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New Device Technologies for Subcutaneous Fat Biopsy

Lawrence G. Kettwich, BS¹, Wilmer L. Sibbitt Jr., MD², N. Suzanne Emil, MD², Usman Ashraf, MD², Leslie Sanchez-Goettler, MD², Yumna Thariani, MD², and Arthur D. Bankhurst, MD²

¹Medical Student, School of Medicine, University of New Mexico Health Sciences Center, Albuquerque, NM, USA

²Department of Internal Medicine, Division of Rheumatology, University of New Mexico Health Sciences Center, Albuquerque, NM, USA

Abstract

Purpose—Subcutaneous fat biopsy is useful for the evaluation of amyloidosis, environmental contaminants, lipid metabolism, genetic studies, and diabetes research. The present study examined new technologies for fat biopsy.

Methods—Subcutaneous fat biopsy in 10 high-risk individuals was randomized to 1) a 10 ml RPD (reciprocating procedure device - RPD), mechanical syringe or 2) a 60 ml vacuum syringe. Outcome measures included pain by the 10 cm Visual Analogue Pain Scale (VAS), adequacy of biopsied tissue, complications, and diagnosis. The operator's ability to control syringes was quantitatively measured by the linear displacement method.

Results—Both syringes permitted facile aspiration of subcutaneous fat with adequate sample without complications. The mechanical and the vacuum syringes enhanced control of the needle compared to conventional syringes, reducing unintended forward penetration by 75% (3.6±0.5 mm) and 87% (12.0±1.4 mm), respectively (p<0.0001). Free adipose cells were obtained in abundance as well as columnar biopsies containing intact blood vessels and connective tissue septa permitting precise microhistological examination. One case of primary AL amyloidosis (kappa light chain disease) was diagnosed in each group.

Conclusions—Subcutaneous fat biopsy by needle aspiration can be facilely achieved with new aspiration syringe technologies with improved needle control and enhanced patient safety.

Keywords

fat; biopsy; amyoidosis; needle; adipose; FNA

Correspondence to: Wilmer L. Sibbitt, Jr. MD, Professor, MSC 10 5550 5th FL ACC, University of New Mexico Health Sciences Center, Albuquerque, NM, USA 87131, Telephone Number: 505 272-4761, Fax Number: 505 272-3624, wsibbitt@salud.unm.edu. This study is IRB approved, has been registered with www.clinicaltrials.gov. The clinical trial number is NCT00651625

Declaration of Interest

Drs. Kettwich, Bankhurst, Emil, Sanchez-Goettler, Thariani, and Ashraf have nothing to declare. Dr. W. Sibbitt is funded by Research Grant RO1 HLO77422-01-A3 from the US National Institutes of Health, and grants from the Public Health Service and Arthritis Foundation. Dr. Sibbitt is a full-time professor at and an employee of the University of New Mexico. Dr. W. Sibbitt also is an expert consultant for Intelligence Management Solutions, Inc., Ferring Pharmaceuticals, Inc., Avanca Medical Devices, Inc; Avasca, Inc., and MediTech Duopross, Inc. Dr. Sibbitt holds stock in Apple Inc, Celgene Corp, Inc, Avanca, Inc, Avasca, Inc., Sun Microsystems, Inc, Symantec Corp, and Java, Inc. In 2009 Abbott Vascular, Inc. acquired 4 patents invented by Dr. W. Sibbitt, but these patents are not relevant to the present research.

Introduction

Subcutaneous fat biopsy performed with needle aspiration is a standard methodology to obtain adipose tissue for histologic, metabolic, immunological, and biochemical analysis [1–4]. Subcutaneous fat biopsy has become the standard for the diagnosis of systemic amyloidosis, for metabolic, immunologic, endocrine, and genetic studies of adipose tissue, and for measuring lipophilic environmental contaminants [3–7]. Most practitioners use a 10 or 20 ml syringe, a 16 to 18 gauge large bore needle, and provide vacuum by pulling back the plunger on the syringe to perform multiple passes until enough sample has been obtained [2–10]. The original description of subcutaneous fat biopsy utilized a 50 ml syringe, which generated considerable vacuum [11]. However, larger syringes are difficult to both operate and control because of the considerable force required to retract the plunger, and can result in needle penetration of the abdominal wall with subsequent hematoma formation [3,12–15].

