DUAL INJECTION SYRINGE FOR ULTRASOUND-GUIDED MUSCULOSKELETAL INJECTIONS

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Dual Injection Syringe for Ultrasound-Guided Musculoskeletal Injections

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Abstract:

Ultrasound-guided musculoskeletal injections are a common procedure in family and sports medicine. These procedures often require the injection of a numbing agent and a corticosteroid at a single injection site. As the physician must use an ultrasound probe to locate the injection site, only one hand is available to inject the medicines. This restriction created a protocol that entails injection of numbing agent, removal and replacing of one syringe with another housing the corticosteroid, relocation of the injection site, and administration of injection. In addition to being inefficient, this procedure also causes discomfort and pain for the patient. Therefore, a clinical need has arisen to improve physician efficiency and patient comfort. The conception of a one-handed syringe capable of delivering two injectates for ultrasound-guided musculoskeletal injections stands to streamline targeted injection procedures for physicians and improve the associated patient experience. It was determined that the proposed device should be capable of being used with one hand, demonstrate no leaking, and be able to aspirate and inject medicine without mixing. Through the iterative design process, 12 prototypes were developed in an attempt to solve this problem. Prototypes were designed using AutoDesk Fusion 360 and 3D printed. While some of these functions were achieved, the team was unable to produce a fully functional prototype as a result of errors associated with 3D printing along with other complications. Prototypes have demonstrated some functionality, however, due to time constraints, a final prototype was not developed. Potential clinical impact includes a more efficient procedure, a better clinical experience for patients, and a new medical device to advance the fields of family and sports medicine.

Keywords: Ultrasound-guided, musculoskeletal injections, 3D printing

Introduction

The current single syringe and needle method is inadequate for performing and undergoing musculoskeletal injections for doctors and patients, respectively. Currently, musculoskeletal injections of therapeutic substances into joints or ligaments constitute nearly 50,000 procedures annually[1]. The scope of this paper focuses specifically on a subset of these procedures, known as ultrasound (US) guided musculoskeletal injections, and on their usage in the context of general practice medicine, including sports medicine and family medicine. A study from the Mayo Clinic GIM Musculoskeletal Injection Clinic, found the three most commonly injected sites were the knee (208 injections, 37%), greater trochanteric bursa (197 injections, 35%), and glenohumeral joint (96 injections, 17%)[2]. In sports medicine, the average age of patients is about 20 years old with the common cause of injury being overuse[3]. However, the majority of these injections are performed in family medicine and are applied to patients between the ages of 40 and 60[3]. These injections are used for treating ailments, such as arthritis, which are associated with sedentary lifestyles and comorbidities, such as obesity. Wittich et al. notes, "musculoskeletal problems are common in primary care and often respond to injections containing both corticosteroids and short-acting anesthetics."[2] The need for two injections is a cause of procedural discomfort for both the patient and physician.

The introduction of a double barreled syringe would greatly improve the field of musculoskeletal injections. Many musculoskeletal injections are guided by ultrasound and require two injections. This setup necessitates the physician to hold and manipulate a US probe in one hand while simultaneously manipulating a syringe with the other (see Figure S1). As current methods

only enable a single injectate per syringe, the physician is required to inject the contents of one syringe, put down the US probe, exchange the empty syringe lumen with another filled with the second injectate, retrieve the US probe, and reorient in order to reguide the syringe to the target location. While the physician performs this inefficient and uncomfortable undertaking, the needle of the syringe being constantly manipulated remains within the patient, causing them to experience discomfort at the injection site. A one-handed device capable of individually housing, injecting, and aspirating multiple injectates would improve experiences associated with musculoskeletal injections for both the physician and patient. This innovation would give physicians freedom to inject and aspirate freely without the need to follow a predetermined sequence of separate injections or aspirations. Clinically, a dual injection system would increase the efficiency of injection procedures for physicians and improve overall patient experience. By circumnavigating the need to exchange syringe lumens mid-procedure, the process becomes streamlined for the physician, saving them time and effort which subsequently lowers patient discomfort. As previously mentioned, around 50,000 injections of therapeutic substances into joints or ligaments occur each year. Our team estimates that use of a dual injection device would save 40 seconds per procedure, equating to roughly 555 hours a year (23 days)[3].

