

Reduced Pain of Intraarticular Hyaluronate Injection With the Reciprocating Procedure Device

Sharon E. Nunez, MD,* Hilda T. Draeger, MD,* Dennis P. Rivero, MD,† Lawrence G. Kettwich, BS,* Wilmer L. Sibbitt, Jr., MD,* and Arthur D. Bankhurst, MD*

Background: Greater than 50% of patients report significant pain with intraarticular injection of hyaluronate. The reciprocating procedure device (RPD), also known as the reciprocating syringe, has 2 plungers that reciprocate with each other, permitting one-handed operation. The RPD increases physician control of the needle and is proposed to reduce patient pain during syringe procedures.

Objectives: To determine in a randomized controlled trial whether the RPD induces less pain than the traditional syringe during intraarticular hyaluronate therapy for the knee.

Methods: Eighty intraarticular injection procedures of the knee were randomized to either the conventional syringe or the RPD using hyaluronate sodium derivative (Hylan G-F-20). Outcome measures included physician's estimate of pain, patient pain (Visual Analogue Pain Scale [VAPS]), procedure duration, operator satisfaction, complications, and response to the injected medication.

Results: Patients reported 85% more pain than physicians estimated. Fifty-one percent (19/37) of subjects experienced moderate to severe pain with the conventional syringe, while only 14% (6/43) experienced pain with the RPD. The RPD reduced pain scores (RPD VAPS score: 2.12 ± 2.15 ; conventional syringe VAPS score: 4.22 ± 3.25 ; $P < 0.001$), reduced procedure time (RPD: 1.34 ± 1.09 , conventional syringe: 1.90 ± 1.35 minutes, $P < 0.001$), and improved physician satisfaction (RPD VASS Score: 9.02 ± 0.80 , conventional syringe 5.69 ± 1.33 , $P < 0.001$).

Conclusions: Patients have considerably more pain with intraarticular needle introduction and injectable hyaluronate therapy than physicians estimate. The RPD reduces patient pain, reduces procedure time, and improves needle introduction compared with the conventional syringe for hyaluronate injection therapy for the knee.

Key Words: syringe, hyaluronate, knee, needle, injection, pain

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From the Departments of *Internal Medicine and †Orthopedic Surgery, University of New Mexico Health Sciences Center, Albuquerque, New Mexico.

Reprints: Wilmer L. Sibbitt, Jr., MD, Internal Medicine and Neurology 5th FL ACC, University of New Mexico Health Sciences Center, Albuquerque, NM 87131. E-mail: wsibbitt@salud.unm.edu

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Intraarticular therapy, that is injection of therapeutic substances, including hyaluronate, into the knee joint, remains an important component of orthopedic and rheumatologic office practice.^{1–9} However, formal pain studies of joint procedures demonstrate that more than 50% of patients have moderate or severe pain with syringe procedures.^{10–12} Pain is typically associated with the needle traversing pain-sensitive skin, joint capsule, and inflamed synovial membrane.¹⁰ However, careful imaging and cadaveric studies have demonstrated that experienced physicians also frequently misdirect the needle into non-target pain-sensitive extraarticular tissues resulting in increased pain and a failed injection procedure.^{13–20}

Inadequate control of the syringe by the physician can contribute to malpositioning and erratic motion of the needle tip in pain-sensitive tissues, thus increasing pain during intraarticular hyaluronate therapy.^{10–12,21} We hypothesized that pain during intraarticular therapy could be reduced by using the reciprocating procedure device (RPD), an injection device with enhanced control characteristics. The RPD (also known as the reciprocating syringe) retains the core of a conventional syringe, but has an accessory plunger that is mechanically linked to the main plunger by means of a pulley system, resulting in a set of reciprocating plungers. When the dominant plunger is depressed the syringe injects, and when the accessory plunger is depressed the syringe aspirates (Figs. 1 and 2). Thus, because the positions of the index and middle fingers do not change, the flexor musculature of the hand is used for both injection and aspiration, and the syringe (barrel-plunger complex) does not become longer during aspiration, the RPD and needle tip are better controlled than a conventional syringe, three-ringed control syringe, syringe pistol, and other specialty procedure syringes, leading to better syringe procedure outcomes.^{11,12,21} We hypothesized that the RPD would also improve physician performance of intraarticular hyaluronate injection and reduce patient pain.

MATERIALS AND METHODS

Subjects

This project was approved by the institutional review board (IRB). Fifteen physicians (7 orthopedic surgeons and 8 rheumatologists) who regularly perform intraarticular therapy performed 80 individual knee joint injections on 61 subjects. Physicians were on the average 38.8 ± 15.7 years old, had a mean syringe experience of 16.0 ± 11.7 years, performed 8.9 ± 2.4 syringe procedures per week, and had more experience with



FIGURE 1. The reciprocating procedure device in aspiration. The RPD (also known as the reciprocating syringe) is in the aspiration phase, where the thumb is on the smaller aspiration plunger. The RPD 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 2 plungers are mechanically linked in an opposing fashion by a pulley system or gears, resulting in a set of reciprocating plungers. Thus, when the accessory plunger is depressed with thumb, the syringe aspirates, and when the dominant plunger is depressed with the thumb, the syringe injects. The free hand can be used for palpation as shown here, or can be used to stabilize the syringe further, steady the extremity, or operate other devices such as an ultrasound transducer.



