A Randomized Controlled Trial of the Reciprocating Procedure Device for Intraarticular Injection of Corticosteroid

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ABSTRACT. ***Objective.*** Injection of intraarticular corticosteroid remains an important therapy for inflammatory arthritis. In a randomized controlled trial we compared the new reciprocating procedure device (RPD) to the traditional syringe for injection of intraarticular corticosteroid.

Methods. One hundred fifty-four intraarticular corticosteroid injection procedures were randomized to the conventional syringe or the RPD. Using the syringe or RPD, the needle was introduced into the joint, any effusion that was present was aspirated, and the corticosteroid (methylprednisolone acetate) was injected. Outcome measures included patient pain measured by visual analog scale (VAS pain), procedure duration, operator satisfaction, complications, and immediate and delayed response to the injected medication.

Results. The RPD reduced pain scores by 49% (RPD VAS pain score: 2.40 ± 2.17; conventional syringe VAS pain score: 4.73 ± 3.39; $p < 0.001$), reduced procedure time by 31% (RPD: 1.28 ± 1.08 min, conventional syringe: 1.86 ± 1.26; $p < 0.01$), and improved physician satisfaction with the joint procedure device by 63% (RPD visual analog satisfaction scale score: 9.12 ± 0.80, conventional syringe 5.59 ± 1.28; $p < 0.001$). Fifty-five percent (43/78) of patients experienced moderate to severe pain (VAS pain ≥ 5) with the conventional syringe, while 17% (13/76) experienced moderate to severe pain with the RPD. The same beneficial response was present when intermediate or large joints were analyzed separately. Longterm outcomes were equivalent.

Conclusion. When a conventional syringe is used for corticosteroid injection, many patients experience significant procedural pain. The RPD significantly reduces patient pain, reduces procedure time, and improves operator satisfaction. The RPD is superior to the traditional syringe for injection of intraarticular corticosteroid. (First Release Dec 1 2006; J Rheumatol 2007;34:187–92)

Key Indexing Terms:
SYRINGE CORTICOSTEROID JOINT INTRAARTICULAR INJECTION PAIN

Intraarticular injection of corticosteroids is an important alternative for the treatment of inflammatory and degenerative arthritis[1-8]. Rheumatologists and orthopedic surgeons will either inject the corticosteroid suspension directly into the joint, or to be safer and more accurate, will use a separate syringe to first place the needle in an intraarticular position, drain any synovial fluid (SF), exclude infection, and then inject the corticosteroid intraarticularly[9-11]. Intraarticular injection procedures are generally considered safe, and the majority of rheumatologists and orthopedic surgeons feel that patients experience minimal pain with these procedures[1-8]. However, the impression that needle procedures on the joints are minimally painful is not based on formal pain studies; indeed, the pain of needle procedures on joints is enough to precipitate the use of local or even general anesthesia[7,8,12,13]. Formal pain studies consistently report that greater than 50% of patients experience moderate to severe pain during needle procedures on joints[13-15].

The causes of pain during syringe procedures on joints are uncertain and inadequately studied, but appear to be related to intrinsic patient factors, transversing pain-sensitive tissues, malpositioning the needle, and erratic control of the syringe and needle by the physician[13-19]. Numerous cadaveric and imaging studies have demonstrated that experienced physicians using a traditional syringe with the palpation method often misdirect the needle into non-target extraarticular tissues, resulting in increased pain and a failed injection procedure[16-26]. Inaccurate placement of the needle with the extraarticular injection of drug is likely to decrease the effectiveness of this therapy and result in a more painful procedure[9,10,13,17,24,26,27].

