# Physician Control of Needle and Syringe During Aspiration-Injection Procedures with the New Reciprocating Syringe

WILMER L. SIBBITT Jr, RANDY R. SIBBITT, ADRIAN A. MICHAEL, DRUCE I. FU, HILDA T. DRAEGER, JON M. TWINING, and ARTHUR D. BANKHURST

ABSTRACT. Objective. To evaluate physician control of needle and syringe during aspiration-injection syringe procedures by comparing the new reciprocating procedure syringe to a traditional conventional syringe. Methods. Twenty-six physicians were tested for their individual ability to control the reciprocating and conventional syringes in typical aspiration-injection procedures using a novel quantitative needle-based displacement procedure model. Subsequently, the physicians performed 48 clinical aspiration-injection (arthrocentesis) procedures on 32 subjects randomized to the reciprocating or conventional syringes. Clinical outcomes included procedure time, patient pain, and operator satisfaction. Multivariate modeling methods were used to determine the experimental variables in the syringe control model most predictive of clinical outcome measures.

**Results**. In the model system, the reciprocating syringe significantly improved physician control of the syringe and needle, with a 66% reduction in unintended forward penetration (p < 0.001) and a 68% reduction in unintended retraction (p < 0.001). In clinical arthrocentesis, improvements were also noted: 30% reduction in procedure time (p < 0.03), 57% reduction in patient pain (p < 0.001), and a 79% increase in physician satisfaction (p < 0.001). The variables in the experimental system — unintended forward penetration, unintended retraction, and operator satisfaction — independently predicted the outcomes of procedure time, patient pain, and physician satisfaction in the clinical study (p < 0.001). **Conclusion**. The reciprocating syringe reduces procedure time and patient pain and improves operator satisfaction with the procedure syringe. The reciprocating syringe improves physician performance in both the validated quantitative needle-based displacement model and in real aspiration-injection syringe procedures, including arthrocentesis. (First Release Mar 1, 2006; J Rheumatol 2006;33:771-8)

Key Indexing Terms: SYRINGE SYNOVIAL

PROCEDURE INJECTION ARTHROCENTESIS RECIPROCATING

Syringes are used in rheumatology, orthopedic surgery, interventional radiology, pediatrics, and internal medicine to aspirate joint and tissue fluids, to inject medications and fluids, and to provide vacuum to obtain tissue biopsies<sup>1-13</sup>. Syringe

From the Department of Internal Medicine, University of New Mexico Health Sciences Center, Albuquerque, New Mexico; Department of Emergency Medicine, Maricopa Medical Center, Phoenix, Arizona; and Department of Radiology, St. Peter's Hospital, Helena, Montana, USA.

AVANCA Medical Devices, Inc., Albuquerque, NM, donated the syringes for this study.

W.L. Sibbitt Jr, MD, Professor of Internal Medicine and Neurology, University of New Mexico Health Sciences Center; R.R. Sibbitt, MD, Director, Interventional Radiology, St. Peter's Hospital; A.A. Michael, MD, Resident, Internal Medicine, University of New Mexico Health Sciences Center; D.I. Fu, MD, Resident, Department of Emergency Medicine, Maricopa Medical Center; H.T. Draeger, MD, Fellow; J.M. Twining, MD, Fellow; A.D. Bankhurst, MD, Professor of Internal Medicine, University of New Mexico Health Sciences Center.

Address reprint requests to Dr. W.L. Sibbitt Jr, Department of Internal Medicine, 5th Floor ACC, Division of Rheumatology, University of New Mexico Health Sciences Center, Albuquerque, NM 87131. E-mail: wsibbitt@salud.unm.edu

Accepted for publication November 25, 2005.

procedures comprise some combination of the elements of (1)pure aspiration (as in arthrocentesis or suction biopsy), (2) pure injection (as injection of corticosteroid into a joint space), or (3) both aspiration and injection (as in local lidocaine anesthesia, bursal or trigger point injection, or singlesyringe joint injections)<sup>14-38</sup>. The traditional conventional syringe, although widely used for both aspiration and injection, is actually designed only for injection. During injection, the conventional syringe is ergonomically held in one hand between the index and middle fingers with the thumb on the plunger, which is depressed by the powerful and exquisitely well controlled flexor muscles of the hand and forearm. As the plunger is depressed, the axial dimension (length) of the barrel-plunger complex decreases, which reduces the possibility of loss of control of the syringe in the forward direction. Thus, the traditional conventional syringe is extremely well controlled and ergonomic in the injection phase.

