Quantifying the Ergonomic Impact on Healthcare Workers Using a Needle-free Injector Device

by

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Disclaimer

The views expressed in this thesis are those of the authors & do not necessarily represent the views of USF or DVA.

Permission

The authors have permission from PharmaJet™ Injector Company to test the device performance and take pictures, as well as permission from COM-Ten Industries, Pinellas Park, FL, to post pictures of their manual digital force gauge and universal testing machine.

Dedication

To my Yashua, loving wife and kids, if not for their support and understanding this project would not have come to fruition. My parents, who have encouraged and supported me throughout the development of my academic formation.

Acknowledgements

I would like to start by thanking the members of this thesis committee who provided continual guidance and support throughout the elaboration of this project. Dr. Hamisu Salihu who provided the leadership necessary to initiate this project and proceed to its completion. Through his teachings, he provided the tools necessary to feel confident in the elaboration of the thesis. Dr. Thomas Truncale for being my residency advisor and program director during the Occupational Medicine Residency Program. Dr. Bernard who enthusiastically supported me throughout this project. His ideas throughout the statistical analysis were essential. Also, Dr. Watkins, Dr. Hanna, and Dr. Rentos for their support and encouragement.

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Abstract

Background: Jet injectors are advantageous over needle injectors by eliminating sharps hazards. The Government Accountability Office estimates 29% preventable sharp injuries with an estimated direct cost of more than $500 million out of the CDC's reported incidence of 385,000 needle stick injuries per year among US hospital healthcare workers. Yet the forces required to set and trigger devices using spring mechanisms for medication delivery have not been explored. This laboratory experiment measured forces exerted by healthcare workers (HCWs) using a particular jet injector approved by FDA in 2011.

Objectives: In order to quantify the ergonomic impact on OCHWs using a needle-free injector, the first objective was to evaluate the dynamic forces required to activate the trigger injector button and the reset station for the injector, with their respective means, for each of the parameters studied. The second objective was to compare these forces to those required to use four previously analyzed retractable intramuscular syringes with needles. Finally, the third objective was to assess potential psychophysics ergonomic impact on OHCWs with use of these devices to formulate future design changes and recommendations for manufacturers and HCWs, respectively.

Methods: This laboratory experiment was conducted through a multi-disciplinary team approach. It included a total of 136 trials (10 validation trials, 116 experimental trials and 10 padded trials for soft tissue simulation), which were conducted using the PharmaJet™ Injector. A force gauge and a load cell were integrated into the triggering setup and reset station, correspondingly, enabling force measurements to be obtained directly from the human-machine interfaces. These force data allowed for observations of force profiles in time by the healthcare worker as researcher while preparing for and administering injections. Data collection used three software applications for force conversions and data manipulation. Data were analyzed using descriptive statistics and analytical results by using ANOVA for the trigger injector & reset station with multiple comparison tests for parametric and non-parametric distributions, respectively.

Results: The descriptive results indicated an average force for triggering the injector in the 116 trials was 15.92 lbs. (70.8 N) with a range of 9.77-26.46 lbs. (43.46-117.69 N). The measured forces for the reset station ranged from 5.35-82.78 lbs. (5.35-368.22 N) with an average of 25.32 lbs. (112.62 N) (SD 12.36). Spurious findings presented with tensile forces to fill the syringes resulting in hand strain in the first metacarpal joint after repetitive pinprick motion. The analytical results showed an ANOVA for trigger injector with a parametric-normal distribution with an F (2,133) Ratio 10.0472, p- value (F) 0.0001<0.05, showing statistical significance and with a Tukey's comparison test showing a significant

difference in between the means of the padded trials vs. the validation & experimental trial groups. The ANOVA for the reset station showed a Kruskal Wallis H-statistic of 0.2568, p-value (H) 0.8795>0.05 presenting NO statistical significance with a Dunn's comparison test confirming NO difference in between the medians or mean ranks of all three groups.

Conclusions: Triggering the injector and resetting the station required considerable effort in comparison to activating 4 retractable intramuscular syringes with needles from our previous studies, the range of mean forces were 3.63-17 lbs (16.19-77.53 N) for those syringes with the trigger injector maximum voluntary force of 71 N being above the recommend 56.6 N.

The jet injector required more force per effort than 2 (4.4x) syringes & similar to other 2 syringes (0.9x) previously tested when considering the compression forces related with the trigger injector.

Additional vector forces (displacement & gripping of reset station) could increase the cumulative effort affecting different musculoskeletal components when the whole components of the procedure are taken into account.

Suggestions for the manufacturer regarding design changes to facilitate HCWs' use of this device are warranted, since some of the summation forces during the 12 mini-steps could be avoided to achieve a higher efficiency. This information may be useful for health care facilities when choosing devices to protect their workers from ergonomic injuries.

Application: The information might be useful for future research to achieve accurate predictions of maximal acceptable efforts for repetitive motion tasks when integrating all cumulative force components of a duty cycle for 8-hour work tasks to establish tolerance limit values. Implications and future research will be leakage of fluids while loading the syringe; fluid in the cap and immediate vicinity-splatter of body fluids or live vaccines; recommended personal protective equipment (PPE) for potential wet shots and splatter; effect of compression and tensile forces with viscous solutions and measurement of dynamic forces with analytical multiple-sensor gloves.

Chapter I

Introduction

Needle-free injector devices (NFIDs) are engineered devices used to deliver a liquid medication by the intramuscular (IM) or subcutaneous (SC) route with a pressure jet stream that is an alternative to conventional needle syringes. Jet injectors are potentially advantageous over needle syringes in employee safety by eliminating sharps and waste disposal. Studies reveal potential advantages for the patient safety, vaccine efficacy, compliance, relative overall comparative cost, reduced psychological stress, reduced pain, lower vaccine volume, antigenic dispersion, elimination of broken needles, reduction of accidental needle stick injuries and occupational preference regarding use of NFIDs over safety engineered needle devices versus the disadvantages of higher start-up cost, higher cost against traditional needle syringes, and higher requirements for training and maintenance of equipment (Christopher 2008; Morrison, 2009; Brito 2010; Weniger, 2005). In spite of much scientific evidence favoring NFIDs' use, the ergonomic forces required for setting and triggering the injector devices exerted by occupational healthcare workers (HCWs) using jet spring mechanisms for liquid medication delivery have not been explored. Measurement of dynamic forces can be expressed in Newtons (N) and pounds (lbs.) exerted by HCWs using a particular jet injector for quantifying the human factor impact on healthcare workers when using NFIDs.

NFIDs are mainly beneficial over needle injectors by eliminating sharps hazards along with compliance of 1991 OSHA standards for Blood Borne Pathogens, by reducing transmission of Hepatitis B & C and HIV, among many others blood borne diseases (Plog, 1973). The U.S. Government Accountability Office (GAO) estimates 29% preventable sharp injuries by using safety engineering needle devices and NFIDs. GAO and the U.S. Centers for Disease Control and Prevention (CDC) estimated direct costs that supersede $500 million. This is without taking into consideration the indirect costs related long term treatment resulting from infectious disease transmission through blood borne pathogens such as Hepatitis B &C and HIV, worker's compensation system & disability, laborer absenteeism and other psychological implications (Saia, 2010). The CDC reported an incidence of 385,000 needle-stick and sharp injuries among hospital-based U.S. healthcare workers (HCWs), without taking into consideration other healthcare settings that approximate the number of cases to 800,000 injuries overall for the nation per year (Saia, 2010; Panlilio, 2000; Henry, 1995; Haiduven, 2006).

NFIDs have been available for humans since the 1930s and used extensively for mass vaccination over a period of five decades for programs of smallpox, polio, and measles. Historically the devices have been gas, spring or electrically powered. NFIDs are reemerging after being put aside for a few decades with FDA fomenting the use of spring powered technology (Reis, 1998; Hingson, 1963; Christopher 2008). According to the Defense Logistics Agency (1997) on chapter 2 of the biological defense program, the U.S. military realm

had some historic concerns with contamination avoidance and individual protection with lacerations and cross contamination regarding re-use of injector systems leaving some caveats and paradigms with the use of this technology in the past. With today's revamping technology with spring-powered regulated injection systems, which penetrate the skin for IM or SC medication administration in less than 1/3 of a second, PharmaJet™ needle-free devices and other injectors eliminate needle re-use and cross-contamination between patients. The polycarbonate cylinder is a sterile, single use with auto-disabling properties and minimization of hazardous waste eliminate the aforementioned risk hazards (Morris, 2009). Safety and effectiveness with Flu vaccines and other potential hazards has been a restraint for many needle-free injector manufacturers to release their products in today's market, even though the PharmaJet™ needle-free device was approved by the Federal Food and Drug Administration in 2011 (Hartman, 2011). A few recent manufacturers, scientific and clinical studies have been done regarding benefits of immunization with safety engineered needles and needle-free injectors to overall effectiveness, efficacy and efficiency of such devices from a patient and occupational safety perspective based on the 2011 World Health Organization (WHO) global vaccine safety Blueprints (Amarasinghe, 2012), while others are comparing the occupational time efficiency in between both methods in humans and animal populations (Morris, 2009; Christopher 2008). Evaluating the forces required to activate the trigger injector button and the reset station for the injector, with their respective means, for each of the parameters studied, attained our first objective.

Comparing forces required between NFIDs to the use of safety-engineered needles with retractable intramuscular syringes with needles was our second objective. Since 1984, there are more than a thousand patents related with safety devices with approximately 25 different designs (Ippolito, 1997; Haiduven, 2006). Several generations of such devices, coined “devices with engineered sharps injury protection” or (ESIP) have been established, but for practical reasons there are 4 generations. The first generation comprises syringes with sheaths that slide frontward after usage. The second generation consists of accessories snapped into the needle. The third generation has retractable needle mechanisms, which retract while still in the patient’s soft tissues (Haiduven, 2006). The forth generation will be described as the re-emerging NFIDs with spring-powered technologies. Even though the mechanism involved for operating these devices might be technically different, comparisons can be attained with previous studies comparing the compressive forces utilized while injecting saline into simulated patient material (SPM). The category 3 studies showed a range of saline injection on SPM for compressive force experiments in between 16 and 77 N, with an average of 57 N or 13 lbs. The kind of the design for category 3 and category 4 devices is to elude reuse (Haiduven, 2006 & 2010). Dynamic force gauge measurement of compressive forces will be utilized to measure forces in N and lbs for the trigger injector button of the NFIDs for category 4 devices.

One of the challenges of human factors engineering is to evaluate different workplace demands and contrast them to their functional capacities at

work to establish tolerance limit values (TLV). The potential psychophysics impact on ergonomic impact on HCWs with use of NFIDs has to be analyzed to create an appropriate tool that would avoid damage to the HCWs during and after the utilization of the tool with repetitive motion (Potvin, 2012). In order to formulate future design changes and recommendations for manufacturers and HCWs, respectively, we need to understand some basic concepts of ergonomics, to ensure safe and productive activities within the workplace while using the tools (LaDou, 2004), especially the ones related with psychophysics to predict the maximum acceptable efforts (MAE) for repetitive tasks for an 8-hr workday, while using the duty cycle (DC), which is the total effort duration divided by the cycle time. By using the Potvin equation and principals, which go, beyond the scope of detailing for this specific project, the maximal acceptable efforts can be obtained as a percentage of the single maximal voluntary effort (MVE), which are multiplied by the DC. The resultant equation after detailed meta-analysis results in the simplified formula 1:

$$MAE = 1 - DC^{(0.24)} \qquad \text{Formula 1 (Potvin, 2012)}$$

The resultant equation describes a strong negative exponential relationship between DC and MAE. This relationship shows a rapid decline in MAE at low DCs with a slow decrease as DC increased to higher values. The advantage of using the equation consists in estimating the absolute magnitude of MAE without specific previous published data. Once MAE is calculated, you can determine the maximal average force (MAF) by multiplying MAE by the recommended MVE (rec MVE) (see formula 2).

