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Soft Pneumatic System for Interface Pressure Regulation and Automated Hands-Free Donning in Robotic Prostheses

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***Abstract*— This paper discusses the design and preliminary evaluation of a soft pneumatic socket (SPS) with real-time pressure regulation and an automated underactuated donning mechanism (UDM). The ability to modulate the pressure at the human-socket interface of a prosthesis or wearable device to accommodate user's activities has the potential to make the user more comfortable. Furthermore, a hands-free, underactuated donning mechanism designed to reliably and safely don the socket onto the user may increase the convenience of prostheses and wearable devices. The pneumatic socket and donning mechanism are evaluated on synthetic forearm model designed to closely match the mechanical properties of the human forearm. The pneumatic socket was tested to determine the maximum loads it can withstand before slipping and the displacement of the socket after loading. The donning mechanism was able to successfully don the socket on to the replica forearm with a 100% success rate for the 30 trials that were tested. Both devices were also tested to determine the pressures they impart on the user. The highest pressures the socket can impart on the user is 4psi and the maximum pressure the donning mechanism imparts on the user is 0.83psi. These pressures were found to be lower than the reported pressures that cause pain and tissue damage.**

I. Introduction

A study investigating the prevalence of limb loss in the United States estimated that in 2005 there were 1.6 million Americans living with limb loss. Of these people, 35% lived with upper-extremity limb loss, and many of them are prescribed prostheses to improve their quality of life [1]. A survey of users' satisfaction with their upper extremity prostheses reported that 28% of users fitted for an upper-extremity prosthesis rejected it [2]. 95%, 93%, and 55% of these users reported that discomfort, inconvenience, and medical factors (i.e. skin irritation, blisters, etc.), respectively, were reasons they choose to not wear their devices. This low rate of upper-extremity prosthesis adoption illustrates a clear need for improved designs and usage models [3], [4].

The importance of the human-device interface. Sockets are the component of prostheses and wearable devices that attach the device to the user and transmit the loads from the user to their environment. Current sockets have passive, nonconformable shells that impart nonuniform pressures on the user as they interact with their environment. These pressures are not regulated by the socket, as such the socket could impart pressures that could cause discomfort and tissue damage [2], [5]. Another issue with the current upper extremity prostheses is the lack of accommodation for growth. Dr. Gloria Gogola* explains that upper extremity pediatric amputees need to have their socket replaced "every 9 to 18 months until age 10-12 years." She stated that a device that could accommodate growth "would be enormously helpful."

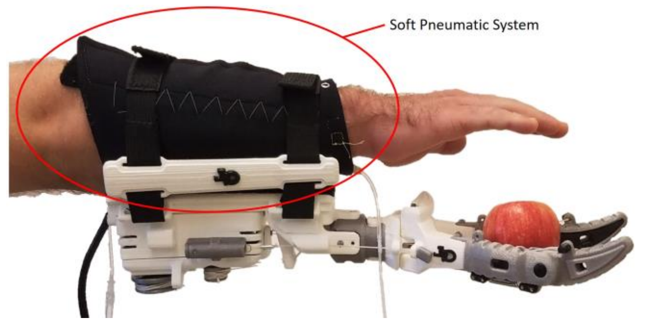

Figure 1.The Soft Pneumatic Socket attaching a prosthesis to a forearm. The socket is supporting the full weight of the wearable device and object.

Automating the donning process for ease of use. Not only could new socket designs impact prosthesis users, but new designs could improve wearable devices used for human augmentation, a growing field of research [6 - 8]. However, the methods for attaching these wearable devices to the user have remained relatively simple, consisting mostly of passive components, such as straps or bands. These passive attachment methods impart nonuniform pressures on the user as the user interacts with their environment. For low-load tasks, this nonuniformity of the load is not a problem, but for high-load tasks, the user may experience discomfort and possibly tissue damage from the long durations of high pressures imparted on them [4], [9].