In contrast, during aspiration, the conventional syringe is very difficult to control. The barrel is held in position with one hand and the plunger is pulled back with the other hand using the powerful, but coarsely controlled musculature of the upper

arms and shoulders. During aspiration, the syringe becomes longer, predisposing to loss of control in the forward direction. Moreover, because the coarsely controlled musculature of the upper arm and shoulder are used and the flexor muscles dominate over the extensors, there is a tendency to also lose control of the syringe in the reverse direction — unintended retraction. Thus, the conventional syringe during aspiration is an extremely poorly controlled and non-ergonomic device. Poor control of a syringe may result in a prolonged procedure time, increased patient pain, a failed procedure, unintended perforation of a blood vessel or other complication, poor sample retrieval, and delayed diagnosis<sup>27-38</sup>.

Recently the US Food and Drug Administration (FDA) approved the highly controllable, one-handed reciprocating procedure syringe<sup>39</sup>. The favorable control and ergonomic aspects of the traditional syringe discussed above are present in the reciprocating syringe, but unlike the traditional syringe they are present in both the aspiration and injection phases. We hypothesized that the improved control characteristics of the reciprocating syringe would (1) improve physician control of needle and syringe during syringe aspiration-injection procedures, in particular, arthrocentesis relative to the conventional syringe.

#### MATERIALS AND METHODS

Subjects. This project was approved by the institutional review board (IRB). In each case, patients individually consented both to the arthrocentesis as required for all procedures and to the IRB-approved research protocol. Twenty-six physicians who regularly perform syringe procedures performed 48 arthrocentesis procedures on 32 individual patients who required a diagnostic or therapeutic arthrocentesis for their usual and customary medical care. The proportion of patients with specific diagnoses in the entire patient population were as follows: 79% rheumatoid arthritis, 13% osteoarthritis, and 8% other diagnoses. Physician characteristics are shown in Table 1. Twentysix physicians (5 orthopedic surgeons, 9 rheumatologists, 1 interventional radiologist, 1 family practice, 3 internists, and 9 internal medicine residents) participated in this study, providing a broad range of experience in terms of syringe procedures. Mean physician age was 38.8 ± 15.7 years, 65% were male and 35% female, with  $13.6 \pm 13.9$  years of mean syringe procedure experience, and performing an average of 8.4 ± 7.1 aspiration-injection procedures per week (Table 1). It was the intentional design of this study to study physicians with differing levels of past and present syringe experience.

Table 1. Physician characteristics and syringe experience.

No. of physicians	26		
Mean age, yrs	$38.8 \pm 15.7$		
Male, %	65		
Female, %	35		
Years of syringe experience	$13.6 \pm 13.9$		
Mean no. syringe procedures/ week	8.4 ± 7.1		
No. of physician lifetime syringe procedures	Conventional $1002 \pm 1390$	Reciprocating $3.6 \pm 4.6$	p < 0.001
Physician satisfaction with syringes (0–10 analog scale)	Conventional $3.6 \pm 2.0$	Reciprocating $9.1 \pm 0.8$	p < 0.001

Each physician participant completed (1) the testing model protocol and (2) at least one clinical aspiration-injection procedure. Each participant used both the conventional and reciprocating syringes in the testing model, providing paired data. However, in the clinical trial, the physicians used either reciprocating syringe or the conventional syringe, providing unpaired 2-group data. Paired data for correlative analysis was obtained by combining both studies where performance by an individual physician with a particular syringe in the testing model could be compared directly to performance of that same physician with that same syringe in the clinical syringe procedure. Precise measurement of syringe and needle control by the physician. A novel quantitative needle-based displacement procedure model was used to precisely measure syringe and needle control by the individual physician. In free space a syringe can be unstable in an axial (forward-reverse) or radial (horizontal plane) direction. However, once the needle has penetrated the tissues the radial (horizontal plane) motion is essentially restricted by the surrounding tissues, and the axial (forward-reverse) instability becomes the dominant process in terms of needle control. In this measurement system, a layer of 1.3 cm thick open-cell flexible polystyrene foam simulates the target tissue. The foam layer is held in place with Velcro constraints and is affixed to a rigid backing that is held upright with a rigid frame (Figure 1). A 20-gauge 11/2 inch hypodermic needle (20G1-1/2 PrecisionGlide Needle, Recorder No. 305176, Becton Dickenson & Co., Franklin Lakes, NJ 07417, USA) is placed on the syringe and a fresh needle is used for each procedure. A rigid polystyrene marker is placed on the needle to a preset indelible mark on the needle at 4 mm, and then the needle is advanced into the target tissue (foam) until the polystyrene marker is touching the surface of the target tissue. The physician operator then performs the syringe procedure. Loss of control in the forward direction (penetration) pushes the polystyrene marker posteriorly on the needle past the indelible mark, permitting precise measurement in mm of loss of control in the forward direction. Loss of control in the reverse direction (retraction) lifts the polystyrene marker off the surface of the target tissue, exposing a length of the needle shaft (a "pull-back"), indicating loss of control in mm in the reverse direction (retraction). The number of "pull-backs" for 5 cycles of the syringe were counted and summed, and this total number of pull-backs was used as a quantitative measure of retraction loss of control in the reverse direction.

