Testing and Results

Preliminary testing provided anecdotal evidence that our digital assistant fills a genuine need within the in-home hemodialysis space. One test user was able to calculate her ultrafiltration rate in under a minute using our hardware; using a pencil, paper, and calculator, it took her over a minute to perform the same task. Error code lookup did not show a commensurate improvement in performance, but this could be remedied by using a more powerful processor that performs dictionary searches more rapidly. To achieve a truly robust analysis of our product, we would need to perform controlled, timed experiments in which users unfamiliar with either dialysis routine (device-aided or purely manual) perform the various tasks associated with machine setup and parameter calculation. For the time being, however, the testimonials of our patient and caregiver contacts speak for themselves: as Mr. Brumm put it, "a touch screen and a bigger brain that does the math and everything else would be welcome."

CANNULATION DEVICE

Background

Another source of insecurity and inefficiency during in-home hemodialysis treatment is cannulation, or the process of inserting the needles which circulate blood from the body to the machine [11]. The most common way to connect the machine to a patient's vasculature is through a fistula, a surgically engorged blood vessel near the surface of the skin. Because typical fistulas have diameters of approximately 6 millimeters and may have

unpredictable orientations along the length of the arm, precision in aligning the needle with the fistula is crucial for successful cannulation. Inaccurate alignment during cannulation can cause pain for the patient and may damage the fistula.

Concept and Design Overview

To address the difficulty with the cannulation process that many in-home patients experience, a device was developed which makes the interaction with the dialysis needle more stable and manageable for a single person. Cannulation for in-home dialysis treatment currently relies on the help of a person other than the patient to perform the needle insertion. Even with the additional help, the act of insertion can be intimidating and difficult to navigate, especially with inexperienced patients and caregivers. To allow the needle insertion to be actuated remotely by a single person, the device required one flexible degree of freedom which coupled motion at the hand of the arm on which cannulation is being performed ("passive hand") to motion of the needle. To position and orient the needle for cannulation, three degrees of freedom at the point where the needle is attached to the device are required. To ensure stability, these degrees of freedom should also be constrained whenever the needle position is not being adjusted by the user. The needle and corresponding tubing also need to easily connect and disconnect from the device with the connection being able to support 5N of force at the needle tip [6].

To fully align the needle with the fistula, the device needs to have three degrees of freedom which the user can adjust during cannulation. Because angular degrees of freedom are much more desirable than linear degrees of freedom, a prototype of the positioning

system was created which utilized a ball joint to define the two necessary angles of alignment and included redundant degrees of freedom to better understand which motions were useful. The prototype revealed that the ball joint paired with a linear track along the length of the arm achieves the adjustments necessary to align the needle with the fistula. Through further experimentation, the ball joint was found to contain an additional undesirable angular degree of freedom. The final prototype of the device therefore used a positioning system which combined a gimbal mechanism and a linear track to achieve the desired degrees of freedom. These degrees of freedom are shown in Figure 09.