MAF= MAE x rec MVE Formula2 (Potvin, 2013)

In this case, we can extract previous published information from Potvin's equation studies and NASA's ergonomic human performance capabilities and forces for the hand and thumb-finger strength. The first author describes the MVEs for the pulp pinch push and finger tip push to be 58.8 N (13.21 Lbs.) and 56.6 N (12.72 lbs.), respectively. This will apply to the study related with the trigger injector button. Other studies relating right-thumb pinch forces are more conservative and use an injury threshold of 10 N (2.24 lbs.) but involve prolonged pushing actions (Shergill, 2009). MAE results were 35 Nm at a low frequency of 2 per minute at the recommended 56.6 Newtons for finger tip push (Potvin, 2013), which is relevant when taking into consideration that the fastest rate for an HCW might be 2 per minute if it takes 30 seconds to give the NFIDs shot (Morrison, 2009). NASA STD-3000 203 describes the thumb-finger tip strength with a limit of 58 Newton's (13 lbs.) for brief hold and 35 N (8 lbs.) for sustained hold (2008). The MVF for the pushing down a hose is 130.2 N, which is a similar motion when comparing the activation of the reset station (Adrews, 2008; Potvin, 2006). All of the values are taking into consideration a neutral wrist position. The need for recuperation time increases exponentially with effort duration (Rohmert, 1973). Long prolonged efforts, even if low forces are applied increase the risk for muscle pain and injury (Veiersted, 1993). Taking into consideration that an 8-hour shift has 480 minutes, it is not recommended to go above this level even at a frequency of 1 per minute for most repetitive activities without taking into consideration the force measurements. The Potvin equation is good for isolated

tasks, but a caveat arises when entirely combined activities like triggering injector button press, resetting station and other tensile forces for loading syringes come into play. The Potvin equation is suitable with a conventional task with similar features for the 75th percentile of the female exertion forces (2011). Studies relating monotonous work with physical factors such as force, repetitive motion and anatomical position related preponderance of force over the other two, showing increasing levels of incidence of hand pain and tendonitis. Studies showing repetitive work are less consistent of hand injury, even though they are always reasonable (Thomsen, 2013). Anatomical position has less predominance, even though neutral anatomical position was utilized in the present project (Thomsen, 2013).

Chapter II

Specific Objectives and Hypothesis

Specific Objectives

1. The first objective was to evaluate the dynamic forces required to activate the trigger injector button and the reset station for the injector for the NFID-category 4 device, with their respective means, for each of the parameters studied.
2. The second objective was to compare these forces to those required to use four previously analyzed retractable intramuscular syringes at the VA lab with needles- category 3 devices.
3. The third objective was to assess potential psychophysics ergonomic impact on HCWs with use of these devices to formulate future intervention design changes and recommendations for manufacturers and HCWs, respectively.

Hypothesis

1. The Ho null hypothesis for the trigger injector was that there is no difference in between the three means of force measurements by using F-statistics:

Null Hypothesis: *Trigger Injector*

Ho: *the means of measured forces (lbs or Newton's) are all equal*

$H0: \mu = 1, \mu = 2, \mu = 3 \qquad df=2$

2. The Ho or null hypothesis for the reset station was analyzed to compare the medians in between each three sets of groups by using the H-statistics:

***Null hypothesis**: Reset Station*

Ho: *the medians of measured forces (lbs or Newton's) are all equal*

H0: M=1, M =2, M =3 (Mean Ranks or Medians)

Chapter III

Materials and Methods

Support for materials and facilities*: This research was funded & supported by the NIOSH SERC- COPH-USF, Department of Environmental & Occupational Health & in part is based upon work supported by the USF-COPH Department of Global Health & Office of Research & Development, Department of Veterans Affairs (DVA), Tampa FL. Conducted by multi-disciplinary team: Occupational Medicine, Infection Control, Mechanical & Biomedical engineers.* ***Research team****: H. Olivero Lara, MD USF OMR resident; and employees of DVA*

P. Ramaiah, MSBME; D. Haiduven, PhD; & M. Kerrigan, MSBME. Other collaborators are mentioned in the acknowledgement (left to right Figure 1).

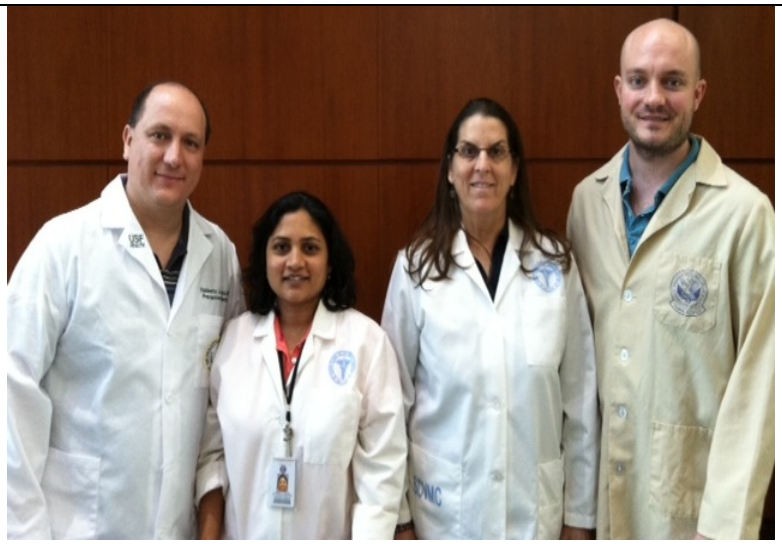

**Photo by VA multi-disciplinary team*

Figure 1. Multi-disciplinary team researchers at VAD facility

Materials

One commercially available NFID, approved by FDA in 2011, was utilized for the experiment. The aforesaid device is the Stratis PharmaJet ™ System Needle-free injector device, which is composed of an injector, reset station, needleless syringe and filling adaptor (see figure 2. Read *L to R*).

**Photo by VA multi-disciplinary team with permission of manufacturer (L to R)*

Figure 2. Components of the Stratis PharmaJet ™ NFIDs

The device works by injecting a liquid under pressure by a spring powered technology, which uses a blue tipped safety feature that avoids misfiring if the device is not aligned perpendicular to the skin with concomitant synchronous pressure applied. Other safety features include a polycarbonate syringe for single use, that cracks without expelling fragments to the surroundings when air contents in the form of bubbles are within the cylinder of the syringe, described by the prior manufacturer as a “wet shot”. (PharmaJet™, Colorado, U.S.A.).

One hundred and thirty-six needleless syringes were prefilled with saline solution, consisting up bacteriostatic 0.9% sodium chloride injection, USP, 30 mL. Liquid was drawn with the needleless syringe by using the filling adapter shown in the right lower corner of figure 2.

Other important materials consist of a laptop, HP Pavilion entertainment notebook PC, with an operating system of Microsoft 7 with 64 bits; a load sensor with PCB piezotronics, model 260A02, three component force sensor; a signal conditioner, PCB piezotronic, model 480B, with three channel 1 CP sensor signal conditioners (see Figure 3).

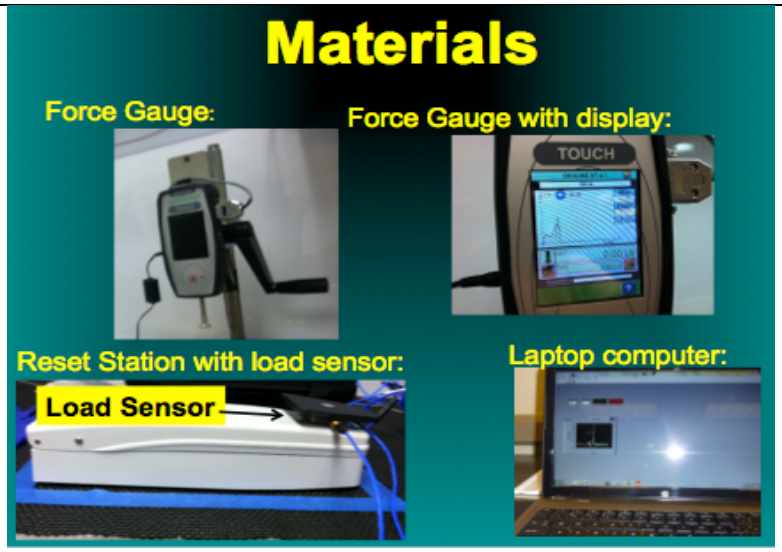

**Photo by VA multi-disciplinary team*

Figure 3. Instruments utilized to measure forces

Additional materials include a digital force gauge by COM-TEN (Com Ten Industries, Pinellas Park, Florida) Andilog technology Stentor II, which draws

curves vs. travel, with incorporation of force gauge sensors with internal sensor up to 100 N and an accuracy of 0.01N.

Other materials include: ductless fume hood from Sentry systems (*Sentry Air Systems, Inc., Houston, TX*) thermometer, for room temperature variations (Figure 4); disposable gloves; a holding bin, to hold the prefilled syringes; waste bin, to hold the used syringes after firing; safety goggles, to protect against inadvertent exposure to solutions or moving parts; a wide base metal stand and ante-cubital fossa simulation pad (ACF PAD) for tissue simulation of injection (see Figure 5) (*Limbs & Things, Savannah, GA*); a communications cable, three USB two RS-232 DB 9/DB-25 serial adapter; the cable; data-transfer software for force gauge to laptop called termite terminal emulator software; a data transfer

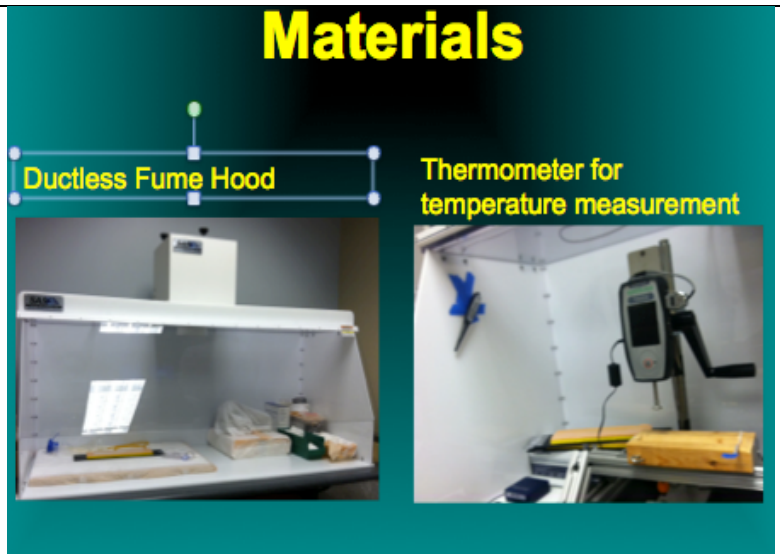

**Photo by VA multi-disciplinary team*

Figure 4. Safety ductless fume hood and thermometers

from load to sensor on reset station to the laptop, which consists of Lab VIEW software from National Instruments *(National Instruments, Austin, TX) (*Figure 6.); a metal stand with a wooden sockets inside straps, to hold injector and force gauge for each trial; a stylus to tare the force gauge; and a wooden ruler, to set the position for the rotating handle on the force gauge.