Individual procedures included (1) an aspiration-injection procedure consisting of injection with 10 ml of air and then aspiration of 10 ml of air against ambient pressure; and (2) aspiration against vacuum to -325 mm Torr (mm Hg vacuum). These maneuvers were performed for 5 cycles each with a conventional syringe operated with 2 hands, a conventional syringe operated with one hand, and the reciprocating syringe operated with one hand. The order of each maneuver with each syringe was randomized so as not to induce a consistent bias.

*Syringes.* The conventional syringe was a 10 ml Luer-Lok<sup>TM</sup> BD syringe (Ref 309604, Becton Dickinson). The reciprocating procedure syringe used in these experiments was the 10 ml reciprocating syringe (the Reciprocator Procedur-10, generously donated by AVANCA Medical Devices, Inc., 801 University Blvd. SE, Suite 102, Albuquerque, NM 87106, USA; website: www.AVANCAMedical.com), recently approved by the FDA. The reciprocating syringe was operated with one hand.

*Clinical syringe procedures.* The aspiration-injection syringe procedures consisted of 48 arthrocentesis procedures with local anesthesia randomized between the 2 test syringes (the reciprocating syringe and the conventional syringe; Figure 2). Arthrocentesis was performed in a standardized manner after a customary fashion with lidocaine anesthesia, and included joints in equivalent proportions between the 2 groups [Reciprocating vs Conventional: knee (37% vs 42%); small joints of fingers (29% vs 23%); shoulder (14% vs 19%), and all other (20% vs 16%)<sup>39-46</sup>]. Synovial fluid obtained was sent for culture, cell count, and crystal examination.

*Outcome data of clinical procedures.* A non-operating observer timed each clinical procedure (minutes), queried the patient in real time regarding pain, and queried the physician after the procedure in terms of satisfaction with the syringe used in the procedure. Patient pain was determined with the stan-



*Figure 1.* Method for measuring physician control of needle and syringe. The reciprocating syringe held with one hand. The foam target is shown only anteriorly. The rigid polystyrene marker is placed on the needle to a preset 4 mm indelible mark on the needle shaft, and then the needle is advanced into the target tissue (foam) until the polystyrene marker is touching the surface of the target tissue. The physician operator then performs the syringe procedure. Loss of control in the forward direction (penetration) pushes the polystyrene marker posteriorly on needle shaft past the indelible mark, permitting precise measurement in mm of loss control in the forward direction. Loss of control in the reverse direction (retraction) lifts the polystyrene marker off the surface of the target tissue, exposing a length of the needle shaft, permitting precise measurement of loss of control in the reverse direction (retraction).

dardized and validated visual analog scale for pain (VAS-P), where 0 cm = no pain and 10 cm = unbearable pain<sup>47,48</sup>. The VAS-P was obtained twice during the procedure — after the anesthesia portion and directly after the arthrocentesis portion, and a mean VAS-P score was obtained by averaging both VAS-P scores together. Operator satisfaction with the syringe after the procedure was determined with the VAS for satisfication (VAS-S), where 0 cm = completely dissatisfied with the performance of the procedure syringe <sup>49,50</sup>. Final clinical outcomes were determined (1) directly at the conclusion of the procedure, and (2) by review of the medical records, including laboratory tests, and a telephone call to the patient at 2 weeks after the procedure.

*Statistical analysis.* Data were entered into Excel (Version 5; Microsoft, Seattle, WA, USA) and analyzed in SAS (SAS/STAT Software, Release 6.11; SAS, Cary, NC, USA). Differences in categorical data were determined with Fisher's exact test, and differences in parametric data with the t test, while differences between multiple parametric data sets were determined with Fisher's least significant difference method. Corrections were made for multiple comparisons. Correlations between parametric data with Spearman correlation and Kendall rank method.

## RESULTS

*Precise measurement of physician control of needle and syringe*. Table 2 gives data for physician performance in terms of needle control with each syringe and technique. In terms of unintended penetration (loss of control in the forward direction) during the aspiration-injection procedure, the conven-

tional syringe used with one hand was the most poorly controlled (16.1  $\pm$  7.2 mm mean penetration), and the conventional syringe used with 2 hands was the next most poorly controlled (12.5  $\pm$  7.1 mm mean penetration), while the reciprocating syringe used with one hand was the best controlled (5.4  $\pm$  4.8 mm mean penetration; p < 0.001). Thus, the reciprocating syringe reduced unintended penetration (loss of control in the forward direction) by 68% and 57%, respectively, relative to the conventional syringe used with one hand or 2 hands. Similar reductions in retraction (loss of control in the reverse direction) were also noted (Table 2).

