THE DEVELOPMENT OF A ONE-HANDED KNEE ASPIRATION MECHANISM TO AID IN ARTHOCENTESIS

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Abstract

Knee osteoarthritis is a common form of arthritis that causes swelling of the knee joint, also known as an effusion. Knee effusions require removal of the excess fluid through a procedure called arthrocentesis. The current method of arthrocentesis is difficult and cumbersome. Physicians must use only one hand to operate the syringe for fluid aspiration while using their non-dominant hand to compress fluid from the patient's knee. In response, the research team proposed the creation of a novel medical device called the one-handed knee aspiration mechanism. This device will encompass the syringe and allow for one-handed aspiration with natural hand positioning. Several prototypes of the device were built before establishing a final design. The first iteration satisfied the requirement of one-handed control of the syringe; however, this design was too bulky and difficult to use. The second iteration used less material, improving upon cost and bulk, but the design was not ergonomic. The third and final iteration was fully skeletonized, providing natural hand positioning and comfortable aspiration. The efficacy of the mechanism was tested in a dry run setting with orthopedic physicians. In this study, the device achieved improved ease of use and comfort when compared to aspiration with the syringe only ($p=0.00024$, $p=0.00003$). Qualitative feedback also indicated general satisfaction with the new mechanism. Future work includes testing the device in a clinical setting and performing a final iteration based on the feedback obtained from testing.

Keywords: arthrocentesis, effusion, ergonomics, one-handed aspiration

Introduction

Osteoarthritis (OA) is a form of arthritis that typically causes chronic pain and disability of the hands, hips, knees, and spine[1]. According to the CDC, OA is a common condition, affecting over 32.5 million U.S. adults[2]. Of this group, the majority suffer from knee OA[3]. Groups who are at higher risk include obese individuals, women, and people over 50. Along with pain, stiffness, and decreased mobility, OA causes swelling of the affected joints, which is often referred to as an effusion. In fact, 90% of people reporting pain for knee OA have knee effusions, which require removal of the excess fluid to alleviate swelling[4]. This procedure is called arthrocentesis, where physicians use a syringe to aspirate synovial fluid from the knee[5]. While often used to relieve pain from OA, knee arthrocentesis can be used for other purposes as well. For example, the procedure treats effusions resulting from acute knee injuries, which ultimately impairs quadricep function if untreated. Additionally, arthrocentesis is beneficial for diagnostic purposes if the source of the effusion is unknown.

To aspirate the knee joint, surgeons must use one hand to operate the syringe and the other to compress the knee, commonly known as "milking the knee"[5]. Due to the force required to extract synovial fluid, as well as mechanical design, the syringe often requires two hands to manage. This repositioning of the physician's hands throughout the procedure causes instability milking the knee and ultimately, reduces the amount of synovial fluid aspirated from the knee. Hence, the goal for this research is to construct a device to mount onto the syringe that enables one-handed use. This will improve stability of the syringe,

enhance consistency of the procedure, and allow for the surgeon's other hand to be free to compress the knee. To ensure successful completion of this project, a list of specific aims was generated.

The first aim was to develop a CAD model for the one-handed knee aspiration mechanism that effectively extracts a syringe plunger to remove synovial fluid from the knee joint with one hand. With this in mind, the researchers proposed to build the computational model in Autodesk Fusion 360 that fits the design parameters. These parameters included the ability to hold a standard 60 cc syringe, the ability to be held around the syringe body to increase stability, and the ability to remain comfortable for most hand shapes and sizes.

The second aim was to build a physical prototype and determine the effectiveness of the mechanism to improve comfort and ease of retraction via a dry run trial and a clinical trial on patients. The physical prototype, needed to effectively pull back the syringe plunger with one hand, must be composed of only mechanical parts, be reusable, and maintain its mechanical integrity during each use. The dry run trial was used to determine the effectiveness and the mechanical integrity of the device before it was used on patients. The clinical trial was used to determine the effectiveness of the device during the actual aspiration procedure and provide constructive feedback for the final iteration of the device. Data collected from the trials was also used to ensure comfort and ease of use of the final mechanism.