Many designs of multi-injection syringes currently exist as prior art; however, none are viable for use in US guided musculoskeletal injections. Most variations in this category of syringe succeed in individually storing multiple medicines while preventing mixing between them. These variations also involve a needle through which the multiple medicines can be injected at a single site. Both of these metrics, adequate storage and injection of substances, are critical metrics of success. However, prior art fails to meet the injectate control requirements necessary for the proposed usage of our project. These syringes, such as the Pizzino (1986) "Dual Syringe," utilize preloaded lumens not intended for aspiration. Furthermore, the volumes and types of medicine to be injected are restricted to what is sold by the supplier[4]. Additionally, many of these models can only inject the medicines in a predetermined order. These traits institute severe limitations on their application across the numerous forms of US guided musculoskeletal injections, which vary in their usage of type and quantity of medicine. While the Kozam multi-barrel syringe series circumvents many of these issues, they still fail to meet optimal injection-related design specifications. The "Successive Delivery Multiple Barrel Syringe" (1978) exhibits aspiration capabilities and an individual lumen injection control, enabling the physician to aspirate their own volumes of medicine[5]. However, this design utilizes a one-way valve which forces the user to completely inject the contents of one lumen before being able to inject the other. This feature limits a physician's level of control during a procedure and prevents the simultaneous injection of both lumens, a critical design criterion of the project. The "Multiple Barrel" (1983) version removes this valve, restoring mid-procedural control, yet the new design still prevents simultaneous injection[6]. The goal for this project was the development of a multi-barrel syringe viable for US-guided, musculoskeletal injections with individual lumen control, aspiration capabilities, and ergonomic design compatible with one-handed usage.

The proposed device provides a novel solution for the current inadequate administration of musculoskeletal injections by overcoming the shortcomings of previous concepts. With our proposed device, physicians will have the ability to aspirate a desired amount of injectate into a desired barrel prior to administration, giving the physician control over the volume and type of medicine. Autonomous injection capabilities will enable successive or simultaneous injectate administration, allowing the administrator to control and change the injection order or volume at any time during the procedure. Furthermore, the device features an ergonomic design conducive to one-handed use, enabling the physician to guide and manipulate the needle comfortably while maintaining a clear visual produced by the US probe operated by their other hand.

Results

12 prototypes were successfully designed and 3D printed, with each design improving upon the last. After each print, the most recent prototype would be presented to our capstone advisor, Dr. Jeremy Kent for feedback. After reviewing the prototype's functionality and ergonomics, modifications were proposed and implemented in AutoCAD for subsequent 3D printing. Three candidates were initially designed and one was selected as a starting model for augmentation. Iteration A exhibited a large handle design deemed too bulky upon consultation with our capstone advisor (Figure 1). Iteration B exhibited a design with three plungers in order to manipulate injection, yet it was determined that control of aspiration would be hindered in the design (Figure 1). Lastly, the third candidate, iteration C, was chosen as a viable candidate as it provided a means of control for injection and aspiration (Figure 1).

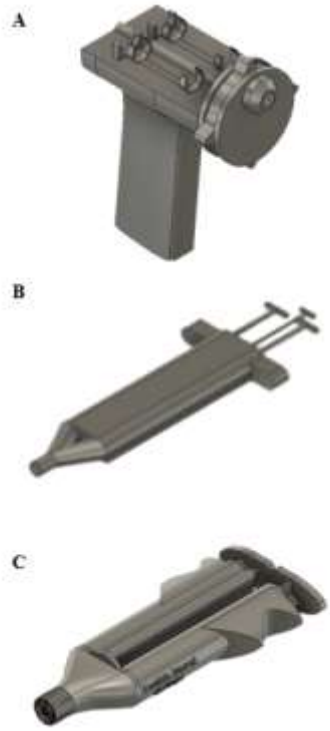

Figure 1: Iterations A, B, and C were initial candidates for iterative design. Due to the established design requirements of our device, iteration C was deemed most promising.

The design that underwent iterative modification and testing exhibited five main components: the "cap", "body", "dial", and two plungers (Figure 2). The cap consisted of a bifurcated channel meeting at a luer lock to interface with a needle (Figure 2). The body consisted of two adjacent lumens and ergonomic grips for physician use while gripping the device (Figure 2). The dial consisted of a "fin" and "wheel" which can be rotated and manipulated by the physician in order to engage one or both lumens during injection or aspiration (Figure 2). The last two main components consisted of two plungers which allow for either aspiration or injection of injectate within lumens of the body (Figure 2).

