

Abstract

Objective: the purpose of this study was to determine if pneumatic compression of the knee joint could displace synovial fluid from various compartments into an access port resulting in a larger volume of fluid available for diagnostic arthrocentesis or therapeutic injections.

Methods: Thirty seven patients who had previously received an arthrocentesis and or a therapeutic injection using a pneumatic compression device were asked to participate in a prospective ultrasound study to quantify displacement of synovial fluid into an access port during inflation versus deflation. All patients had US imaging performed by the same physician but Digital image analysis of the US images were analyzed blinded by another investigator for quantification of anechoic fluid region by area and liner distance from the bone to the superior joint capsule region.

Results: 40 knees form 37 patients of median age 59 years were evaluated for fluid shifts during inflation to 100 mmHg and immediately following deflation. These 28 females and 8 male patients had an average BMI of 26.9 and had the following primary diagnoses: 24 with RA, 9 with osteoarthritis, 2 with psoriatic arthritis, and 1 each with SLE and Gout. All patients had some increase in fluid into the access hole during inflation. The average increase during inflation vs deflation was 2.5 to 3.5 increase in area and 2-3 fold increase in fluid depth range.

Conclusion: This ultrasound study demonstrates that a pneumatic knee compression device significantly increases the synovial fluid available for needle aspiration and or therapeutic injection. The larger area of synovial fluid which is also under positive pressure should allow clinicians a greater chance of success reaching the synovial space during arthrocentesis or injections versus traditional anatomical landmark based techniques.

Background

- Arthrocentesis is a common in office procedure used to determine if a joint effusion is due to; inflammatory Arthritis (such as RA), crystal arthritis, infection , traumatic or degenerative (OA)
- Joint injection of therapeutic agents include:
 - CMS Reimbursed: glucocorticoids , viscosupplementation products
 - Non CMS Reimbursed: biologic agents or regenerative therapeutics (Platelet rich plasma, and bone marrow or adipose derived stem cells.
- Using standard landmark based injection techniques, clinicians may actually miss the intra-articular joint space of the knee up to 70% of attempts.(*Maricar N, et al . Seminars in Arthritis and Rheum 2013;43:195-203*).
- Accuracy can be improved by direct imaging which has limitations
 - fluoroscopy which is expensive and results in radiation risk
 - Ultrasound guided direct visualization is time consuming, requires additional training and expense of an US machine.

Hypothesis

A. External applied pneumatic compression to the knee will result in fluid displacement during inflation from the various compartments (superior, inferior, posterior and medial or lateral) into a target access port.

B. The resulting increase in fluid volume shifted into a needle access port can be detected by quantitative image analysis of the anechoic area by ultrasound during inflation to 100 mg Hg vs deflation of the device.