Currently, there are no medical syringe devices that retract 60 cc syringes, making the one-handed knee aspirator mechanism novel and unique. However, injection- and retraction-oriented medical syringe mechanisms have been developed for giving vaccinations, delivering medicine, and performing cancer biopsies. The aspiration biopsy syringe gun has a gun-shaped hand positioning that uses the index finger to pull back a linear track in order to retract the syringe plunger (Figure 1A)[6]. The hand positioning used on this device is suboptimal because it is located far from the needle, leading to instability. In addition, loose soft tissue sometimes blocks the syringe needle during arthrocentesis, requiring readjustment and a release of pressure in order to continue aspiration. This device has no capability to move the syringe forward to unblock the needle. The one-handed knee aspiration mechanism provides a more natural hand positioning by placing the retraction mechanism along the barrel of the syringe, thus prompting the user to wrap their fingers around the syringe. This proximity to the needle provides added stability and control during the aspiration procedure. The device can also move the plunger in both directions, allowing the physician to adjust the pressure in cases of blockage. This bidirectional movement is also used to reset the device for reuse with a new 60 cc syringe, making this device cheaper for clinicians. The pencil-grip fine needle aspiration syringe holder is used for biopsy procedures, which use smaller 10 cc fine needle syringes (Figure 1B). While this device can be used to aspirate synovial fluid, the hand positioning is not ergonomic and it limits the movement of the plunger, preventing it from its fully extending position[7]. The one-handed knee aspiration mechanism is designed for larger syringes and resolves limited movement by incorporating a two-part rod, which extends into a longer rod and maintains comfortable hand positioning.

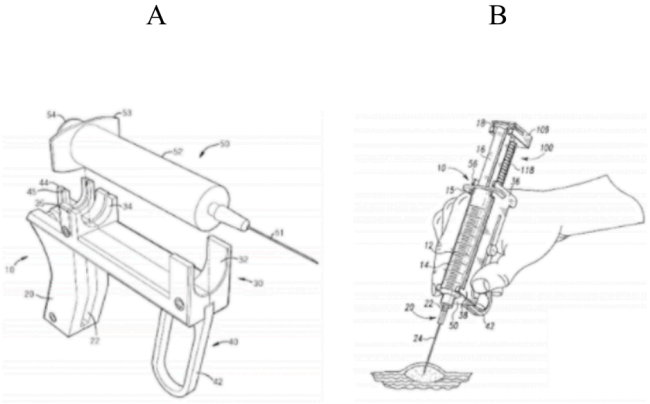

Fig. 1. Existing Patents for One-Handed Syringe Movement. (A) Aspiration biopsy Syringe Gun. (B) Pencil-Grip Fine Needle Aspiration Syringe Holder.

Successful development of this device, as proposed in the specific aims, will allow for a more stable, efficient, and comfortable procedure for extracting synovial fluid from the knee joint. This device ensures that physicians will have one free hand to milk the knee for the entire procedure, establishing a seamless knee aspiration. Overall, it will have the dual effect of improving ease of use and comfort for physicians, as well as enhancing quality of life for patients.

Materials and Methods

Creation of Prototype Designs and Physical Model

Design iterations of the one-handed knee aspiration mechanism were created using the computer-aided design software, Autodesk Fusion 360. Each iteration was 3D printed using acrylonitrile styrene acrylate (ASA) in the

UVA School of Architecture's Fabrication Lab. ASA filament is typical for 3D printing thermoplastic prototypes. It is similar to ABS plastics in terms of chemical composition; however, ASA offers enhanced mechanical properties, including increased ultimate tensile strength and elongation at break when compared to ABS-M30[8]. All of the major components of the physical prototype were printed separately, and then assembled onto a 60 cc syringe (Figure 2A). First, the smaller telescoping rod is inserted into its larger counterpart. Then both pieces are positioned into the body of the device. Once the syringe is fitted into the body, stainless steel lock nuts (size 8-32) and Phillips head bolts (size 8-32 x 3/4 inch) are used to secure the hinge to the body of the device, ensuring stability of the syringe. A bolt is also used to fix the pin, which functions to collapse the telescoping rods post procedure.

