

## Laboratory Investigations

# Control and Performance Characteristics of Eight Different Suction Biopsy Devices

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**PURPOSE:** To determine the control and performance characteristics of eight different suction biopsy devices.

**MATERIALS AND METHODS:** Physician control of the syringe and needle was measured precisely with the validated linear displacement method during the aspiration phase and during five biopsy passes. The visual analog scale was used to measure operator difficulty in the following domains: (i) attachment to the needle, (ii) generation of vacuum, (iii) detection of loss of vacuum, (iv) release of the vacuum, and (v) clearing of the sample from the needle.

**RESULTS:** Performance in various phases of the biopsy procedure varied widely among the biopsy devices tested. Unintended forward penetration (ie, loss of control in the forward direction) was significant with the reverse aspiration syringe ( $31.5 \pm 1.7$  mm), three-ringed control syringe ( $25.4 \pm 4.1$  mm), BioSuc-C7 syringe ( $28.3 \pm 1.9$  mm), conventional syringe with a plunger lock ( $6.1 \pm 1.5$  mm), syringe pistol ( $9.2 \pm 2.4$  mm), and conventional syringe ( $3.8 \pm 2.9$  mm) but was significantly less for the reciprocating procedure device (RPD;  $0.7 \pm 0.7$  mm;  $P \leq .001$ ) and RPD syringe holder ( $0.6 \pm 0.6$  mm;  $P \leq .001$ ). The mean performance rankings were the best for the RPD ( $3.42 \pm 2.57$ ) and RPD syringe holder ( $4.29 \pm 2.50$ ) and worst for the conventional syringe ( $6.14 \pm 2.67$ ;  $P \leq .001$ ) and conventional syringe with a plunger lock ( $6.86 \pm 3.80$ ;  $P \leq .001$ ).

**CONCLUSIONS:** Each of the suction biopsy devices has unique advantages and disadvantages. Suction biopsy devices with the least favorable overall performance were the conventional syringe and the conventional syringe with a plunger lock. The highest overall performance was seen with the RPD and RPD syringe holder.

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**Abbreviations:** FDA = Food and Drug Administration, FNA = fine needle aspiration, RPD = reciprocating procedure device

FINE needle aspiration (FNA) biopsy and related aspiration biopsy techniques with vacuum provided by a syringe remain important diagnostic procedures for palpable lesions of the

breast, thyroid, and salivary gland, as well as lesions in the liver, orbit, testes, kidney, abdomen, thorax, and lung (1–12). A recent survey of radiologists in the United States and Canada demonstrated that FNA remained the procedure of choice for diagnosis of lung lesions by more than 70% of radiologists (13). Although core biopsy is superior in certain situations because of the simplicity, safety, rapid diagnosis, effectiveness, and reduced costs, needle biopsy procedures with vacuum provided by a syringe will remain important in interventional radiology for the foreseeable future (14–18).

The conventional syringe alone or with a plunger lock, handle, or pistol continues to be the dominant suction device used in percutaneous aspiration needle biopsy procedures (19,20).

Syringe holders, handles, guns, and pistols and one-handed procedure syringes have been developed to permit one-handed operation and greater control (21,22). Because there are few head-to-head comparisons among different aspiration syringe devices, selection of an appropriate aspiration biopsy device has traditionally been a matter of operator preference, training, availability, and manufacturer discretion (1–22). Recently, the quantitative linear displacement model of procedural syringe control has been validated as a method to precisely measure an individual physician's ability to control a syringe and needle (23). In the present study, we used this validated quantitative model of syringe control to compare the control characteristics of eight different sy-

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W.L.S. is the inventor of the reciprocating procedure device, reciprocating procedure device syringe holder, and reverse aspiration syringe, all of which are owned by the University of New Mexico.

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**Figure 1.** Method for measurement of physician control of needle and syringe: with the reciprocating syringe held with one hand, the foam target is shown just anteriorly. The rigid polystyrene marker is placed on the needle to a preset indelible mark on the needle shaft, and then the needle is advanced into the target tissue 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 (ie, unintended penetration) pushes the polystyrene marker posteriorly on the needle shaft past the indelible mark, permitting precise measurement of loss of control in the forward direction. Loss of control in the reverse direction (ie, unintended 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 (ie, retraction).

ringe devices used in aspiration biopsy procedures.

## MATERIALS AND METHODS

### Subjects

This project was approved by the institutional review board at the institution at which it was performed. After informed consent was obtained, 10 physicians who regularly perform syringe procedures were asked to perform a protocol of syringe maneuvers with the various syringes.

### Phases of the Syringe Procedure

The syringe procedure was modeled after a biopsy procedure in which a needle with a stylet was used and was divided into seven component measures: (i) difficulty of attachment of the syringe device to the needle in the target after the stylet was re-

moved, (ii) difficulty in generation of vacuum, (iii) precise control of the syringe during generation of vacuum (ie, aspiration), (iv) precise control of the syringe during five biopsy passes, (v) difficulty in sensing loss of vacuum, (vi) difficulty in releasing vacuum to prevent the sample from being aspirated into the syringe, and (vii) difficulty of removing the needle from the syringe, aspirating air into the syringe, reattaching the needle, and injecting air to blow out the sample (ie, biopsy type 1). A syringe procedure in which a needle without a stylet was used was represented by component (ii) through component (iii) (ie, biopsy type 2). A syringe procedure in which a needle without a stylet was used and the needle remained on the syringe for analysis was defined by component (ii) through component (vi) (ie, biopsy type 3). Difficulty in performing components (i), (ii), (v), (vi), and (vii) was measured with the visual analog diffi-

culty scale, in which the difficulty of achieving each phase was rated by each operator on the visual analog difficulty scale from 0 to 10, with 0 representing no difficulty and 10 representing extreme difficulty (24,25).

