A RANDOMIZED, CONTROLLED TRIAL OF THE RECIPROCATING SYRINGE IN ARTHROCENTESIS

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Running Title: Reciprocating Syringe

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This paper was submitted in abstract form to American College of Rheumatology Annual Meeting, San Diego, CA, 2005.
**Objective:** To evaluate the outcomes of arthrocentesis with the new highly controllable, one-handed reciprocating procedure syringe compared to a conventional syringe.

**Methods:** 100 arthrocentesis procedures were randomized between the reciprocating syringe and the conventional syringe. Outcome measures included patient pain, procedure duration, operator satisfaction, synovial fluid volume, cell counts, and complications.

**Results:** 50 arthrocentesis procedures with the conventional syringe resulted in a mean procedure time of 3.39± 1.88 minutes, a mean VAPS (patient pain) score of 5.35 ± 3.15, and a mean VASS (operator satisfaction) score of 4.88± 1.92. 30/50 subjects experienced moderate to severe pain (VAPS score 5 or greater) during arthrocentesis. In contrast, the reciprocating syringe resulted in a reduced procedure time of 1.94± 1.14 minutes (p<0.001), a reduced VAPS (patient pain) score of 2.54± 1.60 (p<0.001), and an increased VASS (operator satisfaction) score of 8.91± 0.79 (p<0.001). Only 5/50 of subjects experienced moderate to severe pain with the reciprocating syringe. Synovial cell counts were similar between the two syringes (p > 0.05), but there was a trend toward greater volume (greater synovial fluid yield) and fewer red blood cells with the reciprocating syringe.

**Conclusions:** Arthrocentesis with a conventional syringe results in moderate to severe pain in 60% of subjects. The reciprocating syringe prevents significant pain, reduces procedure time, and improves physician performance of arthrocentesis. The reciprocating syringe is superior to the conventional syringe in arthrocentesis.
Introduction

Arthrocentesis is the single most important invasive procedure in musculoskeletal medicine (1,2). Arthrocentesis is essential for the diagnosis of septic arthritis and inflammatory joint disease, and is the basic underlying procedure for intraarticular therapy, including therapeutic arthrocentesis, needle lavage, and intraarticular injection of therapeutic substances (3-13).

Recently the Food and Drug Administration (FDA) has formally approved the highly controllable, one-handed reciprocating procedure syringe (14). The reciprocating incorporates a reciprocating plunger mechanism that permits the index and middle fingers to remain in one position during aspiration and injection, while the thumb moves horizontally to the alternative plunger in order to change the direction of aspiration or injection. Due to these favorable performance characteristics, we hypothesized that reciprocating syringe would improve physician performance of arthrocentesis.

Patients and Methods:

Subjects: This project was approved by the institutional review board (IRB). 26 physicians who regularly perform syringe procedures performed 100 arthrocentesis procedures on 46 individual patients who required a diagnostic or therapeutic arthrocentesis for their usual and customary medical care. The mean age of the physicians was 38.8±15.7 years, indicating that the physicians were generally in early to mid career, but the group as a whole had considerable syringe experience with a mean of 13.6±13.9 years of syringe experience and 1002±1390 mean syringe procedures each. The physicians performed a mean of 8.4±7.1 syringe procedures per week, indicating that the test group was an active, practiced group of physicians. There were more male (65%) than female physicians (35%), representative of the local physician population. In each case, patients were individually consented both to the arthrocentesis as required for all procedures, and to the IRB-approved research protocol. The mean age of the subjects was 47.3±15.0 years. The great majority of subjects (76%) had rheumatoid arthritis and the remainder other diagnoses. The 100 syringe procedures included arthrocentesis of the knee (39%), small joints of the fingers (26%) (proximal interphalangeal, metacarpophalangeal, and carpometocarpal joint), the shoulder (17%), and other joints (18%). In each case, each procedure was randomized to either the conventional or reciprocating syringe. If the subject had more than one joint that required arthrocentesis, then each joint was randomized between the reciprocating and conventional syringes. 91% (41/46 subjects) had had a previous arthrocentesis with a conventional syringe before entry into the study, 31 % (14/46) had more than one joint aspirated and randomized between the two syringes during the same visit, and 19% (9/46) had more than one arthrocentesis on two different occasions randomized between the two syringes. The final proportion of arthrocentesis procedures in individual joints within each treatment group were statistically equivalent.