Table 3 gives data for physician performance in syringe and needle control during a pure aspiration procedure against a vacuum with each syringe. In terms of unintended penetration (loss of control in the forward direction), the conventional syringe used with one hand was the most poorly controlled by the physician operators ( $18.5 \pm 8.3$  mm mean penetration) and the conventional syringe used with 2 hands was the next most poorly controlled ( $11.9 \pm 8.7$  mm mean penetration), while the reciprocating syringe used with one hand was the best controlled ( $6.5 \pm 3.8$  mm mean penetration; p < 0.001). Thus, during a pure aspiration procedure against vacuum the reciprocating syringe reduced forward loss of control (penetration) by 65% and 45%, respectively, relative to the conven-

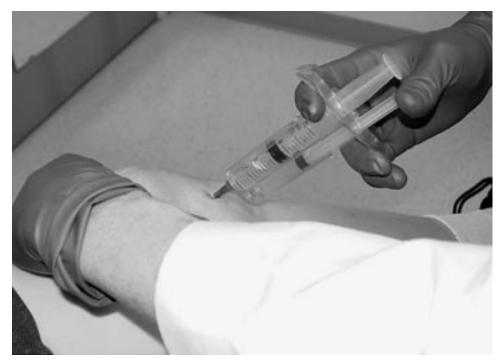


Figure 2. One-handed use of the reciprocating syringe for arthrocentesis. This photograph demonstrates the reciprocating syringe used in a one-handed fashion for aspiration and drainage of a knee effusion. The larger plunger is depressed with the thumb for injection and the smaller plunger is depressed with the thumb for aspiration. As shown here, the smaller plunger is depressed for continuous aspiration. The free hand is used to feel anatomy, steady the extremity or syringe, apply pressure to the effusion, or to operate an ultrasound transducer. Here the free hand is being used to steady the extremity and to apply tactile pressure to the effusion to assist in fully draining the knee effusion.

### Table 2. Physician loss of control of syringe and needle.

Aspiration-					
Injection	receptorating contribution control		Conventional	in children	
Against			Syringe		
Atmosphere	One-handed	One-handed	р	2-handed	р
Penetration, mm	$5.4 \pm 4.8$	$16.1 \pm 7.2$	< 0.001	$12.5 \pm 7.1$	< 0.00
Retraction (no. of pullbacks)	$2.23 \pm 1.7$	$4.0 \pm 1.3$	< 0.001	$2.6 \pm 1.6$	NS
Failure (unable to perform					
procedure)	None	None	NS	None	NS
Pure Aspiration Procedure					
Aspiration	Reciprocating	Conventional	Conventional		
Against	Syringe	Syringe	Syringe		
Vacuum	One-handed	One-handed	р	2-handed	р
Penetration, mm	$6.5 \pm 3.8$	$18.5 \pm 8.3$	< 0.001	11.9 ± 8.7	< 0.01
Retraction (no. of pullbacks)	$1.3 \pm 1.8$	$4.0 \pm 1.3$	< 0.001	$2.7 \pm 1.8$	< 0.05
Failure (unable to perform					
procedure)	None	6	< 0.001	None	NS

Table 3. Validation outcomes in 48 syringe procedures (arthrocentesis).

	Procedure Time, min	Patient Pain Analog Intensity Score	Physician Analog Satisfaction Score	No. of Procedures
Convention: syringe	3.85 ± 1.94	5.29 ± 3.19	4.75 ± 1.10	24
Reciprocation syringe p	ng 2.71 ± 1.13 < 0.03	2.30 ± 1.85 < 0.001	$8.85 \pm 0.85$ 0.001	24

tional syringe used with one hand or 2 hands. Similar reductions in unintended retraction (loss of control in the reverse direction) were also noted (Table 2).

However, it should be noted than none of the physicians were able to achieve maximum vacuum (-325 mm Torr) with the conventional syringe used with one hand, while this level of vacuum could easily be generated by all physician operators with the reciprocating syringe used with one hand. In addition, 6 physicians were completely unable to perform the aspiration procedure against any level of vacuum using the conventional syringe with one hand, resulting in complete procedure failure (Table 3). In contrast, all physicians were easily able to achieve maximum vacuum to -325 Torr with the reciprocating syringe using one hand, and there were no procedure failures.

After performing these syringe procedures, the physicians far preferred the reciprocating syringe (mean operator satisfaction score 9.1  $\pm$  0.8) to the conventional syringe (mean operator satisfaction score 3.6  $\pm$  2.0; p < 0.001; Table 1). Multivariate regression determined that the only factor that determined improvement in syringe and needle control was the use of the reciprocating syringe. Physician age, gender, numbers of total syringe procedures, and years of syringe experience had no discernible effect on control of the needle and syringe by the physician with any of the syringes.

Validation of the syringe procedure model with clinical syringe procedures. The overall outcomes of the clinical syringe procedures are shown in Table 3. There were no differences in ml of fluid removed. 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 and conventional syringes.