New technologies, including mechanical syringes and vacuum syringes, have been developed to perform needle aspiration biopsies, but to date these devices have not been used routinely in needle biopsy of subcutaneous fat [16,17]. Earlier work from our group has demonstrated that mechanical syringes appear to be superior to and safer than the conventional syringe for aspiration procedures [17–21]. Vacuum syringes > 50 ml are used for amniocentesis, suction biopsy, suction curettage, and cosmetic liposuction, but there are few reports of the use of large vacuum syringes for fat biopsy [22–27]. We hypothesized that mechanical syringes and vacuum syringes would provide enhanced needle control for aspiration biopsy of subcutaneous fat. The present trial determined the control characteristics of mechanical and vacuum syringes relative to conventional syringe, and compared fat biopsy performed with a mechanical syringe to that with a vacuum syringe.

Methods

Subjects

This project was in compliance with the Helsinki Declaration, approved by the institutional review board (IRB), and was registered at *ClinicalTrials.gov* (Clinical Trial Identifier NCT00651625). Inclusion criteria included: 1) unexplained arthralgias and neuropathic symptoms consistent with the diagnosis of systemic amyloidosis, 2) negative serological evaluations for the usual causes of these symptomatology, 3) indication for fat biopsy as determined by an expert physician, and 4) formal consent of the patient to undergo the procedure and participate in the research. A total of 10 individuals with unexplained arthralgias and neuropathic symptoms were randomized between 1) a 10 ml mechanical syringe (5 individuals), or 2) a 60 ml vacuum syringe (5 individuals). Costs for fat biopsy were determined by using HCPC/CPT code 10021 as determined by the US Department of Health & Human Services, Centers for Medicare & Medicaid Services [28].

Patient Outcomes

Patient outcomes included 1) procedural pain as measured by the 0–10 cm Visual Analogue Pain Scale (10 cm VAS), 2) adequacy of the fat biopsy specimen for histopathologic analysis, 3) the diagnosis of amyloidosis, and 4) complications, including bruising, hematoma, or infection [29,30].

Technique for Fat Biopsy by Needle Aspiration

The abdominal fat biopsy technique was generally similar to that described previously [3,8,9–11]. After informed consent, the area of skin for biopsy on the lateral side of the abdomen was prepared with chlorhexidine antiseptics. Subsequently local anesthesia with 1% lidocaine (Xylocaine® 1%, AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, P.O. Box

15437, Wilmington, DE, USA 19850–5437) was administered intradermally using a 25 gauge 5/8 inch (1.6 cm) needle on a 5 ml mechanical syringe [31]. As in the original description of abdominal fat biopsy by Hirsch et al, a biopsy needle with a stylet was used (Chiba Biopsy Needle 18 gauge 5 cm (2 inch), GPN G02585, ON DCHN-18-5.0, Cook Medical, Bloomington, IN, USA) [11]. The Chiba needle with the stylet was grasped at the front part of the needle between the index finger and thumb with the hub portion resting in the palm. The abdominal skin and fat were then pinched between the fingers and lifted away from the abdominal wall to prevent accidental penetration of the rectus muscles and deep abdominal structures during needle insertion. The skin was then penetrated and the biopsy needle advanced about 1 inch (2.5 cm) into subcutaneous fat parallel to the plane of the abdominal wall. At that point, the stylet was removed and the aspiration syringe was attached, either the mechanical syringe or the vacuum syringe, by either rotating the needle or rotating the syringe into the needle fitting.

Needle Aspiration Biopsy with the Mechanical Syringe

The mechanical syringe was a 10 ml mechanical syringe (RPD (reciprocating procedure device) 10 ml syringe, AVANCA Medical Devices, Inc, Albuquerque, New Mexico, USA. website: www.AVANCAMedical.com). The mechanical syringe is formed around 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 (Figure 1). The two plungers are mechanically linked by a pulley in an opposing fashion, resulting in a set of reciprocating plungers. Thus, when the injection plunger is depressed with thumb, the syringe aspirates, and when the aspiration plunger is depressed with the thumb, the syringe injects. 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.