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Recent studies have demonstrated that the reciprocating procedure device (RPD) can be controlled more precisely by physicians than conventional syringes, 3-ring control syringes, syringe pistols, syringes with plunger locks, and other dedicated one-handed or 2-handed procedure syringes[14,27]. We hypothesized that the RPD would also improve the performance of intraarticular corticosteroid therapy[14,27]. Therefore, we prospectively studied patients undergoing intraarticular corticosteroid therapy randomized to the traditional syringe versus the RPD and measured outcomes including pain experienced by the patient during the procedure, procedure time, physician satisfaction with the syringe device, complications, and immediate and delayed outcome.

MATERIALS AND METHODS

Subjects. This project was approved by the institutional review board (IRB). Twenty-one physicians (7 orthopedic surgeons, 8 rheumatologists, and 5 internists) who regularly perform intraarticular therapy performed 154 individual intraarticular corticosteroid injections in large to intermediate joints in 104 subjects requiring intraarticular corticosteroid therapy for their usual and customary medical care. Selection criteria for inclusion into the study and exclusion were as follows: (1) a swollen, painful large to intermediate joint (knee, shoulder, hip, ankle, wrist) in typical rheumatic conditions (Table 1); (2) no evidence of infection or trauma; (3) the patient requested a corticosteroid injection; (4) subject had not received a corticosteroid injection in the involved joint for a period of at least 6 months; and (5) subject was willing to participate in the randomized trial. Subjects were consecutively enrolled as encountered in the clinic or wards. Randomization was achieved patient by patient by flipping a coin. In each case, patients individually consented both to the syringe procedure and to the IRB-approved research protocol. Table 1 shows the patient characteristics, which were comparable between the 2 treatment groups. Ninety-four large joints (hips and knees) and 60 intermediate joints (wrist, elbow, ankle, and shoulders) were injected. The procedures were then randomized to either the conventional syringe or the RPD.

Table 1. Characteristics of study patients in 154 corticosteroid injections of large to intermediate-size joints.

	Conventional Syringe	Reciprocating Procedure Device (RPD)	p
Patient age, yrs	51.49 ± 14.45	52.13 ± 13.69	> 0.05
No. of individual subjects	52	52	> 0.05
Men	8	11	> 0.05
Women	44	41	> 0.05
No. of corticosteroid injections	78	76	> 0.05
Large joints (hip, knee)	43	51	> 0.05
Intermediate joints (shoulder, wrist, elbow, ankle)	35	25	> 0.05
Knee	36	44	> 0.05
Hip	7	7	> 0.05
Wrist	15	11	> 0.05
Elbow	3	4	> 0.05
Ankle	7	1	> 0.05
Shoulder	10	9	> 0.05
Rheumatoid arthritis	43	41	> 0.05
Systemic lupus erythematosus	8	8	> 0.05
Idiopathic monarthritis	5	4	> 0.05
Acute gout	3	4	> 0.05
Reactive arthritis	4	4	> 0.05
Osteoarthritis	15	15	> 0.05

Physicians received very brief training with the RPD, amounting to about 2 minutes of oral instruction and hands-on practicing cycling the syringe through aspiration and injection before performing the procedures. 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 16.0 ± 11.7 years of syringe experience. Individual physicians performed a mean of 8.9 ± 2.4 syringe procedures per week, indicating that the test group was an active, practiced group of physicians. Gender proportions were similar, representative of the local physician population. However, the physicians had far more career experience with the conventional syringe (1091 ± 754 total conventional syringe procedures) than with the RPD (8.6 ± 5.3 total RPD procedures; $p < 0.001$).

Syringes. The conventional syringe was a 10 ml Luer-Lok™ BD syringe (Ref. 309604, Becton Dickinson Co., Franklin Lakes, NJ, USA). In order to provide an identical 10 ml BD syringe core for valid comparisons, the RPD was prototyped in the University of New Mexico Syringe Laboratory (Figures 1, 2, and 3). Thus, the RPD used in these experiments was an experimental version made from an identical 10 ml BD core with a reciprocating mechanism attached, and was similar but not identical to the commercially available, US Food and Drug Administration approved, versions of the RPD, which contain a different syringe core[14,15,27,28].

