AUTOMATED AND MANUAL MEASUREMENT OF THE FORCES REQUIRED TO USE RETRACTABLE INTRAMUSCULAR SYRINGES

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ABSTRACT

The purpose of this study is to compare the forces required to activate retractable intramuscular safety syringes using healthcare worker researchers vs. a computer-controlled system. The force required to activate three commercially available retractable safety syringes was measured using two methods: (1) a manually-operated digital force gauge (DFG) and (2) a completely automatic computer-controlled universal testing machine (UTM). To simulate the clinical setting, saline was drawn into the barrel of each syringe before testing and ejected either during or before force measurements were recorded. There was a statistically significant difference in activation force between the two researchers and the UTM \( (p < 0.001) \) for 2/3 devices tested. There was a wide discrepancy in activation forces between the three brands of devices regardless of the testing method. The results imply that a human element exists in the injection process that cannot be discounted. Future studies should explore the sum of forces involved with an injection, the notion of training HCWs to modify these forces, and the relationship between force and occupationally-acquired hand and wrist injuries. Minimizing the impact on the
healthcare worker who may give hundreds of injections per day with these syringes should be a priority for those involved in the health field.

Keywords: Healthcare worker safety; Syringe activation forces; Ergonomic injury potential; Musculoskeletal injury potential.

INTRODUCTION

Since the passage of the Needlestick Safety and Prevention Act with the subsequent revision of the Bloodborne Pathogens Standard, there has been a proliferation of devices with engineered sharps injury protection (ESIP). One such category of devices includes intramuscular (IM) syringes with retractable mechanisms. Manufacturers’ instructions for this category of devices are to activate the mechanism while in the muscle of the patient. There is anecdotal evidence that nurses and other healthcare workers have been injecting medication with these devices, but removing them from the patient before activating the retraction mechanisms. A possible reason for this is fear on the part of the healthcare worker (HCW) that the extra force required to activate the retraction mechanism may cause undue pain or injury to the patient. However, not activating the mechanism before removing the device from the patient poses a percutaneous injury risk to those in the immediate vicinity.

The selection and evaluation of syringes with ESIP differs from traditional product evaluation in that it considers not only effectiveness in patient care but also HCW safety and cost effectiveness in terms of sharps injury prevention. Healthcare workers may refrain from using new products if they do not believe they are acceptable for patient care, often despite any apparent safety advantages.

In addition to the patient safety concerns from use of IM syringes with retractable mechanisms are HCW ergonomic issues. The long term or repeated use of such devices may pose a cumulative trauma injury risk to the HCWs using such devices. For those who administer numerous vaccines in one-day clinics or over a short time period, the repeated use of such devices may contribute to injuries of the fingers, wrist, or forearms.

SUMMARY OF PREVIOUS WORK

The core authors within this research group have worked together on several projects that have investigated safer needle devices. First, a method for evaluating the manual forces required to activate IM syringes with retractable mechanisms has been developed. The activation forces of these devices have been tested while injecting into both a simulated patient material (SPM) and into the air. When using one particular brand of retractable syringe, there was a statistically significant difference in the mean activation forces ($p = 0.05$) between two researchers, both when injecting into the SPM and the air. A wide range of compressive forces (2.31–97.95 N) was detected between four commercially available IM 3 cc syringes by one researcher using a manual force gauge to activate the retraction mechanism.

In a third project, two different researchers activated two different brands of IM syringes with retractable ESIP using either air or saline as the injection media. There was a statistically significant difference between the activation forces when comparing both the device brands and the researchers, but not when comparing the injection media. Finally, when one researcher compared two different brands of retractable syringes, there was a statistically significant difference ($p = 0.000$).
between the compressive forces required to activate the retraction mechanisms, using either air or saline as the injection medium.\textsuperscript{7}

All of these aforementioned projects have utilized a force gauge that is manually operated to measure the activation forces of the retraction mechanism. It is hypothesized that the use of a manual gauge has introduced a human factor variable directly from the person handling the gauge. The forces required to activate these devices, devoid of the human factor variable, have not been explored.

The objectives of this present study were to: (1) measure the compressive forces required to activate three specific brands of retractable IM syringes, both manually with two HCW researchers and with a completely automated force testing system, and (2) compare these compressive activation forces between manual vs. automated systems, researchers, and devices.

