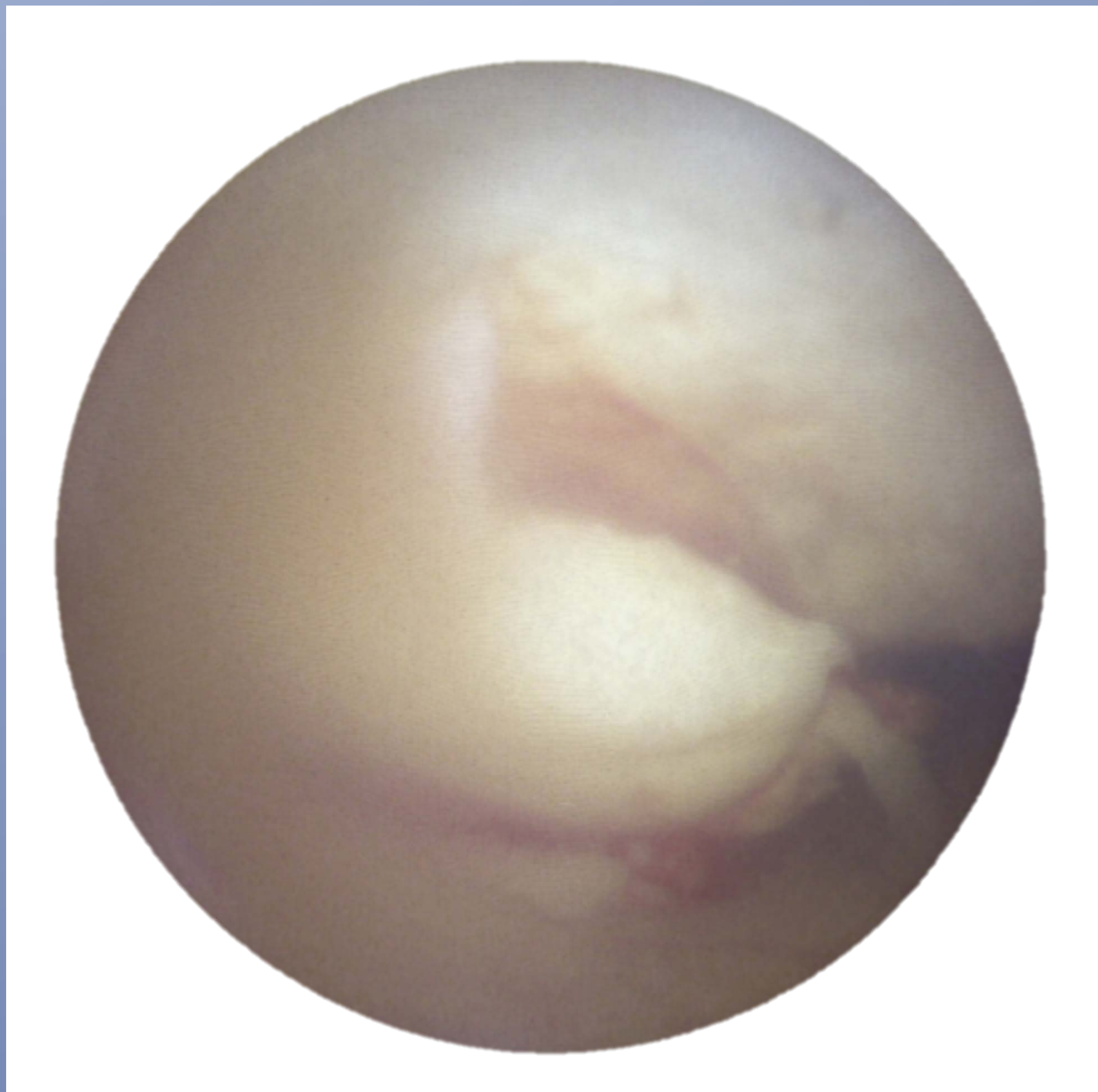
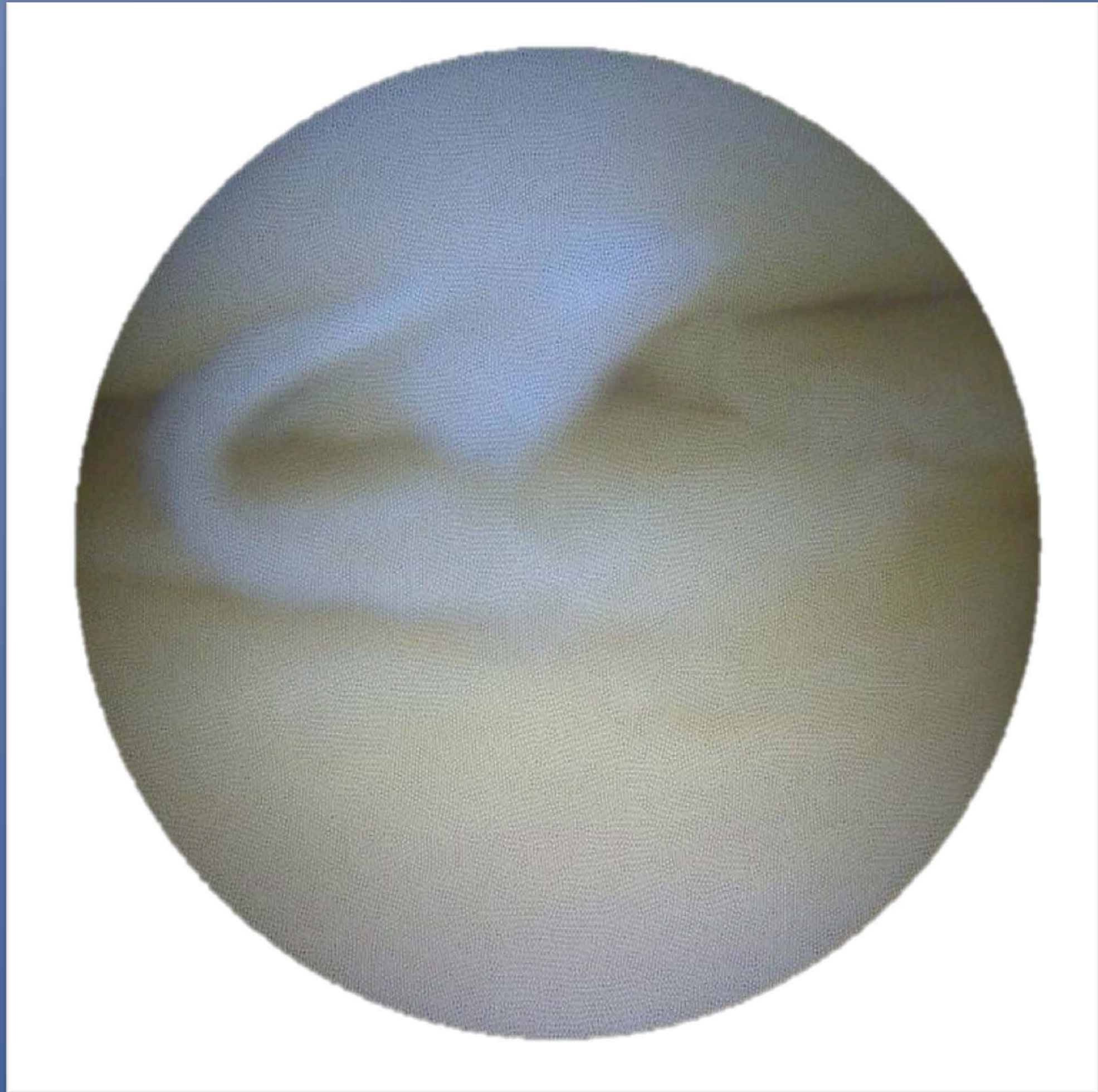


Figure 2. Meniscal pathology diagnosed by VSI



## CONCLUSIONS

- VSI is statistically equivalent to diagnostic surgical arthroscopy.
- A VSI exam can provide a more detailed and accurate diagnostic assessment of intra-articular knee pathology compared to MRI.
- VSI is more accurate than MRI and statistically equivalent to diagnostic arthroscopy in detecting meniscal tears and chondral defects.
- VSI provides an option for an in-office exam that can accurately diagnose intra-articular pathologies in real time without the use of anesthesia or distention fluid.