However, in these interventional syringe procedures (arthrocentesis), the reciprocating syringe resulted in significantly reduced procedure time (reciprocating syringe  $2.71 \pm 1.13$  min; conventional syringe  $3.85 \pm 1.94$  min; p < 0.03), lower pain scores (VAS-P reciprocating syringe  $2.30 \pm 1.85$ ; conventional syringe  $5.29 \pm 3.19$ ; p < 0.001), and improved physician satisfaction (VAS-S reciprocating syringe  $8.85 \pm 0.85$ ; conventional syringe  $4.75 \pm 1.10$ ; p < 0.001). Thus, the reciprocating syringe significantly reduced mean procedure

time by 30%, reduced patient pain by 57%, and improved physician satisfaction by 79%.

We next examined the independent relationships between variables in the syringe procedure model and the variables in the validating clinical study. First, operator satisfaction (VAS-S) in the syringe model was a potent predictor of operator satisfaction (VAS-S) in the validating clinical trial (r = 0.89,slope = 1.11, confidence interval 0.943–1.277,  $p \le 0.001$ ; Table 4). Thus, physician performance in syringe model was validated as a potent predictor of physician satisfaction with the syringe device in the clinical study. Next, physician performance in the syringe model was related to physician syringe performance in the clinical trial. Unintended penetration and retraction with each repetitive aspiration-injection and aspiration vacuum maneuver were examined individually as independent predictor variables in a multivariate linear model to predict (1) procedure time (minutes), and (2) patient pain (VAS-P).

Only unintended penetration with aspiration-injection independently predicted procedure time (r = 0.48, slope = 0.141, CI 0.067–0.215, p  $\leq$  0.001; Table 4). In contrast, only unintended retraction during aspiration against vacuum independently predicted patient pain (VAS-P; r = 0.546, slope = 0.106, CI 0.572–1.55, p  $\leq$  0.001). Thus, specific variables in the syringe model — physician satisfaction, penetration with aspiration-injection, and retraction with aspiration against vacuum — independently predicted physician satisfaction, procedure time, and patient pain, respectively, in the clinical study.

Our data indicate that the quantitative syringe displacement model and clinical syringe procedures both detect syringe-specific differences in physician performance in syringe procedures. Moreover, physician performance in the syringe model predicts physician performance and patient outcomes in actual clinical syringe procedures.

## DISCUSSION

Using a new needle-based displacement model of syringe procedures, our study precisely determined physician control of the conventional and reciprocating procedure syringes. The study then determined whether physician performance in the syringe model would predict physician performance and outcomes of real clinical syringe procedures, in particular, arthrocentesis.

In the model system, the reciprocating syringe markedly improved physician performance in terms of control of the syringe and needle (Table 2). The reciprocating syringe was far better controlled with one hand than the conventional syringe with either one or 2 hands (p < 0.001). Needle and syringe control with the reciprocating syringe was markedly enhanced with a 68% reduction in unintended forward penetration ( $5.4 \pm 4.8$  mm vs  $16.1 \pm 7.2$  mm; p < 0.001) and a 68% reduction in unintended posterior retraction ( $1.3 \pm 1.8$  vs  $4.0 \pm 1.3$ ; p < 0.001). Moreover, during a pure aspiration procedure, maximum vacuum was achieved easily by all operators

C Aspiration- Injection	Dperator Satisfactio Syringe Model (VAS score)	Injection	Aspiration- Injection Retraction (no. of pullbacks)	Aspiration Against Vacuum Penetration, mm	Aspiration Against Vacuum Retraction (no. of pullbacks)
Operator satisfaction clinical study (VAS score)	r = 0.894 Slope = 1.11 CI 0.943-1.277 $p \le 0.001$	NA	NA	NA	NA
Procedure time, min	, NA	r = 0.48 Slope = 0.141 CI 0.067-0.215 $p \le 0.001$	p ≥ 0.05	p ≥ 0.05	p ≥ 0.05
Patient pain (VAS score)	NA	$p \ge 0.05$	p ≥ 0.05	p ≥ 0.05	$\begin{array}{l} r = 0.546 \\ \text{Slope} = 0.106 \\ \text{CI} \; 0.572  1.55 \\ p \leq \; 0.001 \end{array}$

*Table 4.* Validation: independent relationships between variables in the syringe procedure model and variables in the validating clinical study.

NA: not applicable; VAS: visual analog scale.

with the reciprocating syringe used with one hand. The reciprocating syringe also completely eliminated the procedure failure associated with the use of a conventional syringe in these procedures (Table 2).

The improved physician control of the needle and syringe associated with the reciprocating syringe directly translated into improvements in the performance and outcome of clinical syringe procedures. In arthrocentesis, the improvement in syringe and needle control with the reciprocating syringe translated to a reduction of procedure time by 30%, reduction of patient pain of 57%, and improved physician satisfaction of 79% (Table 3). The marked improvement in physician performance 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 (Table 1).

