

## Prospective Comparison of VisionScope Imaging with MRI and Surgical Diagnostic Arthroscopy

Magnetic resonance imaging (MRI) and clinical evaluation are the diagnostic tools most commonly used to assess symptomatic joint pain. With healthcare costs dramatically on the rise, high-cost diagnostic imaging procedures are being scrutinized as insurers work to control and reduce costs. In fact, in many healthcare centers, reimbursement is directly tied to the effective reduction of diagnostic imaging – implicated as one of the driving forces behind the soaring cost of healthcare nationwide.

### THE STATUS QUO

#### A diagnostic odyssey

Diagnosing intra-articular pathology in patients with persistent knee pain can be challenging, especially for articular cartilage damage, or in the post-operative setting. Today, surgical arthroscopy is the gold standard for the diagnosis of intra-articular joint pathology. For patients presenting with ongoing pain and/or disability despite non-operative care, MRI is commonly used as an initial diagnostic modality in conjunction with a clinical exam. Because there is not a minimally invasive in-office option to provide detailed anatomic information about intra-articular pathology, should the MRI report not yield a conclusive root cause of the pain, the only alternative is a surgical diagnostic procedure. This journey to diagnosis can be long, costly and frustrating for all parties – all the while joint pain persists and is exacerbated from prolonged use.

### CLINICAL CHANGE

#### Study compares the options

Recently, a prospective, multi-center, blinded clinical trial was conducted to compare the accuracy, efficacy and safety of VisionScope Imaging (VSI) to MRI and surgical diagnostic arthroscopy. 110 patients, ages 18 -75, who presented with knee pain were enrolled and underwent an MRI, VSI exam and surgical diagnostic arthroscopy. Clinical report forms – comparing VSI and diagnostic arthroscopy findings – were completed by each patient’s attending physician. Two blinded experts, from the Cleveland Clinic and unaffiliated with the clinical patient care, reviewed the VSI and MRI images. The arthroscopy served as the “control” comparator between the VSI and MRI findings.

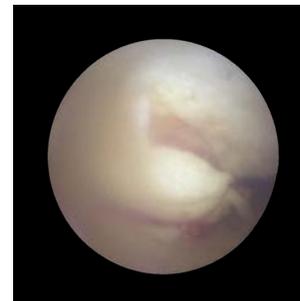
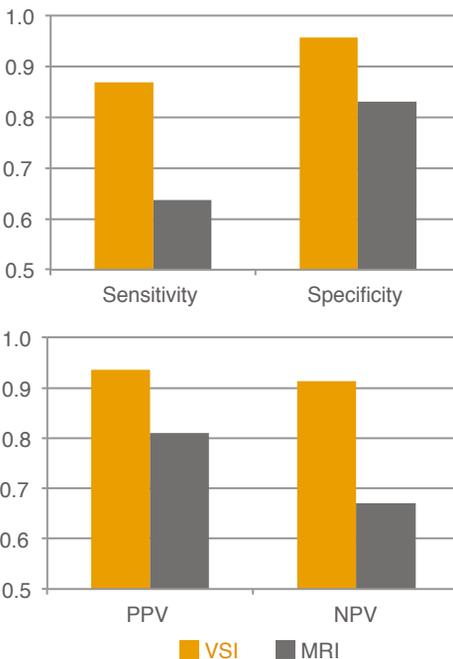
### A POSITIVE CHANGE

#### Office-based arthroscopy validated

This study demonstrated that – in identifying articular cartilage defects and meniscal tears in the knee – the accuracy, sensitivity and specificity of VSI was statistically equivalent to surgical diagnostic arthroscopy and statistically greater than MRI. The sensitivity and specificity of the VSI exam compared to surgical diagnostic arthroscopy was 97% and 92% respectively. When compared to MRI, VSI was 50% more accurate in identifying pathology and significantly more predictive (Table 1). The study reported no adverse events associated with VSI.

**Table 1: Summary of Diagnostic Performance**

Summary of the performance statistics: sensitivity, specificity, positive and negative predictive values computed for the seven area locations of the knee evaluated, using the arthroscopy results as the gold standard.



Chondral defect diagnosed by VSI



Meniscal pathology diagnosed by VSI

### REAL TIME RESULTS

#### VSI brings office-based visualization to light

VSI's equivalence to surgical diagnostic arthroscopy and superiority to MRI provides physicians with an accurate, safe and immediate option for diagnosing atraumatic knee pain.

The result?

- A more detailed and accurate alternative to MRI.
- A streamlined diagnostic process – fewer appointments, fewer tests.
- A patient-centric exam that requires no general anesthesia, no stitches, no recovery time.
- An exam that can contribute to the reduction of overall healthcare costs.

Xerogeanes JW, MD, Safran MR, MD, Huber, SB, MD, Mandelbaum BR, MD, Robertson W, MD, Gambardella RA, MD. "Prospective Comparison of VisionScope Imaging with MRI and Surgical Diagnostic Arthroscopy." The American Orthopaedic Society of Sports Medicine. Seattle. 10 July 2014. Poster Presentation.



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