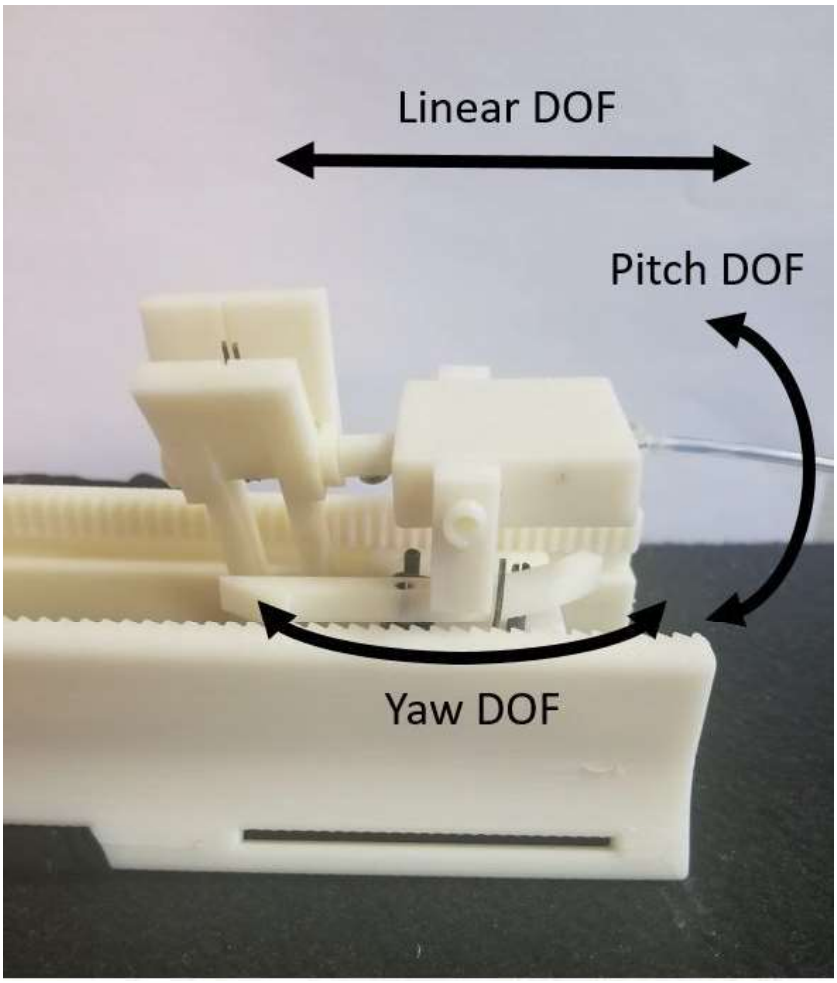

Fig. 9 The device's three degrees of freedom for needle alignment.

For the device to enable precise alignment of the needle and be usable by a single person, the device needed to decouple the insertion motion of the needle from the alignment motion. From the perspective of the dialysis patient, this requirement was most easily accomplished by allowing the free hand (the hand on the arm not being cannulated) to control needle alignment and allowing the passive hand to actuate the needle insertion. The mechanism of actuation therefore needed to be flexible, operate distally to the device, and transmit its motion to the motion of the needle. An initial prototype was implemented using pneumatic cylinders with air as the working fluid because of high degree of flexible provided by fluids in plastic tubing. However, a test of the prototype revealed that motion from the actuating hand was not directly coupled to motion of the needle, and the cylinders were characterized by significant transmission delays. The delays were attributed to the compressibility of air, indicating that an actuation method with more rigidity was necessary for greater control of the motion.

An actuation mechanism was then devised in which a metal cable connected to the actuator at the hand controls the motion of the needle. This technique is similar to how choke cables flexibly transmit force to the brake pads but was adapted such that the needle motion was bidirectional and forces applied to the cable would displace the cable rather than stretch it. The needle was connected to the device using a small clip. The clip rigidly attached to the actuation mechanism to transmit force, remained closed when not engaged by the user, and lowered the needle such that it was positioned closer to the surface of the skin. Figure 10 shows how the two hands are used with the device.