The syringe procedure model demonstrated similar syringe-specific differences in physician performance as did the clinical study, demonstrating superiority of the reciprocating syringe (Tables 2 and 3). Moreover, specific variables in the syringe model — physician satisfaction, penetration with aspiration-injection, and retraction with aspiration against vacuum — independently predicted physician satisfaction, procedure time, and patient pain, respectively, in the validating clinical study (Table 4). Thus, the quantitative syringe displacement model both measures syringe-specific differences in physician performance and predicts the outcome of actual clinical syringe procedures.

Unintended penetration with aspiration-injection in the syringe procedure model predicted increased procedure time in the clinical trial (Table 4). Although it cannot be simplistically construed that this independent association implies cause and effect, there may be a cause-and-effect relation-ship<sup>27,51-53</sup>. Loss of control of the syringe and thus needle in the forward direction results in unintended penetration of the

patient tissues, which could result in misdirection of the needle away from the intended target. Since arthrocentesis requires a narrowly defined anatomic target (the joint space), loss of control of the syringe in the forward direction would have a significantly negative effect on direction of the needle, resulting first in mistargeting, then necessary positional corrections, and thus ultimately in longer procedure times. Indeed, the conventional syringe was associated with markedly increased loss of control in the forward direction (Table 2) and with concomitantly increased procedure times (Table 3), suggesting that loss of control of the syringe was contributing to longer procedure times.

Unintended retraction of the syringe and needle in the syringe procedure model predicted patient pain in the clinical trial (Table 4). Again, it cannot be simplistically concluded that this independent association implies cause and effect. However, it is logical to assume that loss of control of the needle in the reverse direction, resulting in retraction of the needle and syringe, would result in increased patient pain. Unintended retraction from the tissue target would result first in the needle being pulled out of patient tissues. This "pulling" may mechanically activate the stretch receptors in the skin, causing pain. Moreover, if the needle is unintentionally retracted, to then achieve success in the procedure, the direction of the needle must be reversed; thus, the needle must be pushed back again in the forward direction, deeper into the patient tissues towards the target. Because of unintended retraction, the patient thus is "jabbed" multiple times, and the needle may occasionally intrude into the sensitive periosteum and other non-target soft tissues, resulting in an increased perception of pain by the patient.

Because of the lack of significantly large blood vessels or susceptible soft tissues in joints, arthrocentesis rarely results in life-threatening or fatal outcomes. However, misdirection

or loss of control of the needle in the shoulder, wrist, hip, temporomandibular joint, or axial skeletal can result in unintended arterial puncture, hemorrhage, aneurysm, thrombosis, pneumothorax, nerve injury, and other serious complications. Similarly, the complications of other physician-performed syringe procedures (pericardiocentesis, amniocentesis, thoracentesis, and others) directed at non-musculoskeletal target organs can be catastrophic<sup>14-26,28-37</sup>. Such physician-performed invasive procedures may result in complications leading to an excess mortality of 17%, a mean increased hospital stay of 7 days, and excess cost per case of \$12,913<sup>38</sup>. Thus, the poor control of the conventional syringe by the physician as demonstrated in both the model system and in arthrocentesis may translate into more serious and potentially fatal complications when the syringe procedure is directed at the heart, lung, blood vessels, liver, or other critical organs<sup>14-38</sup>.

The conventional syringe is still commonly used for even the most difficult syringe procedures. 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, 2-handed aspiration or aspirationinjection with a conventional syringe, although considered the gold standard for syringe stability, is actually highly unstable and difficult to control (Table 2). One-handed aspiration with a conventional syringe is also commonly used, but is even more poorly controlled.

The reciprocating syringe is substantially different than any existing syringe and is currently available as a FDAapproved proprietary one-handed procedure syringe (the Reciprocator Procedur-10<sup>TM</sup> and Procedur-SF<sup>TM</sup>, AVANCA Medical Devices). The reciprocating syringe is formed around the core of a conventional syringe barrel and plunger, but has a parallel accessory plunger or plunger equivalent and an accessory barrel or track to control the motion of the accessory plunger<sup>39</sup>. The 2 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 aspirates. 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. Thus, the powerful and exquisitely well controlled flexor musculature of the hand and forearm are used for both injection and aspiration. These characteristics of stable finger positioning and the exclusive use of the intrinsic flexor musculature create a powerful and finely controlled one-handed procedure syringe.

Our study critically examined the ability of physicians to control the syringe and needle during a typical syringe procedure, arthrocentesis, and in the quantitative needle-based displacement model. In both the systems, the conventional syringe used with one or 2 hands was more difficult for physicians to control, resulting in longer procedure times, greater patient pain, and decreased operator satisfaction. In contrast, the reciprocating procedure syringe improved physician control of the needle and syringe, reduced procedure time, reduced patient pain, and improved operator satisfaction. The new, better controlled syringe could have a major influence on arthrocentesis and joint procedures in general when more fully implemented, could immediately diminish patient pain, and may ultimately improve procedure success and diagnostic yield. Because of its improved control and one-handed characteristics, the reciprocating syringe may also have other diagnostic and therapeutic uses across procedural medicine.

