

A One-Handed Knee Aspirator Medical Device to Aid in Arthrocentesis

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A One-Handed Knee Aspirator Medical Device to Aid in Arthrocentesis

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Abstract

A knee effusion is an abnormal accumulation of synovial fluid within the knee joint, resulting in pain and swelling. To treat and diagnose knee effusions, physicians aspirate the excess fluid into a syringe in a procedure known as arthrocentesis. Arthrocentesis is cumbersome for the physician, as it requires the physician to use two hands to aspirate the synovial fluid into the syringe, while also needing a free hand to maneuver the fluid to facilitate removal. The goal of this research was to create a medical device that facilitates arthrocentesis, making the procedure faster and more comfortable for both the physician and patient. Our goal was to design an ergonomic device that could be operated using one hand, generate 10 pounds of force with mechanical or electrical assist, and was compatible with a 60-cc syringe. The mechanical model was designed in 3D modeling software and prototyped using a 3D printer. Multiple iterations were developed of the mechanical model, with improvements made for syringe compatibility and mechanism functionality. The final prototype failed to generate enough force, but we hypothesize higher quality material, such as polypropylene, will allow for more force generation. Finite element analysis was performed on a polypropylene model to test the structural integrity. This analysis revealed a small area prone to deformation, informing future design considerations to reinforce this area with an alternate material. A motorized device was designed in 3D modeling software and electronic components and layout were designed and, although this device did not make it to the prototyping and testing phase. Future work includes refining material selection for the mechanical model, prototyping the motorized device and testing and comparing the two designs.

Keywords: medical device, arthrocentesis, knee effusion, orthopedics, syringe

Introduction

Background

A knee effusion is the buildup of synovial fluid within the joint of a knee. It can arise from either trauma or chronic illnesses. Osteoarthritis (OA), a chronic disease associated with knee effusions, affects over 30 million adults in the U.S.¹. Of those afflicted with knee OA, a reported 9 out of 10 patients who experience pain have knee effusions². In healthy tissue, synovial fluid resides within a closed sac, known as a bursa. Bursae provide supported, smooth movement within joints, however with the excess fluid in bursae associated with effusions, patients regularly experience inflammation of the joint, resulting in pain³. The standard of care for treating and diagnosing knee effusions

is aspiration of fluid from the joint. This is performed in an out-patient procedure known as arthrocentesis. During arthrocentesis, the synovial fluid is extracted into a syringe to relieve pain and swelling, and for collection for diagnostic testing. While the aftereffect of arthrocentesis aims to mitigate effusion-associated pain, the procedure itself can also be painful for the patient.

As is currently performed, arthrocentesis is not efficient for a single set of physician hands: one hand is used for holding the syringe in place, another for pulling back the plunger of the syringe to extract the fluid. Since the fluid buildup is not localized, the physician must also manipulate, or “milk,” the fluid sac (bursa) in order to concentrate fluid to facilitate removal. Currently, physicians are unable to stabilize the needle, pull the plunger, and maneuver the fluid

simultaneously. This protocol is unnecessarily cumbersome for the physician, and regularly causes fluctuating needle positioning within the bursa as the physician pulls back the syringe. This needle movement causes inefficient fluid extraction, and commonly results in furthered discomfort for the patient.

Our research aims to improve upon the current procedural metrics of arthrocentesis by creating a medical device that will attach to a syringe and allow the physician to both extract the fluid and milk the knee at the same time (Figure 1). The proposed device works in conjunction with a 60-cc syringe to allow for syringe support and fluid extraction to occur with a single hand position and motion. This approach addresses the instability and discomfort for the physician typically associated with arthrocentesis. Ideally this device will be able to be applied to other medical problems that require some form of aspiration, and should be able to easily translate to other joint effusions (e.g. shoulder effusions) in particular, because the quantity of fluid required to aspirate a knee effusion is much greater than the fluid in another joint.