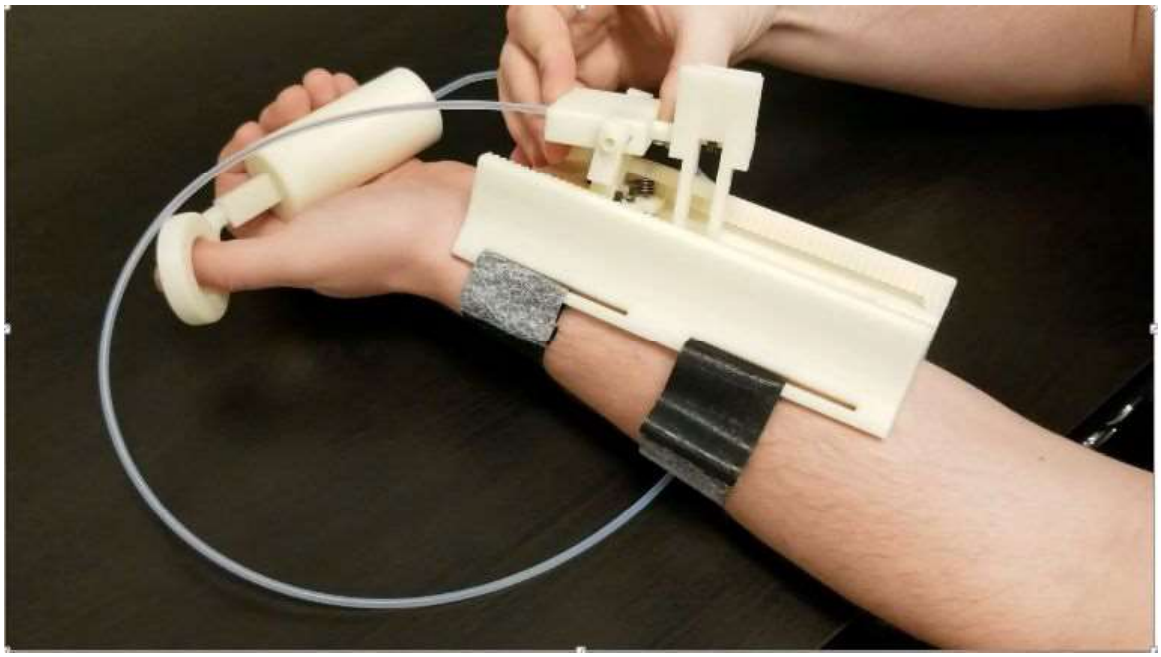

Fig. 10 The base of the device is strapped to the arm being cannulated. The hand of the cannulation arm (left hand in this figure) holds the cylindrical handle while the thumb pushed on the loop, controlling cannulation. The opposite hand (right hand in this figure) is mainly responsible for positioning the needle in the appropriate location.

Detailed Design

The cannulation device is secured to the arm with a velcro strap and form fits the roughly elliptical shape of the lower arm. An area of approximately 165 mm by 38 mm is exposed within the device for cannulation. A track traverses a maximum of 145mm along the length of the arm and to allow the linear positioning of the dialysis needle to be adjusted. The track consists of a ratcheting system as shown in Figure 11 which allows this linear position to be immediately locked in place. The ratcheting system has a precision of 3mm to adjust the linear positioning of the device. A clearance gap was included in the

track such that friction in the track is insignificant when a 5 N compressive load is applied at the arm straps, which may occur when the arm straps are tightened during use.

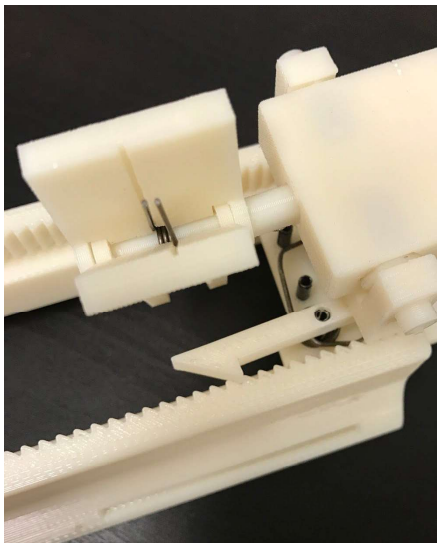

Fig. 11 An overhead view of the linear track with ratcheting features. The ratcheting track has a resolution of 3mm for linear positioning adjustments. The locking piece is spring-loaded such that the platform will not move linearly when not engaged by the user.

A movable platform which can be removed from the track for easy loading provides a mounting area for the needle. The platform consists of a custom gimbal mechanism, shown in Figure 12, which provides control over the angular positioning of the needle and acts as bearing for a sliding shaft. The gimbal has a range in pitch and yaw of approximately 50 degrees and 20 degrees, respectively. The angular positions are sufficient to give the user necessary freedom to adjust the needle. The gimbal includes a Belleville washer which increases static friction between the gimbal and movable platform in the yaw direction (Figure 12). This friction resists rotation of the gimbal when not being adjusted by the user, but allows the pitch angular position to be adjusted with minimal exertion from the user.

Compression springs are mounted in the side buttons to resist angular motion in the vertical plane.

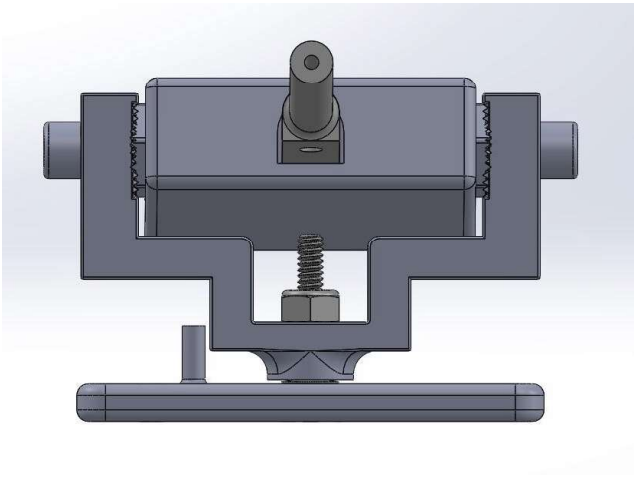

Fig. 12 A front view of the gimbal device on the moving platform. A belleville washer sits between the two components while compression of the washer is applied by the tightened nut on the gimbal. The buttons on the side control the pitch direction. They are in the uncompressed state in this figure, causing the buttons to interfere with the gimbal main structure. When both buttons are pushed, the device is able to rotate freely.