The primary objective of the socket presented in this paper is to help reduce pain and discomfort exhibited in traditional sockets. This will be accomplished by actively regulating the pressure the socket imparts on the user. If the user needs to use their wearable device for a heavy lifting application, the pressure the socket imparts on the user can be increased to more securely attach the wearable device to the user. On the other hand, when the user is resting their wearable device, the socket can decrease the pressure it imparts on the user, improving comfort. The second objective is to design a more conformable socket than a traditional passive socket. As such, when there are changes in the shape and volume of the appendage, due to either daily swelling or more long-term changes in shape, the socket should change shape with the appendage. This socket will be tested to ensure that it is safe for the user and to determine if it can support loads from common activities of daily living (ADL), such as grooming and dressing, eating, locomotion, etc. Since another factor leading to the high rejection rate of upper extremity prostheses is an inconvenience, [2], this paper also presents

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the design of a mechanism that dons the socket for the user, increasing the convenience of the donning process. The objective of this donning mechanism is to be hands-free, which will especially benefit bilateral amputees, who have difficulty donning their wearable devices. The donning mechanism will also be tested to ensure its safety and reliability.

II. Passive Sockets and Related Works

Current passive upper-extremity sockets, like the Muenster-type and the Northwestern University Supracondylar Suspension Technique sockets [10], have components that compress the tissue around the bone to minimize the lost motion from the bone moving in the tissue before moving the wearable device [11]. These sockets usually apply higher pressures in select areas of the human-socket interface and do not accommodate growth or appendage volume changes. There has been research conducted on the design of sockets that use inflatable bladders to adapt to changes in limb volume using inflatable bladders [12] - [14]. These lower-limb prostheses sockets consist of small independent bladders placed around the socket to maintain a good fit of the socket. However, these sockets only regulate the pressure imparted on the user in select areas. The socket presented in this paper is composed of a single pneumatic bladder that forms the entire human-socket interface. This socket regulates the pressure of the entire human-socket interface and allows for the passive redistribution of pressure due to the internal flow of air in the bladder. This novel design is thought to decrease the risk of imparting high pressure on the user that may cause pain and tissue damage.

III. Design And Fabrication

Both the socket and donning mechanism presented in this paper were designed for forearm application, but these designs could be scaled for use in other areas of the body.

A. *Soft Pneumatic Socket*

An inflatable bladder was used to achieve the outlined objectives: minimizing pressure points, high conformability, and pressure regulation since inflatables easily change shape to match their environment. This inflatable bladder is made from a thermoplastic urethane (TPU) vacuum bagging film, 0.0015in thick. The method used to fabricate the bladder from this material was based on the work of Moghadam et al., 2018 [15]. To summarize the process, the TPU sheets were cut to the approximate size of the bladder and temporarily fused using a heat press for 90s at 200°F. The fused layers were cut to final shape using a Universal Laser Systems PLS6.150D Laser Cutter. The laser cutter settings that were found to produce the bladders with the highest burst pressure and lowest leak rate were as follows: 45% speed, 25% power, 500ppi, and a laser head height of 0.25in above the TPU sheets. Positioning the laser head higher up from the workpiece defocuses the laser, increasing the thickness of the weld. These settings produce a robust weld 0.005in wide that permanently fuses the layers of TPU.

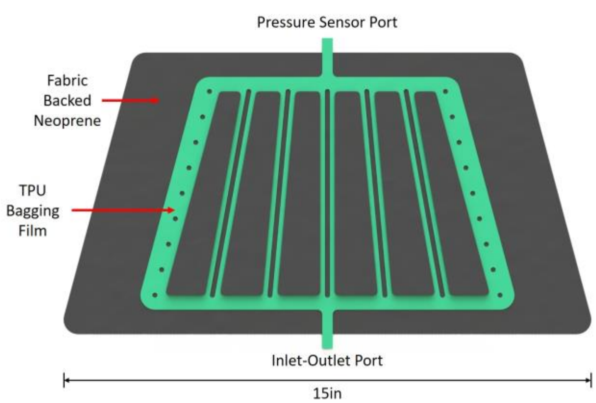

Figure 2. Rendering of Soft-Pneumatic Socket. Hook-and-Loop used to fasten the socket to itself is not shown.