Prior to use, the 10 ml mechanical syringe was first cycled to break the bond of the plunger stopper with the barrel, and the air was then expelled by depressing the injection plunger. The mechanical syringe was then rotated onto the indwelling needle (or the needle rotated onto the syringe) (Figure 2) and then the aspiration plunger was depressed fully, generating 560 Torr (mm Hg) of vacuum (Figure 3). The fat biopsy was then performed in a conventional manner while depressing the aspiration plunger. After the biopsy was performed, the aspiration plunger was released, releasing vacuum in the syringe. The needle was then extracted. If the sample were small and still within the needle, the needle was removed and air aspirated into the mechanical syringe by depressing the aspiration plunger (Figure 4). The needle was then reattached, and the injection plunger was depressed and the sample expelled onto a slide or into cytological processing fluid (Figure 5). The biopsy process was then repeated. If the syringe were filled with tissue and no further biopsies were necessary, the fat was washed out or removed from the barrel in a conventional manner [3,8,9–11].

Suction Biopsy with the Vacuum Syringe

The vacuum syringe consisted of a conventional 60 ml syringe (BD 60 ml Syringe, Luer-Lok™ Tip, REF 309653, BD Franklin Lakes, NJ 07417). This 60 ml conventional syringe was fitted with a sterile flow switch (QOSINA, Flow Control Switch, part number 97337, Quosina Corp., 150-Q Executive Drive, Edgewood, New York 11717–8329 U.S.A), and a custom plunger lock (60 ml plunger lock, AVANCA Medical Devices, Inc, Albuquerque, New Mexico, USA. website: www.AVANCAMedical.com). To create vacuum in the 60 ml conventional syringe, the flow switch was closed, the distal portion of the plunger lock fitted into the thumb rest of the plunger, the plunger pulled back to the 60 ml mark, and the proximal portion of the plunger lock fitted into the syringe barrel so that the plunger

remained at the 60 ml plunger displacement mark (Figure 1). This 60 ml conventional vacuum syringe achieved a vacuum level of 720 Torr (mm Hg).

The 60 ml vacuum syringe was rotated onto the 18 gauge indwelling biopsy needle (or the needle rotated onto the syringe). The flow switch was then opened and the biopsy procedure performed as is fully conventional with multiple passes (Figure 6). Once done with the aspiration procedure, the flow switch was closed and the needle extracted; the closed flow switch prevented air and the sample in the biopsy needle from being sucked into the syringe. To expel a sample in the needle, the flow switch was rotated and loosened to permit air to flow into the syringe barrel, and then rotated in the opposite direction to become airtight again. The plunger lock was removed, and the flow switch opened, and then the plunger was depressed, expelling the sample. If the syringe were filled with fat and no further biopsies were necessary, the fat was washed out or removed from the barrel in a conventional manner [3,8,9–11].

Processing Cytological Specimens

After expelling the biopsy tissues from the needle and barrel, identifiable tissues were fixed in formalin and embedded in paraffin as previously described, then stained with a freshly prepared solution of alkaline Congo Red and examined under polarizing microscopy at a magnification of X10 and X100 to assess the presence of the light pink material typical of amyloid deposits on light microscopy and the focal apple green birefringence of amyloid deposits on polarizing microscopy (Figures 7 and 8). For biopsies without identifiable tissues, the cytologic sample was centrifuged, formalin fixed, and the cellular plug embedded in paraffin and stained with Congo Red and similarly accessed for the presence of amyloid. After demonstrating amyloid deposits, the clinical diagnosis of amyloidosis was confirmed by serum immunoelectrophoresis and measurement of circulating light chains as appropriate.

Quantifying Syringe and Needle Control During Fat Biopsy Procedures

In a series of related, but independent experiment the validated quantitative needle-based displacement method was used to measure needle control in conventional, mechanical, and vacuum syringes. This method measures loss of control in the forward direction (unintended forward penetration) that has been associated with needle trauma, hemorrhage and increased pain in syringe procedures [12,17,19]. A rigid polystyrene marker is placed on the needle to a preset indelible mark on the needle, and then the needle is advanced into the target until the polystyrene marker was touching the surface of the target tissue. The operator then performs the biopsy syringe procedure. Loss of control in the forward direction (unintended forward penetration) pushes the polystyrene marker posteriorly on the needle past the indelible mark, permitting precise measurement in mm of loss of control. The needle is marked every 10 mm, which allows precise measurement of loss of control in either the forward or reverse direction. For recording measurements less than 10 mm, a standard metric caliper is used. Finally, the operator recorded the difficulty of each procedure with each syringe using the visual analog scale for difficulty (10 cm VAS). Using the 10 cm VAS, 0 cm = no difficulty and 10 cm = extreme difficulty [12,29,30].