FIGURE 2. The reciprocating procedure device in injection. The RPD is in the injection phase, where the thumb is on the larger injection plunger. The free hand can be used for palpation as shown here, or can be used to stabilize the syringe further, steady the extremity, or operate other devices such as an ultrasound transducer.

the conventional syringe (1091 ± 754 total conventional syringe procedures) than with the reciprocating syringe (8.6 ± 5.3 total reciprocating syringe procedures, $P < 0.001$).

The 80 procedures were then randomized to either the conventional syringe or the RPD. In each case, patients were individually consented both to the syringe procedure and to the IRB-approved research protocol. Patient characteristics, including age and gender, were statistically comparable between the 2 treatment groups.

Syringes

The conventional syringe was a 10-mL Luer-Lok BD syringe (Ref 309604, Becton Dickinson & Co., Franklin Lakes, NJ). To provide an identical 10-mL BD syringe core for valid comparisons, the RPD was prototyped in the University of New Mexico Syringe Laboratory using an identical 10-mL BD core (Figs. 1 and 2).^{11,12,21,22}

Knee Intraarticular Therapy

The 80 syringe procedures included only intraarticular therapy for the knee. The individual joint procedure was performed in a standardized manner using local lidocaine anesthesia prior to the procedure.^{2,3,11,12,18,20,23} After anesthesia, a 21-gauge 1 1/2-inch needle (21 G 1 1/2 Precision-Glide Needle, Becton Dickinson & Co.) was placed onto the syringe. The 21-gauge needle was then directed into the joint while aspirating with the conventional syringe or RPD (Figs. 1 and 2). The joint space was then entered and synovial fluid aspirated until the flow stopped or the syringe filled. After aspiration, the syringe was rotated off the Luer fitting, permitting the needle to remain intraarticularly, so that the syringe containing the intraarticular therapy could be attached. Hyaluronate sodium derivative (Synvisc, Hyalan G-F-20, Genzyme, Cambridge, MA) was the hyaluronate preparation used in this study.

Outcome Data of Clinical Procedures

Physicians were queried regarding their estimates of patient pain during syringe procedures. Patient pain was measured with the standardized and validated Visual Analogue Pain Scale (VAPS) where 0 cm = no pain and 10 cm = unbearable pain.^{10-12,24-26} Moderate pain to severe pain was defined as a VAPS greater or equal to 5 during the needle introduction phase of the procedure. Procedure duration was defined as that portion of the procedure after local anesthesia. Operator satisfaction with the syringe after the injection procedure was determined with the Visual Analogue Satisfaction Scale (VASS).^{26,27} Final clinical outcomes were determined 1) directly at the conclusion of the procedure, and 2) at 2 weeks.

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 2 group data were determined with the *t* test. Differences in categorical data were determined with Fisher exact test, while differences between multiple parametric data sets were determined with Fisher Least Significant Difference Method. Corrections were made for multiple comparisons. Correlations between parametric data were determined with logistic

TABLE 1. Randomized, Controlled Trial of the Reciprocating Procedure Device in Intraarticular Hyaluronate Therapy of the Knee

	Conventional Syringe	RPD	P
Number of procedures	37	43	
Procedure time (min)	1.90 ± 1.35	1.34 ± 1.09	<0.001
Physician estimate of patient pain (VAPS)	2.30 ± 1.37	2.30 ± 1.37	Not significant
Patient pain (VAPS)	4.22 ± 3.25	2.12 ± 2.15	<0.001
Patients with moderate to severe pain (VAPS ≥5)	51% (19/37)	14% (6/43)	<0.001
Physician satisfaction (VASS)	5.69 ± 1.33	9.02 ± 0.80	<0.001

regression and between nonparametric data with Spearman correlation and Kendall rank method.

RESULTS

The overall outcomes of the musculoskeletal syringe procedures are shown in Table 1. Physicians estimated the pain experienced by a patient during the joint procedure as mild (VAPS score 2.30 ± 1.37); however, when the conventional syringe was used, patients actually suffered levels of pain nearly twice as great as physician estimates (VAPS score 4.22 ± 3.25) ($P < 0.001$) (Table 1). The RPD resulted in reduced pain scores (RPD VAPS score: 2.12 ± 2.15 ; conventional syringe VAPS score: 4.22 ± 3.25 ; $P < 0.001$), a reduced procedure time (RPD: 1.34 ± 1.09 minutes; conventional syringe: 1.90 ± 1.35 minutes, $P < 0.001$), and improved physician satisfaction with the joint procedure device (RPD VASS Score: 9.02 ± 0.80 ; conventional syringe 5.69 ± 1.33 , $P < 0.001$). Fifty-one percent (19/37) of subjects experienced moderate to severe pain (VAPS score ≥ 5) with the conventional syringe, while only 14% (6/43) experienced these levels of pain with the RPD.