A simplified display of the operation movements of the device are shown in Figure 2B. To begin operating the device, the hinge is opened and the syringe is placed into the device with the syringe plunger tab inserted into the groove, which attaches to the bottom of the large telescoping rod. The hinge is then securely closed in order to prevent the syringe from shifting during the procedure. Next, the user's thumb is placed on top of the thumb tab attached to the small telescoping rod, and the user's palm and fingers are wrapped around the top of the hinge. It is imperative that two fingers are placed on either side of the ring protruding from the top of the hinge in order to prevent the hand from sliding down during the procedure. When ready to aspirate synovial fluid, the user pushes down on the small telescoping rod thumb tab until unable to keep pressing. This movement is the first stroke that partially retracts the syringe plunger. Next, the thumb is inserted in between the two thumb tabs on both telescoping rods and pressed upwards in order to extend the smaller telescoping rod tab to its starting position. The small telescoping rod is fully extended when the spring plunger is secured into the hole on the larger telescoping rod. Next, the user's thumb is placed back on top of the small telescoping rod thumb tab. The thumb tab is pressed down again in order to perform the second stroke. This retracts the syringe plunger to its full extension. Upon the end of the procedure, the hinge is opened. The syringe is then removed for proper disposal. In order to collapse the telescoping rods for reuse of the one-handed knee aspiration mechanism, the pin is used to press into the hole on the large telescoping rod. This action compresses the pin into the spring plunger on the small telescoping rod, so the small telescoping rod can be pressed back into the housing within the large telescoping rod.

Dry Run Device Testing

The first phase of device testing occurred in a dry run trial to determine the efficacy of the proposed mechanism. This study was approved by UVA's IRB-HSR for expedited review. Fourteen physicians, residents, and fellows were recruited from the UVA Health Department of Orthopedic Surgery to participate in this study. Subjects were asked to complete the following tasks: extract the syringe plunger using only one hand without the device, extract the syringe plunger using one hand with the device, and aspirate water into the syringe using one hand with the device. In each task, the subject was asked to extract the syringe to the 50mL mark with either air or water depending on the task number. After the completion of each assigned task, the subjects answered survey questions to quantify their experience. Subjects ranked ease of use and comfort of completing each task on a scale from 1 to 10 with 1 indicating a negative experience and 10 indicating a positive experience. The purpose of the first two tasks was to confirm that the device does in fact improve physician comfort and ease of aspiration. The third task was