Intraarticular corticosteroid therapy. The 154 syringe procedures included only intraarticular corticosteroid injection of large to intermediate joints (Table 1). The individual joint procedure was performed in a standardized manner using local lidocaine anesthesia prior to the procedure[12,14,19,22,29]. After anesthesia a 21 gauge 1.5 inch needle (21 G1-1/2 PrecisionGlide Needle; Becton Dickinson) was placed onto the procedure device. The 21 gauge needle was then directed into the joint while aspirating with the conventional syringe or RPD. The joint space was then entered and SF aspirated until the flow stopped or the syringe filled (Figure 1). After aspiration, the syringe or RPD was rotated off the Luer fitting, permitting the needle to remain intraarticularly so that a syringe or RPD containing the corticosteroid could be attached (Figure 2). In each case, the device was aspirated to return SF to assure that the ensuing injection would be intraarticular[9-11].

Corticosteroid methylprednisolone acetate (Depo-Medrol, 40 mg/ml; Pharmacia Corp., Kalamazoo, MI, USA) was used: 2 ml was injected into large joints; 1.5 ml was injected into intermediate joints (Figure 3).

Outcome data of clinical procedures. Patient pain was measured with the standardized and validated visual analog pain scale (VAS pain), where 0 cm = no pain and 10 cm = unbearable pain[13-15,29-32]. Moderate to severe pain was defined as a VAS pain ≥ 5 during the needle introduction phase of the procedure. Procedure duration was defined as that portion of the procedure after local anesthesia. Time was measured in minutes by a non-operating observer. Operator satisfaction with the syringe after the injection procedure was determined with the visual analog 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[14,15,32,33]. Final clinical outcomes were determined (1) directly at the conclusion of the procedure, and (2) at 2 weeks. The physician rated the success of the procedure immediately afterwards as poor, average, good, or excellent. On telephone interview, the patient rated the success of the procedure at 2 weeks as poor, average, good, or excellent depending on their symptoms at that time.

Statistical analysis. Data were entered into Excel (Version 5; Microsoft, Seattle, WA, USA), and analyzed in SAS (SAS/STAT Software, Release 6.11; Cary, NC, USA). Power calculations were performed for a t test for comparing pain in patients with the RPD versus conventional syringe. The power was met and exceeded, and the study could have been performed with fewer subjects. Differences between parametric 2-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 Fisher's least-significant difference method. Corrections were made for multiple comparisons. Correlations between parametric data were determined