A variety of small bladder samples were fabricated to determine the number of layers of TPU needed to create a robust pressure vessel. 2, 4, 6, 8, and 16-layer TPU samples were fabricated and pressurized to successively larger pressure values. The leak rate and failure pressure for each sample were recorded. The bladders composed of 2 and 4 layers of TPU tended to leak at a higher rate than the bladders composed of 6, 8, and 16 layers. Furthermore, the 2- and 4-layer samples tended to fail unexpectedly at pressures between 5 and 10psi. No discernible difference was found between the leak rates and burst pressures for the 6-, 8-, and 16-layer test samples when inflated to pressures below 10psi. For this reason, the full-scale bladder used in the inflatable socket is constructed from 6 layers of the TPU bagging film to minimize material.

The bladder design, shown in figure 2, has holes which allow the bladder to be hand-sewn onto a fabric-backed neoprene sheet of the socket. Fabric-backed neoprene is a commonly used material for prosthesis sockets [16]. The slots that are cut throughout the bladder increase the conformability of the bladder, allowing the bladder to more easily bend around tight curvatures. The two tabs that extend from opposite sides of the bladder are used to seal two flexible tubes into the bladder using Sil-Poxy, a flexible bonding agent. One tube connects to the pneumatic valve system which pressurizes and depressurizes the bladder. The other tube connects to the pressure sensor used to monitor the internal pressure of the bladder. Since the pressure sensor can only detect static pressure, these tabs are on opposite sides of the bladder to minimize disturbances due to the flow of the air in and out of the bladder.

The sealed bladder along with hook-and-loop is sewn to a fabric-backed neoprene sheet on the left and right of the TPU bladder to complete the soft pneumatic socket (SPS). The net weight of the SPS is 70g. The fabric-backed neoprene protects the bladder from being easily punctured while remaining flexible enough to wrap around the user's forearm. Hook-and-loop is used to fasten the socket to itself around the forearm of the user and support the hoop stress that is produced when the socket is pressurized. Fabric-backed neoprene strips were cut and bonded to the TPU to act as a socket liner. The main function of these strips is to wick moisture away from the human-socket interface. This wicking is vital for maintaining a relatively constant coefficient of friction between the socket and the user [17], [18].

The SPS is securely attached to the user when the bladder is inflated and tightens around the user's forearm. The actuation

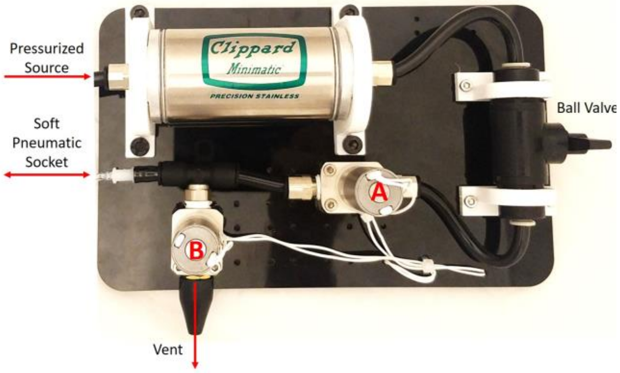

Figure 3. Pneumatic valve system used to actuate the SPS.

of the SPS is achieved with two pneumatic valves, labeled as A and B in figure 3. When valve A is open while valve B is closed the SPS is pressurized. On the contrary, when valve B is open and valve A is closed, the SPS is depressurized. When both valves are closed the SPS holds a constant pressure. An on-off control algorithm determines if the SPS needs to be pressurized or depressurized by monitoring the error of the system (the difference between desired pressure and the current internal pressure of the system). The pneumatic valve system only acts when the absolute value of the error is greater than 10% of the desired pressure. Since this system is designed to be pressurized using a portable cartridge, damping was added to the system to ensure that overshoot or the amount of gas that needs to be vented from the SPS is minimized. The damping of the system is physically adjustable by restricting the flowrate into the SPS using the ball valve shown in figure 3. For the preliminary evaluation of the SPS, the pneumatic valve system was supplied air from a California Air Tools 5510SE shop compressor with a regulated outlet pressure of 10psi.