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### Precise Measurement of Syringe and Needle Control by the Physician

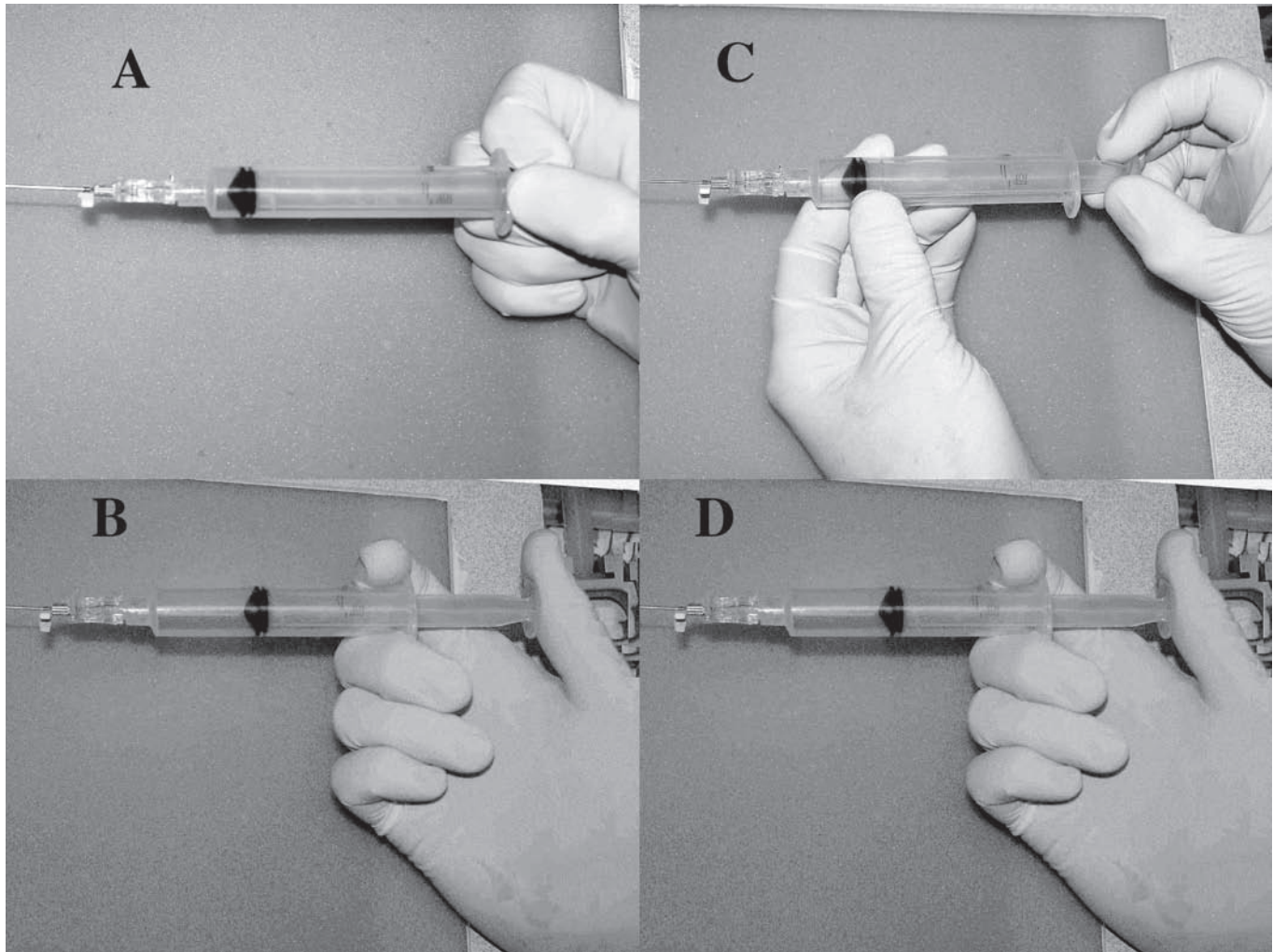
The clinically validated quantitative needle-based displacement procedure model was used to precisely measure syringe and needle control by the individual physician (23). In this measurement system, a layer of 1.3-cm-thick open-cell flexible polystyrene foam simulates the target tissue (Fig 1). A 20-gauge, 5.875-inch (14.9-cm) aspiration biopsy needle (53820 Sample-Master aspiration biopsy with Hiliter needle; INRAD, Kentwood, MI) is placed into the model with the stylet in. A rigid polystyrene marker is placed on the needle to a preset indelible mark on the needle shaft at 4 mm, and then the needle is advanced into the target tissue (ie, foam) until the polystyrene marker is touching the surface of the target tissue (Fig 1). When the needle has penetrated the foam model to the proper depth, the stylet is removed and the syringe device is attached. The physician operator then performs the syringe procedure. Loss of control in the forward direction (ie, 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 (ie, unintentional retraction) lifts the polystyrene marker off the surface of the target tissue, exposing a length of the needle shaft (ie, "pullback"), indicating loss of control (measured in mm) in the reverse direction (ie, retraction).

F1

Individual control measurements during syringe procedures included unintentional forward penetration during the aspiration (vacuum-generation) phase (ie, phase iii) and unintentional forward penetration during five passes of the aspiration biopsy needle (ie, phase iv) while vacuum was maintained.

### Syringes

The conventional syringe was a 10-mL Luer-Lok syringe (Becton Dick-



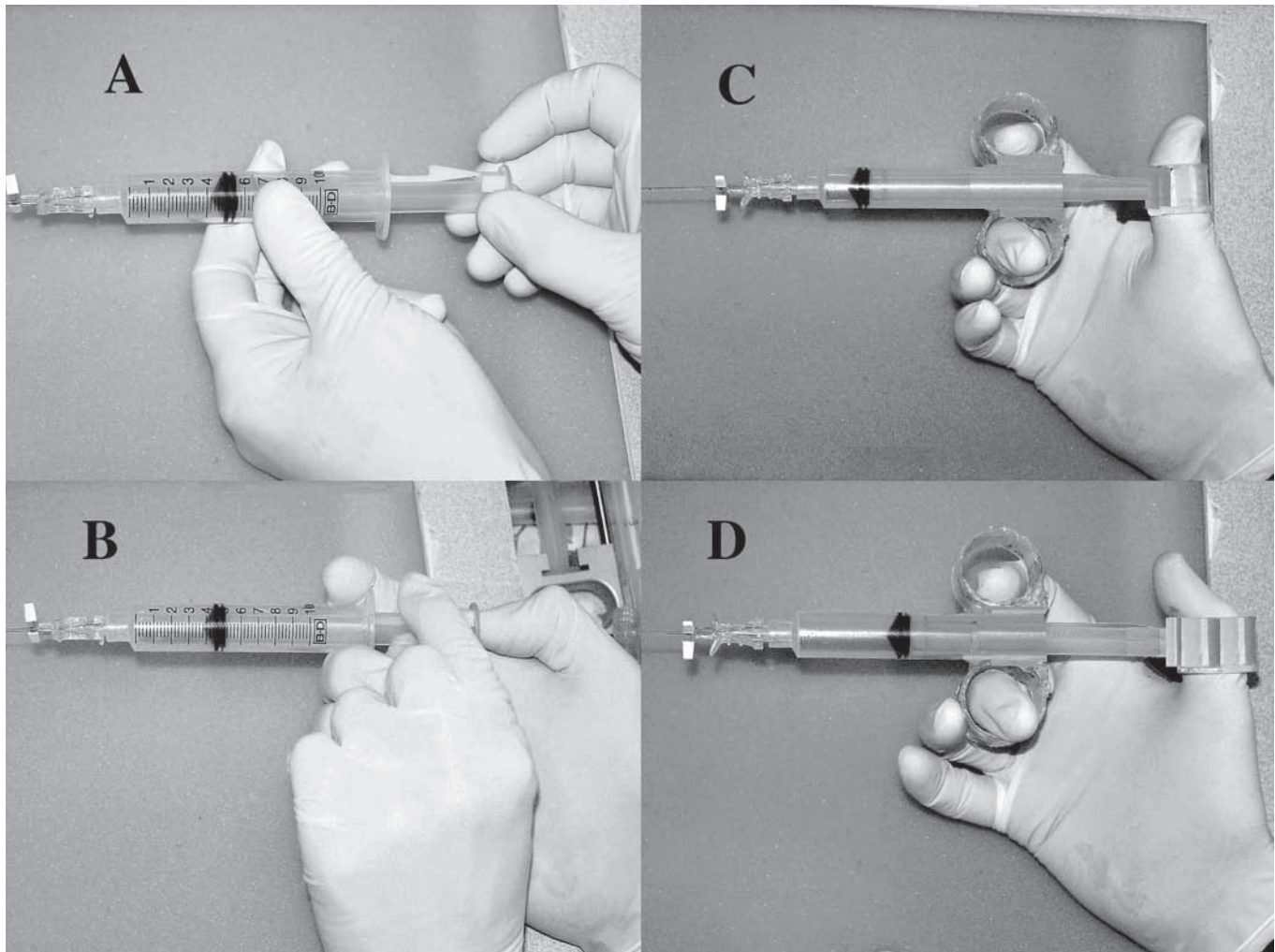
**Figure 2.** Conventional syringes: the one-handed conventional syringe is aspirated (a) and injected (b) with one hand. Note the major change of positioning of the thumb and index and middle fingers from aspiration to injection. The two-handed conventional syringe is aspirated with two hands (a) and injected with one hand (b). Note the major change of positioning of the thumb and index and middle fingers from aspiration to injection.