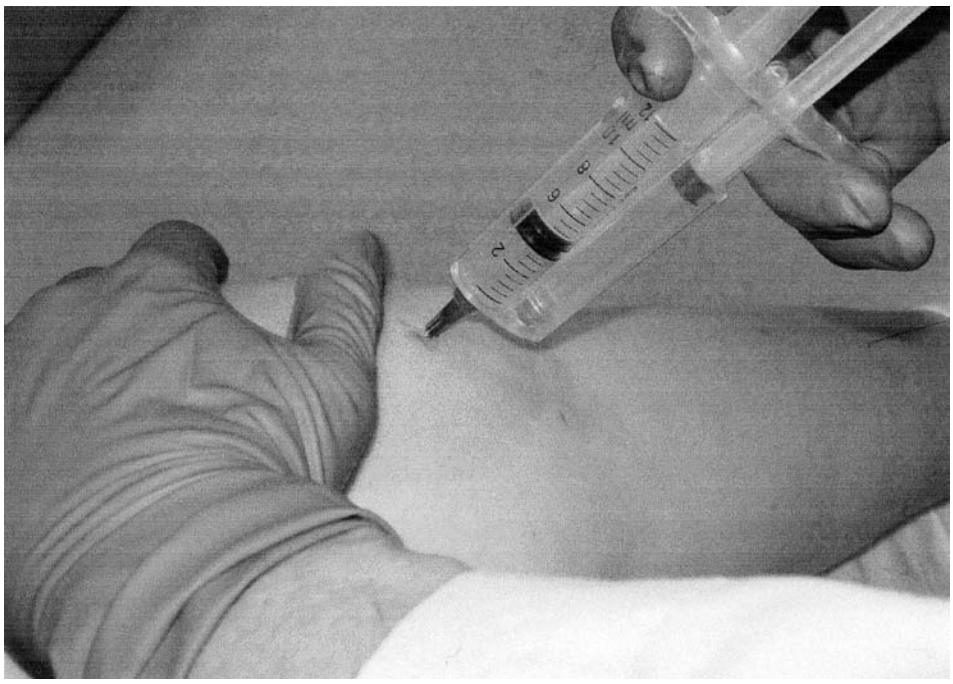

Figure 1. The reciprocating procedure device (RPD) for needle introduction and arthrocentesis. The RPD is in the aspiration phase during needle introduction and arthrocentesis, where the thumb is on the smaller aspiration plunger. As can be seen, synovial fluid is being removed by aspiration as the RPD is being operated under great control with one hand. 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 by gears or a pulley system in an opposing fashion, resulting in a set of reciprocating plungers. Thus, when the accessory plunger is depressed with the thumb, the RPD aspirates, and when the dominant plunger is depressed with the thumb, the RPD injects. The free hand can be used for palpation or to compress the synovial effusion as shown here, or can be used to stabilize the RPD further, steady the extremity, or operate other devices such an ultrasound transducer.

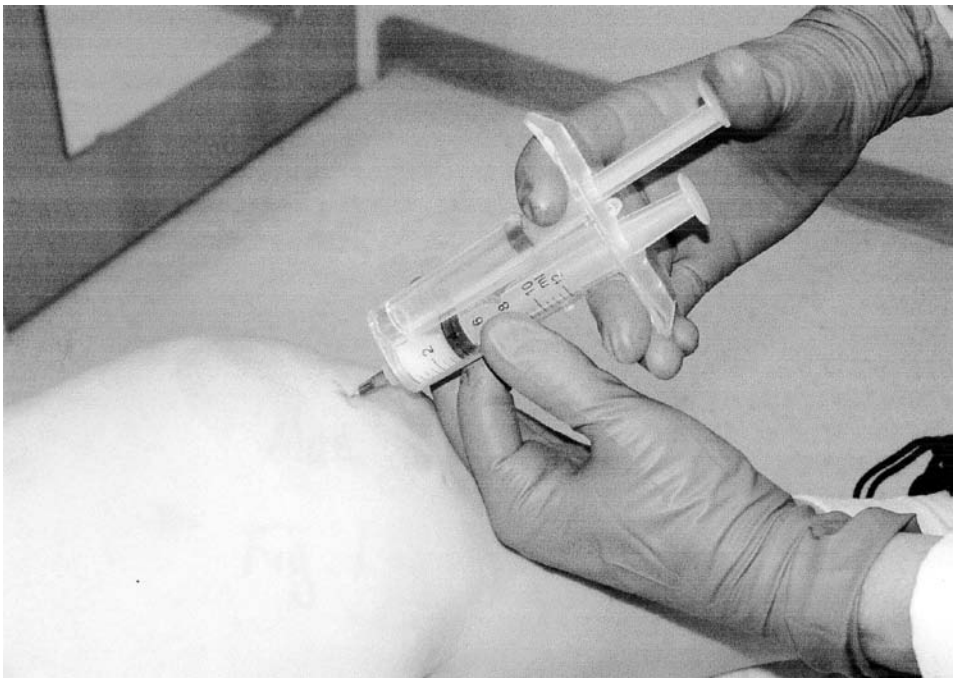

Figure 2. The reciprocating procedure device (RPD) in aspiration. After the joint has been entered and any synovial fluid aspirated, the introduced needle remains intraarticularly. The RPD with the synovial fluid aspirate is removed from the needle, and the RPD with corticosteroid is attached. Prior to injecting corticosteroid, the small plunger is depressed with the thumb in order to aspirate with certainty that synovial fluid is returned prior to injection. This assures intraarticular rather than periarticular or extraarticular injection of the medication. Here the free hand further stabilizes the RPD, reducing erratic motion and decreasing pain.