B. Underactuated Donning Mechanism

To help a user don the pneumatic socket, an automated, underactuated donning mechanism (UDM), shown in figure 4, is also presented in this paper. The donning mechanism is a tendon-driven underactuated mechanism which roughly weighs 2kg. Underactuated devices are more compliant than a rigid mechanism, meaning that the pressures exerted on the human are more evenly dispersed. The joints of the fingers of the UDM are made from a stiff silicone (Smooth-Sil 960, Smooth-On, Inc.). Each joint increases in cross-sectional area

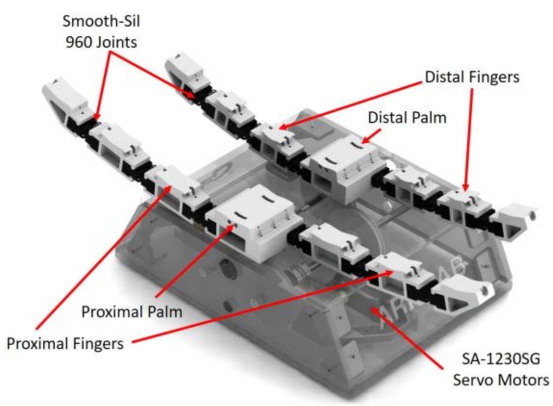

Figure 4. Underactuated Donning Mechanism.

to increase their stiffness as they progress away from the palms of the device. This ensures that the fingers of the UDM actuate in the correct progression. If the joints were all the same stiffness, the distal sections of the fingers would cause them to deflect at a higher rate than the proximal sections, which would result in the UDM pinching the user's arm rather than wrapping around the user's arm. The inspiration for using different stiffness joints came from the Yale OpenHand project [19]. The fingers of the UDM are 3D-printed from PLA, and house ball bearings to reduce the friction where the tendons route through the fingers.

The open-loop controller of the UDM is implemented on an Arduino Nano and is triggered by the FSR. The donning process is a two-step process; first, the SPS is placed on top of the UDM, and then the user places their forearm onto the SPS. The UDM wraps the SPS around the user's forearm when the weight of the user's arm is detected using the force-sensitive resistor (FSR). The donning mechanism is actuated with two Savox SA-1230SG servo motors, one for the left fingers and one for the right fingers. The donning process requires that the left fingers of the donning mechanism to be folded into position before the right fingers can be folded up to mesh the hook and loop of the socket.

IV. Evaluation

Both the socket and the donning mechanism were tested to determine the successes and shortcomings of their designs. Since neither the socket nor the donning mechanism was tested on humans, a human forearm replica was made that approximates both the tribological properties and the average durometer of the human forearm. The average shore hardness of a healthy human forearm is between 00-20 and 00-30 [20]. To approximate this durometer, 0.25in layers of Ecoflex 00-30 (shore hardness of 00-30) were wrapped around a plastic mannequin forearm. The static coefficient of friction (COF) between fabric-backed neoprene, the material that lines the inflatable socket, and human skin was found to be 0.69±0.11 [18]. Synthetic leather was found to most closely match the static COF of human skin [21]. The Instron 5965 was used to determine the static COF between the fabric-backed neoprene and synthetic leather. A mass of 1kg was placed on top of the two materials to provide a known normal force and the Instron pulled on the top material until slip occurred. The static COF between the fabric-backed neoprene and the synthetic leather was found to be 0.49±0.02. This COF is lower than the reported COF between fabric-backed neoprene and human skin, meaning that the loads that the socket can withstand on humans will be higher than the loads reported in this paper.

Using this forearm replica, the SPS was tested to determine the maximum working load and to characterize the effect of varying the size of the replica forearm on the SPS performance. The UDM was tested to determine its successful donning rate and the effect it has on the working load of the SPS. However, the safety of both the SPS and UDM needed to be established first.

A. SPS and UDM Safety Tests

To ensure that both the SPS and UDM are safe for human users, tests were designed to characterize the pressure that the devices impart on the user. To determine the pressure the SPS imparts on the forearm, the SPS was inflated to a variety of pressures and an Instron 5965 measured the force that the socket imparted. This test only determined the average pressure the SPS imparts on the forearm; however, it is assumed that the SPS imparts a uniform pressure on its surroundings. The test setup for determining the pressure the bladder imparts on the user is shown below in figure 5.