**METHODS**

**Materials**

Three commercially available 3 cc IM syringes with 1 inch needles, incorporating retractable ESIP, were tested in this study and can be seen in Fig. 1. The devices and brands tested were from Retractable Technologies Inc. (VanishPoint\textsuperscript{®} Syringe); Becton, Dickinson and Company (Integra\textsuperscript{TM} Syringe); Safety 1st Medical Incorporated (Safe-1\textsuperscript{®} Safety Syringe), hereafter referred to as Devices A, B, and C, respectively. All devices tested contained a mechanism that retracted the needle into the barrel of the syringe after use. However, two of the devices (A and B) utilized an integrated retraction feature that allowed for activation as the final step of plunger depression. Device C featured an activation mechanism located on the external surface of the barrel of the syringe.

To more realistically simulate actual healthcare protocols, each syringe was filled with 2 cc (from a 30 cc multidose vial) of bacteriostatic 0.9% sodium chloride for injection (saline) obtained from Hospira Inc., Lake Forest, IL.

**Digital force gauge (DFG)**

Force data for Method 1 testing were obtained using a manually controlled DFG (Com-Ten Model #CERO 2000) (Com-Ten Industries, Pinellas Park, FL). This manual DFG has a load capacity of 89 N with a resolution of 0.09 N. The gauge was attached to a rack and pinion mechanism that is controlled by a manual hand wheel. A custom testing stand was made, seen in Fig. 2, for the manual gauge to securely hold the syringes in place during data collection. A small metal fixture was attached to the underside of the DFG and properly aligned to each device to assure a normal coupling. A more detailed description of the components of this stand is outlined in a previous study.\textsuperscript{5}

![Fig. 1](image1.png)

**Fig. 1** Devices A, B, and C pre- and post-activation.
Universal testing machine (UTM)

Force data were also captured using a computer-controlled, twin column, UTM (COM-Ten Model #705-TN) (Com-Ten Industries, Pinellas Park, FL) seen in Fig. 3. This sophisticated testing machine measures both tensile and compressive forces and sends data to a personal computer (PC) for real-time graphical display and subsequent post-test analysis. Machine speed is controlled by the PC and can be set to any value between 0.01 and 381 mm/min with an accuracy of ±2%. An “S” block load cell with an 89 N capacity was used to collect all force data in the machine. A custom fixture was made and attached to the machine to securely hold each syringe in place during testing. The machine was properly aligned with each device before testing to assure a proper normal coupling. Both mechanical and software stops were used to assure the machine stopped testing immediately upon retraction of the needle into the barrel of the syringe. A closer view of the UTM testing system can be seen in Fig. 4.

Procedure

Compressive force data were collected for the three brands of syringes with a total sample size of 200 per device. Compressive force was defined
as the required force, in Newtons (N), to activate the retraction mechanism of the syringe. Force testing was conducted in two phases using two separate testing methods. With Method 1, two healthcare worker researchers, designated as HCW1 (right-handed female) and HCW2 (right-handed male), independently activated the syringes using a DFG. Method 2 entailed testing the same three devices in a computer-controlled force testing machine and was devoid of any human component. Strict protocols were followed in both phases to assure testing consistency and data integrity.

Manual testing protocol (Method 1)

Devices A and B were tested in one continuous motion while in a vertical orientation. Each syringe was filled with saline and then placed into the custom testing stand. The HCW researchers then lowered, through means of the manual wheel mechanism, the DFG onto the plunger of each syringe. The plunger continued to be pushed, thereby expelling the saline, until the retraction mechanism was activated, pulling the needle back into the barrel of the syringe.

Device C was tested using a slightly different protocol due to differences in device design. Before testing this device, it was necessary to first expel all of the saline before placing it into the testing stand horizontally in order to access the activation button; no plunger contact was required with the DFG. This device was required to be mounted 90° off the vertical in order to assure a similar normal coupling with the activation button and the testing system, as seen in Fig. 5.

For each trial, the manual wheel mechanism was lowered by HCW1 while HCW2 monitored the time. A period of 4 to 5 s was used to simulate the time required to give an injection in a clinical setting. If any evaluation was completed before 4 or after 5 s, it was discounted. Only those evaluations lasting 4–5 s were included. The peak force was read from the DFG after each trial and recorded in an Excel spreadsheet. When testing under each condition, a new syringe was used. No syringes were reset.