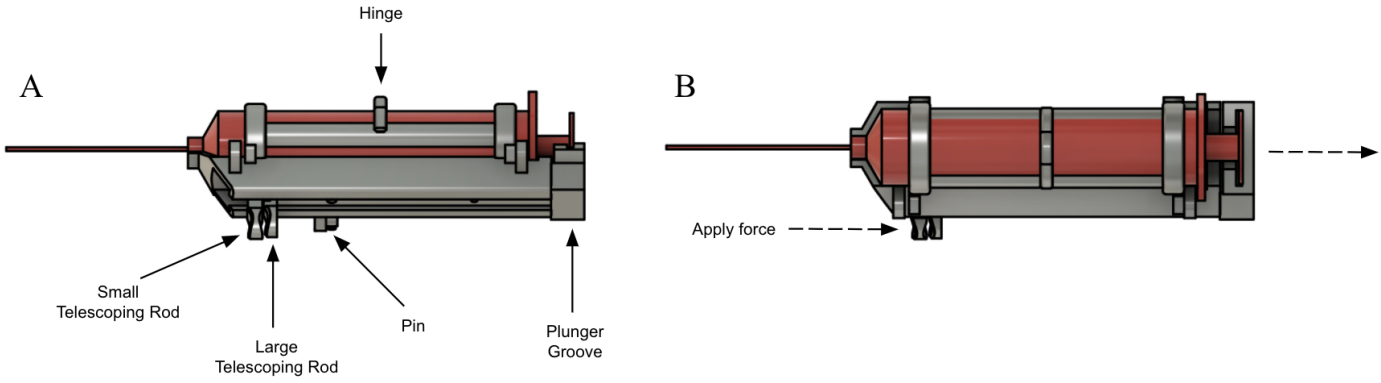

Fig. 2. Final Prototype Design with Key Components Labeled. (A) Side-view of the device. (B) Top-down view of the device showing mechanism. The dashed arrows indicate movement. Note that the 60 cc syringe is colored red and the device is colored gray to easily distinguish each component.

designed to gain qualitative feedback on using the device for fluid aspiration.

Proposed Clinical Testing

Although the second phase of device testing was never achieved, the following text outlines the proposed method. The final testing to be performed on the one-handed knee aspiration mechanism will occur during knee arthrocentesis procedures on patients. This study is currently under review by UVA's IRB-HSR for full board review. Dr. Mark Miller, the Capstone team's advisor, will use the device in fourteen procedures, and fill out a survey after each procedure is completed. The survey questions include the same ease of use and comfort rankings as the phase 1 testing survey. Because there is no control group to compare these results with, the feedback provided by Dr. Miller will be compared over time to determine consistency of the device's performance and mechanical integrity.

Results

Device Iterations

Several prototypes of the one-handed knee aspiration mechanism were designed and fabricated throughout the development process. Figure 3A displays iteration 1. Iteration 1 was able to effectively pull back the syringe plunger with one hand. However, the finger grips on the back were not universal to different hand shapes and sizes. In addition, the telescoping rod mechanism produced uneven strokes, making it difficult to use for the physician. The design itself was also too bulky. Smaller hand sizes found the device on initial use too large to be functional. Lastly, this iteration did not have a built-in part that could collapse the telescoping rods after each use of the mechanism. This meant that the device could not be reused without a separate piece.

Figure 3B displays iteration 2. Iteration 2 became more skeletonized by thinning out the exterior walls around the device that surrounded the syringe. The skeletonization not only reduced the cost of construction, but also made the device easier to grip and use for smaller hand sizes. The second iteration also included the addition of a built-in pin that collapses the telescoping rod mechanism after each use of the device. The telescoping rods were formed at the correct dimensions that produced equal stroke lengths during the use of the device. Iteration 2 did however have its drawbacks. This iteration was still slightly too bulky for smaller hand sizes to functionally use without readjustment. The thumb pieces located on the telescoping rods were at an uncomfortable and cumbersome angle. The grips on the hinge did not prevent the hand from slipping down while the telescoping rods were pressed down. Lastly, the pin was too small and fragile, resulting in unstable use.

Figure 3C displays iteration 3, which is the current and final product. Iteration 3 is fully skeletonized, which further reduces manufacturing material cost, as well as making the device easier to use and more functional for smaller hand sizes. The hinge was completely redesigned to decrease the bulkiness of the device and remove the existing grips altogether. Instead, it now utilizes a protruding ring, which fits in between two fingers in order to prevent the hand from slipping downwards while the rods are pressed down. The pin is larger, so it can be easily manipulated and used. Lastly, the device was mirrored and the telescoping rod track was angled at 45 degrees in order to provide a more natural hand and finger positioning for the thumb pieces on the telescoping rods.

Dry Run Testing Quantitative Results

In order to test the efficacy of the final prototype, a group of fourteen physicians consisting of orthopedic attendings, residents, and fellows used the device for a variety of tasks