Immediately after these procedures, 2 subjects had a complication, 1 in each group. One patient suffered a vasovagal reaction with hypotension, and the other a transient flushing reaction. Both resolved within 10 minutes. At 2 weeks, there were no complications in any patient, and outcomes in general were good to excellent with both the RPD and conventional syringes.

DISCUSSION

Intraarticular hyaluronate therapy is a useful alternative for treatment of mild to moderate osteoarthritis of the knee.⁶⁻⁹ Although intraarticular needle introduction for hyaluronate therapy using palpation is generally considered a trivial procedure by most physicians, in fact, experienced operators frequently misdirect the needle into extraarticular positions in a surprisingly high percentage of cases.^{13-17,19,20,28} This malpositioning of the needle is likely to decrease the effectiveness of hyaluronate and increase the pain of the procedure due to the needle being in pain-sensitive extraarticular tissues.¹⁰⁻¹⁷

The present study demonstrates that certain subjects do experience significant pain with palpation-guided intraarticular hyaluronate therapy, and physicians routinely underestimate the degree of this pain (Table 1). Physicians estimated that the average patient experiences only mild pain during an intraarticular hyaluronate injection procedure (VAPS score 2.30 ± 1.37), whereas in reality, patients suffered pain scores 85% greater than what the physician estimated (VAPS score 4.22 ± 3.25 , Table 1), indicating a significant unrecognized prevalence of pain. Physicians estimated that only 12% of subjects experience significant pain during a syringe procedure, whereas in reality, 51% of patients experienced moderate to severe pain (Table 1). These significant levels of pain are consistent with pain scores reported previously for similar joint procedures, including arthrocentesis and corticosteroid injections.¹⁰⁻¹² Thus, physicians routinely underestimate both the prevalence and intensity of pain that patients experience during a typical syringe procedure on the knee.

Misdirected, erratic motion of the needle tip is likely to be further exacerbated during the aspiration phase of a syringe procedure.^{11,12,21} During aspiration with a syringe, the index and middle fingers move from the finger flanges to the barrel or plunger, and thus, during this transition, the syringe goes through a phase of relative instability and loss of control. Also, during aspiration, the syringe becomes longer in physical dimensions (the barrel-plunger complex become longer), which tends to push the needle forward more than the operator might intend, increasing the interaction of the sharp tip with periosteum, joint capsule, synovial membrane, or other pain-sensitive structures.¹⁰⁻¹²

The RPD, also known as the reciprocating syringe, represents a new class of syringe devices that are operated exclusively with the flexor musculature of the hand. The RPD has retained the core of a conventional syringe barrel and plunger, but has a parallel accessory plunger and an accessory barrel to control the motion of the accessory plunger (Figs. 1 and 2). The 2 plungers are mechanically linked in an opposing fashion by means of a pulley system or gears, resulting in a set of reciprocating plungers, so that when the dominant plunger is depressed the syringe injects and when the accessory plunger is depressed the syringe aspirates. Although the device looks as though it might be pneumatic or as if fluid might move between the 2 barrels, the device is not pneumatic and has no valves but rather has a simple mechanical reciprocating mechanism, which provides a smooth and controlled reciprocating motion.^{11,12,21,22}

Because of the mechanical advantage provided by the linked plungers, it is easier for the operator to move between aspiration and injection with the RPD than with a conventional syringe using either 1 hand or 2 hands.^{11,12,21} The mechanical advantage permits the fingers of 1 hand to completely operate and control the device, promoting stability (Figs. 1 and 2). The RPD reduces unintended forward penetration (loss of control of the needle and syringe in the forward direction) by 65% (5.6 mm) and reduces mean unintended retraction (loss of control of the needle and syringe in the reverse direction) by 68% (2.7 mm)—a dramatic improvement in syringe device control.¹² Thus, physicians control the RPD far better than a conventional

syringe, and this better control results in improved outcome for syringe procedures, including aspiration of joints.^{11,12} Physicians also control the RPD significantly better than other control syringe devices, including the three-ringed control syringe, syringe pistols, plunger locks, and specialty control syringes.²¹

The better control characteristics of the RPD significantly improved physician performance and reduced patient pain during intraarticular hyaluronate therapy (Table 1). Fifty-one percent of subjects experienced moderate to severe pain with the conventional syringe, while only 14% experienced significant pain with the RPD. The RPD resulted in reduced pain scores, reduced procedure time, and improved physician satisfaction with the joint procedure device. The improvement in physician performance in terms of reduced patient pain and procedure time with the RPD could not be attributed to practice effects, as the physicians had on average 127 times more practice with the conventional syringe, suggesting that improved physician performance was related to the better intrinsic control characteristics of the RPD.

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