inson, Franklin Lakes, NJ). This syringe was used in one-handed (Fig 2a,b) and two-handed techniques (Fig 2c,d). Other commercially available U. S. Food and Drug Administration (FDA)-approved syringes included an identical 100-mL syringe fitted with a plunger lock (Becton Dickinson) (Fig 3), the commercially available 10-mL BioSuc-C7 (Hakko, Tokyo, Japan) (Fig 4), and the commercially available but not FDA approved 10-mL syringe pistol fitted with the 10-mL BD syringe (Cameco, London, UK) (Fig 5). To provide an identical 10-mL BD syringe core for valid comparisons, the remainder of the procedure syringes were prototyped in the University of New Mexico syringe lab-

oratory with use of an identical 10-mL BD core.

The three-ringed control syringe, versions of which are FDA approved and available commercially from multiple manufacturers, was prototyped from identical 10-mL BD syringes by replacing the conventional flanges on the barrel and the thumb rest on the plunger with ringed flanges (Fig 3c,d). The reverse aspiration syringe, which is neither FDA approved nor commercially available, is a syringe with an external slide that is attached to the plunger (Fig 4c,d). Versions of the reciprocating procedure device (RPD) are commercially available and FDA approved (23,26). The RPD has two

barrels, two plungers, and a mechanical linkage between the plungers (gears or a pulley system) that permits the plungers to reciprocate. Therefore, the index and middle fingers do not change position, but the thumb moves from one plunger to the other to transition between aspiration and injection. This creates an extremely stable procedure device (23,26). The RPD used in these experiments was an experimental prototype made of a 10-mL reciprocating procedure device syringe with a reciprocating mechanism attached so it could be directly compared with other BD-based syringes (Fig 6a,b). The RPD syringe holder, which is neither commercially avail-



**Figure 3.** Conventional syringe with a plunger lock and the three-ringed control syringe. The conventional syringe with a plunger lock is aspirated (a) and injected (b) with two hands. Note the major change of positioning of the thumb and index and middle fingers from aspiration to injection. The three-ringed control syringe is aspirated (c) and injected (d) with one hand. Note the lack of change of positioning of the thumb and index and middle fingers from aspiration to injection.

able nor FDA approved, was also an experimental device with a reciprocating mechanism that permitted a conventional 10-mL BD syringe to be inserted and removed (Fig 6c,d). All these devices had the same identical 10-mL BD syringe core that permitted valid functional comparisons among syringes.

#### Vacuum Generation

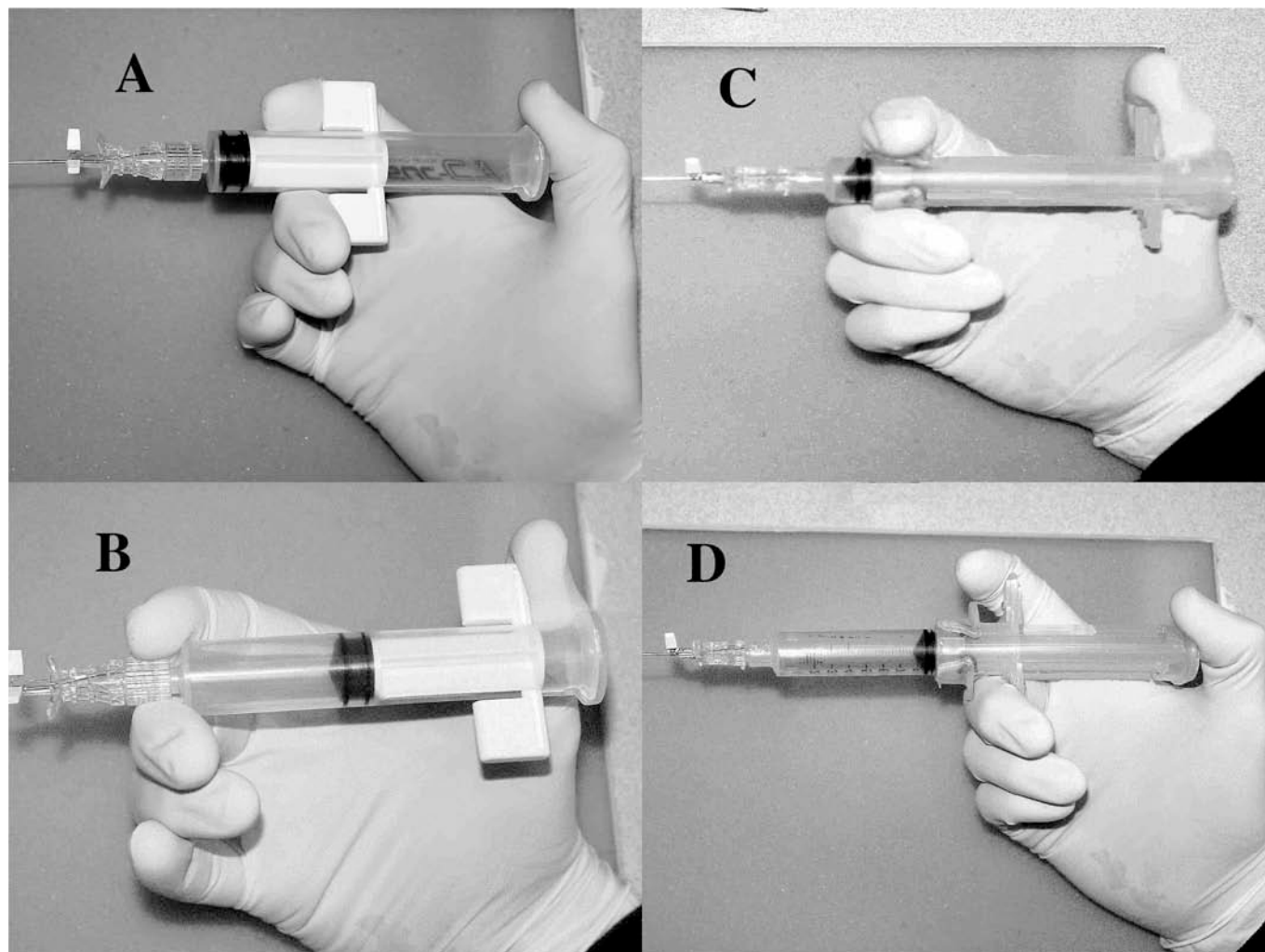
Vacuum (ie, negative pressure) was standardized in each syringe with a digital pressure meter with Luer fittings (DPM-2000 digital pressure meter; BC Group, Chicago, IL). One discrete level of vacuum ( $-275$  Torr) was created by each operator. The dif-