The initial chosen candidate upon testing demonstrated leaking into an internal compartment at the cap and dial interface. To prevent this leaking, iteration D eliminated the compartment yet still demonstrated leaking (Figure 3). In addition to leaking, it was determined upon testing that the shape of the grip was not comfortable. Iteration D changed the initial grips so that a more comfortable design was integrated. However, in order to incorporate the grip, the fin of the dial was adjusted to

Figure 2: The five main components of our main design consist of the labelled "Cap", "Dial", "Body", and "Plungers." Additional features of the design include sub-components such as: "Fin", "Wheel", "Grips", "Lumens", "Bifurcated Channel", and "Luer Lock."

avoid contact with the grips and maintain freedom of rotation. A drawback from this change was that the fin was unable to rotate the wheel of the device against frictional forces. To address leaking exhibited by iteration D, iteration E attempted to provide a water tight design utilizing flexible 3D printed components (Figure 3).

However, the flexible components were insufficient in solving the issue of leaking. Iteration F served as an improvement on iteration E in that it maintained the strength of the fin to turn the wheel following engagement from the physician (Figure 3). To improve strength of the fin interacting in rotating the wheel, a thickened wheel was designed. Leaking was still an issue upon testing of iteration F. To address the issue of leaking, an alternative avenue was taken to mitigate risk of leaks. The design change chosen was to add a bump and groove interface between channel interfaces of the body, dial, and cap in iteration G (Figure 3). Iteration G demonstrated that the bumps made forced separation of the main components and facilitated continued leaking of the device. In order to avoid separation of components, iteration H created a continuous groove slot for the bumps to move through upon rotation of the dial (Figure 3). Testing of iteration H yielded leaking of liquid from the device. Based on design characteristics of iteration H, it was surmised that the presence of a space within the groove for liquid to escape into was a possible complication. In order to counteract this, iteration I elongated the bumps of the interface such that the presence of empty space within the groove was mitigated (Figure 3). Upon testing of iteration I, leaking was still experienced. In order to provide a tighter fit between components of the device, a ramped design was enacted in iteration J such

that rotation of the dial would increase force of contact between surfaces of the device (Figure 3). Iteration J also demonstrated leaking upon testing. Upon this discovery, it was deemed that the FDM 3D printing process was insufficient in providing precise models that would provide water-tight interfaces between components.

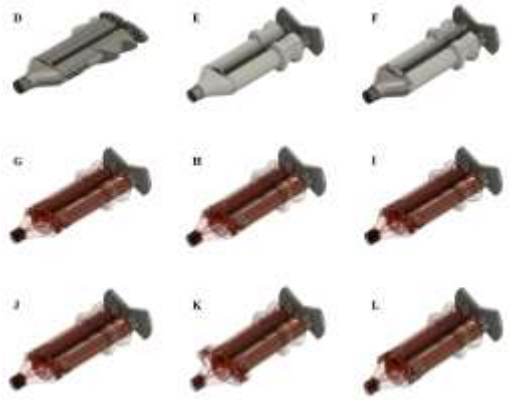

Figure 3: Iterations D, E, F, G, H, I, J, K, and L were all successive iterations. Improvements of design were based upon testing and user feedback.

To overcome this hurdle, the team coordinated with the "FabLab" at the University of Virginia's Architecture school to use their high resolution SLA printing. Along with improved SLA printing techniques, two last iterations, K and L, were developed (Figure 3). Iteration K served as an attempt to maximize water-tight contact between components utilizing extrusions that would allow tightening with M3 hardware. Iteration K was effective in producing a water-tight result; however, the ability of the dial to rotate was inhibited. Iteration L was produced due to a perceived need to produce a prototype that could be easily modified. Iteration L enacted this advantage by exhibiting five constant main components with two additional bracket components. In order to optimize fit, many bracket components of varying dimensions would be produced rapidly and subsequently be tested for optimized function.