Automated testing protocol (Method 2)

The testing protocol for Method 2 using UTM was similar to that of Method 1 with the exception that it was devoid of any human interaction. Devices A and B were placed into the custom testing stand vertically before expelling the saline. To access the activation button, Device C was mounted horizontally in the testing machine after the saline was manually expelled. The speed of the movable crosshead was set to 381 mm/min.
This speed was calculated based on the length of the syringe, the extended plunger, and the 4 to 5 s required to simulate an injection in a clinical setting. The machine was then started and the crosshead moved down onto the activation mechanism of each device. Force data were sent to the PC to create a real-time force vs. time graph. Upon device activation, the machine stopped collecting data and returned to its original pretest position. The measured peak force was recorded in a table, as well as in an Excel spreadsheet. Peak force was measured in pounds (lb) in the Excel sheet and converted to Newtons before conducting the statistical analysis.

Data management
Descriptive statistics were used to characterize the data, and independent sample t-tests were run to test differences between devices, researchers, and methods. A triple data check was conducted by the research team of the force values entered on the Excel sheet for each trial.

RESULTS
The results for all of the evaluations are presented in Tables 1—3.

In all but one instance (Device B, HCW2) the mean force measured using Method 2 was lower than that measured by Method 1. Additionally, the standard deviation for each device was lower using UTM than any of the HCWs using Method 1 by as much as 246% (Device B). The range of activation forces was also widely scattered with the UTM having the smallest spread of forces. The mean force to activate Device C using both the manual and machine methods was substantially lower than the mean force required to activate Device A or Device B (see Table 1).

There was a statistically significant difference between the mean activation forces for both researchers (1) when testing Device A (p < 0.000), but not Device B or C and (2) between methods when testing Devices A and C (p < 0.001). When examining the mean activation forces within devices it was found that there was a statistically significant difference between HCW1 and HCW2 for Device A (p < 0.001); however, that was not the case with Devices B and C. In addition, the

<table>
<thead>
<tr>
<th>Device</th>
<th>Method</th>
<th>Mean Force (N)</th>
<th>Standard Dev (N)</th>
<th>Force Range (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1(HCW1)</td>
<td>42.08</td>
<td>8.05</td>
<td>30.87–75.44</td>
</tr>
<tr>
<td></td>
<td>1(HCW2)</td>
<td>51.78</td>
<td>11.17</td>
<td>32.65–83.36</td>
</tr>
<tr>
<td></td>
<td>2(UTM)</td>
<td>38.92</td>
<td>5.83</td>
<td>26.82–50.13</td>
</tr>
<tr>
<td>B</td>
<td>1(HCW1)</td>
<td>57.25</td>
<td>5.69</td>
<td>47.86–72.77</td>
</tr>
<tr>
<td></td>
<td>1(HCW2)</td>
<td>56.00</td>
<td>5.69</td>
<td>50.00–77.40</td>
</tr>
<tr>
<td></td>
<td>2(UTM)</td>
<td>56.49</td>
<td>2.31</td>
<td>49.11–61.30</td>
</tr>
<tr>
<td>C</td>
<td>1(HCW1)</td>
<td>10.28</td>
<td>2.57</td>
<td>4.72–20.73</td>
</tr>
<tr>
<td></td>
<td>1(HCW2)</td>
<td>11.20</td>
<td>2.71</td>
<td>7.30–22.60</td>
</tr>
<tr>
<td></td>
<td>2(UTM)</td>
<td>8.70</td>
<td>1.68</td>
<td>4.72–11.74</td>
</tr>
</tbody>
</table>

HCW1 = Healthcare worker 1; HCW2 = Healthcare worker 2; Standard Dev = Standard Deviation; UTM = Universal testing machine; for HCW1 and HCW 2, n = 50 per device; for UTM, n = 100 per device.