The needle is mounted to the gimbal mechanism through a spring-loaded clamping mechanism as shown in Figure 13. The holes in the clamping pieces form fit to plastic areas of the needle, allowing for full insertion of the needle tip as needed while maintaining sanitary conditions of the needle by avoiding direct contact between the metal area of the needle and the device. The extended surfaces were designed to withstand 15 N of force at the needle tip, which is well above the force required for needle insertion [6]. A central shaft holds the clamp together and slides in and out of the shaft bearing in the gimbal. Thin (0.031" diameter) 1080 spring steel wire surrounded by PTFE plastic tubing attaches through the center of the shaft and is held in place using a set screw. The other end of the

steel wire extends to a handheld mechanism. The handheld mechanism can be moved bidirectionally through a custom plastic bearing. Motion at the hand is directly coupled to linear motion of the needle through the wire and tubing. The clamping mechanism and handheld mechanism are shown in Figures 13 and 14.

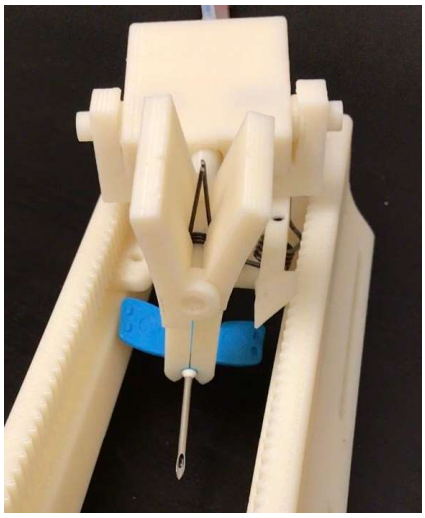

Fig. 13 The clamp mechanism used to attach the needle to the cannulation device. The clamp is spring-loaded to keep the needle in place when the device is in use, but allows for the needle to be easily attached or detached by applying force at the clamp wings.

Spring steel wire and PTFE tubing were chosen to reduce friction during force transmission, resist buckling during actuation, and make the device comfortable to handle. To quantify the friction in the system, the interaction between the tubing and the wire was modeled as a capstan with applied forces in compression instead of tension. Assuming negligible friction between components in the rest of the the system, the relation between the force applied at the needle and the force applied at the hand is given by:

$$F_{needle} = F_{hand}\, e^{-\mu\theta} \qquad (1)$$

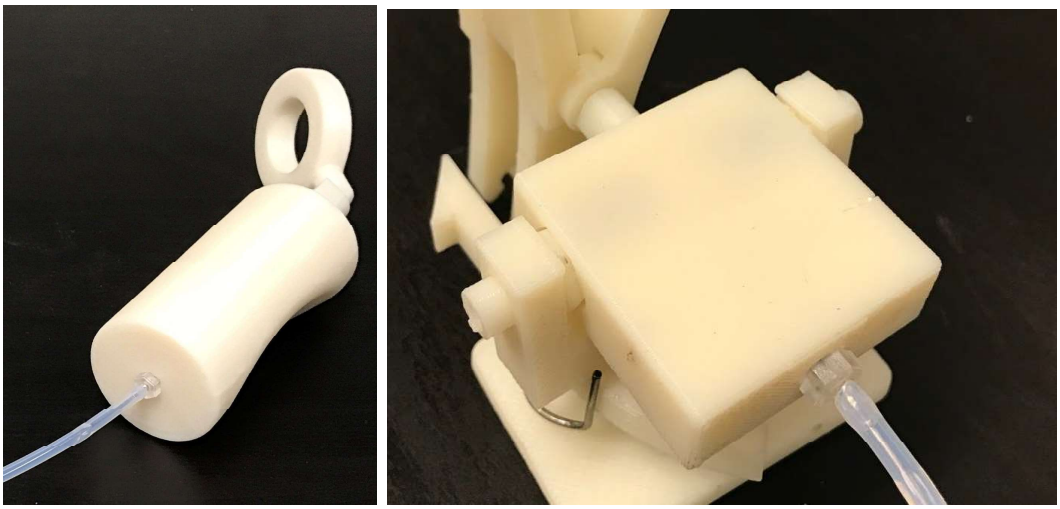

Fig. 14 The actuation mechanism for remotely controlling the insertion of the needle. The mechanism uses spring steel wire rigidly attached to two sliding shafts. One shaft is encased by a handheld bearing (left) and the other shaft is connected to the needle clamp and slides through a hole in the gimbal (right). The wire slides through PTFE tubing to transmit force and motion from the hand to the needle.