Syringes: The conventional syringe was a 10 ml Luer-Lok™ BD syringe (Ref 309604, Becton Dickenson & Co., Franklin Lakes, NJ 07417). The reciprocating procedure syringe used in these experiments was the recently FDA-approved 10 ml reciprocating syringe (The RECIPROCATOR Procedur-10, AVANCA Medical Devices, Inc, 801 University Blvd SE, Albuquerque, NM 87106, website: www.AVANCAMedical.com).
Arthrocentesis: Arthrocentesis was performed in a standardized manner in a customary fashion (15-21).

Outcome Data of Clinical Procedures: A non-operating observer timed each clinical procedure (minutes), and queried the patient in real time regarding pain and after the procedure queried the physician in terms of satisfaction with the syringe used in the procedure. Patient pain was determined with the standardized and validated Visual Analogue Pain Scale (VAPS) where 0 cm = no pain and 10 cm = unbearable pain (22,23). The VAPS was obtained twice during the procedure - after the anesthesia portion and directly after the arthrocentesis portion, and a mean VAPS score was obtained by averaging both VAPS scores together. Moderate to severe pain was defined as a VAPS greater or equal to 5. Operator satisfaction with the syringe after the procedure was determined with the Visual Analogue Satisfaction Scale (VASS) where 0 cm = completely dissatisfied with the performance of the procedure syringe and 10 cm = completely satisfied with the performance of the procedure syringe (24, 25). Final clinical outcomes were determined 1) directly at the conclusion of the procedure and 2) at 2 weeks after the procedure. Synovial fluid outcome measures included culture results, cell count, cell differential counts, crystal examination, and volume determination.

Statistical Analysis: Data were entered into Excel (Version 5, Microsoft, Seattle, WA), and analyzed in SAS (SAS/STAT Software, Release 6.11, Cary, NC). Differences between parametric two group data were determined with the t-test. Differences in categorical data were determined with Fisher’s Exact Test, while differences between multiple parametric data sets were determined with Fishers Least Significant Difference Method. Corrections were made for multiple comparisons. Correlations between parametric data were determined with logistic regression and between non-parametric data with Spearman correlation and Kendall rank method.

Results

At the conclusion of the study, the physicians had more experience with the conventional syringe (1002 ± 1390 total conventional syringe procedures) than with the reciprocating syringe (3.6 ± 4.6 total reciprocating syringe procedures, p < 0.001)

The overall outcomes of the clinical syringe procedures are shown in Table 1. 100 arthrocentesis procedures were randomized to either the reciprocating syringe or the conventional syringe, resulting in 50 procedures for conventional syringe and 50 for the reciprocating syringe. Overall in arthrocentesis procedures, the reciprocating syringe resulted in reduced procedure time compared to the conventional syringe (Reciprocating Syringe: 1.94±1.14 min, Conventional Syringe: 3.39±1.88, p <0.001), reduced patient pain (Reciprocating Syringe VAPS score: 2.54±1.60; Conventional Syringe VAPS score: 5.35 ±3.15; p < 0.001), and improved physician satisfaction (Reciprocating Syringe VASS Score: 8.91±0.79, Conventional Syringe 4.88±1.92, p < 0.001). Thus, relative to a conventional syringe, the reciprocating syringe resulted in a 43% reduction in procedure duration (p<0.001), 53% reduction in patient pain (p<0.001), and an 83% percent increase in operator satisfaction with syringe performance (p<0.001). 60% of subjects (30/50) experienced moderate to severe pain during arthrocentesis with the conventional syringe, while only 10% (5/50) of subjects experienced moderate to severe pain with the reciprocating syringe.