In addition, a level, adhesive labels, and heavy utility gloves to wear while bracing the ACF pad against the tip of the syringe for safety purposes (see Figure 5), a non-slip mesh liner, a microfiber towel, compressed air can, clipboard and waste basket were materials used for the elaboration of the experiment.

**Photo by VA multi-disciplinary team*

Figure 5. Ante-cubital fossa simulation pad (ACF Pad) and normal saline

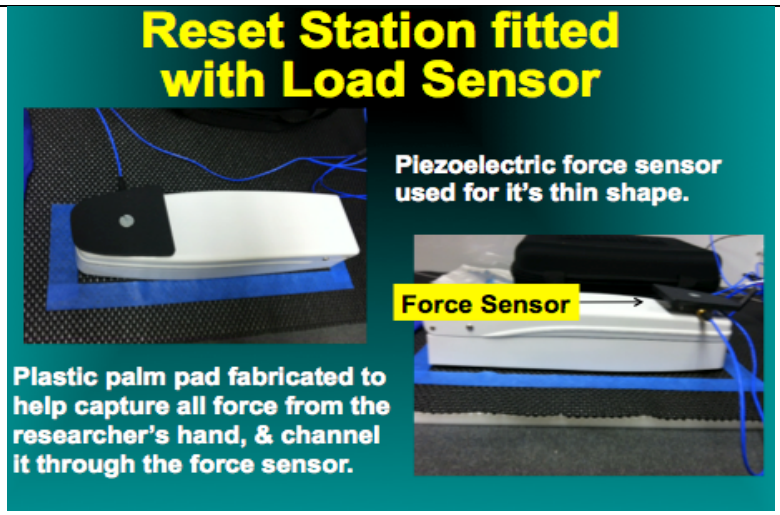

**Photo by VA multi-disciplinary team*

Figure 6. Reset station with load sensor adhered on surface

Procedures

The following experiment was conducted by using a rigorous protocol of force measurements for the Pharm jet ™ injector that is described in full detail as part of the annex A for this laboratory research study. It portrays all the materials, activities performed, protocols for pre-trial activities, which include the set-up of the reset station equipment and the force gauge equipment. It displays the force gauge settings set with the Termite software™ *(Hernel Hempstead, UK)*, which occurred pre-experiment. Description of the protocol activities while running the trials, which consist of a rigorous 94-step protocol developed for conducting trials to avoid variability. Activities for the experiment trials were done by having three personnel labeled as R1, R2 and R3. R1 activities consists mainly of handling all technological software and computer activities, from a spectrum of setting to analyzing the data, R2 activities are mainly described as the executing and

reporting trials for all measured activities, and R3 main role is recording and supervising all activities followed in chronological order.

A total of 136 total trials were conducted using the PharmaJet™ Injector (10 validation, 116 trials, & 10 trials with padding) for both the trigger injector button and the reset station, follow-up by a 94-step protocol developed for conducting trials to avoid variability with repeat step description for additional trials (Annex A).

A force gauge and load cell was integrated into the triggering setup & reset station, respectively, enabling force measurements to be obtained directly from the human-machine interfaces (See Figure 7 a & b).

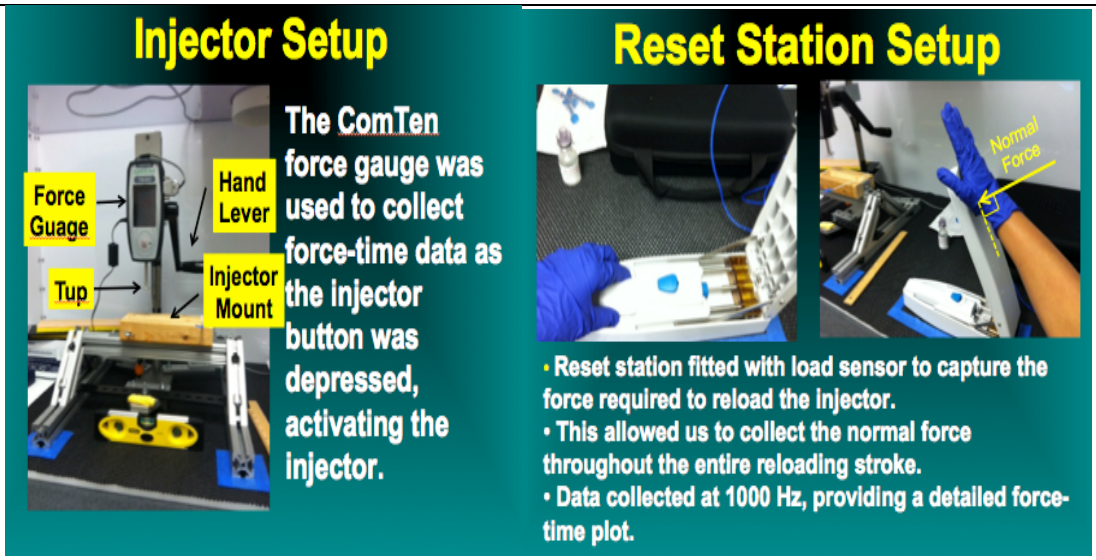

**Photo by VA multi-disciplinary team*

Figure 7. a & b) Trigger injector setup & Reset station setup

Data collection used 4 software applications for force conversions & data manipulation, which include Termite Terminal Emulator software *(Hernel Hempstead, UK),* Lab View software from National Instruments (*Austing, TX, U.S.A*), Mat lab (*Natick, Massachusetts, U.S.A.)* and Excel spreadsheets *(Redmond, WA, U.S.A.)(*See figure 8 a & b and Figure 9 a & b).

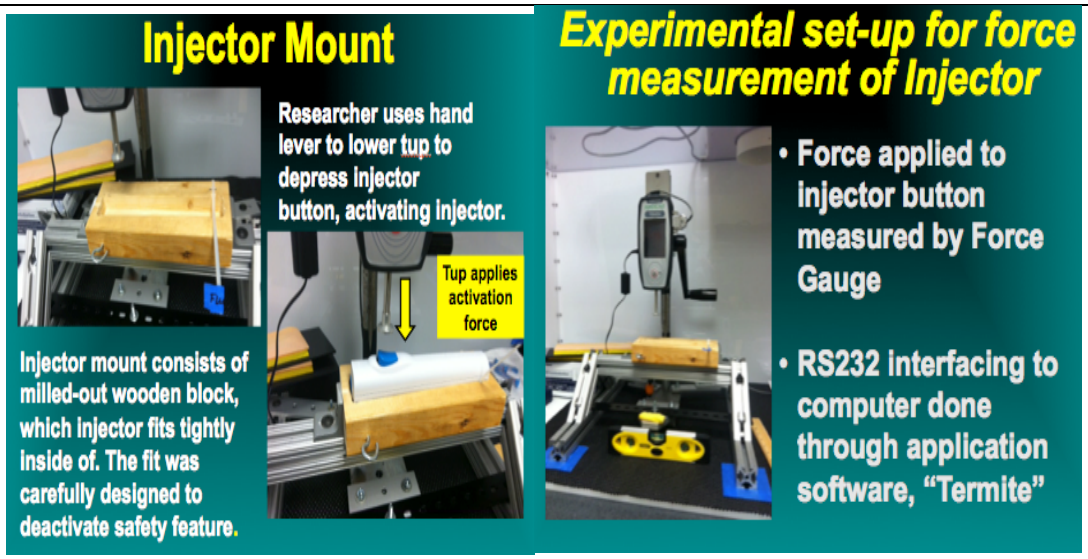

**Photo by VA multi-disciplinary team*

Figure 8. a & b) Injector mount for deactivation of safety tip

The injector mount consists of a milled-out wooden block which defeats the safety tip for the trigger injector device and the researcher uses a hand lever to activate the injector in which the force is detected by the manual force gauge with an RS232 interfacing through the Termite software application (Figure 8 a & b).

The experimental set up for force measurement of the reset station consists of a load sensor adhered to the arm of the reset station with a sample

rate of 1,000/second for duration of 7 seconds, with subsequent data collection to a laptop by using a USB port to Lab View Software (Figure 9 a & b).

Floor markings were used on the floor with the shape of two “WW”. That way the operator will have less room for variation with the lower stance that indirectly affects the trunk and upper body position (Figure 10).

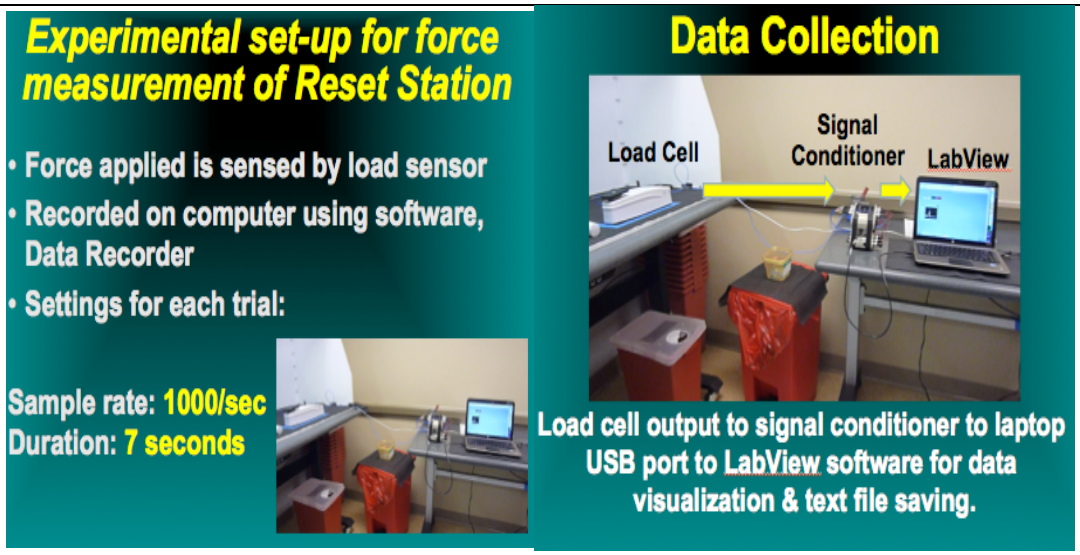

**Photo by VA multi-disciplinary team*

Figure 9. a & b) Reset station force measurements and data collection

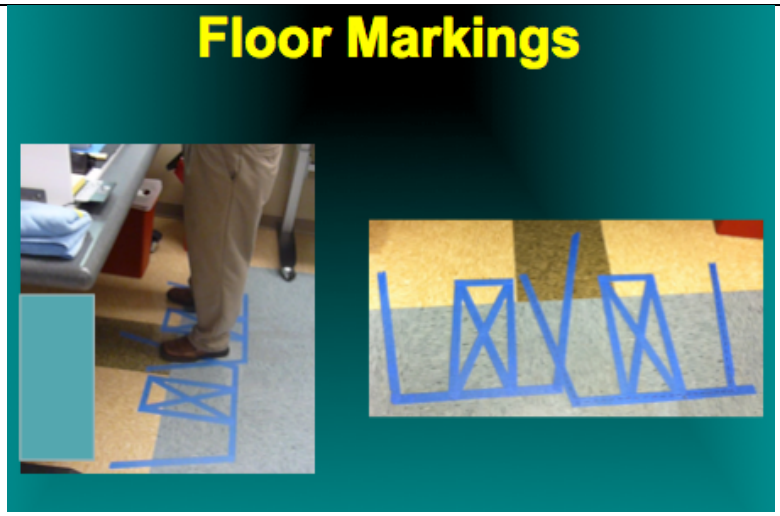

Figure 10. Markings on the floor-determining stance of R2 operator

Methods

This work consisted of an investigational experimental project for product evaluation of technological development with an interventional aim towards future manufacturing designs and practices towards HCWs. The research consisted of the product evaluation of the NFIDs Stratis manufactured by PharmaJet TM-category 4 devices. During the time the project protocol plans commenced late 2011, it was the only product that was approved by FDA in the market that allowed the bench testing of the product as well. Another manufacturer was getting clearance at that time, but was not allowing the product to be tested. That is why the product was not compared to similar products of its kind (category 4) for its use and the objectives generated were very specific to allow measurements of the device, compare the measurements with previously studied

category 3 devices in the VAD lab, and future interventional aims towards the ergonomically designed NFIDs regarding utilization for HCWs.