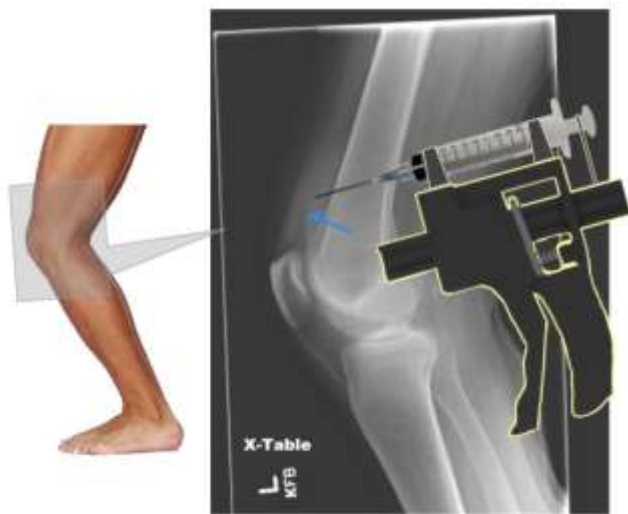


Fig. 1. Proposed Solution to Arthrocentesis. A depiction of the clinical application of our proposed medical device. This image shows the general inspiration for a one-handed, syringe-attachable device, as well as the physiological location of where the device would be applied.

Prior Art

Our proposed design will be of similar structure to devices used to inject large quantities of medicinal fluid into a joint, such as treatments for gout or rheumatoid arthritis, but of different functionality⁴. The “Gray Syringe Assist with Ergonomic Handle” by Innomed is one such device which works to prevent hand physician fatigue when injecting

large quantities⁵. This device attaches to a syringe and uses ratcheting mechanisms and an attached trigger-pull to push fluid out of the syringe. This gun-like design will be applied to the model of the knee aspirator due to the ease-of-use, and general familiarity with common devices, such as a caulking gun⁶. A previous capstone team designed a device for knee aspiration, but the ultimate design was not functional or ergonomic. Our proposed design will incorporate elements of their design, such as the gun shape, but improve ergonomics and functionality⁷. Many of the design considerations for this device are common among orthopedic medical devices, however the proposed device provides a new application for these designs and mechanisms.

Materials and Methods

Materials

The materials used for the prototyping and building of both the mechanical and motorized models are outlined in supplemental Table S1.

While we were unable to produce a manufactured final iteration of our mechanical device, we researched a proposed material to be used in a clinical setting: polypropylene. Polypropylene is classified as under the branch of thermoplastics within the plastics family⁸. It is a material ideal for formation and moldability, and additionally can maintain form at high temperatures, such as during autoclaving processes⁸. Its ability to withstand multiple cycles of steam-sterilization, its durability and its recyclability, makes polypropylene a common plastic used for medical devices, as well as our material of choice⁹.

Methods

Mechanical Design Modeling and Building

All iterations of the device were modeled in the computer-aided design software, Autodesk Fusion. Iterations were 3D printed in polylactic acid (PLA) using either a MakerBot Replicator 2, Lulzbot TAZ 5, or Prusa i3 MK3S. The different device components were printed separately, and assembled after print. Certain components, such as the rings used for the syringe housing, had to be epoxied onto the device frame for assembly.

After assembly, basic functionality of each iteration was tested by hand to observe overall comfort and mechanism performance. If the mechanism moved properly without a syringe, a syringe was then attached to the housing to test if the force generated by each hand pump of the handle was sufficient to extend the plunger

of the syringe. The verification of met criteria are listed in the “Results” section and summarized in Table S2. If the current iteration did not properly meet the design criteria, particularly the ability to extend the syringe, then considerations were made for changes in the model. Those changes were then made to the CAD model, and altered components were re-printed, re-assembled, and re-tested for functionality.

Finite Element Analysis

Finite element analysis (FEA) was performed on the final mechanical model in Autodesk Fusion. The main component of concern on our model is the point at which the syringe housing connects to the model frame. This component will have to withstand considerable localized stress in order to maintain the syringe in place during extensive force of fluid aspiration. To ensure that this component would retain its structural strength throughout multiple uses during arthrocentesis procedures, we performed a finite element analysis (FEA) stress test by loading static stress planar loads to the regions where the syringe housing and frame interact.

Motorized Device Modeling

The final proposed model of the motorized device was modeled in Autodesk Fusion. Due to time and resource constraints, the model was not able to be 3D printed. The motorized device housing was modeled in addition to proper electrical component configuration. As a proof-of-concept, the electrical components were modeled using an Arduino Uno board, connected to a servo motor and toggle switch. Several types of motors were tested, as shown in the Table S1. Due to time and resource constraints, the electrical configuration testing was halted at a proof-of-concept phase.