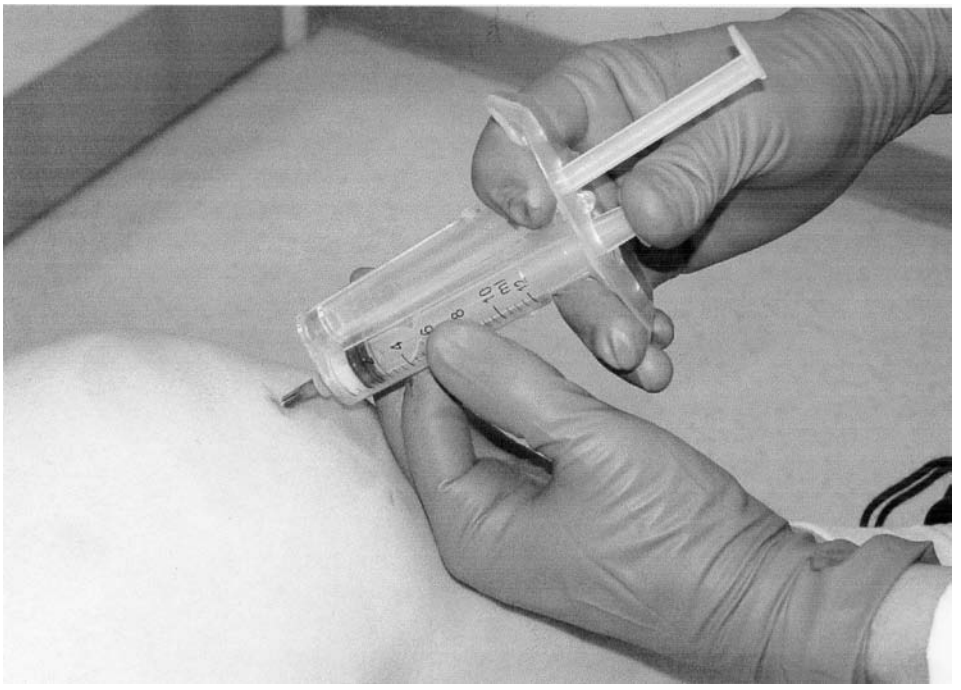

Figure 3. The reciprocating procedure device (RPD) in injection. The RPD is in the injection phase, where the thumb is on the larger injection plunger. The free hand can be used to stabilize the RPD, as shown here, or to palpate the anatomy, steady the extremity, or operate other devices such as ultrasound transducer. Here the free hand further stabilizes the RPD, reducing erratic motion and decreasing pain.

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

RESULTS

The overall outcomes of the corticosteroid injection procedures are shown in Table 2. The RPD reduced pain scores by 49% (RPD VAS pain: 2.40 ± 2.17; conventional syringe VAS pain: 4.73 ± 3.39; $p < 0.001$); RPD reduced procedure time by 31% (RPD: 1.28 ± 1.08 min; conventional syringe 1.86 ± 1.26; $p < 0.01$); the RPD also improved physician satisfaction with the joint procedure device by 63% (RPD VASS score: 9.12 ± 0.80, conventional syringe 5.59 ± 1.28; $p < 0.001$). Fifty-five percent (43/78) of patients experienced moderate to severe pain (VAS pain score ≥ 5) with the conventional syringe, while only 17% (13/76) experienced moderate to severe pain with the RPD. When analyzed separately, the same beneficial response to the RPD was noted for large joints (Table 3) and intermediate joints (Table 4). Multivariate regression determined that the only independent factor that determined improvement in procedure time, reduced patient pain, and improved physician satisfaction was the use of the RPD. Physician age, gender, numbers of total syringe procedures, and years of syringe experience had no effect on outcome measures with any of the devices independent of the use of the RPD.