Control of the 10 ml mechanical fat biopsy syringe was compared to control of 10 ml conventional syringe; control of the 60 ml vacuum syringe was compared to the 60 ml conventional syringe. Aspiration procedures were performed for 10 cycles each with a conventional syringe and the mechanical and vacuum syringes and mean and standard deviation calculated. The order of each procedure with each syringe was randomized to reduce the possibility of a consistent bias or a bias from a training effect.

Statistical Analysis

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

Results

The results of the needle control experiments are shown in Table 1. Both aspirating syringe technologies were better controlled and easier to operate compared to the corresponding conventional syringe. The 10 mechanical syringe reduced unintended forward penetration of the needle tip during aspiration by 75% (**3.6±0.5 mm**) ($p<0.0001$), and reduced the difficulty of aspiration by 64% (**4.9±0.5 cm**) ($p<0.0001$). The vacuum syringe was also superior to the conventional syringe, reducing unintended forward penetration of the needle tip during aspiration by 87% (12.0 ± 1.4 mm), and reduced the difficulty of operating the syringe by 74% (7.2 ± 0.5 cm) ($p<0.0001$). Thus, both aspirating syringe technologies, the vacuum syringe and mechanical syringe, were superior to the corresponding conventional syringe in needle control characteristics and ease of use.

Direct clinical comparisons between the mechanical syringe and vacuum syringe are shown in Table 2. Both technologies permitted facile fat aspiration, and were equivalent in procedural pain, adequacy of the sample, and clinical diagnosis. Complications including an incidence of minor bruising in the vicinity of the puncture site occurred in 20% of the individuals, but no infections and no hematoma.

By coincidence, one individual in each group demonstrated typical amyloid deposits, and after further evaluation, was diagnosed with primary AL amyloidosis confirmed by biopsy of bone marrow and/or bowel and with serum confirmation of elevated immunoglobulin free light chains. Although providing considerable fat droplets and septal debris as previously described in aspiration fat biopsy, the Chiba cutting biopsy needle also provided more often intact columns of tissue (2 with vacuum syringe, 3 with mechanical syringe, and both cases of amyloidosis) including fat septa and vascular elements that permitted precise anatomical structure and facilitated both Congo Red and polarizing microscope examinations (Figures 7 and 8) [3,8,9–11]. In the remaining cases the centrifugal plug was analyzed.

Discussion

The present study demonstrates that the mechanical syringe and the vacuum syringe are better controlled and are easier to operate than a conventional syringe for fat aspiration biopsy. Further, the study demonstrates that biopsy is facilely achieved with the vacuum syringe and the mechanical syringe with equivalent outcomes including procedural pain, adequacy of tissue, and clinical diagnosis (Tables 1 and 2). Although fat droplets, individual adipose cells, and septal fragments are obtained as in other biopsy studies, certain subcutaneous fat biopsy samples obtained with the mechanical syringe and vacuum syringe, because of the cutting Chiba biopsy needle and higher levels vacuum, retained the native architecture with less fragmentation (Figures 7 and 8) typical with conventional fat biopsy methods [3,8,9–11]. The typical needles conventionally used for fat biopsy are conventional non-coring needles, where the surface of the bevel of the needle is designed to move tissue to the outside of needle and not enter the bore [32–35]. Thus, in most fat biopsies, the tissue

must be macerated by the multiple thrusts of the needle breaking the septa and freeing the fat cells so that the tissue becomes a suspension and can be aspirated into the needle [3,8,9–11]. Although the same mechanical breaking occurs with the Chiba cutting needle providing a suspension of fat cells and fragmented septa, columnar biopsies including intact blood vessels and septa are also obtained permitting precise histological staining and examination for amyloid deposits (Figures 7 and 8). Of course, standard and non-coring needles could also be used with the vacuum and mechanical aspirating syringes.