### ACKNOWLEDGMENT

The authors thank Jackie Aragon for assistance in the preparation of this manuscript.

#### REFERENCES

- Aceves-Avila FJ, Delgadillo-Ruano MA, Ramos-Remus C, Gomez-Vargas A, Gutierrez-Urena S. The first descriptions of therapeutic arthrocentesis: a historical note. Rheumatology Oxford 2003;42:180-3.
- Johnson MW. Acute knee effusions: a systematic approach to diagnosis. Am Fam Physician 2000;61:2391-400.
- Guggi V, Calame L. Contribution of digit joint aspiration to the diagnosis of rheumatic diseases. Joint Bone Spine 2002;69:58-61.
- Lane JG, Falahee MH, Wojtys EM, Hankin FM, Kaufer H. Pyarthrosis of the knee. Treatment considerations. Clin Orthop Rel Res 1990;45:198-204.
- Manadan AM, Block JA. Daily needle aspiration versus surgical lavage for the treatment of bacterial septic arthritis in adults. Am J Ther 2004;11:412-5.
- Dooley P, Martin R. Corticosteroid injections and arthrocentesis. Can Fam Physician 2002;48:285-92.
- Samuelson CO Jr, Cannon GW, Ward JR. Arthrocentesis. J Fam Pract 1985;20:179-84.
- Brown PW. Arthrocentesis for diagnosis and therapy. Surg Clin North Am 1969;49:1269-78.
- Lee AH, Chin AE, Ramanujam T, Thadhani RI, Callegari PE, Freundlich B. Gonococcal septic arthritis of the hip. J Rheumatol 1991;18:1932-3.
- Kesteris U, Wingstrand H, Forsberg L, Egund N. The effect of arthrocentesis in transient synovitis of the hip in the child: a longitudinal sonographic study. J Pediatr Orthop 1996;16:24-9.
- Weidner S, Kellner W, Kellner H. Interventional radiology and the musculoskeletal system. Best Pract Res Clin Rheumatol 2004;18:945-56.
- Bureau NJ, Ali SS, Chhem RK, Cardinal E. Ultrasound of musculoskeletal infections. Semin Musculoskelet Radiol 1998;2:299-306.
- Grassi W, Farina A, Filippucci E, Cervini C. Sonographically guided procedures in rheumatology. Semin Arthritis Rheum 2001;30:347-53.
- Jones PW, Moyers JP, Rogers JT, Rodriguez RM, Lee YC, Light RW. Ultrasound-guided thoracentesis: is it a safer method? Chest 2003;123:418-23.
- 15. Fartoukh M, Azoulay E, Galliot R, et al. Clinically documented pleural effusions in medical ICU patients: how useful is routine thoracentesis? Chest 2002;121:178-84.
- Brandstetter RD, Karetzky M, Rastogi R, Lolis JD. Pneumothorax after thoracentesis in chronic obstructive pulmonary disease. Heart Lung 1994;23:67-70.
- 17. Yankelevitz DF, Hayt D, Henschke CI. Transthoracic needle biopsy.

What size syringe? Clin Imaging 1995;19:208-9.

- Castellote J, Xiol X, Cortes-Beut R, Tremosa G, Rodriguez E, Vazquez S. Complications of thoracentesis in cirrhotic patients with pleural effusion. Rev Esp Enferm Dig 2001;93:566-75.
- Doyle JJ, Hnatiuk OW, Torrington KG, Slade AR, Howard RS. Necessity of routine chest roentgenography after thoracentesis. Ann Intern Med 1996;124:816-20.
- Sassoon CS, Light RW, O'Hara VS, Moritz TE. Iatrogenic pneumothorax: etiology and morbidity. Results of a Department of Veterans Affairs Cooperative Study. Respiration 1992;59:215-20.
- Callahan JA, Seward JB. Pericardiocentesis guided by twodimensional echocardiography. Echocardiography 1997;14:497-504.
- Bastian A, Meissner A, Lins M, Siegel EG, Moller F, Simon R. Pericardiocentesis: differential aspects of a common procedure. Intensive Care Med 2000;26:572-6.
- Salem K, Mulji A, Lonn E. Echocardiographically guided pericardiocentesis — the gold standard for the management of pericardial effusion and cardiac tamponade. Can J Cardiol 1999;15:1251-5.
- Tsang TS, Barnes ME, Gersh BJ, Bailey KR, Seward JB. Outcomes of clinically significant idiopathic pericardial effusion requiring intervention. Am J Cardiol 2003;91:704-7.
- 25. Tsang TS, El-Najdawi EK, Seward JB, Hagler DJ, Freeman WK, O'Leary PW. Percutaneous echocardiographically guided pericardiocentesis in pediatric patients: evaluation of safety and efficacy. J Am Soc Echocardiogr 1998;11:1072-7.
- Duvernoy O, Borowiec J, Helmius G, Erikson U. Complications of percutaneous pericardiocentesis under fluoroscopic guidance. Acta Radiol 1992;33:309-13.
- 27. Roberts WN, Hayes CW, Breitbach SA, Owen DS Jr. Dry taps and what to do about them: a pictorial essay on failed arthrocentesis of the knee. Am J Med 1996;100:461-4.
- Lobo A, Lightman S. Vitreous aspiration needle tap in the diagnosis of intraocular inflammation. Ophthalmology 2003;110:595-9.
- Qublan HS, Al-Jader KM, Al-Kaisi NS, et al. Fine needle aspiration cytology compared with open biopsy histology for the diagnosis of azoospermia. J Obstet Gynaecol 2002;22:527-31.
- Jauniaux E, Holmes A, Hyett J, Yates R, Rodeck C. Rapid and radical amniodrainage in the treatment of severe twin-twin transfusion syndrome. Prenat Diagn 2001;21:471-6.
- Cederholm M, Haglund B, Axelsson O. Maternal complications following amniocentesis and chorionic villus sampling for prenatal karyotyping. BJOG 2003;110:392-9.
- Farran I, Sanchez MA, Mediano C, et al. Early amniocentesis with the filtration technique: neonatal outcome in 123 singleton pregnancies. Prenat Diagn 2002;22:859-63.
- 33. Goldstein AI, Dumars KW. Minimizing the risk of amniocentesis for prenatal diagnosis. J Am Med Assoc 1977;237:1336-8.
- Papp C, Papp Z. Chorionic villus sampling and amniocentesis: what are the risks in current practice? Curr Opin Obstet Gynecol 2003;15:159-65.
- 35. Moore KP, Wong F, Gines P, et al. The management of ascites in cirrhosis. Hepatology 2003;38:258-66.