Study design and population*:* The project entailed of an experimental prospective cohort study design that studied three different groups of trials with similar effort-conditions across time with an expected outcome measurement of dynamic forces for both trigger injector button and reset station for the NFID. A total of 136 total trials were conducted using the PharmaJet™ Injector. The experiment consisted of 10 validation trials, 116 experimental trials, and 10 trials with padding simulation for both the trigger injector button and the reset station.

Variables: Those that might come into consideration for the reproducibility of the study will be age, gender, body constitution of operator, precision of measuring devices, smoking habits, educational level, maturation of operator, padding finger simulation, prior health conditions and injuries. In order to control threats for internal variability, three researchers, R1, R2 and R3 were involved in the experiment. R1 ran the software applications for all operations involved and R3 supervised both R1 and R2 step-by-step operations. A single R2 operator executed all 136 trials. A protocol consisting of 94-steps was created to promote repeatability for the trials and reproducibility for future comparison studies; maturation of operator was taken into consideration as part of the validation trial group and differentiated from the experimental group (Annex A).

The idea was to come close to a summation equation of dynamic forces for the revamping technology involving the device. Since several steps could potentially be excluded, several criteria where taken into consideration. During the procedure we only measured the trigger injector forces and reset station forces with only one operator R2 doing all the sampling execution to avoid additional interpersonal variability. Excluded criteria included measurement of tensile forces related with the filling of the needless syringes due to the potential for the user of buying prefilled syringes, displacement forces while gripping, and different users during the operation of the device. Even though the excluded criteria might affect the overall summation of forces, annotations were done with detail by R3 regarding any discomfort or pain while filling the needleless syringes with saline reported as spurious findings.

Timing and setting*:* The protocol was elaborated during the first monthly quarter of 2012, and the experimental project preparation was in April 2012. The actual research was done during the month of June 2012. Subsequently, software analysis and tabulation of data with further statistical analysis was done. The experiment took place in the Department of Veterans Affairs (DVA) Research Center of Excellence in Tampa, Florida. The Product Evaluation Laboratory, directed by Donna Haiduven, PhD, RN, CIC. was funded by the DVA Occupational Health Strategic Healthcare Group in the Office of Public Health. This laboratory, using simulated patient materials, has as its initial charge, evaluation of devices with engineered sharps injury protection.

Short training of use of device was provided by manufacturer, which is also found on the web site for future inquires. There were no financial relationships with commercial interests between the manufacturer and the research team.

Data collection: A force gauge and load cell was integrated into the triggering setup & reset station, enabling force measurements to be obtained directly from the human-machine interfaces. Data collection used 4 software applications for force conversions & data manipulation. All the information was finally stored in the Excel database for simplicity of further use. Observations of specific events were annotated in paper with timing for each of the experimental trials.

Statistical Analysis: For simplicity of understanding, the results were divided into descriptive statistics and analytical statistics. The first part of the study consisted of graph tracings displayed to obtain clear pattern of force vs. time (effort across time or sample rate) for the trigger injector and the reset station. Several tables demonstrating the average force, minimum force, maximum force, standard deviation and range were obtained for the three group sets of data described as validation trials (n=10), experimental trials (n=116), and trials with padding simulation (n=10) with their respective trigger injector button and reset station. Values obtained will be recorded and compared to literature standards and subsequently, compared to 4 previously studied category 3-syringe devices from the VAD previous studies.

The second part of the study consists of analytical study in which validation trials (n=10), experimental trials (n=116), and trials with padding simulation (n=10) with their respective trigger injector button and reset station are analyzed to compare the means in between each three sets of groups for the trigger injector and mean ranks or medians for the reset station. For this part, Excel spreadsheets were used as database and the information was analyzed by using the Prism 6 Statistical Software, 2013. For the trigger injection button a one-way ANOVA was utilized to compare the means for forces in pounds of the three different groups of trials. Since the study is not comparing two different injector devices, the comparison was done in between the three abovementioned trials. The validation and the experimental trials are easy to understand, but the padded simulation trials were done to notice any differences with the curves of force vs. timed effort-sample rate obtained to analyze any benefit by adding a soft tissue that will simulate the tip of the finger fat pad simulating the human-machine interference. An ACF padding simulating soft tissue was used for this purpose.

The Ho or null hypothesis was that there is no difference in between the three means of force measurements by using F-statistics, known as the one-way analysis of variance. $\mu = 1$, $\mu = 2$, $\mu = 3$ were representing the validation trial, experimental trials and trials with padding simulation force means that were compared in pounds, respectively. In addition, the valued were also given in Newtons to provide adequate comparisons with prior studies:

***Null hypothesis**: Trigger Injector Button*

***Ho:** the means of measured forces (lbs or Newton's) are all equal*

H0: μ =1, μ =2, μ =3 (Means)

Analytical studies were also done for the reset station by using non-parametric one-way ANOVA Kruskal-Wallis. Data was tested for normality and converted to logarithmic values. The reset station validation trials (n=10), experimental trials (n=116), and trials with padding simulation (n=10) were analyzed to compare the medians in between each three sets of groups by using the H-statistics:

***Null hypothesis**: Reset Station*

***Ho:** the medians of measured forces (lbs or Newton's) are all equal*

H0: M=1, M =2, M =3 (Mean Ranks or Medians)

Multiple comparison tests were performed on both trigger injector and reset station to notice group differences. The data was finally compared to previous recommended limit values and analyzed by comparing it to the ergonomic equations that are in use for finger and arm measurement forces, particularly to the current recommended ergonomic values and Potvin's equation for repetitive motion equations to develop future suggestions for manufacturers and HCWs recommendations.

Ethical considerations: In spite of the fact that it was mainly a product evaluation under controlled laboratory conditions, the ethical standards and training were highly taken into consideration prior starting the analysis, by following requirements for the VA IRB and USF-NIOSH ERC to maintain excellence in research standards. The research project, which this experiment was part of, received approval from the VA Office of Research & Development, Protocol #006142, “Laboratory Evaluation of Sharps Devices to Prevent Blood Exposures and Ergonomic Injuries in Healthcare Workers.”

Chapter IV

Results

The results presented in this experimental investigational project for product evaluation will be presented in sequence with the established objectives in matter. For ease of interpretation, the results were divided into descriptive statistics and analytical statistics.

Results for Descriptive Statistics

In the descriptive statistics, the compressive force experiments were analyzed in a series of 136 graphs in an Excel spreadsheet for the trigger injector and for the reset station. Figure 11 displays a single graph for the

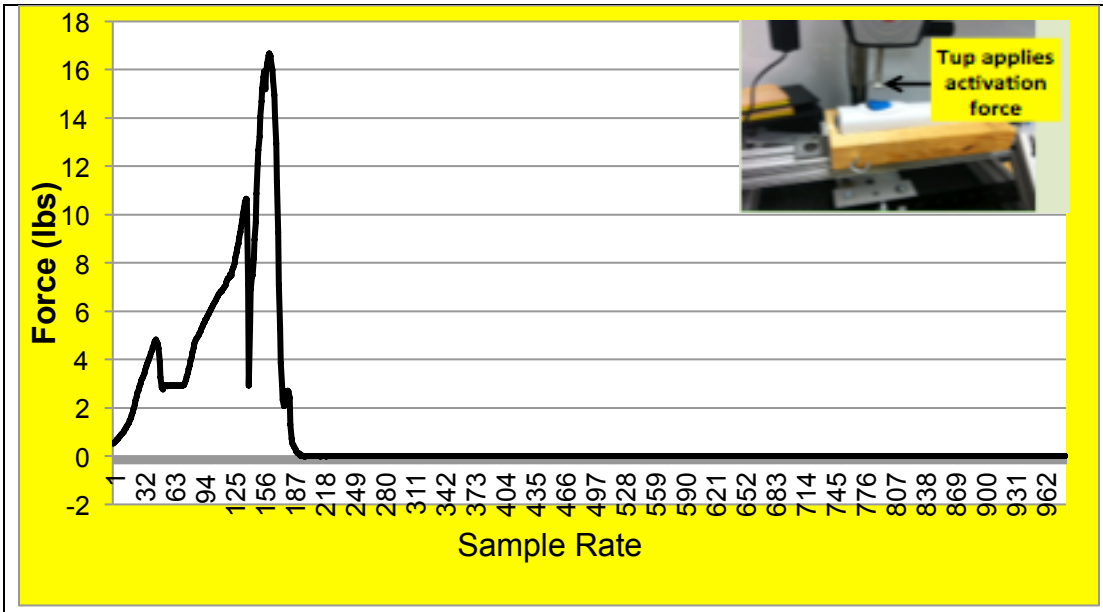

Figure 11. Trigger injector single data trial of sample rate (1000/sec) Vs. Dynamic force (lbs.)

trigger injector that was randomly picked showing a sample rate of the x-axis across time vs. the dynamic force on the Y- axis. The graph shows three peak spikes and an acute slump after the second spike. The sample rate was set at 1000 Hz and the measured forces in pounds. All graphs analyzed had a similar pattern with slight variations in between each other.