Proposed Device Testing

Although we did not reach this phase due to COVID-19 related barriers, the following is our proposed method of testing our devices. An artificial knee effusion will be created to mimic the change in synovial fluid of a normal and diseased knee. This testing will provide metrics for the ability of our device to properly withdraw fluids given increased resistances from increased fluid viscosities. In order to mimic the viscous nature of synovial fluid, we propose two possible fluids to serve as an artificial synovial fluid for testing purposes. First, motor oil is very viscous and has a variety of different viscosities which could be used to measure changes in healthy versus diseased synovial fluid. Motor oil is a temporary shear thinning fluid

and polymer additives can increase the viscosity¹⁰. The property of establishing a gradient of controlled viscosities with measurable fluid characteristics is favorable for an experiment that simulates various levels of synovial fluid hyaluronic acid concentrations. Second, we propose a formulation which incorporates compounds found in real synovial fluid, with changing component proportions corresponding to viscosity changes found in healthy versus diseased synovial fluid. The main component change would be in the quantity of hyaluronic acid (HA), the component which has the greatest influence on synovial fluid viscosity. The differing formulations are based on the changing amounts of HA and corresponding changes in synovial fluid viscosity in healthy versus diseased synovial knee cavities. The formulation for healthy tissue begins with 0.2 mg/mL of HA increasing to 1 mg/mL and then 4 mg/mL for synovitis tissue.

The control fluid will be water. The water will allow for a simple base measurement of fluid to test that our device can aspirate a fluid into the syringe.

The process of performing arthrocentesis will be mimicked by withdrawing the different fluids in two proposed phases. The first phase of testing will involve filling plastic bags with the different fluid types. The different fluids chosen will be placed inside of a Ziploc bag to mimic a bursa with an effusion. This first iteration will test the ability of both the final iteration of the mechanical model and the motorized model to properly aspirate fluid from the plastic into the syringe. As a control, a syringe-only test will be compared against both models.

The second phase of testing involves more substantial equipment, and should be used as the final round of testing before either device reaches a clinical phase of testing. An “Arthrocentesis Knee,” such as those made by SynDaver, allow for physicians and students to practice an arthrocentesis procedure before performing the procedure on patients¹¹. Ideally, this device, or one similar to it, would be used to mimic procedure room mechanics prior to patient testing. Because these artificial knees allow for replaceable fluids, we would be able to test the same fluids previously mentioned for the first iteration of testing.

In addition to testing the ability of our devices to improve the process of aspirating fluid compared to a syringe-only procedure, we will request feedback from physicians testing the devices. Considerations for model changes will be given in regards to physician feedback on comfort and ergonomics of the device compared to holding the syringe only.

Comparisons between the performance of a syringe only and syringe with our device will be tested to verify that our device improves (decreases) the time to perform arthrocentesis and improves physician comfort.

Results

Design Constraints

Design criteria were identified based on specific procedural metrics we wanted to improve. Because the overall goal for the device was to improve physician comfort and efficiency in order to improve patient comfort, the design had to be ergonomic, and make the syringe significantly easier to handle than when using the syringe-only method to perform arthrocentesis. In addition to the ergonomic form of the device, it had to be operable one-handed, which would allow for a physician to use the other hand for bursa manipulation during the procedure. The device had to also be able to generate a vacuum within a syringe, in addition to overcoming the resistance caused by the viscous nature of synovial fluid in diseased tissue. The calculated force to overcome this resistance is approximately 45-55 N, or 10 pounds¹². A later design consideration included bidirectional movement of the plunger of the syringe in order to enable a release of pressure if tissue were to clog the needle of the syringe during the procedure.

We considered both single-use and reusable forms of the device. A single-use device would likely allow for cheaper and easier manufacturing of the device and place fewer constraints on the durability of the device, but contribute to a growing medical plastic waste problem. A reusable device would likely be more expensive, as it would be designed with higher quality and more durable materials that could withstand the sterilization process.