Subcutaneous fat biopsy performed with needle aspiration has become a routine methodology in rheumatology, neurology, environmental medicine, nephrology, and endocrinology to obtain adipose tissue for histologic, metabolic, immunological, and biochemical analysis [1–4]. Subcutaneous fat biopsy has become the standard for the diagnosis of systemic amyloidosis, for metabolic, immunologic, endocrine, and genetic studies of adipose tissue, and for measuring lipophilic environmental contaminants especially pesticides and halogenated hydrocarbons [1–11]. Most practitioners use a 16 to 18 gauge large bore needle, and provide vacuum by pulling back the plunger on the syringe, and performing multiple passes until enough sample has been obtained [3,8,9–11]. Typically, as described by Hazenberg et al, Westermarck et al, and Daum et al a 10 to 33 ml syringe is utilized to provide vacuum [3,8,9]. However, the original description of needle biopsy of fat by Hirsch et al in 1960 describes the use of the larger 50 ml syringe, which generates considerable vacuum to promote increased biopsy yield [11,35]. However, larger syringes are difficult to operate and control because of the force required to extract the plunger, and can result in unintended forward penetration of the needle with injury to the abdominal musculature or blood vessels with subsequent hematoma formation [3,12–19]. Even a 10 ml syringe can be dangerous when aspirating, resulting in loss of control of up to 6 mm, resulting in perforation or hemorrhage [12,16–19]. This is especially a problem in a slender individual with little abdominal fat, and consequently the skin and subcutaneous tissues must be grasped and lifted off of the abdominal wall (Figure 3) so that unintended puncture of the abdominal musculature or wall does not occur, particularly in a novice operator's hands.

A number of devices have been developed to improve vacuum assisted needle biopsy, including syringe handles, plunger locks, syringe pistols syringe guns, three-ringed syringes, and mechanical syringes [16,17]. Our group has demonstrated mechanical syringes to be the best controlled of devices during aspiration, and have the advantage that these devices can both facilely aspirate and inject [12,16–19]. Mechanical syringes have a reciprocating mechanism that prevents device lengthening during aspiration-injection, and permit improved needle control and aspiration-injection characteristics. Clinical trials have demonstrated that mechanical syringes are superior for aspiration procedures to a conventional syringe, resulting in greater needle control, less procedural pain, greater sample yield, less needle trauma, and a reduced incidence of hemorrhage [12,17–21]. Mechanical syringes also provide greater safety and improved outcomes for other needle procedures, including thyroid aspiration procedures, suction biopsy, abscess aspiration, administration of local anesthesia, sclerotherapy, central venous access, breast procedures, and ultrasound-guided procedures [17–21,36–39]. The present study confirms that mechanical syringes are superior in control characteristics to conventional syringes, reducing the dangerous unintended forward penetration by 75% during an aspiration procedure, and further demonstrates that effective subcutaneous fat biopsy can be facilely performed with these devices (Tables 1 and 2). Mechanical syringes cost approximately \$2 US amounting to 2% of the total cost of a fat biopsy and because of improved outcomes and safety, are considered cost-effective [28,40].

Hazenberget al first described the use of a vacuum syringe for fat biopsy consisting of a needle cap as a plunger lock on a 10 ml syringe (“Tarek’s trick”) for fat biopsy, but this maneuver is not adequate for larger syringes, which require a longer, more robust plunger locks and, because of the considerable forces required to generate vacuum in a large syringe, are more dangerous in terms of needle control *in situ* while the needle tip is close to abdominal wall (Table 2) [9,12]. Dedicated large-volume vacuum syringes have been used for amniocentesis, liposuction, vacuum curettage, and fine-needle aspiration biopsy [16,17,22–27]. Certain these syringes are both reusable and expensive in the range of \$100 per syringe [27]. The expense of these dedicated vacuum syringes are related to the low volume of production, the use of non-standard non-conventional syringe components, the requirement that the devices be sturdy during the aspiration procedure and not permit flexing, bending, or dislocation at the needle fitting, and the presence of non-standard non-luer fittings. All of these characteristics make dedicated vacuum syringes unsuitable for diagnostic fat biopsy that must utilize inexpensive technologies to be cost-effective.