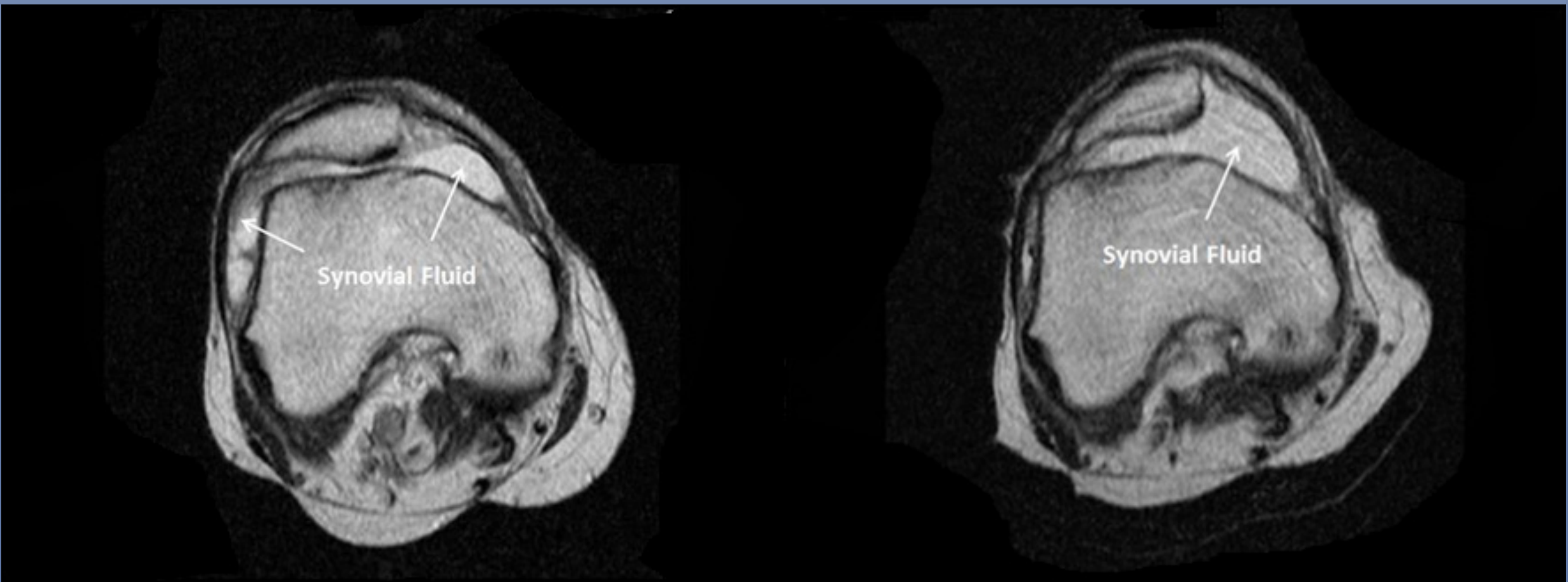


Figure 1: Device Deflated

Figure 2: Device Inflated

Study Methods

- Images were analyzed in Matlab 2015a.
- The anechoic region was first estimated using the *imfreehand* tool.
- A histogram equalization, followed by a 3x3 pixel Gaussian filter was applied
- The resulting image within the estimated region of interest (ROI) was converted to a binary image by solving for the threshold which minimizes intra-class pixel intensity variance (Otsu’s Method).
- Observations are paired, thus paired t-tests were conducted on:
 - Change in Depth
 - Change in Area
 - Ratio of Depth
 - Ratio of Area