These design constraints motivated the development of both a mechanical and motorized version for the aspirator device. We started first by designing a purely mechanical device, in hopes that this was the simplest solution to the problem and would enable easy and inexpensive downstream manufacturing. Later we began designing a motorized model to allow for easier operation of the device and to allow comparison with our mechanical model.

Mechanical Device

All iterations of our printed mechanical device consisted of a bar-ratchet mechanism. The overall configuration for our bar-ratchet mechanism included a rod, plate, trigger, frame and spring (Figure 2). As the device is held and the trigger is pulled towards the palm of the hand, the plate is pushed by the upper portion of the trigger. As the plate is pushed by the trigger, it engages with the rod, and forces the rod to move backward with each pump of the trigger. At the same time, a spring, positioned against the plate and attached to the device frame, is compressed. The spring forces the return of the plate to its resting position after each pump of the trigger.

Additionally, it provides plate stability and greater overall force to be generated from the mechanism with increasing spring constant. The end of the rod is to be attached to the back end of the plunger of the syringe, so each squeeze of the mechanism incrementally pulls back the plunger of the syringe.

Iteration Development

The first iteration of the device was a proof-of-concept to test the efficacy of the bar-ratchet mechanism (Figure 2). The device was too small, and did thus not meet the ergonomic requirements for hand-held comfort. We were also unable to generate enough force to retract the plunger of the syringe. While this iteration did not meet yet meet functional requirements, the mechanism did move as desired, and thus this provided sufficient support for the bar-ratchet mechanism being a feasible option. An image of this prototype can be seen in Figure S1.

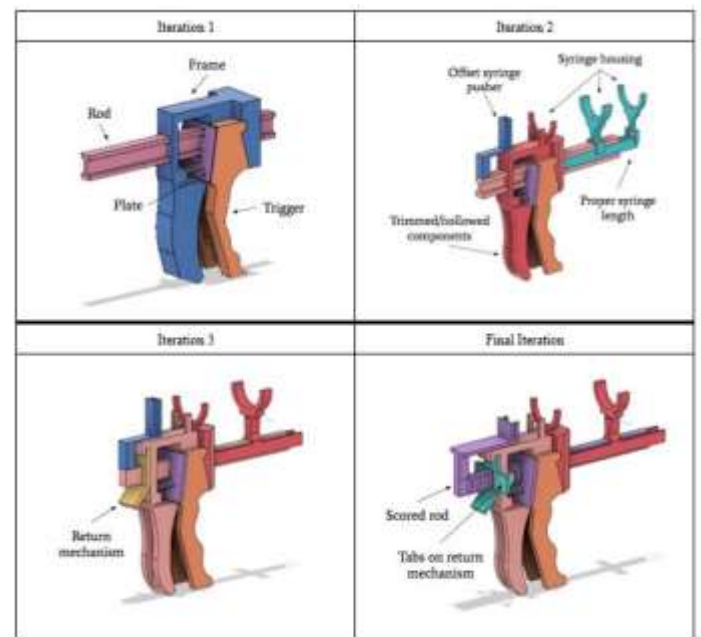


Fig. 2. Labeled Mechanical Model Iterations. A figure depicting the labeled component modifications made during the CAD modeling of each iteration.

In the second iteration we added several new design components in order to allow our device to interact with a 60-cc syringe. Offset semi-circle channels were added to the top of the rod to provide housing for the syringe body (Figure 2). An offset syringe pusher, meant to attach to the end of the syringe plunger in order to pull it back with each movement of the rod, was added to the end of the rod. The frame of the device was lengthened

to allow for the utilization of the entire volume of the syringe. In this iteration, we began designing with downstream manufacturing in mind. The previous iteration was a very complicated 3D print and therefore resulted in prolonged print times. To mitigate this problem, we broke the device into more parts that could separately be assembled and considered what shapes were the most printable. The rod, frame and trigger were trimmed and hollowed in the model to reduce printing time. These changes also made for a more ergonomic and sleek design. This iteration showed significant improvements and successfully interacted with the syringe, but did not yet generate enough force to operate the syringe.