In the present study, to generate high levels of vacuum yet keep costs low, a conventional 60 ml syringe out of the package (approximately \$1.00 US per syringe) was used for the vacuum syringe. A variable control on-off flow valve (approximately \$0.50 US per valve), and a custom plunger lock (estimate \$0.50 per plunger lock) were then attached to permit precise release of vacuum and generation of vacuum, respectively. This type of simple vacuum syringe increases the cost of fat biopsy by a net of \$1.00 US, approximately 2% of the total costs of a fat biopsy procedure, yet permit one-handed operation, high levels of vacuum, and exquisite needle control. Alternative designs of plunger locks that require special integrated parts, that are internalized into the syringe barrel, require changes in the design of the plunger, or require assembly before the syringe is packaged all could have functional advantages, but have a tendency to increase costs due to low-volume production, the need for new precise molds, additional assembly costs, and the inability to use low-cost off-the-shelf sterile syringes. The type of vacuum syringe with an integrated plunger lock would make sense if the same vacuum syringe technology were used frequently in other aspiration procedures (amniocentesis, thoracentesis, paracentesis, arthrocentesis, fine needle aspiration biopsy, etc) so that the volume of production would lower costs; for fat biopsy alone, as shown here, the use of a off-the-shelf sterile conventional 60 ml syringe with simple application of an external on-off valve and plunger lock is probably the most cost-effective approach.

The present study demonstrates that vacuum and mechanical syringes are superior in control characteristics to conventional syringes, reducing the dangerous unintended forward penetration by 87% (12.0 ± 1.4 mm) in vacuum syringes and 64% (4.9 ± 0.5 cm) in mechanical syringes during an aspiration procedure (Tables 1 and 2). The study also demonstrates that the vacuum syringe provides outcomes equivalent to that obtained with the highly controllable mechanical syringe, a syringe technology that has proven to improve outcomes of syringe procedures relative to conventional syringes [12,17–21,36–39].

There are recognizable limitations to the present study. First, the number of patients is too small to determine the rate of complications, although it is anticipated that these will be low as in similar methods of fat biopsy [1–10]. Further, the use of a particular device could be not be blinded to the operator, providing the possibility for operator bias in performance of the procedure, the VAS scores, and linear displacement observations. This is inability to blind the operator, of course, is inherent in all studies of surgical devices where the operator can recognize structural or functional differences between two alternative devices.

In summary, fat biopsy can be facilely achieved with new syringe technologies, including mechanical syringes and vacuum syringes and provide improved needle control, one-handed operation, and enhanced patient safety.

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Abbreviations

RPD	reciprocating procedure device
AL	amyloid light chain disease
VAS	visual analogue scale
SAS	SAS/STAT Software

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Figure 1. Aspiration Syringe Technologies

This photograph shows a mechanical syringe (left bottom) and a vacuum syringe (right top). With the mechanical syringe, the larger plunger is depressed with the thumb for injection and the smaller plunger is depressed with the thumb for aspiration. The 10 ml mechanical syringe can generate 560 Torr (mm Hg) of vacuum. The free hand is used to steady the patient, feel the surface anatomy, or operate other devices. The vacuum syringe consists of an on-off or variable flow valve at the needle fitting, a conventional 60 ml syringe, and a plunger lock. The 60 ml vacuum syringe can generate 720 Torr (mm Hg) vacuum.

Figure 2. Preparing to Aspirate with the Mechanical Syringe

The mechanical syringe is rotated onto the indwelling biopsy needle (or the needle rotated onto the syringe) and the thumb is placed on the aspiration plunger. When the aspiration plunger is depressed, vacuum is generated in the main barrel of the syringe.

Figure 3. Aspirating and Generating Vacuum with the Mechanical Syringe

As the aspiration plunger is depressed, vacuum is generated in the main barrel of the syringe. With the aspiration plunger depressed fully, 560 Torr (mm Hg) of vacuum is generated. The fat biopsy is then performed in a conventional manner making multiple passes with the biopsy needle while depressing the aspiration plunger of the mechanical syringe.

Figure 4. Preparing the Syringe to Expel the Sample

After the biopsy has been performed, the aspiration plunger is released, releasing vacuum in the syringe so that the sample is not sucked out of the needle into the barrel. The needle is then extracted from the patient tissues. If the sample were small and still within the needle, the needle is removed and air aspirated into the mechanical syringe by depressing the aspiration plunger as shown.