- Murthy SV, Hussain ST, Gupta S, Thulkar S, Seenu V. Pseudoaneurysm of inferior epigastric artery following abdominal paracentesis. Indian J Gastroenterol 2002;21:197-8.
- Webster ST, Brown KL, Lucey MR, Nostrant TT. Hemorrhagic complications of large volume abdominal paracentesis. Am J Gastroenterol 1996;91:366-8.
- Nettleman MD, Bock MJ, Nelson AP, Fieselmann J. Impact of procedure-related complications on patient outcome on a general medicine service. J Gen Intern Med 1994;9:66-70.
- Food and Drug Administration. Substantial equivalence determination: 510 (K) Summary. FDA Document: K042487.pdf; January 21, 2005.
- Schaffer TC. Joint and soft-tissue arthrocentesis. Prim Care 1993;20:757-70.
- Pfenninger JL. Injections of joints and soft tissue: Part II. Guidelines for specific joints. Am Fam Physician 1991;44:1690-701.
- 42. Zuber TJ. Knee joint aspiration and injection. Am Fam Physician 2002;66:1497-500; 1503-4; 1507.
- 43. Tallia AF, Cardone DA. Diagnostic and therapeutic injection of the shoulder region. Am Fam Physician 2003;15;67:1271-8.
- 44. Tallia AF, Cardone DA. Diagnostic and therapeutic injection of the wrist and hand region. Am Fam Physician 2003;67:745-50.
- 45. Cardone DA, Tallia AF. Diagnostic and therapeutic injection of the elbow region. Am Fam Physician 2002;66:2097-100.
- Armstrong P, Young C, McKeown D. Ethyl chloride and venepuncture pain: a comparison with intradermal lidocaine. Can J Anaesth 1990;37:656-8.
- 47. Katz J, Melzack R. Measurement of pain. Surg Clin North Am 1999;79:231-52.
- Bhachu HS, Kay B, Healy TE, Beatty P. Grading of pain and anxiety. Comparison between a linear analogue and a computerised audiovisual analogue scale. Anaesthesia 1983;38:875-8.
- Sutherland HJ, Lockwood GA, Minkin S, Tritchler DL, Till JE, Llewellyn-Thomas HA. Measuring satisfaction with health care: a comparison of single with paired rating strategies. Soc Sci Med 1989;28:53-8.
- Miller MD, Ferris DG. Measurement of subjective phenomena in primary care research: the visual analogue scale. Fam Pract Res J 1993;13:15-24.
- Partington PF, Broome GH. Diagnostic injection around the shoulder: hit and miss? A cadaveric study of injection accuracy. J Shoulder Elbow Surg 1998;7:147-50.
- 52. Solomon DH, Bates DW, Panush RS, Katz JN. Costs, outcomes, and patient satisfaction by provider type for patients with rheumatic and musculoskeletal conditions: a critical review of the literature and proposed methodologic standards. Ann Intern Med 1997;127:52-60.
- Hicks CM, Gonzalez R, Morton MT, Gibbons RV, Wigton RS, Anderson RJ. Procedural experience and comfort level in internal medicine trainees. J Gen Intern Med 2000;15:716-22.