<table>
<thead>
<tr>
<th>Device</th>
<th>Comparisons</th>
<th>Absolute Value of Mean Difference in Force (N)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>HCW1 vs. UTM</td>
<td>4.55</td>
<td>0.001*</td>
</tr>
<tr>
<td></td>
<td>HCW2 vs. UTM</td>
<td>14.26</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>HCW1 vs. HCW2</td>
<td>9.71</td>
<td>0.000*</td>
</tr>
<tr>
<td>B</td>
<td>HCW1 vs. UTM</td>
<td>0.78</td>
<td>0.359</td>
</tr>
<tr>
<td></td>
<td>HCW2 vs. UTM</td>
<td>0.49</td>
<td>0.564</td>
</tr>
<tr>
<td></td>
<td>HCW1 vs. HCW2</td>
<td>1.27</td>
<td>0.271</td>
</tr>
<tr>
<td>C</td>
<td>HCW1 vs. UTM</td>
<td>1.58</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>HCW2 vs. UTM</td>
<td>2.49</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>HCW1 vs. HCW2</td>
<td>0.92</td>
<td>0.086</td>
</tr>
</tbody>
</table>

N = Newton; *p < 0.005, statistically significant; for HCW1 and HCW2, n = 50 per device; for UTM, n = 100 per device.
absolute value of the mean differences between HCW1, HCW2, and Method 2 for Device A was markedly higher than those for Devices B and C (see Table 2).

Using Method 2, the mean difference in activation force between all three devices was statistically significant ($p < 0.001$). Device C was associated with the two largest mean differences in activation forces (see Table 3).

**DISCUSSION**

The data indicate that there is a difference in forces between a HCW manually activating a retractable safety syringe (Method 1) and the UTM (Method 2). The mean force measured with the UTM was lower in eight out of nine evaluations with only a 0.49 N difference in the sole instance where that force was greater. The standard deviation was also significantly greater when measured with a HCW as opposed to the UTM. This data suggest that the human component plays a factor in the actual force required to activate these safety syringes. This is a logical deduction as the UTM can be set to repeatedly replicate the exact scenario, whereas a HCW will inherently have slight deviations in technique from sample to sample.

Data also suggest that device design can play an important role in activation force. Device A had a wide distribution of mean forces between HCW1, HCW2, and the UTM, varying as much as 25% (HCW2 vs. UTM). Conversely, Device B had a very tight distribution among mean forces with the largest divergence being 2% of the mean (HCW1 vs. HCW2). Activation force using the UTM varied as much as 47.77 N between devices (Device B vs. Device C), suggesting that device design is an integral determinant of required activation force.

The finding that Device B required similar forces between methods and researchers was an interesting one. This could be advantageous in that the implication in the device’s design is not influenced by the human component in relation to compressive force. Conversely, this device had the highest range and mean force among all three tested. If used for numerous injections (e.g. in a flu clinic), compared to the other two devices, it may have more potential for cumulative trauma or ergonomic injuries.

The range of values measured for the activation force when combining methods and researchers was 4.72–83.36 N. The average tip pinch force for typical females between the ages of 40 and 44 is only 50 N.¹¹ Thus, the average tip pinch force was exceeded on the present project for a majority of the evaluations. Whether use of devices with higher activation forces poses a risk for ergonomic injuries warrants further investigation.

The National Research Council and Institute of Medicine reported that high-risk factors for musculoskeletal disorders resulting from repetitive strain injuries include the primary one of awkward posture to which repetition and force may substantially contribute.¹² Use of retractable IM syringes requires an awkward posture, varying degrees of repetition (depending upon how many injections are administered within a short period of time), and varying degrees of force. While no reports at the time of this study have covered the relationship between using retractable

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**Table 3 Inter-Device Force Comparisons Using Method 2.**

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Absolute Value of Mean Difference in Force (N)</th>
<th>95% CI (N)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device A vs. Device B</td>
<td>18.96</td>
<td>17.51, 20.40</td>
<td>0.000*</td>
</tr>
<tr>
<td>Device A vs. Device C</td>
<td>28.82</td>
<td>27.40, 30.23</td>
<td>0.000*</td>
</tr>
<tr>
<td>Device B vs. Device C</td>
<td>47.77</td>
<td>47.21, 48.34</td>
<td>0.000*</td>
</tr>
</tbody>
</table>

For each device type, $n = 100$; CI = Confidence Interval; *$p < 0.005$.  

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syringes and ergonomic injuries, there are analogies with two other clinical activities, performance of hand pipetting and colonoscopies.