Figure 3: Device Deflated

Figure 4: Device Inflated

Patient Demographics

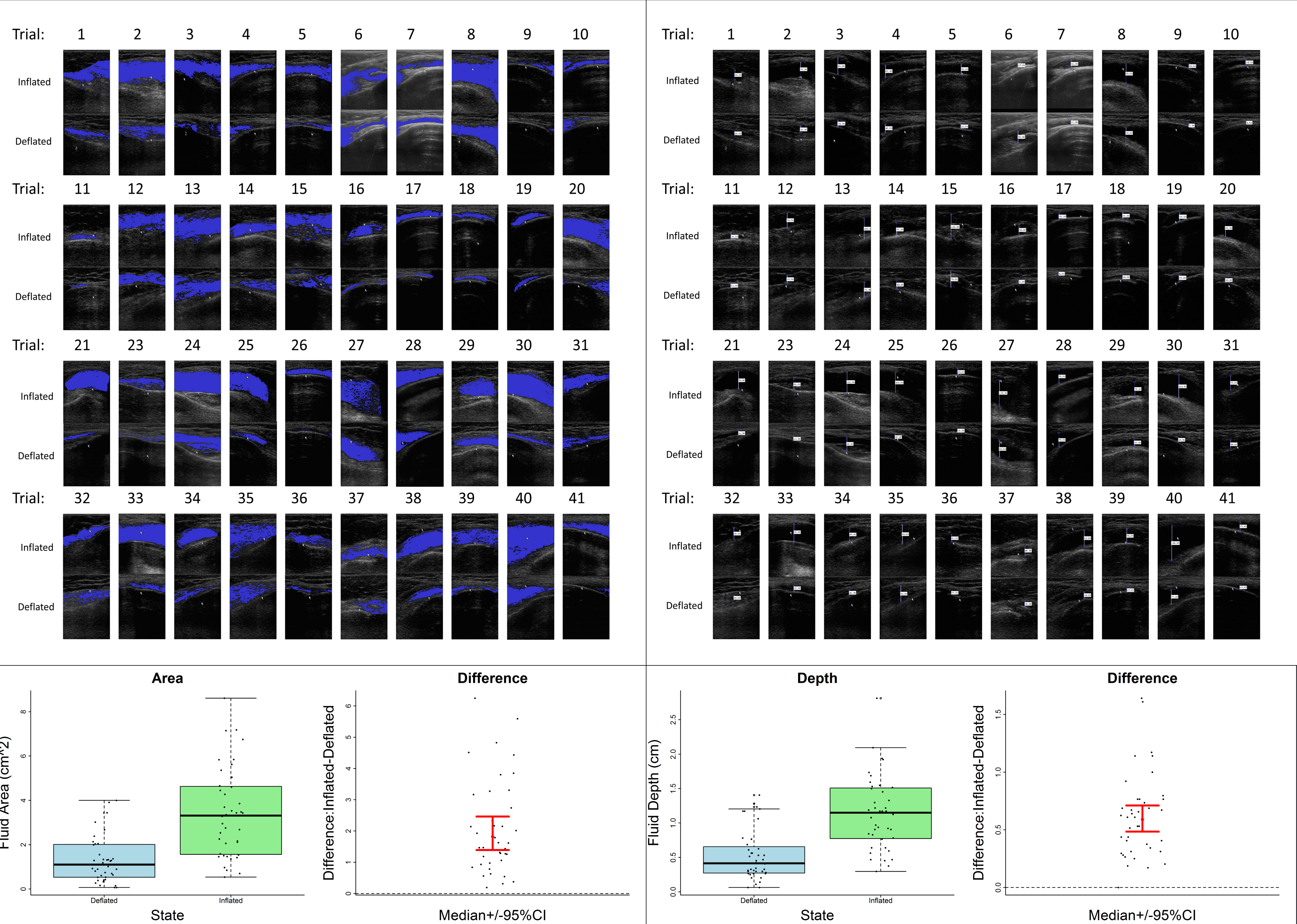
Mean Age (Years)		58.6	(23-86) range
Mean BMI (Kg/m ²)		26.9	(19-35.6) range
Gender			
	Male	9	
	Female	28	
Diagnosis			
	RA	25	
	OA	8	
	PsA	2	
	SLE	1	
	Gout	1	
Site			
	Left Knee	22	
	Right Knee	19	
	Medial	26	
	Lateral	15	
	Bilateral	3	

Analysis Methods

- Images were analyzed in Matlab 2015a. The anechoic region was first estimated using the *imfreehand* tool.
- A histogram equalization, followed by a 3x3 pixel Gaussian filter was applied
- The resulting image within the estimated region of interest (ROI) was converted to a binary image by solving for the threshold which minimizes intra-class pixel intensity variance (Otsu’s Method).
- Depths were measured manually.

Results

- 40 knees form 37 patients were evaluated for fluid shifts during inflation to 100 mmHg and immediately following deflation.
- All patients had some increase in fluid into the access hole during inflation.
- The average increase during inflation vs deflation was 2.5 to 3.5 increase in area and 2-3 fold increase in fluid depth range.
- All paired t-tests were significant (p<0.0001)



Conclusions and Disclosures

- This ultrasound study demonstrates that a pneumatic knee compression device using positive pressure significantly increases the synovial fluid volume available for needle aspiration and or therapeutic injection.
- Disclosures.
 - Funding by Colorado Office of economic Development Grants; Biologic Discovery Evaluation Grant and Phase I and II Advanced Industry Accelerator grants to E Hoffman and R Meehan
 - US Patent 7,4688.048 B2 awarded to NJH, (R Meehan inventor)
 - NJH License awarded to Arthroventions LLC (E Hoffman and R Meehan) for commercial development