The third iteration was focused on generating more force. To achieve this, the clearance between the plate and the rod in the resting position was adjusted. This allowed for stronger and prolonged contact of the plate with the rod, generating a more forceful movement of the rod backwards. A stopper mechanism was also added to the design (Figure 2). This is a mechanism added to the back of the frame of the device, and serves to disengage the rod from its normal, stopped resting position and allow for forwards (opposite) movement of the rod. This was a key feature to add to the device because of the clinical applications. During arthrocentesis, it is common that a small amount of tissue will get caught at the end of the needle, thus preventing any further suction of the syringe. The added stopper would allow for the pressure to be relieved, and the vacuum to be released. Additionally, the stopper mechanism provided additional tension on the rod that we hypothesized would aid in force generation. This iteration showed improvement from the second iteration, but still did not generate the necessary force to consistently pull back the syringe. The stopper mechanism was not successful in reversing the direction of the rod.

In our final iteration we modified the rod and stopper mechanism to allow for successful reversal of rod direction. Divots were scored throughout the length of the rod. Tabs were added to the side of the stopper, which engaged with the divots along the rod to provide for incremental release of the rod with the stopper mechanism (Figure 2). A number of different springs were tested with this iteration, in combination with a number of plate and rod sizes. None of these combinations provided the consistent force generation we were seeking. The 3D printed material (PLA) was of low quality. We hypothesized that prototyping our device out of a higher quality plastic, such as polypropylene, would allow for higher and more

consistent force generation by improving the contact between the plate and the rod. A photograph of our final iteration can be found in supplementary Figure S2.

Finite Element Analysis

Since our device is designed with ultimate intentions of being used in a clinical setting, it is imperative that the device is able to withstand applied loads. Durability and structural integrity of the device is crucial for the physician to properly perform arthrocentesis, as well as to ensure patient safety during the procedure.

The frame of the device was used as the component for FEA because it is the physical component undergoing mechanical loading at the two supports that secure the syringe as it is pulled back. The material used in the simulation was polypropylene for reasons outlined in the Materials section. The frame was constrained on the two side faces, where a user would hold the device. The two raised support faces on the frame were each loaded with 22.7 N to accumulate an evenly distributed total force of 55 N, the estimated force required to pull back the 60-cc syringe. These faces were selected to load force because they are the site at which the frame pushes against the body of the syringe as the plunger of the syringe is pulled back.

The force to failure produced from the FEA results was 23.126 N. This force is slightly larger than the expected target force of 22.7 N. Although the device did not fail at the recorded force of 23.126 N, it underwent permanent deformation. Because our device will be used on a patient for medical purposes, deformation is unacceptable. The minimal safety factor was found to be 15, representing the proportion of force at failure to force allowable. The heat map for deformation the device underwent in stress testing is shown in Figure 3.

Using the information gathered for maximum device deformation, we will inform future modifications and iterations of the device to withstand greater loads to

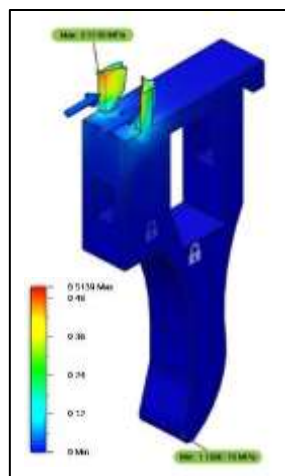


Fig. 3. Frame Deformation Heat Map. A heat map depicting the deformation due to loading of the supports with 22.7 N of force. The minimal safety factor was found to be 15.

ensure that the device will not undergo permanent deformation. Possible improvements include reinforcing or reshaping the raised supports where the syringe housing and frame connect, or replacing the raised supports with a stronger material. The bulk of the frame did not undergo deformation, evidence that polypropylene is a viable material for the frame, with supports reinforced with a stronger material.

