

AANA 33rd Annual Meeting ePoster Presentation 1-3 May 2014 Hollywood, Florida

Prospective Comparison of VisionScope with MRI and Diagnostic Arthroscopy e111

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Introduction: Until now, arthroscopic surgery has been the gold standard for the diagnosis of intraarticular pathology. When a patient presents with ongoing pain and/or disability despite non-operative care, MRI is commonly used as a diagnostic modality. However, it is expensive, can require intra-articular contrast, and is often non-diagnostic. To date, there is no minimally- invasive option that can provide detailed information about the intra-articular pathology of a joint. The purpose of the multi-center clinical trial was to compare the efficacy, accuracy and

safety of the VisionScope Imaging system compared to MRI and diagnostic arthroscopic surgery. This was a prospective study to compare the specificity and sensitivity of VSI compared to MRI and diagnostic arthroscopy.

Methods: A prospective, multi-center, blinded clinical trial was performed. The patient cohort consisted of 80 patients age 18 - 75 years. Each patient underwent and MRI, VSI exam and surgical diagnostic arthroscopy. Subjects were identified from patients who presented with orthopaedic knee ailments and were candidates for arthroscopy. For each patient, the attending physician completed the clinical trial forms comparing the VSI exam findings to the diagnostic arthroscopy findings. Two blinded experts unaffiliated with the study reviewed the VSI, arthroscopy and MRI images. The experts were blinded to all prior radiology readings, clinical notes, and arthroscopy findings. The arthroscopy served as the "control" comparison between the VSI and MRI findings.

Results: In this study, the accuracy, sensitivity and specificity of VSI was equivalent to surgical diagnostic arthroscopy in identifying articular cartilage defects and meniscal tears in the knee and more accurate than MRI. The sensitivity of the VSI exam compared to diagnostic arthroscopy was 97% and the specificity was 92%. Therefore, VSI can accurately diagnose chondral lesions, the degree of arthrosis and meniscal tears. When identifying meniscal tears, the VSI exam was comparable to arthroscopy and more accurate than MRI in diagnosing the specific tear type and extent.

Conclusion: VSI is comparable to diagnostic surgical arthroscopy with regard to the diagnosis of intraarticular pathology. When compared to MRI, a VSI exam can provide a more detailed and accurate diagnostic assessment of intra-articular knee pathology. VSI provides an accurate, real-time, minimallyinvasive diagnostic modality that can be performed to evaluate intra- articular pathology in the office setting.