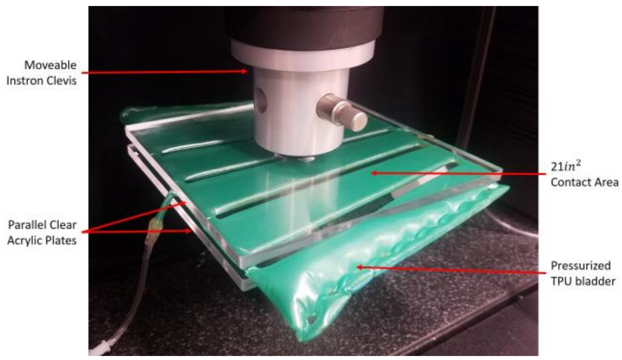

Figure 5. Test setup to determine the pressure the bladder imparts on user.

The contact area between the plates and the bladder needed to be determined to convert the Instron load to the pressure imparted on the Instron. This contact area was measured using calipers through the clear plates that sandwiched the bladder. The measured area was approximated using trapezoids and triangles. The approximated contact area was $21in^2$. The result from when the SPS was inflated to 1.5psi is shown in figure 6. The large uncertainty in the pressure the Instron measured is due to the uncertainty of the measured area. Regardless, there does not appear to be a difference in the average pressure the SPS imparts on the Instron and its internal pressure.

To test the pressure the UDM imparts on the forearm, a bladder the size of a human forearm was placed in the UDM and the change in internal pressure was recorded while the UDM actuated. The bladder was inflated to 0.5psi and the change in the internal pressure of the bladder measured to be 0.065±0.033psi. This change in internal pressure was used to determine the pressure the UDM imparts on the user's forearm during the donning. Free-body analysis was done

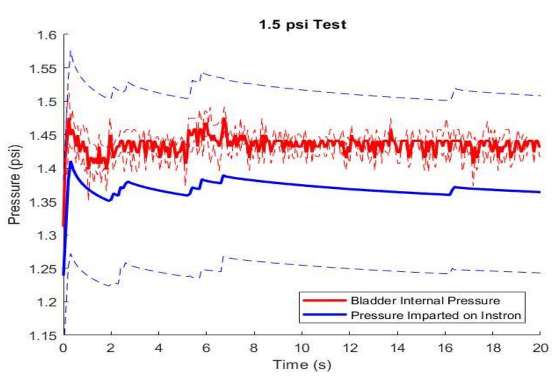

Figure 6. Pressure the bladder imparted on Instron compared to internal pressure of the bladder. Dashed lines are corresponding 95% confidence intervals.

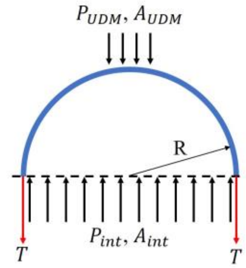

Figure 7. Free body diagram of the cross-section of the human forearm sized bladder used to determine the pressure the UDM imparts on user. L is the length of the walls of the bladder in and out of the page. P_{int} and A_{int} represent the internal pressure and cross-sectional area respectively. Likewise, P_{UDM} and A_{UDM} represent the pressure and contact area imparted on the bladder by the UDM.

assuming that the pressure distributions are uniform and that the pressure imparted on the bladder is undergoing an increase in pressure, ΔP_{UDM}. This increase in pressure can mathematically obtained from taking the partials of the force balance with respect to the internal pressure, P_{int} , and internal bladder tension, T shown in equation 1.

$$A_{UDM} \cdot \Delta P_{UDM} = A_{int} \cdot \Delta P_{int} + \Delta A_{int} \cdot P_{int} - 2 \cdot \Delta T \quad (1)$$

Since the initial pressure exerted on the bladder is 0, the change in external pressure is equal to the pressure imparted by the UDM, P_{UDM}. The internal area of the bladder is assumed to be constant since there was no measurable change in radius after the UDM actuated. Assuming the change in bladder tension is negligible, the pressure imparted by the UDM is

$$P_{UDM} \cong \frac{A_{int}}{A_{UDM}} \cdot \delta P_{int} \quad (2)$$

The areas were approximately measured using calipers. The resulting pressure that the UDM imparts on the forearm is roughly 0.55±0.28psi, which is less than the reported pressures that would cause pain or tissue damage when applied for short durations [22].