Motorized Device

The motorized design did not go through iterative phases, thus there is one model for the device and no prototype. The form of this model took a different approach to the ergonomic criteria. The shape of the device is triangular with grooves for fingers and thumb, to take advantage of a natural hand holding position used when operating a syringe (Figure 4). There is an on-off-on toggle switch at the thumb for bidirectional movement of the syringe plunger. The servo motor is connected to a rack and pinion mechanism, which interacts with the syringe plunger to allow for movement. The device will withdraw the connected syringe. The motor and toggle are wired to a controller. All device components are designed to be inside the

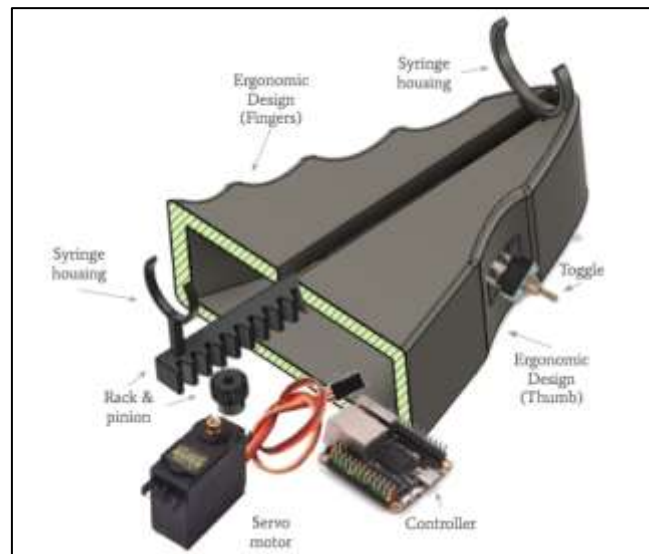


Fig. 4. Motorized Model with Electrical Components. A CAD rendering of the motorized aspirator model. This figure depicts a cross-sectional cut of the model to indicate where the components would be located. This model utilizes a rack and pinion mechanism, connected to a servo motor, with direction indicated by toggle switch movement.

triangular device housing, and oriented for ergonomic weight distribution.

The triangular housing is designed to be both ergonomic for holding, but is also physician-inspired for arthrocentesis in particular. When performing the procedure, a physician cups the syringe from below, with fingers wrapped upwards on the syringe body, and thumb pointing towards the needle end of the syringe. This holding position is mimicked in the triangular design of the motorized model, with aims of creating a familiar, low-profile device to improve the procedure.

In addition to a model of the housing of the motorized device, a proof-of-concept electrical schematic that we used to test the set up was developed (Figure S3).

This setup used an Arduino board to power a servo motor. A high torque motor was selected to power the rack and pinion that would drive the plunger of the syringe. Additionally, we configured a proposed future electrical component configuration of the motorized device (Figure 5). The future configuration includes the

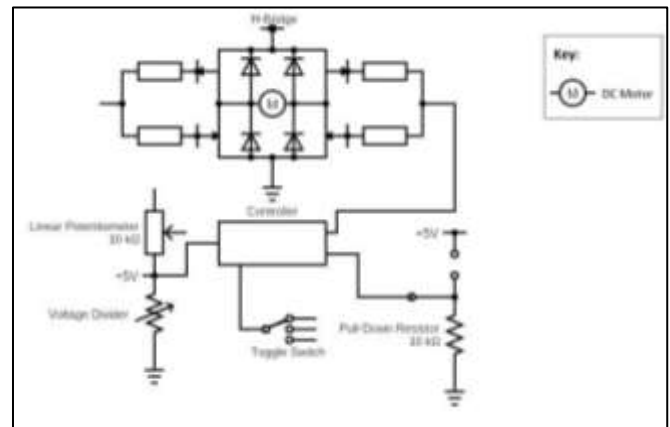


Fig. 5. Future Proposed Electrical Schematic. An electrical schematic depicting the proposed future electrical component configuration for the final motorized model. This final configuration consists of a toggle switch, a servo motor, an H-bridge chip, a voltage divider, and a linear potentiometer. These added features will allow for control of the motor in multiple directions, as well as location sensing of the syringe plunger in accordance with the toggle movements and corresponding servo turns.

use of a servo motor and toggle switch, with the addition of a non-Arduino controller, an H-bridge chip for bidirectional movement motor through polarity switching, and a linear potentiometer corresponding servo movement to syringe plunger movement. This

setup is much smaller than an Arduino board and thus can seamlessly be incorporated into our housing model.

Discussion

Challenges

Designing

Throughout the research process, we had limited access to clinical settings to gain observation of the procedure we were designing a medical device for. We had to rely entirely on videos and descriptions of arthrocentesis provided by our advisors. This led to challenges when determining a mechanism that would best fit the needs of our advisors, and physicians in general. Orthopedic surgeons are the ones specifically asking for this device to be created. If we can design a proper device for them, we can hopefully make the procedure faster, and thus better, for patients.