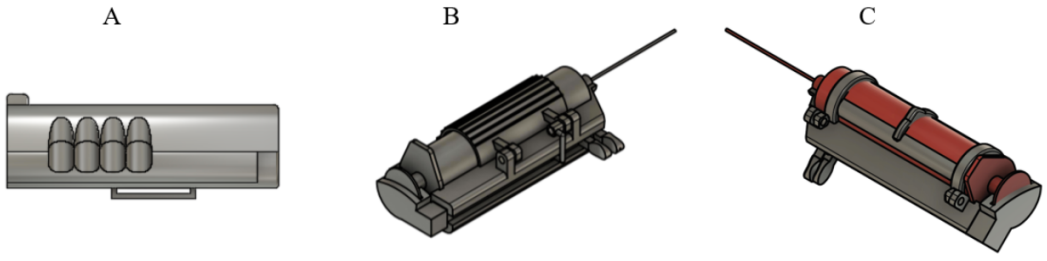

Fig. 3. One-Handed Knee Aspiration Mechanism Device Iterations. (A) Iteration 1 Bottom View. (B) Iteration 2 Isometric View. (C) Iteration 3 Isometric View.

described in the Methods/Materials section. A higher rating signified greater ease of use or comfort. The quantitative results can be seen in Table 1, and the average results for each group are shown in Figure 4. A paired t-test was used to compare the differences for the ease of use and comfort during the mock procedure between task 1 and task 2 for each user. The null hypothesis of the dry run trial stated that the true mean difference of the ease of use and comfort ratings would be 0. The alternative hypothesis stated that the true mean difference of the ease of use and comfort would be greater than 0, making this a one-tailed paired t-test. The associated t-values for ease of use and comfort during the procedure were 4.61643 and 5.75642, respectively. The associated p-values for ease of use and comfort during the procedure were 0.00024 and 0.00003, respectively. Using an alpha value of 0.05, both of these tests showed that they were statistically significant, and the null hypothesis was rejected.

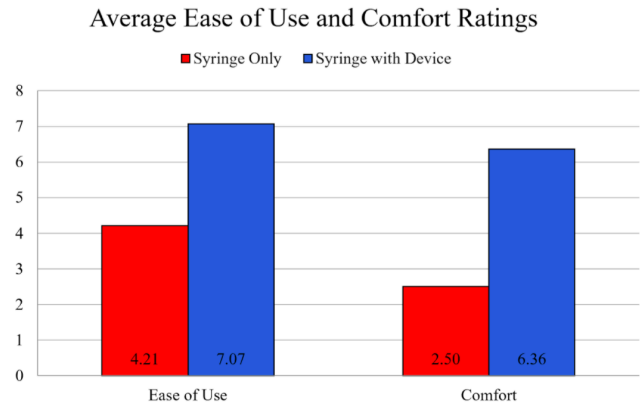

Fig. 4. Dry Run Trial Results. Average ease of use and comfort rankings by fourteen attendings, residents, and fellows. Participants were instructed to retract a syringe with only one hand. Then, they were asked to complete the same task with the one-handed knee aspiration mechanism. Participants ranked ease of use and comfort of both tasks.

Dry Run Testing Qualitative Results

In addition to the quantitative results, qualitative feedback was collected from the trial participants. This feedback aligned with the quantitative results and was generally positive, stating that syringe extraction was more stable with the device than without. Many results stated that the device fit nicely in hand and simplified the movement of the syringe plunger extraction. The primary complaints were that the device was slightly large, could use grips and more comfortable thumb positioning, and that it took a few attempts to learn how to use. Interestingly, more people stated that task 3, retracting fluid with the device, was easier than task 2, retracting with the device but no fluid.

Discussion

Dry Run Testing and Final Product Considerations

The results of the dry run testing showed statistical significance of an increase in ease of use and comfort ratings for retracting the syringe with the device, according to the alpha value of 0.05. A p-value shows the probability of the alternative hypothesis, which stated the mean difference between the values were greater than 0, occurred due to chance alone. The calculated p-values were both orders of magnitude lower than 0.05 and 0.01, which is a commonly used but more stringent alpha value. Therefore, the null hypothesis was rejected, and the higher ratings were accepted to be due to increased ease of use and comfort that the device offered. Also, the qualitative results and feedback showed that the device made one-handed retraction of the syringe plunger more comfortable, easier and more consistent to perform, and stabilized the syringe needle.

Table 1. Dry Run Trial Ranking Results.