Immediately after these procedures 4 subjects had complications, 2 in each group. Two complained of increased joint pain for 2 to 3 days, and 2 complained of lightheadedness during and immediately after the procedure, which resolved. 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.

Table 2. Randomized, controlled trial of the reciprocating procedure device (RPD) in corticosteroid injection of large to intermediate-size joints.

	Conventional Syringe	RPD	p
No. of procedures	78	76	
Procedure time, min	1.86 ± 1.26	1.28 ± 1.08	< 0.01
Patient pain, VAS	4.73 ± 3.39	2.40 ± 2.17	< 0.001
Pateints with moderate to severe pain, VAS ≥ 5, % (no.)	55 (43/78)	17 (13/76)	< 0.01
Physician satisfaction, VASS	5.59 ± 1.28	9.12 ± 0.80	< 0.001

Table 3. Randomized, controlled trial of the reciprocating procedure device (RPD) in corticosteroid injection of large joints (hip and knee).

	Conventional Syringe	RPD	p
No. of procedures	44	50	
Procedure time, min	1.86 ± 1.26	1.28 ± 1.08	< 0.02
Patient pain (VAS)	4.73 ± 3.39	2.40 ± 2.17	< 0.01
Pateints with moderate to severe pain, VAS ≥ 5, % (no.)	51 (23/44)	16 (8/50)	< 0.01
Physician satisfaction (VASS)	5.59 ± 1.28	9.12 ± 0.80	< 0.001

Table 4. Randomized, controlled trial of the reciprocating procedure device (RPD) in corticosteroid injection of intermediate joints (shoulder, wrist, ankle).

	Conventional Syringe	RPD	p
No. of procedures	35	26	
Procedure time, min	1.54 ± 1.21	1.07 ± 0.97	< 0.1
Patient pain, VAS	4.54 ± 3.53	2.37 ± 3.52	< 0.04
Patients with moderate to severe pain, VAS ≥ 5, % (no.)	57 (20/35)	19 (5/26)	< 0.001
Physician satisfaction (VASS)	5.71 ± 1.67	9.04 ± 0.72	< 0.01

DISCUSSION

Intraarticular corticosteroid injection therapy is an important therapeutic approach for inflammatory arthritis of individual joints[1-8]. Most physicians use palpation for intraarticular corticosteroid injection, but in applying this method with the traditional syringe, experienced physicians frequently misdirect the needle into extraarticular positions and induce significant levels of pain in a surprisingly high percentage of cases[9-26]. Unintentional malpositioning and erratic motion of the needle in pain-sensitive extraarticular tissues, periosteum, joint capsule, and inflamed synovial tissues are likely to increase the pain of the procedure, and if the corticosteroid is injected extraarticularly, the effectiveness of the injected corticosteroid decreases[9,10,13-24]. Our findings are consistent with prior imaging, cadaveric, and clinical syringe studies: physicians have difficulty adequately controlling the traditional syringe, resulting in malpositioning and erratic control of the needle and moderate to severe pain in a significant number of patients[9-27].

Although the conventional syringe is a well controlled one-handed device in the injection phase of a syringe procedure, control is much more difficult during the aspiration phase, contributing to misdirection and erratic control[14,27]. To aspirate with a traditional syringe, the index and middle fingers move from the finger flanges to the barrel or plunger, causing a phase of relative instability and loss of control during transition. As the plunger is pulled back in the barrel during aspiration, the barrel-plunger complex (the syringe length) also becomes longer, which tends to push the needle forward beyond what the operator might intend, thus increasing the risk of the needle touching pain-sensitive structures such as periosteum, joint capsule, synovial membrane, or pain-sensitive extraarticular structures[13,14,27].