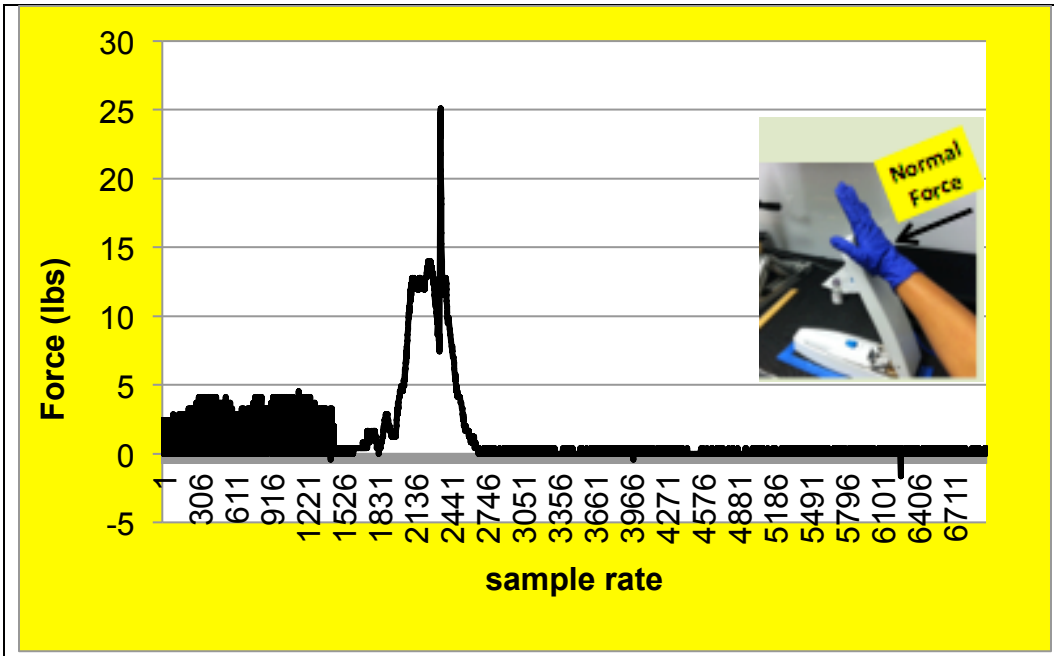

Figure 12. Reset station single data trial of sample rate (1,000/sec * 7 seconds) Vs. Dynamic force (lbs.)

In Figure 12, there is a graph representing a typical tracing of a reset station in between a sample rate of 1000 Hz during a total period of seven seconds vs. force measured in pounds. There is some interference in the first part of the tracing and then a sudden up-rise of the slope with a variable peak followed by a sudden decrease in the force until it plateaus to zero. The areas

under the curve will be representative for the total workload exerted by the individual without taking into account the initial artifact. A picture displays the force vector that was summarized as a dynamic force across time.

To evaluate the PharmaJet™ Needle-free trigger injector button and the reset station, with their respective means, for each of the parameters studied the results were tabulated exhibiting the average force, minimum force, maximum force, standard deviation and range.

The average force for the 10 validation trials for the trigger injector was 16.29 lbs (72.2 N) with a standard deviation of 5.78 lbs. (25 N) and a range of 9.69 -28.17 lbs. (43.25 – 125.75 Newton's) (See table 1). The average force for the 116 experimental trials for the trigger injector was 15.92 lbs (71.07 N) with a standard deviation of 5.78 lbs. (25.8 N) and a range of 9.77 -26.46 lbs. (43.61- 118.12 Newton's) (See table 3). The average force for the 10 padding simulation trials for the trigger injector was 21.84 lbs (97.5 N) with a standard deviation of 6.74 lbs. (30.08 N) and a range of 11.74 -33.17 lbs. (52.41- 148.08 Newton's) (See table 5).

The average force for the 10 validation trials for the reset station was 23.10 lbs (103.25 N) with a standard deviation of 6.95 lbs. (31.02 N) and a range of 11.94 -33.36 lbs. (53.3 – 148.92 Newton's) (See table 2). The average force for the 116 experimental trials for the reset station was 25.32 (113.03 N) with a standard deviation of 12.36 lbs. (55.17 N) and a range of 5.35 -82.78 lbs. (23.88-369.55 Newton's) (See table 4). The average force for the 10 padding simulation

trials for the reset station was 22.03 (98.34 N) with a standard deviation of 8.02 lbs. (35.80 N) and a range of 10.29-32.94 lbs. (45.93- 147.05 Newton's) (See table 6).

Table 1. Descriptive data for validation trials (n=10) for trigger injector applied force measured in pounds

Average Force	Minimum Force	Maximum Force	Standard Deviation	Range
16.29	9.69	28.17	5.78	18.48

Average, minimum, maximum, standard deviation and range of forces in pounds were described in Tables 1 through 6.

Table 2. Descriptive data for validation trials (n=10) for reset station applied force measured in pounds

Average Force	Minimum Force	Maximum Force	Standard Deviation	Range
23.10	11.94	33.36	6.95	21.41

Table 3. Descriptive data for experimental trials (n=116) for trigger injector applied force measured in pounds				
Average Force	**Minimum Force**	**Maximum Force**	**Standard Deviation**	**Range**
15.92	9.77	26.46	3.51	16.69

Table 4 Descriptive data for experimental trials (n=116) for reset station applied force measured in pounds				
Average Force	**Minimum Force**	**Maximum Force**	**Standard Deviation**	**Range**
25.32	5.35	82.78	12.36	77.43

Table 5 Descriptive data for padding simulation trials (n=10) for trigger injector applied force measured in pounds				
Average Force	**Minimum Force**	**Maximum Force**	**Standard Deviation**	**Range**
21.84	11.74	33.17	6.74	21.43

Table 6 Descriptive data for padding simulation trials (n=10) for reset station applied force measured in pounds				
Average Force	**Minimum Force**	**Maximum Force**	**Standard Deviation**	**Range**
22.03	**10.29**	**32.94**	**8.02**	**22.65**

Spurious findings: The tensile forces to fill the syringes were not measured in this experiment with a tensile force gauge device, but observational recording showed an increase of pain and hand strain in both R1 and R2 subjects while filling the syringes with normal saline after approximately 50 consecutive syringe fills. Pain was notorious in the 1st Metacarpal joint and first dorsal compartment while doing repetitive pinprick motion when the normal saline was extracted by pulling the emboli of the syringe that had a round flat surface.

Results for analytical statistics for trigger Injector

The results for the analytical statistics were presented as a series of tables and figures by distinguishing the statistical analysis ANOVA for the Trigger Injector for parametric data and the ANOVA Kruskal Wallis Reset Station for non-parametric data, by comparing the validation trials (n=10), the experimental trials (n=116) and the padding simulation trials (n=10). All of the comparisons presented in the tables are in pounds (lbs.).

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The one-way ANOVA for the trigger injector are described in Table 7 with their means and medians with standard deviations. Additional information displays confidence intervals for the three groups of trials.

Table 7	One Way ANOVA – for Trigger Injector (TI) Descriptive Statistics		
Descriptive Statistic	Trigger Injector-Validation (lbs)	Trigger Injector - Experimental (lbs.)	Trigger Injector - Padded (lbs)
	Validation	**Experimental**	**Padded**
Number of values	**10**	**116**	**10**
Minimum	9.690	9.770	11.74
25% Percentile	13.14	13.20	16.97
Median	13.97	16.18	20.56
75% Percentile	18.88	18.14	27.87
Maximum	28.17	26.46	33.17
Mean	16.30	15.93	21.84
Std. Deviation	5.780	3.516	6.742
Std. Error of Mean	1.828	0.3264	2.132
Lower 95% CI of mean	12.16	15.28	17.02
Upper 95% CI of mean	20.43	16.58	26.67
95% CI of median			
Actual confidence level	97.85%	96.77%	97.85%
Lower confidence limit	11.99	15.55	16.68
Upper confidence limit	24.75	17.00	31.24

The p- value summary for the trigger injector data is shown on table 8, with results consistent with an F ratio of 10.05 with a significant p-value below 0.0001 with significant differences among the mean values while using 2,133 degrees of freedom, with a total of three treatment columns and 136 number of total values.

Table 8	One Way ANOVA– P-Value Summary Parametric ANOVA for Trigger Injector (TI)				
Table Analyzed	One-way ANOVA data				
ANOVA summary					
F					**10.05**
P value					**< 0.0001**
P value summary					****
Are differences among means statistically significant? (P < 0.05)					**Yes**
R square					0.1313
ANOVA table	SS	DF	MS	F (DFn, DFd)	P value
Treatment (between columns)	322.0	2	161.0	**F (2, 133) = 10.05**	**P < 0.0001**
Residual (within columns)	2131	133	16.03		
Total	2453	135			
Data summary					
Number of treatments (columns)			3		
Number of values (total)			136		

The results on Table 9 for the trigger injector consisted of normality tests to assess the distribution of the data. By using D'Agostino & Pearson omnibus, Shapiro-Wilk normality test and Kolmogorov Smirnoff we saw normality in 2 out of 3 tests with an alpha set at 0.05. That allowed us to proceed with the one-way ANOVA tests, meaning that the data were normally distributed with a similar Gaussian distribution. From the normality tests, the D'Agostino & Pearson Omnibus test and the Kolmogorov Smirnoff passed the normality test in comparison to Shapiro-Wilk normality test.

Table 9	One Way ANOVA – Normality Test for Trigger Injector		
Column Statistics	Trigger Injector-Validation (lbs)	Trigger Injector-Experimental (lbs)	Trigger Injector-Padded (lbs)
	Validation	**Experimental**	**Padded**
Mean	16.30	15.93	21.84
Std. Deviation	5.780	3.516	6.742
Std. Error of Mean	1.828	0.3264	2.132
D'Agostino & Pearson omnibus normality test			
K2	4.487	1.650	0.5706
P value	0.1061	0.4383	0.7518
Passed normality test (alpha=0.05)?	Yes	Yes	Yes
P value summary	ns	ns	ns
Shapiro-Wilk normality test			
W	0.8373	0.9716	0.9496
P value	0.0410	0.0145	0.6632
Passed normality test (alpha=0.05)?	No	No	Yes
P value summary	*	*	ns
KS normality test			
KS distance	0.2570	0.06492	0.1665
P value	0.0600	0.2000	0.2000
Passed normality test (alpha=0.05)?	Yes	Yes	Yes
P value summary	ns	ns	ns

On table 10, a one-way ANOVA with Tukey's multiple comparison tests for means of the force outcomes obtained showed a significant difference between the simulated padded trials vs. the validation and experimental trial. A trigger injector (TI) padded trials vs. TI validation trials p-value less than 0.0067; a TI padded trials vs. TI validation trials less than 0.0001; and a compared to TI experimental trials vs. TI validation trials p-value above 0.9584. The means were greater by almost 6 lbs (27 N) for the padded simulation trials.

Table 10	One Way ANOVA – Multiple Comparisons of Means Parametric ANOVA for Trigger Injector (TI)				
Tukey's Multiple Comparison Test and Test Details					
Number of families	1				
Number of comparisons per family	3				
Alpha	0.05				
Tukey's multiple comparisons test	**Mean Diff.**	**95% CI of diff.**	**Significant?**	**Summary**	**Adjusted P Value**
TI- Experimental (lbs) vs. TI-Validation (lbs)	-0.3663	-3.494 to 2.761	No	ns	0.9584
TI- Padded (lbs) vs. TI-Validation (lbs)	**5.547**	**1.304 to 9.790**	**Yes**	**	**0.0067**
TI- Padded (lbs) vs. TI-Experimental (lbs)	**5.913**	**2.786 to 9.041**	**Yes**	****	**< 0.0001**
Test details	**Mean 1**	**Mean 2**	**Mean Diff.**	**SE of diff.**	**n1**
TI- Experimental (lbs) vs. TI-Validation (lbs)	15.93	16.30	-0.3663	1.319	116
TI- Padded (lbs) vs. TI-Validation (lbs)	21.84	16.30	5.547	1.790	10
TI- Padded (lbs) vs. TI-Experimental (lbs)	21.84	15.93	5.913	1.319	10

In Figures 13 & 14 there is a graph representing the force with standard deviation for each of the three groups with, and a comparison of the means and 95% confidence intervals with Tukey's post-test showing the difference between group means for the padded simulation trials for the injector button. In Figure 15, there is an overall summary of the ANOVA statistical data for the trigger injector showing the F ratio of 10.0472 with two degrees of freedom.

