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Prospective Comparison of VisionScope Imaging (VSI) with MRI and Diagnostic Arthroscopy

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Prospective Comparison of VisionScope Imaging (VSI) with MRI and Diagnostic Arthroscopy

The following relationships exist:

1. Royalties and Stock Options: None
2. Consulting Income: None
3. Research and Education Support: None
4. Other Support: None

Background

Diagnosis of intra-articular pathology:

- Arthroscopic surgery: gold standard
- No minimally-invasive option
- MRI is used as diagnostic modality
 - Expensive
 - Inconclusive

Background

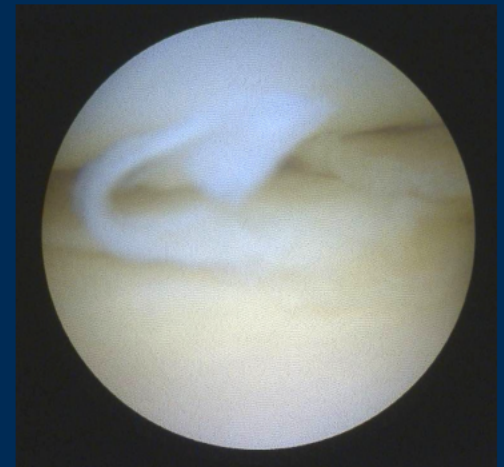
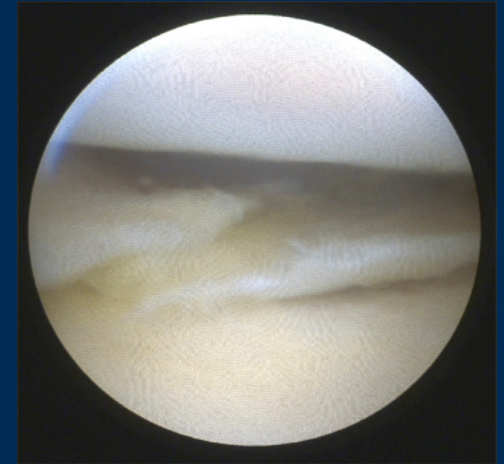
VisionScope Imaging (VSI) System:

- Office-based
- 1.4mm, semi-rigid needle endoscope
- Sub-2mm entry portal
- No circulating fluid or sterilization required



VSI Clinical Applications

- ‘Negative’ MRI
- Chondral Defects
- Meniscal Tears
- Post Surgical
‘second look’
- OA baseline



Clinical Trial Purpose

Multi-center, prospective, blinded study

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Clinical Trial Purpose

Comparison of VSI to MRI and Diagnostic Arthroscopy:

- Accuracy
- Efficacy
- Safety

Materials and Methods

Study population:

- N=110
- Age: 18-75 years
- Subjects presenting with symptomatic knee ailments were identified
- Subjects underwent MRI, VSI and diagnostic arthroscopy

Analysis

- Two unaffiliated experts reviewed VSI and MRI images
- Experts blinded to:
 - Radiology Readings
 - Clinical Notes
 - Arthroscopy Findings
- Diagnostic Arthroscopy served as the 'control' comparator

Results: Accuracy

VSI, in diagnosing intra-articular pathologies of the knee, proved to be:

- Statistically equivalent to diagnostic arthroscopy (Kappa: 0.76 – 0.90)
- More accurate than MRI
 - MRI was in slight-to-moderate agreement with both VSI and Dx Arthroscopy (Kappa: 0.11 – 0.54)

Results: Efficacy

When evaluating intra-articular pathologies, VSI was:

- Comparable to diagnostic arthroscopy
 - Type and extent of tear
 - Degree of arthrosis
- More detailed than MRI
 - Chondral surfaces (defects/healing)
 - Meniscal Pathology
 - Patella Femoral

Results: Specificity and Sensitivity

VSI, in diagnosing intra-articular pathologies of the knee, proved to be equivalent to diagnostic arthroscopy.

- Specificity of VSI: **92%**
- Sensitivity of VSI: **97%**

Results: Specificity and Sensitivity

VSI, in diagnosing intra-articular pathologies of the knee, proved to be more specific and sensitive than MRI.

	SENSITIVITY		SPECIFICITY	
	VSI	MRI	VSI	MRI
ARTICULAR SURFACE (FEMUR)	0.889	0.666	0.944	0.819
ARTICULAR SURFACE (TIBIA)	0.841	0.398	0.957	0.880
MENISCUS	0.924	0.740	0.949	0.737
PATELLO-FEMORAL JOINT	0.788	0.696	0.981	0.844

Results: Safety

No adverse events were attributed to VSI during the study.

Conclusions

In the diagnosis of intra-articular knee pathologies, VSI proven to be:

- **Comparable to diagnostic arthroscopy**
- **More detailed and accurate than MRI**

Significance of Findings

When evaluating intra-articular pathologies of the knee:

VSI is an accurate, real time, minimally-invasive diagnostic modality that can be performed in the office.