ficulty of achieving this level of negative pressure with each syringe was rated by each operator on the visual analog difficulty scale from 0 to 10, with 0 representing no difficulty and 10 representing extreme difficulty (24,25).

#### Statistical Analysis

Data were entered into Excel (version 5; Microsoft, Redmond, WA), and analyzed with SAS software (release 6.11; SAS/STAT Software, Cary, NC). Differences in categorical data were determined with the Fisher exact test, and differences in parametric data were determined with the *t* test,

whereas differences among multiple parametric data sets were determined with the Fisher least significant difference method. Corrections were made for multiple comparisons. Overall comparisons of syringes were made by ranking each syringe in each test on a 1–10 scale on which 1 represents the best performance and 10 represents the worst performance of the set, summing these ranks, and deriving a mean rank score for each syringe for the following categories: (i) cases in which a needle with a stylet is used, (ii) cases in which a needle without a stylet is used, and (iii) cases in which the needle remains on the syringe after the procedure and is sent for analysis.



**Figure 4.** The BioSuc-C70 and reverse aspiration syringes. The BioSuc-C70 syringe is aspirated (a) and injected (b) with one hand. Note the major change of positioning of the thumb and index and middle fingers from aspiration to injection. The reverse aspiration syringe is aspirated (c) and injected (d) with one hand. Note the major change of positioning of the thumb and index and middle fingers from aspiration to injection.

## RESULTS

The difficulty in attaching the syringe device to a needle already in the biopsy site is shown in **Table 1**. All the syringes with enlarged or modified finger flanges or grips (three-ring control syringe, reverse aspiration syringe, BioSuc-C7 syringe, syringe pistol, RPD, and RPD syringe holder) were more difficult to attach to the needle hub than the conventional syringe or the conventional syringe with the plunger lock ( $P < .001$ ).

**Table 2** demonstrates physician performance in terms of syringe and needle control with each syringe device during the aspiration phase of the

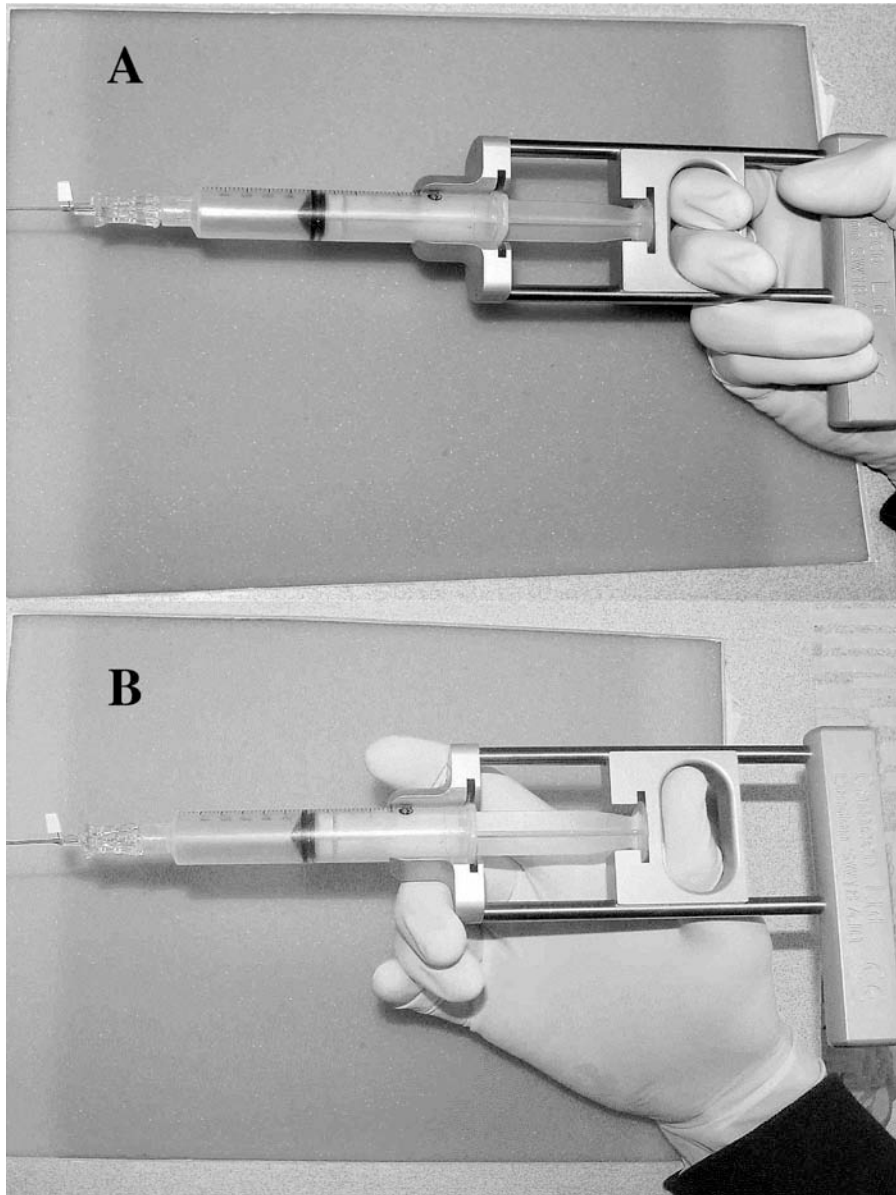
procedure. In terms of unintended penetration (ie, loss of control in the forward direction) during an aspiration procedure, the reverse-aspiration syringe penetrated  $31.5 \pm 1.7$  mm, followed closely by BioSuc-C7 ( $28.3 \pm 1.9$  mm) and the three-ringed control syringe ( $25.4 \pm 4.1$  mm). The syringe pistol penetrated  $9.2 \pm 2.4$  mm, more than the conventional syringe whether it was used with one hand ( $2.9 \pm 1.1$  mm penetration) or two hands ( $3.8 \pm 2.9$  mm penetration). Also, the conventional syringe with a plunger lock penetrated farther than the conventional syringe alone (**Table 2**). The devices with the least unintended forward