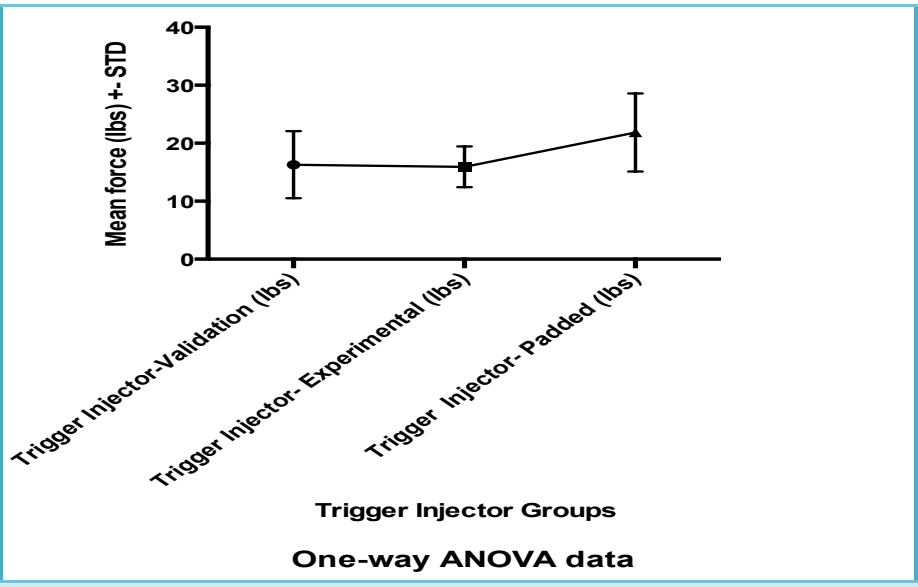

Figure 13. One-Way ANOVA data for trigger injector (TI)

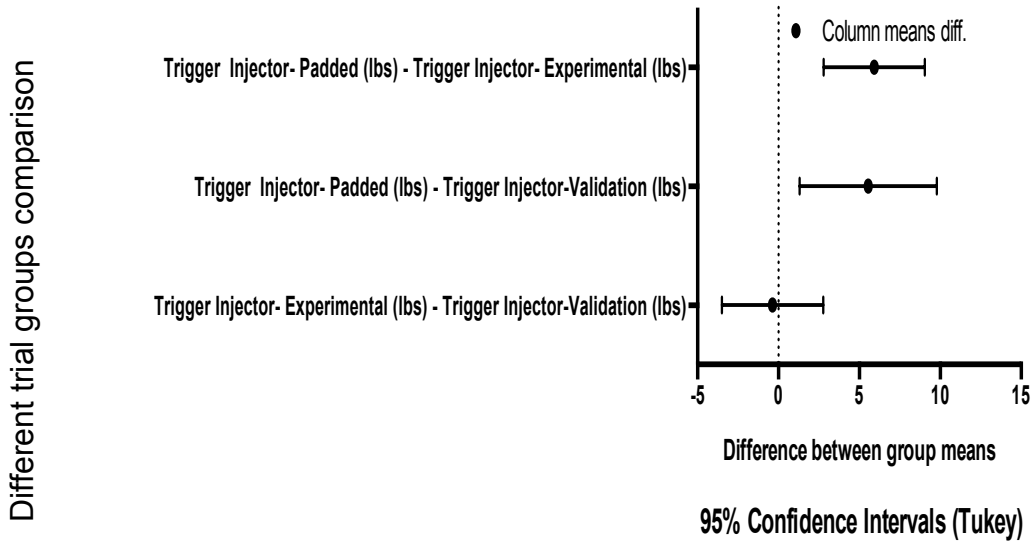

Figure 14. One-Way ANOVA with Tukey's Multiple Comparison Confidence intervals for trigger injector

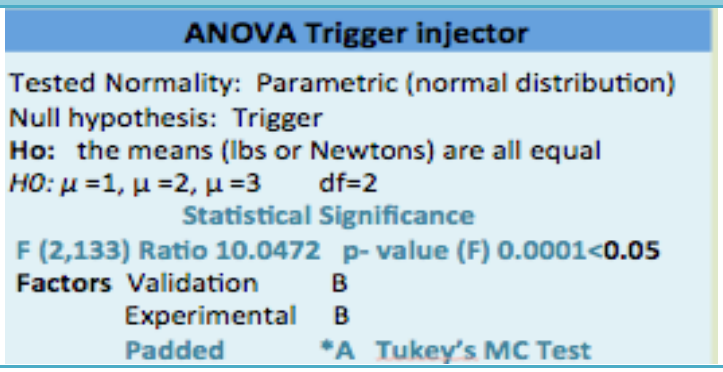

Figure 15. One-Way ANOVA overall summary for trigger injector

Notice that the null hypothesis is that there is no difference in between means of outcome forces for the trigger injector. The null hypothesis was rejected due to significant difference between groups with a p-value less than 0.0001 and an F ratio slightly greater than ten. On the Tukey's multiple comparison test, the group that is different is the Padding simulation trial, which is marked on Figure 15 as *A. There was no difference in the post-test between validation and experimental trials.

Results for Analytical Statistics

Reset Station

The results for the reset station were converted to logarithmic values to achieve closeness to normality of data. Then, Kruskal Wallis test for non-parametric data was applied to the data. If the reader wants to see descriptions of the gross value data, please refer to tables 2, 4 & 6. The mean and standard deviation for the converted data are shown is table 11, with mean ranks of 67 for group 1- validation trials, 69.13 for group 2-experimental trials and 62.75 for

group 3, padded simulation. The Kruskal Wallis test displays an H-statistic of 0.2568 and a p-value of 0.8795 (see table 12), with no significant variation in the median values. The results on Table 13 for the reset station consisted of normality tests to assess the distribution of the data. By using D'Agostino & Pearson omnibus, Shapiro-Wilk normality test and Kolmogorov Smirnoff normality was verified after converting the data to logarithmic values. In 3 out of 3 tests with an alpha set at 0.05, Dunn's multiple comparison tests showed no significant difference in between the mean rank or median obtained (see table 14).

Table 11 Kruskal-Wallis Test – Descriptive Statistic Nonparametric ANOVA for Reset Station (RS)

***Logarithmic conversion of data**

Descriptive Statistics	RS- Validation (lbs)	RS-Experimental (lbs)	RS-Padded (lbs)
Number of values	10	116	10
Minimum	1.077	0.7287	1.013
25% Percentile	1.208	1.228	1.149
Median	1.370	1.363	1.386
75% Percentile	1.469	1.488	1.439
Maximum	1.523	1.918	1.518
Mean	1.344	1.357	1.313
Std. Deviation	0.1436	0.2020	0.1797
Std. Error of Mean	0.04542	0.01876	0.05681
Lower 95% CI	1.241	1.320	1.184
Upper 95% CI	1.446	1.394	1.441
Mean ranks	67.00	69.13	62.75

Figures 16 a & b, show graphic distribution of the three groups with their respective confidence intervals and the rank distribution for the data set of the reset station. Values show a distribution of rank data points with similar distribution of data and similar confidence intervals. Obviously the RS experimental shows an abundant number of data ranks, due to the uneven number of trials, in which the experimental group had n=116.

Table 12	**Kruskal-Wallis Test – P-Value Summary Nonparametric ANOVA for Reset Station (RS) *Logarithmic conversion of data**
Table Analyzed	One-way ANOVA data
Kruskal-Wallis test	
P value	**0.8795**
Exact or approximate P value?	Approximate
P value summary	**ns**
Do the medians vary significantly (P < 0.05)	No
Number of groups	3
Kruskal-Wallis H- statistic	**0.2568**
Data summary	
Number of treatments (columns)	3
Number of values (total)	136

Table 13	Kruskal-Wallis Test Normality Test Nonparametric ANOVA for reset station (RS) *Logarithmic conversion of data		
Column Statistics	Reset Station-Validation (lbs)	Reset Station-Experimental (lbs)	Reset Station-Padded (lbs)
Number of values	10	116	10
Minimum	1.077	0.7287	1.013
25% Percentile	1.208	1.228	1.149
Median	1.370	1.363	1.386
75% Percentile	1.469	1.488	1.439
Maximum	1.523	1.918	1.518
D'Agostino & Pearson omnibus normality test			
K2	1.080	0.6791	1.327
P value	0.5828	0.7121	0.5150
Passed normality test (alpha=0.05)?	**Yes**	**Yes**	**Yes**
P value summary	ns	ns	ns
Shapiro-Wilk normality test			
W	0.9388	0.9934	0.8938
P value	0.5399	0.8587	0.1871
Passed normality test (alpha=0.05)?	**Yes**	**Yes**	**Yes**
P value summary	ns	ns	ns
KS Kolmogorov Smirnoff normality test			
KS distance	0.1869	0.05124	0.2426
P value	0.2000	0.2000	0.0980
Passed normality test (alpha=0.05)?	**Yes**	**Yes**	**Yes**
P value summary	ns	ns	ns
Coefficient of variation	10.69%	14.89%	13.69%
Geometric mean	1.336	1.342	1.301

Table 14	Kruskal-Wallis Test – Multiple Comparisons of mean ranks Nonparametric ANOVA for reset station (RS) *Logarithmic conversion of data				
Multiple Comparison Test and Test Details					
Alpha	0.05				
Dunn's multiple comparisons test	**Mean rank diff.**	**Significant ?**	**?**	**Summary**	**Adjusted P Value**
RS-Experimental (lbs) vs. RS-Validation (lbs)	2.125	No		ns	> 0.9999
RS-Padded (lbs) vs. RS-Validation (lbs)	-4.250	No		ns	> 0.9999
RS-Padded (lbs) vs. RS-Experimental (lbs)	-6.375	No		ns	> 0.9999
Test details	**Mean rank 1**	**Mean rank 2**	**Mean rank diff.**		
RS-Experimental (lbs) vs. RS-Validation (lbs)	69.13	67.00	2.125		
RS-Padded (lbs) vs. RS-Validation (lbs)	62.75	67.00	-4.250		
RS-Padded (lbs) vs. RS-Experimental (lbs)	62.75	69.13	-6.375		