Figure 5. Expelling the Sample

After the mechanical syringe has been filled with air, the needle is then reattached, and the injection plunger depressed so that the sample is expelled onto a slide or into cytological processing fluid. The biopsy process can then be repeated. If the syringe is filled with tissue and no further biopsies are necessary, the fat is washed out or removed from the barrel in a conventional manner.

Figure 6. The 60 ml Vacuum Syringe

The vacuum syringe consists of an on-off-variable flow valve at the needle fitting, a conventional 60 ml syringe, and a plunger lock. After closing the valve, the plunger is pulled back and the plunger lock engaged, generating 720 Torr (mm Hg) vacuum. After attaching to an indwelling needle, the valve is opened and the biopsy procedure performed. Once done with the aspiration procedure, the flow switch is closed and the needle extracted. To expel a sample, the flow switch is rotated to permit air to flow into the syringe barrel, and then rotated in the opposite direction to become airtight again. The plunger lock is removed, and the flow switch opened, and then the plunger is depressed, expelling the sample.

Figure 7. Amyloid Deposits by Congo Red Staining

This aspiration biopsy sample obtained by an 18 gauge Chiba needle shows the classic shape of a columnar cutting tip biopsy needle. After tissues were fixed in formalin and embedded in paraffin, the samples were then stained with a freshly prepared solution of alkaline Congo Red and examined under microscopy at a magnification of X10 demonstrating the presence of the light pink material typical of amyloid deposits in the septa and blood vessels.

Figure 8. Amyloid Deposits by Polarizing Microscopy

This aspiration biopsy sample, the same as in Figure 7, was obtained by an 18 gauge Chiba needle and shows the classic shape of a columnar cutting tip biopsy needle. After tissues were fixed in formalin and embedded in paraffin, the samples were then stained with a freshly prepared solution of alkaline Congo Red and examined under polarizing microscopy at a magnification of X10 demonstrating the presence of the focal apple green birefringence typical of amyloid deposits in the septa and blood vessels.

Needle Control with Aspirating Syringe Technologies

Table 1

	10 ml Conventional Syringe (n = 10) Two-handed	10 ml Mechanical Syringe (n=10) One-handed	% Difference	95% Confidence Interval	Significance p
Unintended Forward Penetration (mm) *	4.8±0.6 mm	1.2±0.4 mm	-75% (-3.6±0.5 mm)	-82% to -68%	<0.0001
Difficulty (10 cm VAS) *	7.7±0.5 cm	2.8±0.4 cm	-64% (-4.9±0.5 cm)	-67% to -60%	<0.0001
	60 ml Conventional Syringe (n=10) Two-handed	60 ml Vacuum Syringe (n=10) One-handed			
Unintended Forward * Penetration (mm)	13.4±2.3 mm	1.4±0.5 mm	-87% (-12.0±1.4 mm)	-98% to -82%	<0.0001
Difficulty (10 cm VAS) *	9.8±0.4 cm	2.6±0.5 cm	-74% (-7.2±0.5 cm)	-76% to -71%	<0.0001

* Mean± Standard Deviation

Table 2

Clinical Outcomes of Biopsy Procedures

	60 ml Vacuum Syringe	10 ml Mechanical Syringe	Percent Difference	95% Confidence Interval	P Value
Number of Subjects	<i>S</i>	<i>S</i>			
Procedural Pain (10 cm VAS Pain Score) *	2.9±3.1 cm	3.1±2.5 cm	+7%	-54% to +68%	0.82
Mild Peripheral Puncture Site Bruising	20% (1/5)	20% (1/5)	0%	Not Applicable	1.00
Overt Hematoma	0% (0/5)	0% (0/5)	0%	Not Applicable	1.00
Puncture Site Infection	0% (0/5)	0% (0/5)	0%	Not Applicable	1.00
Specimen Adequate for Analysis	100% (5/5)	100% (5/5)	0%	Not Applicable	1.00
Positive Diagnosis of Amyloidosis	20% (1/5)	20% (1/5)	0%	Not applicable	1.00
Amyloidosis Classification	AL (amyloid light chain disease)	AL (amyloid light chain disease)	0%	Not applicable	1.00

* Mean± Standard Deviation