penetration were the RPD ( $0.7 \pm 0.7$  mm penetration) and the RPD syringe holder ( $0.6 \pm 0.6$  mm penetration).

**Table 3** shows the difficulty in generating a standard vacuum (negative pressure to  $-275$  Torr) with each syringe device. The three-ringed control syringe was the most difficult syringe to generate vacuum, followed closely by the conventional syringe with or without a plunger lock. The reverse-aspiration syringe, the BioSuc-C7, the syringe pistol, RPD, and RPD syringe holder had the least difficulty in generating a defined level of vacuum ( $P < .001$ ).

FNA remains an important proce-

T3



**Figure 5.** The Cameco Syringe Pistol is aspirated (a) and injected (b) with one hand. Note the major change of positioning of the thumb and index and middle fingers from aspiration to injection.

cedure in biopsies of lesions of the lung, mediastinum, and thorax (8,13,14). During thorax biopsy procedures, air can unintentionally be introduced into the suction device by hitting an air pocket in lung or mediastinum or by leakage around the needle fitting. This reduces the vacuum and reduces biopsy tissue yield. Therefore, it is important when using a suction biopsy device to be able to sense when the vacuum has been inadvertently released, especially for image-guided

procedures of the lung and thorax. **Table 4** shows the difficulty in sensing loss of vacuum with each syringe device. The BioSuc-C7 and the conventional syringe with a plunger lock were not sensitive to loss of vacuum ( $P < .005$ ). The most sensitive devices for detecting loss of vacuum were the RPD, which was the most sensitive, followed by the three-ringed control syringe and the conventional syringe used with two hands (**Table 4**).

Precise control of the syringe dur-

ing five biopsy passes is shown in **Table 5**. The most poorly controlled device was the syringe pistol, followed closely by the conventional syringe used with one or two hands. The conventional syringe with a plunger lock, the three-ringed control syringe, the reverse aspiration syringe, the BioSuc-C7, the RPD, and the RPD syringe holder were all roughly equivalent in control characteristics, and all were statistically superior to the conventional syringe ( $P < .001$ ) (**Table 5**).

Release of vacuum before the syringe is pulled out from the biopsy site is important in a syringe procedure to prevent the sample from being forced by ambient pressure into the syringe barrel, from which it is often difficult to expel. The performance in terms of vacuum release is shown in **Table 6**. The conventional syringe with the plunger lock was by far the most difficult syringe to release vacuum, followed by the conventional syringe used with one hand. The conventional syringe used with two hands, the three-ringed control syringe, the reverse aspiration syringe, the BioSuc-C7, the syringe pistol, the RPD, and the RPD syringe holder were all roughly equivalent in vacuum release characteristics, and all were statistically equivalent to the conventional syringe operated with two hands (**Table 6**).

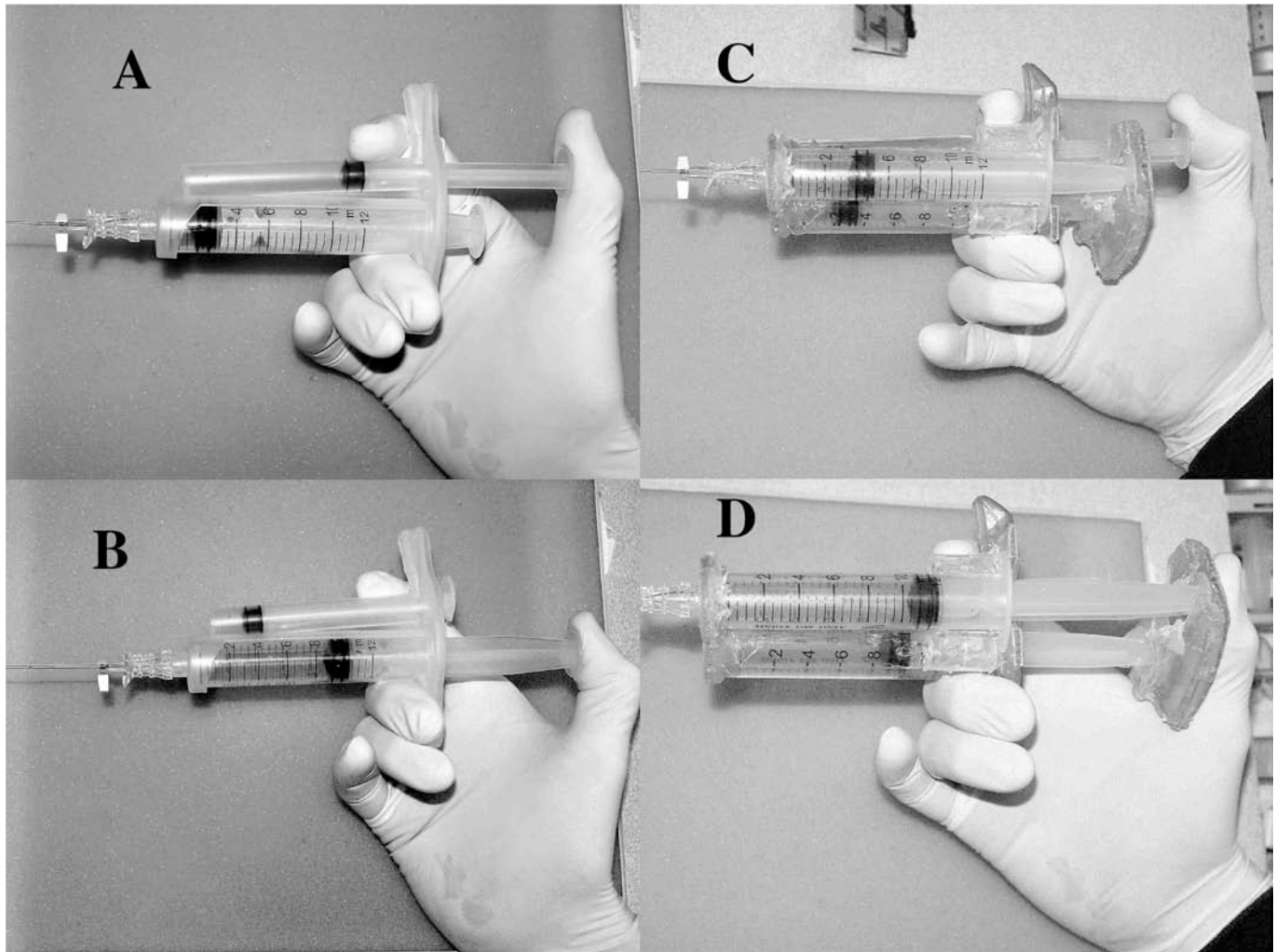
After a biopsy specimen has been obtained, it is often necessary to expel the sample onto a slide or into a fixative agent for further processing. For this component of the procedure, the biopsy needle is removed from the syringe; the plunger of the syringe is moved back to aspirate, filling the syringe with air; the biopsy needle is reattached; and the sample is expelled by injection pressure. **Table 7** shows the relative difficulty in ejecting a sample from the needle for each syringe device. The RPD, the RPD syringe holder, and the three-ringed control syringe had the lowest difficulty scores for the procedure of ejecting a sample ( $P < .001$ ). The devices that required a major change in hand position—the conventional syringe, the reverse-aspiration syringe, and the BioSuc-C7 syringe—exhibited intermediate levels of difficulty scores to expel a sample (**Table 7**). The most difficult devices to expel a sample were the syringe pistol and the conventional syringe with a plunger lock ( $P < .005$ ).