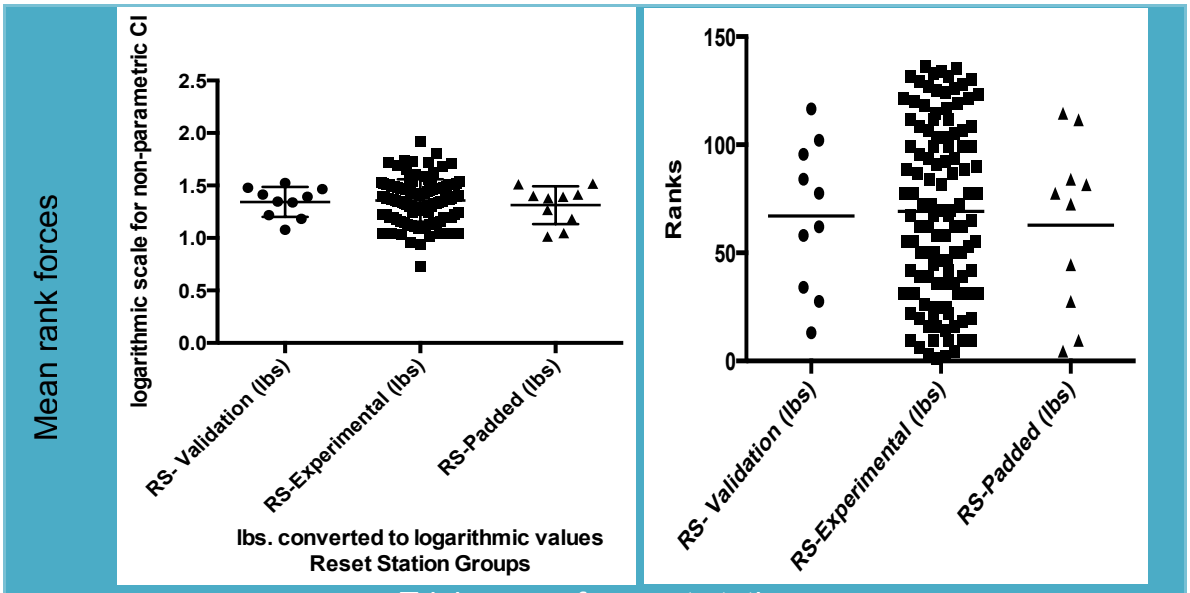

Figure 16 a & b. Kruskal Wallis One-Way ANOVA data for reset station and ranks distribution

Tested Normality: non-parametric
data converted to logarithms
Null hypothesis: Reset Station
Ho: the medians (lbs or Newtons) are all equal
H0: M=1, M =2, M =3 (Mean Ranks or Medians)
KW (H) statistic 0.2568 NO Statistical Significance
p –value (0.8795) >**0.05**

Groups	**Validation**	**B**	**Dunn's MC Test ns**
	Experimental	B	
	Padded	B	

Figure 17. ANOVA Kruskal Wallis (KW) Reset Station

Figure 17 shows an overall summary for the KW for the reset station. The null hypothesis was that there is no difference in between the medians or mean ranks of the three different groups. KW analysis shows no difference in between groups with an H-statistic of 0.2568 and a p-value of 0.8795, which was not significant. On Dunn's multiple comparison test the letter B on the three groups describes no difference for validation, experimental and padded trials. So the null hypothesis is not rejected.

Chapter V

Discussion

Many authors have discussed the needle free injector devices advantages over needle devices with ESIP with regards to patient safety and elimination of sharp hazards. This requires health care workers to learn and train how to use new devices. Many of these recently acquired skills require human factors engineering processes yet to be measured and determined when using practical tools. Even though technology helps to simplify many of the steps in a procedure, or gain efficacy over predecessor instruments, in many instances the ergonomics in the design of new tools tend to be one of the last details taken into consideration. The different components of the PharmaJet ^{TM} Stratis System will be taken into consideration for the experimental product evaluation with the aim of creating simple intervention or suggestions for both the manufactures and the HCWs when using category 4 devices.

Even though many variables can come into play in any experiment, our approach was to reduce threat to the internal validity of the study by creating an elaborate protocol with more than 94 steps that will guide the researcher to ensure repeatability and promote reproducibility for studies. Sophisticated technological software and computers were employed to obtain precise measurements and recordings of the forces involved in the compressive force experiments for the trigger injector and reset station. Even though our initial

intent was to create a formula that incorporated a summation of forces and vectors involved during the whole sequence of steps involved in the use of the device to provide a full injection, the complexity of the different maneuvers and steps in the procedure impeded the elaboration of a formula to attain a precise threshold limit value for the repetitive motion analysis. In spite of the complexity, the measurement of compressive forces for the trigger injector button and loading of the injector with a manual reset station were taken into consideration. The implication of tensile forces for filling the syringes appeared to be of less concern during the initial phase, due to the fact that any employer could potentially buy the pre-filled needless syringes for injection. Another factor not taken into account was the horizontal hand displacement forces when defeating the blue tip safety feature. This was not considered important for the present experiment because the safety feature for the injector was disabled when placing it inside the wooden injector mount, but a factor to take into consideration for the overall summation of forces. Our best approach was to come up with the compressive dynamic force measurements across time, and subsequently compare these measurements with 4 previously measured category 3 devices. One of the challenges of human factors engineering is to evaluate different workplace demands and contrast them to their functional capacities at work to establish tolerance limit values (TLV). The potential psychophysics ergonomic impact on HCWs with use of NFIDs was discussed to create appropriate suggestions for manufacturer design and administrative considerations for future usage implication for HCWs during and after procedure with repetitive motion

involving fingertip push and pushing down with the upper extremity (Potvin, 2012).

Compressive forces for trigger injector button: The results for the descriptive analysis were first preceded by a depiction of 136 graphs that were carefully analyzed for shape and variability of the trigger injector. The compressive forces were achieved by using a manual Andilog digital Com-Ten force gauge with an external sensor that was in direct contact with the trigger injector button. As shown in figure 11, the trigger injector displays a sample rate on the x-axis across time vs. the dynamic force on the Y- axis. The graph shows three peak spikes and an acute slump after the second spike. The sample rate was set at 1000 Hz and the measured forces in pounds. The first peak was generated when the manual force gauge sensor area came in contact with the trigger injector button. The second peak was generated to defeat the trigger mechanism blocking the release of kinetic energy in the spring. The abrupt slump or down-slope was generated when the trigger mechanism was physical defeated through a pushing down an effort. The third peak was interesting because it was initially thought to be the counter force generated by the spring device in the machine-to-machine interface. That led to the ideas of creating three different groups. The first one will include the n=10 validation trials, the second n=116 experimental trials, and the third group n=10 padding simulation trials. The padding simulation trials were initially thought to make it more realistic when considering that the human thumb has a soft-tissue pad before coming into contact with bone.

The second potential advantage was to study the effect of adding a soft tissue pad to help explain the phenomenon noticed on the third peak of the trigger injector graph in Figure 11.

For our surprise, the peak effect did not disappear when the pad simulation was added in case it was a counter force related with the spring device. Instead, the peak only increased in width and height. That led us to believe that is was not related to the counter force for the recoil spring device, but the simple reaction time of the operator to react when pushing the TUP lever back which was timed slightly under 0.2 seconds. That by itself increased the average force of the trigger injector from 15.92 lbs. to 21.84 lbs. with a difference of 6 lbs. of added force when adding a padded simulation or soft cushion compared to the experimental trials.

After comparing the average forces obtained in all three-group trials for the trigger injector, it was noticeable to appreciate a significant increase in dynamic force required when adding the padded simulation, which resembles the human-to-machine interference. Adding a rubber or soft cushion will not be a recommended for comfort purposes, since it can potentially increase the force required to defeat the trigger button.

That also accomplished the first part of the objectives and became an average force measurement for further comparison to achieve the second set of the objectives which consists of comparing the forces obtained to those required to use with four previously analyzed retractable intramuscular syringes with needles or category three devices.

Triggering the injector button through thumb push required considerable effort in comparison to activating 4 retractable intramuscular syringes with needles from our previous lab studies (Haiduven, 2011), the range of mean forces were 3.63-17 lbs (16.19-77.53 N) for those syringes. The jet injector required more force per effort than 2 (4.4 times for effort) syringes & similar to other 2 syringes (0.9 times the effort) previously tested.

Compared to the best category three devices in terms of ergonomic efficiency, there is almost a 12 lbs. (53.57 N) excess of compression force implied in the action. This comparison might be considered a simple relative value, but it becomes significant once it is compared against the NASA STD-3000 203 which describes the thumb-finger tip strength with a limit of 13 lbs.(58 N) for momentary hold (2008) and the maximal voluntary forces for the finger tip push of 56.6 N described by Potvin (2012). Since each effort time is short in the order of 0.5-0.9 seconds, when plotting the value in Potvin's equation it is above the recommended level, with the advantage that there is no sustained effort.

The average maximal voluntary force for the experimental trials was 70.07 N, with a machine-to-machine interface, which can only be suggested to be of higher value when using the real thumb soft tissue by 26.78 N. Even though the trigger button was softer than prior the prior version of the NFIDs, it is above the recommended value for maximal voluntary effort, which can be translated into additional conflict once there is consideration of 480 minutes in an 8-hour period with a potential of 480 shots or more during a day per operator use during

massive vaccination campaigns. This outcome value of force measured could potentially higher if taken into consideration that a skilled operator goes through 12 mini-steps of the procedure in less than 30 seconds. In that case maximal achievable effort will have to cut the trigger button resistance by almost half of the current value to around 35 N. Instead of limiting the number of thumb efforts per cycle, the suggestion for the manufacturer will be either to further improve the mechanism of the trigger injector or redesigning the trigger button to be used with the palmar grasp of a squeezing mechanism consisting of pulling with 4 fingers rather than pushing with the thumb. If not taken into consideration, that could potentially result in hand and wrist pain secondary to strain of the metacarpal joint or first ventral and dorsal compartment. Even though the time used per trial averaged in between 3 to 4 minutes per trial due to strict adherence to the protocol, no sustained effort for the critical measurements were done that would affect the outcome. That is without considering the spurious finding that after filling more than 50 syringes with tensile forces not being measured in the experiment, two operators had pain and discomfort in the first metacarpal joint of the dominant hand. Even though similar forces will be exerted when filling a regular syringe, pre-filled syringes might be beneficial for HCWs' prevention of occupational hand injuries. In massive campaigns, it is recommended to have an hour break in between and administrative controls consisting of rotating the personnel activities, if the activities are segregated and encouraging frequent recovery breaks to avoid repetitive motion injury.

The one-way ANOVA for the trigger injector data with normal distribution are described in Table 7 with their means and medians with standard deviations. Additional information displays confidence intervals for the three groups of trials. The p- value summary for the trigger injector data is shown on table 8, with results consistent with an F ratio of 10.05 with a significant p-value below 0.0001 with significant differenced among the mean values of the three groups while using 2,133 degrees of freedom. The null hypothesis of equality of the mean force values was rejected, and a difference in between the groups was noted. When comparing the three groups with Tukey's multiple comparison post-test, the padded simulation trials were significantly different than the validation and experimental trials. Since there was no significant change in the shape for the third peak of the trigger injector graph, and only an increase was seen in the amount of force require to push which was 6 additional pounds, our simple reasonable deduction will be that having the soft tissue of the thumb will add force when measured in real human-to-machine interface. Even though that was an additional suggestion by ergonomists to make it more real with respect to the human body, that might potentially increase 26 N to the 71 N obtained for the trigger injector button of machine-to-machine interface. Regardless of the prior, the 71 N is already above the recommended level of 56.6 obtained by Potvin (2012).