Noting that the coefficient of friction between steel and PTFE plastic is approximately 0.04 and conservatively assuming an angle of engagement of 45 degrees (0.785 radians), 97% of the force at the hand will be transmitted to the needle. This amount of transmitted force was sufficient when ease of use of the device and the potential for other sources of friction were considered. Buckling of the steel wire becomes a concern in areas where the wire is not enclosed in tubing, such as within the custom ball bearing. The buckling load can be estimated as

$$F_{buckling} = \frac{\pi^2 EI}{L^2} = \frac{\pi^3 E D^4}{64 L^2} \quad (2)$$

where E is the tensile modulus of the material, D is the diameter of the wire cross section, and L is the length of exposed wire. Because the device was designed to have a stroke

length of approximately 1.25”, a lower bound on the buckling force can be found by estimating L to be the stroke length. The estimated force required to induce buckling is approximately 38N, which is well above the forces seen during the cannulation process.

A picture of the overall system is shown in Figure 15.

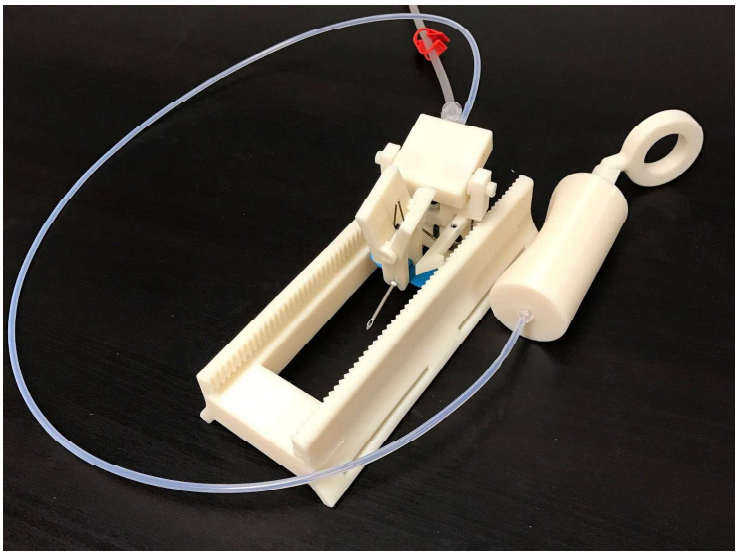

Fig. 15 Mechanical structure of the cannulation device. The device consists of mechanisms for remote, needle positioning and alignment, and needle attachment.

Testing and Results

Load Capabilities

Durability of the insertion device is important for ensuring the safety of the user. To assess durability, the device was constrained by hand near the needle attachment point while the device was actuated with maximum force at the passive hand. The clip mechanism was constrained both directly at the center of the shaft as well as at the clipping mechanism where the needle would attach. In both cases, material did not fracture and the

device remained intact. This result indicates that the device can withstand the forces typically exerted as a result of the cannulation process.

Stroke Length

While the stroke length was designed to be 1.25" in solid modeling of the device, the observed stroke length could vary from this value due to shaft and bearing misalignments that may cause the center shaft of the needle clip mechanism to disengage from the bearing at a shorter stroke length. A test was conducted in which the device began in its retracted state and was extended until deviation of the center shaft of the clip mechanism from its central axis was visually observed. The distance traveled was then measured. This procedure was repeated 5 times. The test revealed that the average stroke length of the device was 0.93 ± 0.01 inches. The stroke length was therefore smaller than was originally designed for. This difference can be attributed to the clearance misalignments between the shafts and bearings, and further tolerancing can be more accurately determined in future iterations based on user testing and preferences.

DISCUSSION

Three solutions were developed which address common fears associated with that deter dialysis patients from making the transition from in-center to in-home treatment. These fears included concerns about errors in machine setup, uncertainty in managing machine errors during the dialysis process, and performing cannulation correctly with minimal to no pain. Extensive interviews with in-home patients, patient caretakers,

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