T5

T6

T7

T4



**Figure 6.** The RPD and RPD syringe holder: the RPD is aspirated (a) and injected (b) with one hand. Note the absence of change of positioning of the index and middle fingers, with only the thumb moving to the alternative plunger from aspiration to injection. The RPD syringe holder is aspirated (c) and injected (d) with one hand. Note the absence of change of positioning of the index and middle fingers, with only the thumb moving to the alternative plunger from aspiration to injection.

Overall performance rankings are shown in **Table 8**. For biopsy type 1 (ie, needle with stylet), biopsy type 2 (ie, needle without stylet), and biopsy type 3 (ie, needle remains on syringe), the RPD and the RPD syringe holder demonstrated the best rankings, whereas the conventional syringe operated with one hand and the conventional syringe with a plunger lock consistently demonstrated the worst overall scores for all three biopsy types.

## DISCUSSION

Suction needle biopsy techniques that use a syringe for application of vacuum by aspiration remain impor-

tant diagnostic techniques in interventional radiology (1–22). Although initial core biopsy of nonpalpable breast lesions is now the method of choice in most centers, FNA techniques, even in the breast, have not been completely supplanted by core biopsy techniques. Rather, there is growing evidence that core biopsy combined with simultaneous FNA biopsy is better than either technique alone (9,10,15). For some lesions, especially palpable lesions of the thyroid, breast, and salivary gland and lesions of the chest, liver, kidney, lymph nodes, and abdomen, initial FNA biopsy is still considered the method of choice by many radiologists (1–20). Although fine needle nonaspi-

ration biopsy (ie, capillary action biopsy), which does not use a syringe, is generally equivalent to FNA in the thyroid, fine needle nonaspiration biopsy is inferior to FNA in other tissues, including breast, liver, kidney, and lung, generally because of inadequate samples, especially in benign lesions (27–31). Relative to isolated core biopsies, FNA is easier to perform, faster, and less traumatic; provides a diagnosis more rapidly; and is more cost effective (10,11,13,16,17). Therefore, despite the popularity of isolated core biopsies in some centers, needle biopsy techniques that require a syringe device to apply suction as the primary diagnostic procedure or as a

## 8 • Control and Performance of Eight Suction Biopsy Devices

October 2006 JVIR

**Table 1**  
**Difficulty in Attaching the Syringe to the Biopsy Needle**

Biopsy Device	Visual Analog Score	Ranking (1, Best; 10, Worst)	P Value (vs Conventional Syringe with Two Hands)
Conventional syringe			
One-handed	1.0 ± 0.2	1	NS
Two-handed	1.1 ± 0.1	2	NS
Conventional syringe with plunger lock			
One-handed	1.2 ± 0.1	3	NS
Two-handed	1.3 ± 0.5	4	NS
Reverse aspiration syringe (one-handed)	1.8 ± 1.7	5	≤.001
BioSuc-C7 syringe(one-handed)	1.9 ± 1.9	6	≤.001
Three-ringed control syringe (one-handed)	2.3 ± 4.1	7	≤.001
RPD (one-handed)	4.3 ± 0.7	8	≤.001
RPD syringe holder (one-handed)	5.2 ± 0.6	9	≤.001
Syringe pistol (one-handed)	9.2 ± 2.4	10	≤.001

Note.—Values presented as means ± SD where applicable. NS = not significant.

**Table 2**  
**Physician Loss of Control of Syringe and Needle with Unintentional Penetration while Generating Vacuum**

Biopsy Device	Unintended Penetration (mm)	Control Ranking (1, Best; 10, Worst)	P Value (vs Conventional Syringe with Two Hands)
RPD syringe holder(one-handed)	0.6 ± 0.6	1	≤.001
RPD (one-handed)	0.7 ± 0.7	2	≤.001
Conventional syringe			
One-handed	2.9 ± 1.1	3	NS
Two-handed	3.8 ± 2.9	4	NS
Conventional syringe with plunger lock			
One-handed	5.9 ± 2.6	5	NS
Two-handed	6.1 ± 1.5	6	NS
Syringe pistol(one-handed)	9.2 ± 2.4	7	≤.001
Three-ringed control syringe (one-handed)	25.4 ± 4.1	8	≤.001
BioSuc-C7 syringe (one-handed)	28.3 ± 1.9	9	≤.001
Reverse aspiration syringe (one-handed)	31.5 ± 1.7	10	≤.001

Note.—Values presented as means ± SD where applicable. NS = not significant.

synergistic procedure combined with a core biopsy to improve diagnostic effectiveness will remain an important and useful diagnostic technique in interventional radiology for the foreseeable future (1–17).