Discussion

Limitations due to the COVID-19 Pandemic

The COVID-19 pandemic introduced various barriers to completion of our project. Externalities presented by the pandemic limited progress by preventing in-person meetings and restricting resources available to students. Effective iterative design requires team members to be able to observe the functionality of the prototype and the nuances of its mechanics in order to propose the best modifications for the next round of prototyping. The efficacy of this process was greatly hindered due to being constrained to a virtual environment as a majority of the team was unable to interact with the prototype directly. Instead, the team had to rely on descriptions of prototype ergonomics and function provided over online meetings. The impact of this limitation became evident as a first in-person meeting highlighted numerous design flaws which had been overlooked in previous iterations.

Due to safety concerns and restrictions related to the COVID-19 pandemic, access to relevant resources was substantially limited. In the early stages of the project, the team aimed to inform design development of the syringe by observing Dr. Kent performance of an US-guided musculoskeletal injection in clinic. In a normal year, the approval for this process would have only had to come from the patient being observed and Dr. Kent himself. However, due to the pandemic, Dr. Kent had to seek permission from health administrators, significantly delaying the process. Additionally, the pandemic prevented the team from obtaining patient and physician feedback which slowed prototype design. Beyond the design phase, the team lacked many technical means to produce a quality prototype. The Scholar's Lab Makerspace in Clemons library, which normally offers an assortment of high quality 3D printers and materials for students, was inaccessible for a majority of the year. This left the team to rely on personal 3D printers which lacked the level of printing resolution needed to create a watertight prototype. As restrictions were lifted in the spring semester, the team secured access to higher resolution 3D printing at the University of Virginia School of Architecture; however, these printers continued to introduce printing errors which prevented watertight design.

Due to time constraints and lack of access to high resolution 3D printing, the prototype under development was unable to functionally aspirate and inject without leaking. For this reason, the prototype did not progress to device verification or validation.

Understanding Prototype Verification

The process of prototype verification is the basis of determining whether a given prototype is considered functional. Verification tests consisted of a leak test and a volumetric assessment. The leak test would have been a qualitative assessment testing the capability of the syringe to hold fluid without losing any to the surrounding environment. This test also would have checked to see if solutions mixed within the lumens upon injection or aspiration. A prototype which passed the leak test would be considered watertight and aligned with the design

criteria. This criteria entailed the ability to hold and prevent the mixing of two injectates during aspiration and injection. The volumetric assessment was a quantitative test which would have determined the accuracy of the injection volume of the syringe. This experiment would identify how much fluid is lost during injection and would be conducted for each lumen independently. A prototype which consistently ejected a fluid volume within the predetermined margin of error would be considered capable of aspirating and injecting accurately, indicating no significant leakage between the interfaces of the lumen, dial, and cap during injection.

Understanding Prototype Validation

After successful completion of verification testing, validation testing would be conducted for the device. The validation process aimed to show the viability of the prototype in a clinical setting. Physicians who commonly perform musculoskeletal injections as well as medical residents new to the procedure would have been asked to carry out a US-guided musculoskeletal injection on a cadaver practicing both traditional standard syringes and with the verified prototype. Their time of completion would serve as a benchmark of efficiency, with a shorter procedure time demonstrating a more efficient method. The volunteers would have then been asked to fill out an IRB-approved survey afterwards to understand experience with both methods. This feedback would serve as a qualitative metric by which the team would gauge comfort associated with the prototype. By involving medical practitioners with various levels of experience, an analysis could be produced to highlight the willingness of those stakeholders to adopt the device into their daily practice. For example, if medical residents were found to consistently prefer the novel syringe to the standard method, while older physicians with more experience showed strong preference for the traditional approach, this inclination would inform the team of the potential of adoption and integration.

Due to unexpected delays in the IRB approval process, the team was unable to receive approval for the survey in time. This issue primarily arose from a miscommunication about the category of the novel double-barrel syringe. Originally, the survey was to be placed in an expedited IRB approval category. However, the IRB determined the device's medical nature required it to undergo additional review. A prototype which consistently scored higher than the standard syringe method in both time and comfort would be considered sufficiently validated in its clinical capabilities to apply for FDA clinical trials. Prototypes which were invalidated would undergo another round of iterative design based on the available feedback.

Patenting the Novel Device

Due to the novelty of the device and its capability of improving clinical efficiency, results from the physician survey would have demonstrated a clinically relevant device. Accordingly, the team had aimed to file a provisional patent application through the University of Virginia Licensing and Venture Group (UVA LVG). After a preliminary meeting with UVA LVG, initial engineering drawings were submitted to begin the application process. However, further communication with UVA LVG never resumed as a working prototype was not developed.