The pain scores reported in our study indicate significant levels of pain in many patients undergoing corticosteroid injection, and are consistent with the significant pain scores reported in previous formal pain studies of syringe procedures on joints[13-15]. The RPD reduced pain scores by 49% (RPD VAS pain score: 2.40 ± 2.17; conventional syringe VAS pain score: 4.73 ± 3.39; $p < 0.001$), reduced procedure time by 31% (RPD: 1.28 ± 1.08 min, conventional syringe: 1.86 ± 1.26; $p < 0.01$), and improved physician satisfaction with the joint procedure device by 63% (RPD VASS score: 9.12 ± 0.80, conventional syringe 5.59 ± 1.28; $p < 0.001$). Fifty-five percent (43/78) of patients experienced moderate to severe pain (VAS pain ≥ 5) with the conventional syringe, while only 17% (13/76) experienced moderate to severe pain with the RPD. The same beneficial response was present when intermediate or large joints were analyzed separately (Tables 3 and 4). The improvements associated with use of the RPD in terms of reduced patient pain and shortened procedure time were not due to bias associated with practice effects because the physicians had on average 127 times more practice with the conventional syringe.

The RPD is a syringe-like device that retains the core of a conventional syringe barrel and plunger; however, the RPD also has an accessory plunger and barrel (Figures 1-3). The dominant and accessory plungers are linked mechanically in a reciprocating fashion, so that when the dominant plunger is depressed the syringe injects and when the accessory plunger is depressed the syringe aspirates. The device is not pneumatic and has no valves, but rather has a simple mechanical reciprocating mechanism (the pulley or gear system), which provides a smooth and controlled reciprocating motion[14,15,27,28].

Because the index and middle fingers need not change position, the operator can move easily between aspiration and injection with the RPD (Figures 2 and 3)[14]. In contrast, alternating between aspiration and injection with a conventional syringe whether using one hand or 2 hands requires major changes in hand and finger positioning[14,27]. The RPD permits the fingers of one hand to completely operate and control the device, promoting control and stability (Figures 1-3). Use of the RPD is associated with a significant reduction in unintended forward penetration (loss of control of the needle and syringe in the forward direction) by 65% (5.6 mm) and a reduction in mean unintended retraction (loss of control of the needle and syringe in the reverse direction) by 68% (2.7 mm) — a significant improvement in syringe control[14]. Indeed, physicians control the RPD better than a conventional syringe, the 3-ring control syringe, syringe pistols, and other specialty syringe procedure devices, and this improved control results in improved outcome for syringe procedures[14,15,27].

There are potential limitations to the findings of this study. The RPD is asymmetrical, and thus, does not rotate off the needle symmetrically as does a conventional syringe, and thus could present a difficulty to novice operators[27]. Despite this, all physicians were able to remove the RPD from the needle successfully without patient complaint, and physicians maintained a high satisfaction rating with the device (Table 2). Similarly, patients and physicians could see the device that was actually being used, thus the trial could not be truly blinded. However, patients were actually initially frightened by the RPD because the RPD is larger than a conventional syringe and looks so different. Thus, it would be anticipated that they might rate the RPD as more painful — but they did not (Table

2). Similarly, physicians could have a bias toward the newer technique, but it was physician satisfaction that was being measured, which is inherently subjective[31-33]. Still, it is difficult to argue that physician satisfaction with the procedure device is not important in invasive procedures. In addition, our study did not address corticosteroid injection of small joints, which would require a smaller volume RPD than used in this study.

Our study demonstrates that the enhanced control of the RPD significantly improves physician performance of intraarticular corticosteroid injection of large to intermediate-size joints, significantly reducing patient pain and procedure time. Previous studies have demonstrated that the RPD is superior to the conventional syringe in terms of performance of arthrocentesis, physician control of the syringe, and typical syringe biopsy procedures[14,15,27]. The study demonstrates that the RPD is also superior to the conventional syringe for intraarticular injection of corticosteroid.

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