



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

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Objectives: Until now, arthroscopic surgery has been the gold standard for the diagnosis of intra-articular pathology. When a patient presents with ongoing pain and/or disability despite non-operative care, MRI is commonly used as a diagnostic modality. To date, there is not a minimally-invasive 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 with higher accuracy and reliability compared to static MR images. The purpose of this study was to compare the efficacy, accuracy and safety of VSI compared to MRI and surgical diagnostic arthroscopy.

Methods: A prospective, blinded, multi-centered study was performed of all patients who had a routine surgical arthroscopy at one of the six participating clinical sites between July 2012 and May 2013. 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 hemarthroses, (2) concomitant ligament injury, (3) active systemic infection, (4) allergy to silicone or any medication used during the procedure. All patients had a MRI and a comprehensive physical exam prior to their surgical arthroscopy. Each patient underwent a MRI, VSI exam and surgical diagnostic arthroscopy. The attending physician completed standard forms comparing the VSI exam findings to the diagnostic arthroscopy findings on each patient. Two blinded experts unaffiliated with the study reviewed the VSI and MRI images. The arthroscopy served as the “control” comparison between the VSI and MRI findings.

Results:

There were 110 patients included in this study. The accuracy, sensitivity and specificity of VSI were equivalent to surgical diagnostic arthroscopy and more accurate than MRI (Table 1). When comparing VSI to Arthroscopy, all of the Kappa statistics were above 0.766, and went as high as 0.902. For MRI compared to Arthroscopy, Kappa values ranged from a high of 0.535 to 0.130. Comparing VSI to MRI showed very similar results as Arthroscopy to MRI, with a highest Kappa of 0.546 and a lowest Kappa of 0.112. Our Kappa statistics would indicate substantial or near perfect agreement. Therefore, looking across all locations, there is a clear pattern that VSI and Arthroscopy are consistently in very close agreement, while MRI did not agree with either modality.

Conclusions: VSI is statistically equivalent to diagnostic surgical arthroscopy with regard to the diagnosis of intra-articular knee joint pathology. When compared to MRI, a VSI exam can provide a more detailed and accurate diagnostic assessment of intra-articular knee pathology. Based on these study results, VSI is more accurate than MRI and statistically equivalent to diagnostic arthroscopy in detecting meniscal and chondral defects in the knee, therefore, providing an option for an in-office exam that can accurately diagnose intra articular pathologies in real-time without the use of anesthesia or fluid.

Table 1: Present a summary of the performance statistics (sensitivity, specificity, positive and negative predictive values) computed for each location, using the Arthroscopy results as the “gold standard.”

Table 1: 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
Articular Cartilage: Femur, Lateral	Surgeon	VSI	0.818	0.948	0.818	0.948
	Blinded	MRI	0.575	0.855	0.742	0.734
Articular Cartilage: Tibia, Medial	Surgeon	VSI	0.875	0.957	0.875	0.957
	Blinded	MRI	0.408	0.896	0.800	0.597
Articular Cartilage: 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
Patellar Articular Cartilage	Surgeon	VSI	0.788	0.981	0.963	0.879
	Blinded	MRI	0.696	0.844	0.886	0.614