Immediately after these procedures and at 2 weeks, there were no complications in any patient, and outcomes were good to excellent in all patients with both the
reciprocating or conventional syringes (Table 1). There were no statistically significant differences in cell counts, including white blood cells, red blood cells, neutrophils, lymphocytes, and monocytes (Table 2). However, there was a trend to greater synovial fluid yield (volume) and fewer red blood cells with the reciprocating syringe. One subject with the conventional syringe had a positive synovial fluid culture for *Neisseria gonorrhoea*.

**Discussion**

This study represents the first large randomized clinical trial with the reciprocating syringe in invasive syringe procedures, and demonstrates measurably better outcomes in the case of arthrocentesis. The reciprocating syringe resulted in a 43% reduction in procedure duration (p<0.001), 53% reduction in patient pain (p<0.001), and an 83% percent increase in operator satisfaction with syringe performance (p<0.001) (Table 1). Significant patient pain was reduced from 60% to 10%, indicating a 84% effectiveness in preventing moderate to severe pain during arthrocentesis. Synovial fluid characteristics were similar between the two syringes (Table 2), but there was a trend towards greater synovial fluid yield and fewer red blood cells with the reciprocating syringe. The improvement in physician performance in terms of procedure duration and reduced patient pain with the reciprocating syringe could not be attributed to practice effects, as the physicians had on average 278 times more practice with the conventional syringe.

An important finding to this study is the unexpectedly high degree of pain that patients experience during arthrocentesis with mean pain scores (VAPS scores) greater than or equal to 5, indicating moderate to severe pain in many patients (Table 1). This study used local anesthesia with lidocaine which has been shown to be superior to that provided by ethyl chloride (21); despite this, the patients experienced considerable pain. With the conventional syringe and individual patients, 30 out of 50 (60%) subjects reported individual pain scores (VAPS scores) of 5 or greater. This is far more pain that most musculoskeletal experts commonly believe that patients experience with arthrocentesis. However, pain with arthrocentesis has not been rigorously measured prior to this study, and this rigorous characterization of pain is one of the most important findings of this study. Poor control of the needle may be a significant cause of pain in arthrocentesis (26-29), and this degree of pain is certainly a major reason why pediatric patients abhor arthrocentesis (30-32). Due to the significant reduction in pain, the reciprocating syringe may be of particular value in pediatric syringe procedures, in individuals with known needle phobia or vasovagal responses to pain, and in individuals allergic to local anesthetics (33,34,35).

The conventional syringe is still commonly used for even the most difficult syringe procedures in most fields of medicine. Despite the recognized instability and danger of conventional syringes, the major reason for persistence of conventional syringes in procedures is the low cost of conventional syringes and the lack of an effective alternative. However, as noted in this study, the conventional syringe is associated with significantly greater patient pain, longer procedure times, and reduced physician satisfaction - all indicating a fundamental design inadequacy for syringe procedures.

The reciprocating syringe is formed around the core of a conventional syringe barrel and plunger, but has a parallel accessory plunger and an accessory barrel or track.
to control the motion of the accessory plunger. The two plungers are mechanically linked in an opposing fashion, resulting in a set of reciprocating plungers. Thus, when one plunger is depressed with the thumb, the syringe injects and when the accessory plunger is depressed with the same thumb, the syringe aspires. This permits the index and middle fingers to remain in one position during both aspiration and injection, while the thumb only needs to move in a horizontal plane to the alternative plunger in order to change the direction of aspiration or injection. This permits the powerful and exquisitely well-controlled flexor musculature of the hand and forearm to be used for both injection and aspiration. These characteristics of stable finger positioning and the exclusive use of the flexor musculature create a powerful and finely controlled one-handed device. A one-handed procedure syringe would have obvious applications in ultrasound-guided arthrocentesis where a free hand is needed for the ultrasound transducer, and in applying vacuum for synovial and deep tissue biopsy (36-46).