Needle biopsies with aspiration and core techniques are much safer than equivalent open techniques, and serious complications are unusual (19,20). However, complications do occur from needle biopsies and can be fatal (19,20,32,33). Needle biopsies, depending on the location, can result in pain, bruising, arterial puncture, hematoma, massive exsanguination, pneumothorax, hemothorax, infection, cardiac perforation, airway compromise, and death, resulting in lawsuits

and increased health care costs (32–42). Better control of the procedure device has been shown to improve outcomes in various syringe procedures (23,26). Therefore, needle techniques, although much safer than open techniques, are not without risk, and technologic advances that permit better control of the procedure device may improve outcomes (19,20,23,26,32,33).

The present study addresses the performance characteristics of several different suction biopsy devices. The results demonstrate that each device has specific advantages and disadvantages during individual components of the aspiration syringe procedure. The RPD and RPD syringe demonstrated the most favorable overall per-

formance rankings of the various devices ( $P < .01$ ) (Table 8). By contrast, the conventional syringe used one handed and the conventional syringe with a plunger lock consistently had the least favorable rankings (Table 8), suggesting that these latter devices have considerable disadvantages and serious performance inadequacies.

The present study used the linear displacement model of physician syringe control: a validated method to measure physician control of syringe and needle that directly corresponds to outcomes of real syringe procedures (23). With this model, the RPD and RPD syringe holder were the best controlled of all devices, with less than 1 mm of unintended penetration,

**Table 3**  
**Difficulty in Generating Vacuum (Aspiration to -275 Torr)**

Biopsy Device	Visual Analog Score	Ranking (1, Best, 10, Worst)	P Value (vs Conventional Syringe with Two Hands)
Syringe pistol (one-handed)	2.0 ± 2.4	1	≤.01
BioSuc-C7 syringe (one-handed)	2.3 ± 1.0	2	≤.01
RPD (one-handed)	2.4 ± 0.5	3	≤.01
Reverse aspiration syringe (one-handed)	2.4 ± 1.0	4	≤.01
RPD syringe holder (one-handed)	2.5 ± 0.6	5	≤.01
Conventional syringe (two-handed)	4.0 ± 0.3	6	NS
Conventional syringe with plunger lock (two-handed)	4.1 ± 0.3	7	NS
Conventional syringe (one-handed)	6.4 ± 1.1	8	≤.01
Conventional syringe with plunger lock (one-handed)	6.5 ± 1.1	9	≤.01
Three-ringed control syringe (one-handed)	6.6 ± 1.1	10	≤.01

Note.—Values presented as means ± SD where applicable. NS = not significant.

**Table 4**  
**Difficulty in Sensing Loss of Vacuum (Loss of -270 Torr)**

Biopsy Device	Visual Analog Score	Ranking (1, best, 10, worst)	P Value (vs Conventional Syringe with Two Hands)
Three-ringed control syringe (one-handed)	1.1 ± 1.4	1	NS
RPD (one-handed)	1.4 ± 2.1	2	NS
Conventional syringe (two-handed)	2.5 ± 1.6	3	NS
Syringe pistol (one-handed)	3.0 ± 2.8	4	NS
RPD syringe holder (one-handed)	4.9 ± 1.5	5	≤.01
Conventional syringe (one-handed)	5.0 ± 2.2	6	≤.01
Reverse aspiration syringe (one-handed)	6.1 ± 1.2	7	≤.01
BioSuc-C7 syringe (one-handed)	10	8	≤.001
Conventional syringe with plunger lock (two-handed)	10	9	≤.001
Conventional syringe with plunger lock (one-handed)	10	10	≤.001

Note.—Values presented as means ± SD where applicable. NS = not significant.

**Table 5**  
**Physician Loss of Control of Syringe and Needle with Unintentional Penetration during Five Biopsy Passes**

Biopsy Device	Unintentional Penetration (mm)	Ranking (1, Best, 10, Worst)	P Value (vs Conventional Syringe with Two Hands)
Conventional syringe with plunger lock (one-handed)	4.4 ± 2.7	1	≤.001
Conventional syringe with plunger lock (two-handed)	4.4 ± 2.7	2	≤.001
Reverse aspiration syringe (one-handed)	4.5 ± 1.4	3	≤.001
RPD syringe holder (one-handed)	4.7 ± 3.2	4	≤.001
BioSuc-C7 syringe (one-handed)	5.0 ± 2.7	5	≤.001
RPD (one-handed)	6.3 ± 2.9	6	≤.001
Three-ringed control syringe (one-handed)	7.6 ± 1.3	7	≤.04
Conventional syringe (two-handed)	10.4 ± 2.2	8	NS
Conventional syringe (one-handed)	12.9 ± 5.6	9	NS
Syringe pistol (one-handed)	13.9 ± 3.5	10	NS

Note.—Values presented as means ± SD where applicable. NS = not significant.

whereas the most difficult devices to control were the three-ringed control syringe, the reverse-aspiration sy-

ringe, and the BioSuc-C7 syringe (Table 2). Each of the latter consistently exhibited a mean of approximately 30

mm in unintended forward penetration during the aspiration, far greater than the other devices ( $P < .001$ ) (Ta-

**Table 6**  
**Difficulty in Releasing Vacuum (Loss of -275 Torr)**

Biopsy Device	Visual Analog Score	Ranking (1, Best, 10, Worst)	P Value (vs Conventional Syringe with Two Hands)
Syringe pistol (one-handed)	0.3 ± 0.5	1	NS
RPD (one-handed)	0.4 ± 0.5	2	NS
RPD syringe holder (one-handed)	0.4 ± 2.5	3	NS
BioSuc-C7 syringe (one-handed)	0.5 ± 1.1	4	NS
Three-ringed control syringe (one-handed)	0.6 ± 0.5	5	NS
Reverse aspiration syringe (one-handed)	0.6 ± 1.5	6	NS
Conventional syringe (two-handed)	0.9 ± 1.5	7	NS
Conventional syringe (one-handed)	2.4 ± 2.1	8	≤.01
Conventional syringe with plunger lock (two-handed)	8.4 ± 3.5	9	≤.001
Conventional syringe with plunger lock (one-handed)	9.4 ± 3.8	10	≤.001

Note.—Values presented as means ± SD where applicable. NS = not significant.

**Table 7**  
**Difficulty in Removing Needle from Syringe, Placing Air in Syringe, Reattaching Needle, and Expelling Sample from Needle**

Biopsy Device	Visual Analog Score	Ranking (1, Best, 10, Worst)	P Value (vs Conventional Syringe with Two Hands)
RPD (one-handed)	1.2 ± 0.8	1	≤.01
Three-ringed control syringe (one-handed)	1.3 ± 1.5	2	≤.01
RPD syringe holder (one-handed)	2.4 ± 2.7	3	≤.01
BioSuc-C7 syringe (one-handed)	3.2 ± 1.5	4	NS
Conventional syringe (two-handed)	3.4 ± 1.5	5	NS
Reverse aspiration syringe (one-handed)	3.4 ± 1.8	6	NS
Conventional syringe (one-handed)	3.4 ± 2.1	7	NS
Syringe pistol (one-handed)	6.2 ± 1.5	8	≤.001
Conventional syringe with plunger lock (two-handed)	8.5 ± 3.5	9	≤.001
Conventional syringe with plunger lock (one-handed)	9.5 ± 3.8	10	≤.001

Note.—Values presented as means ± SD where applicable. NS = not significant.

ble 2). Control of the syringe and needle during five biopsy passes was least favorable with the conventional syringe and the syringe pistol, but roughly equivalent among the other syringe devices (Table 5). These data show that engineering modifications to a syringe to permit one-handed use can actually decrease control of the syringe and needle (Tables 2, 5).