Participant Number	Gender	Glove Size	Role	Task 1 Ease of Use	Task 1 Comfort	Task 2 Ease of Use	Task 2 Comfort
1	F	6.5	Resident	6	5	8	6
2	M	8.5	Resident	8	1	9	10
3	F	6.5	Resident	4	2	7	6
4	M	8	Attending	1	4	8	6
5	F	6.5	Resident	3	3	7	7
6	M	7.5	Resident	2	2	8	8
7	M	8.5	Attending	7	1	6	7
8	M	8	Attending	5	2	6	6
9	M	7.5	Resident	4	2	9	7
10	M	7.5	Resident	2	1	5	3
11	M	8	Fellow	2	3	7	5
12	F	6.5	Resident	3	3	5	4
13	M	7	Resident	4	1	6	8
14	M	7.5	Resident	8	5	8	6

The final design for the one-handed knee aspiration mechanism successfully fulfilled the design goals and parameters originally set by the specific aims. The device holds a 60 cc syringe and mechanically retracts the syringe plunger via the telescoping rods. The device maintains its mechanical integrity after multiple uses on a viscous liquid. The mechanism improves the stability of the needle during the procedure motion. The ergonomics of the design make the procedure more comfortable for physicians of all hand sizes. Lastly, the procedure motion was easier to conduct with the assistance of the one-handed knee aspiration mechanism.

Impact

The one-handed knee aspiration mechanism defined in this project will help to eliminate the issues currently present in knee arthrocentesis. Based on feedback from physicians, residents, and fellows, the device provides a more comfortable hand positioning, which alleviates pain and stiffness while extracting the syringe. In addition, this mechanism increases stability of the syringe needle, which will improve patient comfort by minimizing tissue damage. Allowing physicians to aspirate fluid with one hand will also enable them to stabilize and milk the knee throughout the procedure, optimizing the amount of synovial fluid extracted from the joint. These patient benefits will expedite the healing process. Due to the prevalence of osteoarthritis, the one-handed knee aspiration mechanism will have a widespread impact on patients as well as physicians.

Limitations

Throughout device development, the researchers faced several limitations, including the global pandemic of COVID-19. Access to academic buildings and 3D printers was also limited. The researchers began prototyping with an at-home 3D printer until ultimately gaining access to the Fabrication Lab in the Architecture School. However, an extended winter break also limited access to 3D printers in the middle of the project. Due to social guidelines, the research team did most of their work remotely. This increased the amount of time required to finish certain design tasks and prevented the team from getting accurate feedback from the advisors, Dr. Miller and Dr. Backlund. Various changes were made once the advisors had hands-on exposure to the device, although this was rather late in the timeline.

Lack of awareness of the need for IRB approval and unfamiliarity with the approval process delayed testing to the last few weeks of the project. The dry-run trial was approved and yielded useful feedback, but the clinical trial is still under review. As a result, the one-handed knee aspiration mechanism was never tested in a real arthrocentesis procedure. This will be a necessary step before the device can gain approval for clinical use and be brought to market.

Future Work

Several of these limitations can be addressed in future work on this mechanism. Once the IRB-HSR approves the clinical phase of testing, this study will be completed and provide the researchers with more feedback on the device. This phase will further confirm the device's efficacy as well as determine its mechanical integrity during actual arthrocentesis procedures. The latter will provide important data on how many times the device can safely be used. Once this phase of testing is complete, another design iteration will be performed and the final prototype will undergo dry run and clinical testing. If the desired results are achieved, the researchers plan to apply for a provisional patent. To expand upon this work, the one-handed knee aspiration mechanism can be adapted to syringes of all sizes, allowing for the device to be utilized in other procedures and thus broadening the impact of this device.

End Matter

Author Contributions and Notes

Annen, V., Rothemich, B., and Woessner, E. created CAD designs, constructed prototypes, designed and submitted trial protocols to the IRB-HSR, and wrote the final report. Backlund, I., and Miller, M. advised on device designs. Backlund, I. conducted the dry run phase testing and collected data. The authors declare no conflict of interest.

Acknowledgments

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