In terms of procedure time, patient pain, and operator satisfaction during arthrocentesis, the reciprocating syringe is clearly superior to the conventional syringe (Table 1). Synovial fluid analysis (Table 2) suggests that a larger study may also demonstrate greater synovial fluid yield (volume) and higher quality (less blood contamination) with the reciprocating syringe. Further study of this new class of reciprocating interventional devices in specific procedures will be required to determine specific indications and future applications of this new technology to the broad field of syringe procedures in musculoskeletal medicine.

Competing Interests
None of the authors have a competing interest in this study, including no patents, stock interests, royalties, consulting interests, grants, or other financial interests.

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Sponsor Support
This study was performed with internal resources of the University of New Mexico Health Sciences Center, and donated time and resources of the investigators. AVANCA Medical Devices, Inc. donated the reciprocating syringes.

Ethics Approval and Patient Consent
This study was approved by the institutional review board (Human Research Review Committee) and all individual subjects provided informed written consent.

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References

Table 1. Outcome of 100 Arthrocentesis Procedures Randomized to Either the Conventional Syringe or the Reciprocating Syringe

<table>
<thead>
<tr>
<th></th>
<th>Conventional</th>
<th>Reciprocating</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Procedures</td>
<td>50</td>
<td>50</td>
<td>Not significant</td>
</tr>
<tr>
<td>Procedure Time (minutes)</td>
<td>3.39± 1.88</td>
<td>1.94± 1.14</td>
<td>P&lt;0.001</td>
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<tr>
<td>Patient Pain (VAPS)</td>
<td>5.35 ± 3.15</td>
<td>2.54 ± 1.60</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Physician Satisfaction (VASS)</td>
<td>4.88± 1.92</td>
<td>8.91± 0.79</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Successful Immediate Outcome (good to excellent)</td>
<td>100%</td>
<td>100%</td>
<td>Not significant</td>
</tr>
<tr>
<td>Successful Outcome at 2 weeks (good to excellent)</td>
<td>100%</td>
<td>100%</td>
<td>Not significant</td>
</tr>
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</table>
Table 2. Synovial Fluid Analysis from the Knee with the Reciprocating and Conventional Syringes

<table>
<thead>
<tr>
<th></th>
<th>White blood cell/mm³</th>
<th>Neutrophil %</th>
<th>Monocyte %</th>
<th>Lymphocyte %</th>
<th>Red blood cells/mm³</th>
<th>Volume ml</th>
<th>Number of knee fluid samples</th>
</tr>
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<tr>
<td>Conventional Syringe</td>
<td>11439±9786</td>
<td>60.6±35.5</td>
<td>27.8±25.4</td>
<td>11.7±10.7</td>
<td>49222±79513</td>
<td>8.89±2.47</td>
<td>9</td>
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<tr>
<td>Reciprocating Syringe</td>
<td>16950±14089</td>
<td>59.7±25.8</td>
<td>29.7±27.8</td>
<td>8.29±5.54</td>
<td>14832±14906</td>
<td>13.26±6.47</td>
<td>9</td>
</tr>
<tr>
<td>Significance</td>
<td>P = 0.20</td>
<td>P = 0.91</td>
<td>P = 0.65</td>
<td>P = 0.49</td>
<td>P = 0.24</td>
<td>P = 0.06</td>
<td></td>
</tr>
</tbody>
</table>
Legends for Figures:

**Figure 1. One-handed Use of the Reciprocating Syringe for Musculoskeletal Procedures.** This photograph demonstrates the reciprocating syringe being used in a one-handed fashion for aspiration and injection of the glenohumeral joint. The larger plunger is depressed with the thumb for injection and the smaller plunger is depressed with the thumb for aspiration. The free hand is used to steady the patient, feel the surface anatomy, or operate other devices.

**Figure 2. One-handed Use of the Reciprocating Syringe for Aspiration of a Large Shoulder Effusion.** This photograph demonstrates the reciprocating syringe being used in a one-handed fashion for aspiration and drainage of a shoulder effusion. The larger plunger is depressed with the thumb for injection and the smaller plunger is depressed with the thumb for aspiration. As shown here the smaller plunger is depressed for continuous aspiration. The free hand is used to feel, steady, and apply pressure to the effusion or operate an ultrasound transducer.
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