Compressive forces for reset station: As shown in (Figures 9 a & b), the experimental set up for force measurement of the reset station consists of a small load sensor adhered to the arm of the reset station with a sample rate of 1,000/second for duration of 7 seconds, with subsequent data collection to Lab View Software depicts a common graph tracing as seen in Figure 12. This graph represented a typical tracing of a reset station in between a sample rate of 1000 Hz during a total period of seven seconds vs. force measured in pounds. There was some interference in the first part of the tracing and then a sudden up-rise of the slope with a variable peak followed by a sudden decrease in the force until it plateaus to zero. That represents the push down arm exertion done by the R2 experimenter. The areas under the curve will be representative for the total workload exerted by the individual without taking into account the initial artifact. To evaluate the PharmaJet™ Needle-free reset station, with their respective means, for each of the parameters studied the results were tabulated exhibiting the average force, minimum force, maximum force, standard deviation and range.

After statistically comparing the average forces obtained in all three-group trials for the reset station, it was clear that there was no obvious difference in the average forces for the three compared group trials. Comparing this value to similar activities consisting of pushing down from prior literature, the maximal volume effort for pushing down a hose is 130.2 N, which is a similar motion when comparing the activation of the reset station (Adrews, 2008; Potvin, 2006). The average was below that reported repetitive motion effort which is considered to

be safe. Even though it is a simple and clever reloading device for the needle-less injector, this action can potentially be eliminated completely out of the summation equation if an automated device similar to the automatic staplers commonly used for daily working tasks mechanisms was employed. That comes into play especially during massive vaccination campaigns in which the R2s or HCWs will have to push down constantly and potentially end up with pain in the hand, wrist or upper arm strains. No pain was reported while using the device because it was carefully placed in between waist level and below nipple level for maximal protection of the R2 operator. If that simple principle is not respected, the groups of muscles that will come into consideration above nipple level could potentially induce excessive strain to the shoulder muscle group or lower back. This was an additional force vector measurement when comparing to the effort to category 3 devices. It adds time and effort when comparing to the simplicity of the needle syringe devices. That is why this author recommends the optional automated reload station for massive campaign vaccinations to avoid excess repetitive motion.

In addition, the data for the reset station was not normally distributed, so it was converted to logarithmic values to approximate normal distributed data, and the three groups were subsequently analyzed to see any difference in the medians or mean ranks among the groups which were evenly distributed Ranks as seen in Figure 16 a and b. There was no statistical significance with a p-value of 0.8795 and an H statistic of 0.2568. The null hypothesis cannot be rejected and the Dunn's multiple comparison-test showed no difference among the three

groups. The mean ranks were 67, 69.13 and 62.75 for the three groups for the validation, experimental and padded trials, respectively. We can conclude that the reset station step for loading the injector is an easy step with a similar learning distribution curve, but one that can be fully avoided if automatizing the process is considered.

Additional comments will include additional consideration for the tensile forces required to fill the syringes, since pain was elicited in two operators R1 and R2 after filling more than 50 syringes. The suggestions will be to buy pre-filled syringes or implement a design with a spherical holder instead of a flat circular holder to avoid the pinprick action that elicits pain. Instead, the action for filling the syringe can be done with the first, second and third fingers. The anatomical consideration was not added to the factor of the summation equation, since the recommended suggestions by the manufacturer teach the usage of the device in a neutral position. That assumption can be violated if the injection is not given at the HCWs' height in between the waist and the shoulders. The third additional factor into consideration was that minimal amounts of air within the syringe could lead to a wet shot or breaking of the needleless syringe. There was only one wet shot during the learning phase, and it was observed under the stereoscope with a cracked polycarbonate syringe with no missing pieces. That provides a safety component for both the patient and the HCWs. The fourth component was based on observations with regards to leakage of fluid while loading the needleless syringe, and fluid in the cap with immediate vicinity-splatter. Even though it occurred in less than 5-10 % of the trials, the use of live

vaccine components should be warranted and gloves and safety goggles were considered wise when dealing with such tools, to avoid exposures of HCWs to live vaccine

Strengths and limitations of the study: The strengths consisted of a strict protocol to guard for internal validity. The R3 was double-checking all the steps throughout. The recommendations and training from the manufacturer were completely followed and practices with safe protocol of personal protective equipment was ensured. Constant visual confirmation of injector alignment was attained with the reset station. The fluid shot was simulated in ACF pad to notice the effects on skin. The experimental study was conducted by a group of multi-disciplinary team members and dynamic force measurement attained. The author, R2, was the only one testing the device after thorough training, increasing intra-rater reliability

The limitations were a delay in the data recorder, a small sensitive load sensor area for evaluation of ergonomic issues in case the protocol is not reproduced with precision in future studies, cost of the experiment, presence of bubbles in syringes that might induce wet shots, increased time for visual confirmation by R3 during the experiments, leveling and handle rotation, along with the fact that strict adherence to the protocol might make a 30-45 second trials into a 4 to 5 minutes strict trial per injection evaluated.

Chapter VI

Conclusions

Triggering the injector and resetting the station required considerable effort in comparison to activating 4 retractable intramuscular syringes with needles from our previous studies. The range of mean forces was 3.63-17 lbs (16.19-77.53 N) for those syringes with the trigger injector maximum voluntary force of 71 N being above the recommend 56.6 N.

The jet injector required more force per effort than 2 (4.4x) syringes & similar to other 2 syringes (0.9x) previously tested when considering the compression forces related with the trigger injector (Haiduven et al., 2006; 2010).

Additional vector forces (displacement & gripping of reset station) could increase the cumulative effort affecting different musculoskeletal components when the whole components of the procedure are taken into account.

Suggestions for the manufacturer regarding design changes to facilitate HCWs' use of this device are warranted, since some of the summation forces during the 12 mini-steps could be avoided to achieve a higher efficiency. This information may be useful for health care facilities when choosing devices to protect their workers from ergonomic injuries. Suggested automated reset station, power grip with four fingers for trigger injector button and using prefilled syringes or changing the pin-prick action to the use of three fingers.

Future research implications with analytical sensor gloves to attain the full effect of compression and tensile forces during the entire procedure will be ideal to improve laboratory measures that will translate into clinical effectiveness to make it more functionally appealing for its use for HCWs when compared to simple category 3 devices.

This author wishes to emphasize that this work is not intended to discredit the exhaustive effort of the manufacturer in question, but to aid in the fine-tuning of a useful tool already showing clinical effectiveness throughout clinical trials and revamping it to a state of the art tool that is safer and more efficient for use by HCWs.

Suggestions for future research include but are not limited to the following:
Need to replicate with more than one HCW as operator, including shorter and taller individuals and both genders; need to test with reset station moving versus stationary, need to test with different orientations of the hand on the reset station, need to use multi-sensor glove for dynamic measurements during a complete duty cycle.

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Appendix A

IRB VA & USF-NIOSH ERC

Product evaluation under controlled laboratory conditions; the ethical standards and training were highly taken into consideration prior starting the analysis, by following requirements for the VA IRB and USF-NIOSH ERC to maintain excellence in research standards with CITI search training completed.

The research project, which this experiment was part of, received approval from the VA Office of Research & Development, Protocol #006142, “Laboratory Evaluation of Sharps Devices to Prevent Blood Exposures and Ergonomic Injuries in Healthcare Workers.”

The abstract initial date was 11/10/2011 with a protocol original proposal on 06/09/2010. Approval to conduct this research was granted on 06/18/2012 by Dr. William R. Gower, Hr., Ph.D. as the ACOS for Research Service as well as the executive Secretary of the R&D Committee.

The proposal for this project was reviewed both scientifically and administratively and fully approved by the Research and Development Committee.

Documentation from the USF Health Sciences IRB was granted approval, having both R&D, IRB, and Privacy Officer approvals, the project was approved and subjects were allowed to be admitted to the study as stated in paragraph 2 of the last page of the document of the current appendix.

Appendix A (continued)

Research & Development Committee
James A. Haley Veterans' Hospital
13000 Bruce B. Downs Blvd. • Tampa, FL 33612 • 813-972-2000

APPROVAL - Initial Review (Final Approval)

Date: June 13, 2012
From: Robert Campbell, J.D, Ph.D.
Investigator: Donna Haiduven, Ph.D.
Protocol: Laboratory Evaluation of Sharps Devices to Prevent Blood Exposures and Ergonomic Injuries in Health Care Workers
ID: 006142 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 06/08/2012 meeting:

- Abstract - Initial (11/10/2011)
- Biosafety Form (10-0398 rev. 1) - Initial (11/10/2011)
- Code of Ethics - Initial (11/10/2011)
- Conflict of Interest - Haiduven (11/10/2011)
- Conflict of Interest - McGuire - Wolfe (11/10/2011)
- Conflict of Interest - Ramaiah (11/10/2011)
- Data Security Checklist - Initial (11/10/2011)
- Intellectual Property and Invention Disclosure - Initial (11/10/2011)
- Investigator Data (page 18) - Haiduven (11/10/2011)
- Key Personnel - Initial (11/10/2011)
- Acknowledgement of VA in Research (11/10/2011)
- ROI - Haiduven (11/10/2011)
- ROI - McGuire-Wolfe (11/10/2011)
- ROI - Ramaiah (11/10/2011)
- Ramaiah Info Sec Awareness (11/02/2011)
- McGuire Wolfe Mandatory Trainig for Trainees (10/29/2011)
- Ramaiah - Mandatory Training for Trainees (10/10/2011)
- Haiduven-Info Sec Awareness (06/14/2011)
- CITI - McGuire-Wolfe (02/14/2011)
- CITI-Ramaiah (01/10/2011)
- Ramaiah Info Sec 201 (12/19/2010)
- CITI - Haiduven (08/09/2010)
- Info Sec 201 - Haiduven (06/11/2010)
- McGuire-Wolfe Info Sec 201 (06/09/2009)
- Protocol - Initial (11/10/2011)
- Protocol - Original Proposal (06/09/2010)
- Request to Review Research Proposal/Project - Initial (11/10/2011)

Appendix A (continued)

This research project has received administrative and scientific quality review by the VA R&DC. The scientific review finds the project offers: clarity of purpose or hypothesis, appropriateness of study design and procedural repeatability, significance of statistical procedure and/or power, contribution of useful knowledge and relevance to the patient care mission of the Department of Veterans Affairs.

R&D/C has approved all notification(s) of all relevant committee and subcommittee approval(s).

Robert R. Campbell
R&D Committee Member

6/15/12
Date

I have been notified by the R&D/C of this approval, and as such approval to conduct this research is granted.

William R Gower
ACOS, Research and Development

6/18/12
Date

Dr. William R. Gower, Jr., Ph.D. is the ACOS for Research Service as well as the Executive Secretary of the R&D Committee.

REMINDER: It is the Principal Investigator's responsibility to assure that all continuing reviews and modifications are submitted as required:
-- Continuing review(s) by all applicable committee(s) must occur at least every 365 days.
-- Modifications related to Safety must be submitted to the JAHVH SRS Committee and the USF IBC, if applicable.
-- Modifications related to Privacy and Information Security must be submitted to the PO/ISO, if applicable.
-- Modifications related to addition of personnel. The JAHVH Research Service must be notified and personnel processed prior to their being added to the study.

1. Your proposal was reviewed both scientifically and administratively and fully approved by the Research and Development Committee.

2. Documentation from the USF Health Sciences IRB has been received granting approval. Having both R&D, IRB, and Privacy Officer approvals, the project is now fully approved and subjects may now be admitted to the study.

Approval by each of the following is required prior to study initiation:
Research & Development Committee