There were also discrepancies over the final form the device should take in regards to single-use versus reusable. Our goal was to create a device that would translate well in terms of manufacturability, and ultimately be affordable to reduce procedure costs for patients.

3D Printing

Throughout printing the mechanical device, we encountered many machine-associated errors. Frequently, several of the iteration components would properly print, but would not be fully functional with the entire model. This required re-printing specific components, and thus increasing the time for modeling, printing, and testing.

Access to facility resources was one of the greatest challenges in being able to print our designed iterations. This caused considerable delays in the development process. However, this did provide an opportunity to pursue the mechanical and motorized models in tandem. Additionally, limited access to high quality 3D printers and 3D printer materials prevented us from being able to try a number of materials to determine which was best suited for force generation.

Alternatives

Extensive considerations were given to design a mechanical model that was inspired by simple, efficient mechanical systems. Our chosen system was a bar-ratchet mechanism, found in a common clamp spreader. The mechanism used in a clamp spreader is sufficient to one-handedly generate the necessary force to pull back a syringe plunger, which is why this device served as an inspiration for our aspirator model. We also considered

and modeled a ratchet-pawl mechanism; however, this mechanism was not feasible beyond the modeling phase for our device.

Additionally, prior to pursuing any set model for the device, we had designs based on creating a vacuum, using a push-spring system, and creating linear motion from a wheel mechanism. These mechanisms as well as other gear-based mechanisms are viable approaches to this problem.

End Matter

Author Contributions and Notes / Acknowledgements

Dr. Mark Miller, M.D. and Dr. Ian Backlund, M.D. for guidance and advising throughout the project, as well as idea development for this medical device.

Dr. William Guilford, Ph.D. and Dr. Shannon Barker, Ph.D. for advising on device design.

Dr. Gavin Garner, Ph.D. for advising on mechanical and motorized system design.

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SUPPLEMENTAL MATERIALS & FIGURES

Table S1. Materials Used for Mechanical and Motorized Models. A table of the materials used throughout the developmental process of both the mechanical and motorized aspirator models.

	Mechanical	Motorized
Software	<ul style="list-style-type: none"> - Autodesk Fusion 360 	<ul style="list-style-type: none"> - Arduino IDE - Autodesk Fusion 360
Prototyping Materials	<ul style="list-style-type: none"> - Irwin Quick-Grip One-Handed Bar Clamp - 60 cc syringe 	<ul style="list-style-type: none"> - Arduino Uno - Motors: Tower Pro MG995R Digi Hi Torque Servo, ANNIMOS DS3225MG Digital Servo
Building Materials	<ul style="list-style-type: none"> - 3D printers: MakerBot Replicator 2, Lulzbot TAZ 5, Prusa i3 MK3S - Polylactic acid (PLA) - Coiled Spring - Epoxy 	N/A

Table S2. Original Design Constraints Achieved for Each Mechanical Model Iteration. The table outlines the initial project design criteria and its justification as well as the corresponding completion of the criteria with each mechanical iteration.

Design Considerations / Constraints	Justification	Iteration 1	Iteration 2	Iteration 3	Iteration 4 (Final)
Device requires a reasonable (45-55N, or ~10 lb.) ⁴ amount of force to pull back the plunger	Ensure device is easier to use compared to current methods	—	—	—	—
Compatible with 60 cc syringe	Allow for easy clinical adoption	X	✓	✓	✓
Suction release mechanism to allow for needle repositioning	Allow to dislodge tissue blockages	X	X	✓	✓
Suction 60 cc of fluid in 30 sec. or less	Enable fast procedure time	—	—	—	—
One-handed operation	Enable efficient procedure	✓	✓	✓	✓
Ergonomic	Comfortable for the physician	✓	✓	✓	✓



Figure S1. First Iteration Prototype. A photograph of the first mechanical prototype.