In the present study, the performance of plunger locks was disappointing, with less control during aspiration (Table 2), increased difficulty in generating vacuum (Table 3), inadequate sensing the loss of vacuum (Table 4), difficulties in releasing vacuum (Table 6) and expelling the sample from the syringe (Table 7), and reduced overall syringe performance

(Table 8). Therefore, these data indicate that plunger locks have serious performance inadequacies.

Syringe pistols and guns have also been very popular in some centers, especially for aspiration biopsies of the thyroid and breast, among other uses (19–22). The advantages of syringe pistols and guns are one-handed use, the ability to easily generate vacuum or pressure, and the ability to exchange several different syringes during the biopsy procedure. In the present study, the syringe pistol performed well in terms of ease of vacuum generation (Table 3), sensing vacuum (Table 4), and releasing vacuum (Table 6). Surprisingly, the control of the syringe pistol was inferior to that of the conventional syringe

during an aspiration procedure (Table 2) and during the five biopsy passes (Table 5). The syringe pistol was also associated with increased difficulty in terms of attaching to the needle and clearing the sample from the needle (Tables 1, 7). We believe that control of the syringe pistol is reduced by abutting the handle of the pistol against the base of hand and thumb, transferring control of the device to the coarsely controlled musculature of the arm rather than the finely controlled musculature of the hand. These data do not support the superiority of the syringe pistol over the conventional syringe in terms of control of the needle and syringe.

Because of the need for stable one-handed aspiration and the need to

**Table 8**  
**Cumulative Suction Device Rankings**

Ranking	Biopsy Type 1: Removable Stylet in Biopsy Needle		Biopsy Type 2: Removable Stylet in Biopsy Needle		Biopsy Type 3: Needle Remains on Syringe	
	Device	Cumulative Ranking Score	Device	Cumulative Ranking Score	Device	Cumulative Ranking Score
1	RPD*	3.42 ± 2.57	RPD*	2.67 ± 1.75	RPD*	3.00 ± 1.23
2	RPD syringe holder	4.29 ± 2.50	RPD syringe holder	3.50 ± 1.51	RPD syringe holder	3.60 ± 1.67
3	Conventional syringe (two- handed)*	4.86 ± 2.41	Syringe pistol*	5.17 ± 3.76	Syringe pistol*	4.60 ± 3.91
4	Reverse aspiration syringe	5.57 ± 1.72	Conventional syringe (two- handed)*	5.50 ± 1.87	Conventional syringe (two- handed)*	6.6 ± 2.88
5	BioSuc-C7 syringe*	5.57 ± 2.70	BioSuc-C7 syringe*	5.50 ± 2.95	Reverse aspiration syringe	5.60 ± 2.07
6	Three-ringed control syringe*	5.85 ± 3.39	Reverse aspiration syringe	5.67 ± 1.86	BioSuc-C7 syringe*	5.80 ± 3.19
7	Syringe pistol*	5.86 ± 3.89	Three-ringed control syringe*	5.67 ± 3.67	Three-ringed control syringe*	6.40 ± 3.58
8	Conventional syringe (one- handed)*	6.14 ± 2.67	Conventional syringe (one- handed)*	6.83 ± 2.14	Conventional syringe with plunger lock (two-handed)*	6.6 ± 2.88
9	Conventional syringe with plunger lock (two-handed)*	6.57 ± 2.76	Conventional syringe with plunger lock (two- handed)*	7.17 ± 2.93	Conventional syringe (one- handed)*	6.80 ± 2.39
10	Conventional syringe with plunger lock (one-handed)*	6.86 ± 3.80	Conventional syringe with plunger lock (one- handed)*	7.50 ± 3.72	Conventional syringe with plunger lock (one-handed)*	7.00 ± 3.93

\* Commercially available device.

maintain the ability to inject, one-handed procedure syringes have been developed. Such devices include the commercially available BioSuc-C7 (Fig 4a,b) and the experimental reverse-aspiration syringe (Fig 4c,d). These syringes were good for generating vacuum but exhibited significant unintended forward penetration during the aspiration phase (Table 2). In addition, the BioSuc-C7 device had the additional disadvantage of extreme insensitivity to the detection of loss of vacuum (Table 4). The traditional one-handed syringe is the three-ringed control syringe, which is a commercially available conventional syringe with annular flanges replacing the conventional ones on the barrel and the plunger (Fig 3c,d). The three-ringed control syringe exhibited a high degree of loss of control during aspiration (Table 2), difficulty gener-

ating vacuum (Table 3), and generally poor overall rankings as a biopsy device (Table 8).

The RPD and RPD syringe holder represent a new class of syringe devices that are operated exclusively with the flexor musculature of the hand. The RPD syringe holder is neither commercially available nor FDA approved, but versions of the RPD are commercially available in FDA-approved forms (41,42). The RPD has 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 (Fig 6a,b). The conventional plunger and the accessory plunger are mechanically linked in an opposing fashion by a pulley or gear system, resulting in a set of reciprocating plungers. Therefore, 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 aspiration and injection, while the thumb needs only to move laterally to the alternative plunger to change the direction of aspiration or injection. These characteristics create a very well-controlled syringe that can generate vacuum or pressure easily with one hand (23,26).

The conventional syringe with a plunger lock, the three-ringed control syringe, the reverse aspiration syringe, the BioSuc-C7 suction device, and the syringe pistol demonstrated no improvement in control compared with the conventional syringe used with two hands (Table 2). By contrast, the reciprocating devices (the RPD and RPD syringe holder) were the best

controlled of all devices (Table 2) and had most favorable overall rankings for all three types of biopsy, including cutting-needle biopsy with stylet aspiration (type 1 biopsy), FNA with sample blowout (type 2 biopsy), and FNA biopsy in which the sample remains in the needle (type 3 biopsy) (Table 8). Two previous clinical trials have demonstrated that physicians control the RPD better than they control conventional devices (23,26) and that this improved control results in reduced patient pain and improved syringe procedure outcomes. The present study confirms that the reciprocating mechanism of the RPD confers certain performance advantages over typical syringe devices used in suction biopsy procedures.

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1

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