Clinical Importance

If a working prototype was developed, there would be several clinical implications of note. Firstly, the procedure by which physicians administer musculoskeletal injections would be improved. The procedure itself would become more efficient as physicians would save time no longer needing to exchange syringes mid-procedure. While the current procedure requires the syringes to be exchanged during injection, physicians would simply rotate the dial on the proposed device. This design would also eliminate the need for the physician to reorient the US probe to find the target site. The one-handed ergonomic features of the novel syringe would prevent the need to put down the US probe mid-procedure. The proposed prototype would also improve the patient's comfort as procedure length would be shortened.

It is important to note that the double barrel syringe has applications beyond musculoskeletal injections. The capability to separately store, inject, and aspirate multiple injectates has the potential to provide increased efficiency and comfort in other procedures currently requiring multiple injections.

Materials

Preliminary conceptual design was conducted with sketches and discussions as a group alongside our physician consultant and capstone advisor, Dr. Kent. After deciding on a possible viable design, a model was generated using Autodesk Fusion 360. The .stl files generated from models were converted to .gcode files using the slicer software Cura for subsequent 3D printing. Two methods of 3D printing were used for iterative prototyping: fused deposition modelling (FDM) and stereolithography (SLA) printing. Initial 3D printing was conducted utilizing a privately owned Ender 3 3D printer with black polylactic acid (PLA) filament. Later 3D printing was conducted utilizing a Formlabs Form 3 3D printer from the University of Virginia School of Architecture using Formlabs' clear and white resin. The

transition to SLA printing from FDM printing was conducted due to perceived limitations in the FDM process for producing precise, watertight outputs. SLA produced a smooth exterior surface, giving this printing method a functional and ergonomic advantage over the layered, ridged surface of a model produced by a FDM printer. For testing, unique plungers were developed by 3D printing while flexible 3D printed components were purchased. In order to lower the cost and time associated with printing new plungers for each iteration of the prototype, standard 5 mL syringe plungers were later used for testing of the device.

Methods

Prototype Development

Prior to ideation of a design, background research was performed by interviewing physicians and patients that take part in multi-injection musculoskeletal injection procedures. The interviews focused on the experience of both parties and aimed to validate the technical specifications of the project as well as identify any additional, previously unforeseen, needs.

Using this gathered information, novel syringe designs were generated using iterative design sessions. Designs which theoretically met the requirements as agreed on by the team were recreated using computer aided design (CAD) on the AutoDesk Fusion 360 platform and 3D printed using an Ender 3 3D printer or Formlab 3 3D printer. Completed designs were presented to Dr. Kent during scheduled weekly meetings. This feedback informed revision of future designs for reiteration and re-presentation.

Prototype Verification: Leak Test

The lumen permeability, aspiration capability, injection capability, and injection accuracy of the syringes must be verified prior to clinical testing. The device would have undergone a standard manufacturing leak test[7]. To test lumen permeability of the device, red water would have been aspirated into one lumen while blue water would have been aspirated into the other. The syringe then would have been submerged in hot water for 10 minutes during which visual inspection would reveal whether the lumens leak. The syringe then would have been removed from the water and the contents of the lumens would have been inspected to confirm no mixing between the colors.

To test the aspiration capabilities of the syringe, red and blue colored water would have been aspirated into each barrel individually. Visual inspection of the lumens for mixing of colors would have confirmed whether the syringe was capable of isolated aspiration. Each lumen would have been individually injected into separate glass vials and undergone a second round of visual inspection to confirm the isolated injection capabilities of the syringe. After rinsing out the lumens, colored water would have been aspirated simultaneously into both lumens and injected simultaneously from both lumens into a container. Visual inspection would have qualitatively confirmed these capabilities.

Prototype Verification: Volumetric Assessment

To calculate the injection volume accuracy of the novel syringe, theoretical volume calculations would have been made using dimensions of the device. The syringe lumen would have been marked standard intervals of 1mL for the total volume. Subsequently, DI water would have been aspirated to the first mark and injected into a weight boat. The mass of the water would have been weighed and recorded. A standard error calculation would have been performed based on the theoretical volume. This process would have been repeated for each volume mark and each aspiration or injection mode. The results for each mode would have been compared to the results of an identical protocol performed on a traditional 5 mL syringe. A two-tailed t-test ($p < 0.05$) would have been used to determine whether there was a significant difference in injection accuracy between the modes and the control.