One study compared the prevalence of musculoskeletal problems in the hand and shoulder among laboratory technicians performing hand pipetting in relation to the amount of time spent performing this activity. The authors concluded that a “dose of more than 300 hours per year is associated with an increased risk of hand and shoulder ailments” (p. 93).2 There have been no similar studies to determine if a specific length of time is required for an adverse ergonomic outcome to result from use of retractable IM syringes. Another study reported a range of 5 to 45 N for the forces exerted on the thumb when using a plunger-operated mechanical pipette. There was an increase in static activity of the muscles of the hand using the pipettes, which the authors concluded might increase the risk of tenosynovitis.1 The dexterous motion of pipetting is similar to delivering an injection and the values measured in the current study match closely with this pipetting study.

Performance of colonoscopies also requires awkward posture, repetition, and force. In a survey of 400 endoscopists who perform colonoscopies, almost 60% reported suffering thumb, hand, elbow, low back, and possibly shoulder pain related to performing endoscopies.3 In a similar survey of 2173 members of the American Society of Colon and Rectal Surgery, 39% of those performing colonoscopies reported at least one injury or pain believed to be the result of such activity.10 No similar surveys have been conducted among healthcare workers using retractable IM syringes and this may be a point of further investigation.

A pilot study of pinch force and forearm muscle load was conducted among three experienced gastroenterologists performing colonoscopies. The mean right-thumb pinch forces exceeded the injury threshold of 10 N.14 The results from this colonoscopy study are important to consider when comparing them to the data collected in the current study. Often HCWs are required to perform injections hundreds of times a day and sometimes under awkward postures. The threshold of injury used in the colonoscopy study was quite low (10 N) and exceeded most of the force data collected in the current needle study.

Thus, published data on activities analogous to use of syringes with retractable mechanisms, such as hand pipetting and performance of colonoscopies, have been examined. It can be inferred that there is a potential risk for muscle damage in the hand to occur when giving an injection with these devices due to both repetitive use and excessive load. Repetitive use could occur in injection clinics (e.g. influenza, weight loss) and excessive force could occur with long-term or high volume use of devices, which require larger activation forces.

Strengths and Limitations
This research team has evaluated compressive forces of three commercially available IM syringes with retractable mechanisms and reported these findings here. This information may be useful to healthcare facilities in evaluating and selecting devices with ESIP.

It is possible that the mechanism used for applying manual force could result in higher forces than are used in actual applications. Future studies might investigate the actual human force component by using small-scale tactile load cells attached to the working syringe to address this limitation.

Future Directions
The results of this study generate several avenues for future research. First, the compressive force required to activate the retraction mechanism is
only one of the forces involved with administering an injection. Future work should focus on the entire injection process from beginning to end. This would include forces required for all of the following: opening the package, any initial motion of the plunger (breakaway force), tensile force required to withdraw the injection solution (medication) into the syringe, needle insertion into the muscle, the internal friction as the plunger moves through the shaft of the syringe, drug delivery (varying viscosities), and device activation. By assessing all of these forces with both an automated system and with the human component, comparisons can be made and the results can be used to diminish the burden on the human as much as possible.

Next, if a wide variance continues to be measured between the automated forces and the human forces, solutions need to be incorporated to lessen the force burden on the human. One possible strategy is to consider device redesign. The notion of whether HCWs can be trained to modify the amount of force exerted is another potential solution requiring further investigation.

Finally, testing and development of ESIPs with retractable syringes should explore the relationship between activation forces and the potential risk of occupationally acquired hand and wrist injuries. This may be a key factor in instances of repetitive use in high volume settings, such as injection clinics.

CONCLUSIONS
Findings from this study underscore the importance of an automated testing method when measuring activation forces in retractable syringes. An automated testing system may be used to provide useful baseline data to determine the forces required to use the device. However, the contribution of the human dynamic to the forces exerted cannot be discounted. The authors recommend that the UTM be used for comparison of devices and that the DFG would be used when trying to compare differences among users (such as the impact of gender, size, left-right-handedness, etc.) on forces required to use IM syringes with retractable mechanisms.

As indicated in this study, the UTM force data do not account for the human component and in fact may underestimate the true force that is actually required. It is important to point out that this study only investigated one component of the multifaceted injection process (drug delivery). Future studies should explore the sum of forces involved with an injection, the notion of training HCWs to modify these forces, and the relationship between force and occupationally acquired hand and wrist injuries. This area of research lays the foundation for assessing the impact of the human component on the injection process and steering the direction of future product design and healthcare worker training.

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PERMISSION
The authors have permission from COM-Ten Industries, Pinellas Park, FL, to post pictures of
their manual digital force gauge and universal testing machine.

References