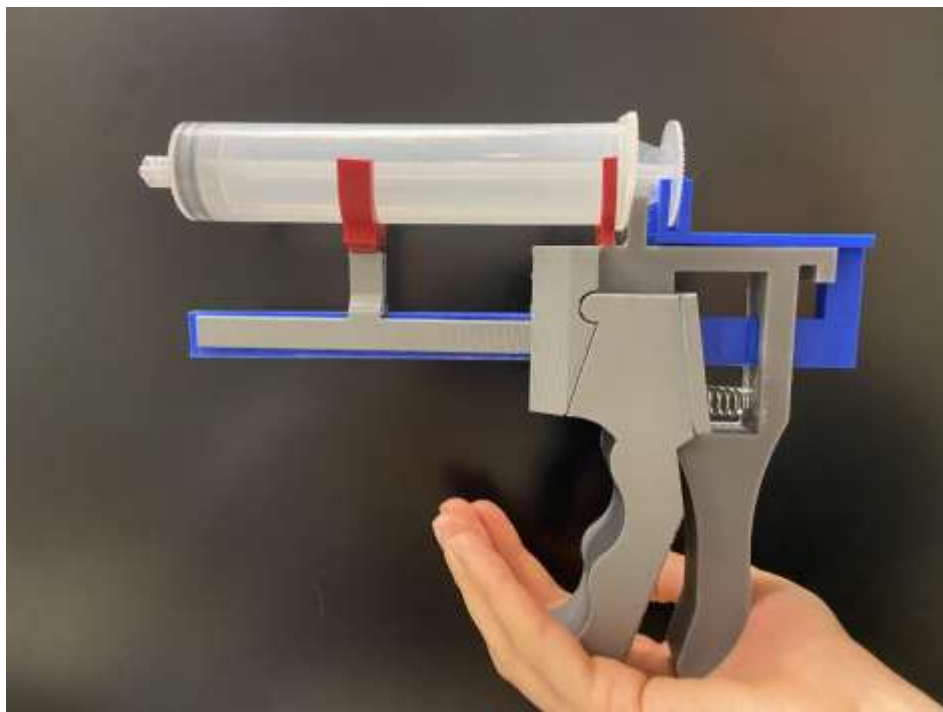


Figure S2. Last Iteration Prototype. A photograph of the final mechanical prototype.

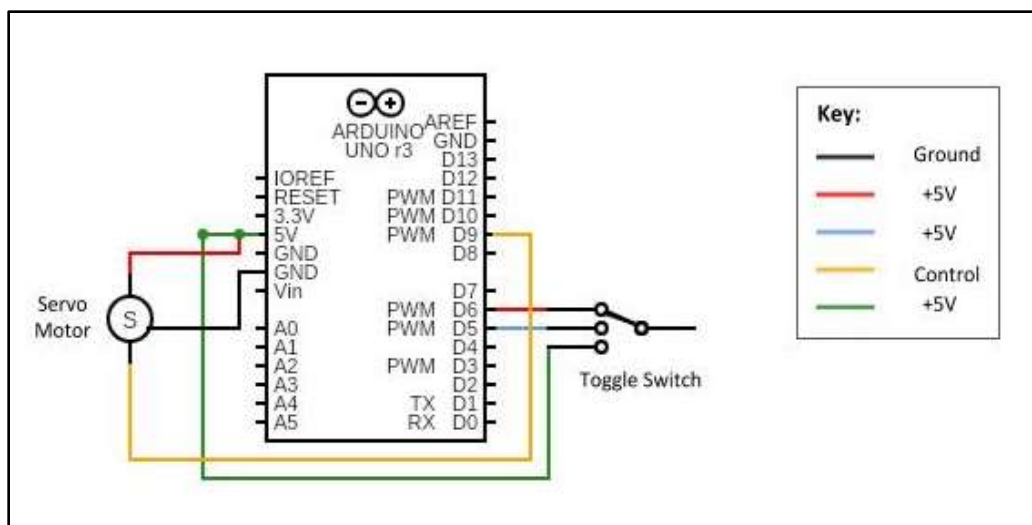


Figure S3. Proof-of-Concept Electrical Schematic. An electrical schematic depicting the original proof-of-concept electrical component configuration for the motorized model. The components consist of an Arduino Uno board, a toggle switch, and a servo motor. This initial configuration served as a test for the basic electrical components expected to be used in the final motorized model.