Prototype Validation: Cadaver Trials

Following device verification, viability in the clinical setting would have to be validated. Physicians and medical residents with varying levels of experience performing musculoskeletal injections would be asked to perform two US-guided musculoskeletal injections on a cadaver in the University of Virginia Cadaver Lab. One of these procedures was to be performed with a standard syringe method and the other would have been conducted with the novel prototype. The order in which each method would be performed would have been randomized per study participant. These simulated trials were to be conducted in a similar manner to those typically performed in clinic with the physician using an US probe to guide the proposed device to a targeted area. The duration of these trials would have been recorded, beginning at the instance of needle insertion until the instance of needle removal. The timed durations would have been used in analysis of procedural efficiency. Procedure duration data would have been analyzed to determine the average time of each procedure type. Data between the standard procedure and those using the novel prototype would have been set to be compared using a one-tailed t-test. This statistical test would have determined if there was a significant decrease in procedural time with the use of the novel device.

Following the use of the novel device, the physician or resident who performed the procedure would

have been given a survey to evaluate physician comfort associated with each respective method. Survey questions would have quantified physician comfort on a range from one to ten for the following key ergonomic metrics: comfort of grip, comfort during injection, comfort during aspiration, and comfort maneuvering the syringe. The survey also would have assessed perceived efficiency of each device as well as personal preference between the two methods. A one-tailed t-test would have been utilized to determine whether the quantitative data collected from the physician survey showed a statistically significant increase in associated comfort for physicians using the proposed device compared to standard methodology.

Future Work

Future efforts should be focused on improving the watertightness of the dial-cap interface. This site was the most problematic location of leakage. Additionally, upon developing a functioning and valid prototype as defined by the prototype verification and validation process, submission of a provisional patent application should be pursued. More research should be conducted to investigate the efficacy of this device in other fields of medicine in order to explore its clinical range.

End Matter

Author Contributions and Notes

N. Diskin, T. Levy, J. Morris, and N. Zegarski wrote the paper, designed research protocol, conducted preliminary research, conducted 3D printing, and performed device testing. T. Levy created CAD model iterations of the device, J. Kent provided guidance and feedback throughout the project. The authors declare no conflict of interest.

Acknowledgments

We would like to thank Jeremy Kent, M.D., from the University of Virginia Department of Family Medicine, for advising our project. We would also like to thank the members of the FabLab at the University of Virginia's Architecture School for allowing us access to their 3D printers.

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Appendix

Supplement 1

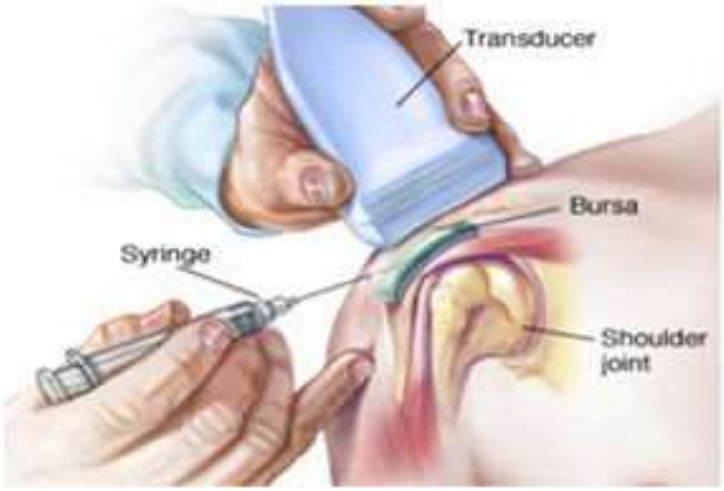

Figure S1: Visual representation of ultrasound-guided musculoskeletal injection administration. The physician uses one hand to maneuver the probe and the other to inject the site of pain.

Musculoskeletal Ultrasound. *Carolina Hand Sports Medicine* https://www.carolinahand.com/asheville-physiatry-non-surgical-orthopedics/musculoskeletal-ultrasound/.