B. Soft Pneumatic Socket (SPS) Testing

Most upper extremity amputees want to perform ADL with their prostheses [23], [24]. ADL can be performed without transferring more than 15lbf. Studies have shown that a humanoid robot used less than 10lbf to open doors, drawers, and bathe humans [25], [26]. To determine if the SPS could support ADL the SPS maintained a desired internal pressure while it was loaded with respect to the replica forearm using the Instron 5965. The replica forearm was rigidly attached to the static clevis of the Instron machine while the socket was attached to the movable clevis of the machine. The socket was loaded in three orientations: axial, normal and torsional. For the axial testing, the socket was inflated to 1, 2, and 4psi while the socket was loaded to the desired load and then unloaded over two minutes. The displacement of the socket from beginning to the end of the test was recorded to characterize the amount of socket deformation that the user should expect whenever loading the socket. The test setup is shown in figure 8. As was expected, the tests at higher pressures experienced fewer socket displacements compared to the tests with lower pressures. These results are shown in figure 9.

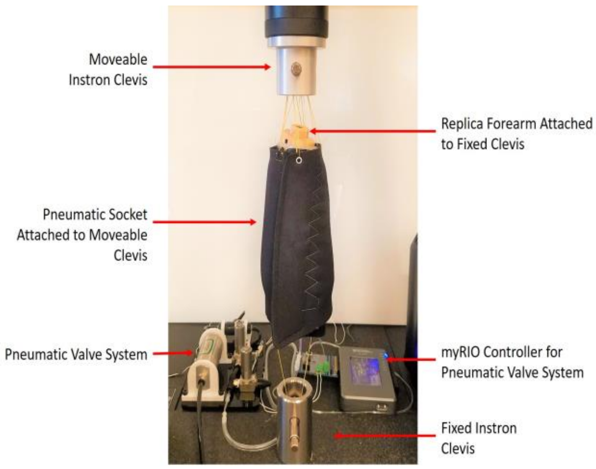

Figure 8. Test setup for axial loading tests.

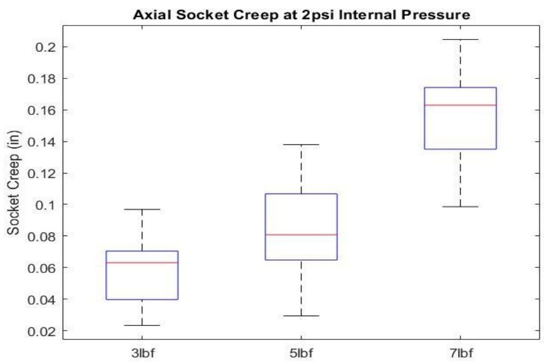

Figure 9. SPS displacements after axial loads applied when the SPS is inflated to 2psi.

The SPS was also tested to determine the maximum axial load it can withstand before slipping on the forearm. For this test, the Instron pulled on the SPS with a constant extension rate until the measured load dropped by 10%, corresponding to the SPS slipping. Ten trials with the SPS pressurized to 1, 2, and 4psi were recorded and the results are shown with the boxplot in figure 10. The maximum axial load the socket supported at 4psi was 10.8±1.3lbf.

For the normal loading tests, the replica forearm was transversely affixed to the static Instron clevis with Kevlar thread and fabric reinforced with Kevlar was wrapped around the socket and attached to the movable clevis of the Instron. The socket was inflated to 1 and 2psi and the Instron extended at a constant extension rate until the Instron measured a load of 30 and 35lbf respectively. As a result of the SPS pressure regulation, the load vs displacement obtained from the Instron shows curves that have constant slopes. Once the pressure imparted on the SPS by the Instron exceeded the internal pressure of the SPS, it was observed that the slope of these load vs displacement curves increased. The pressure at which the slope of these curves increases show the load that the SPS can support while maintaining the desired internal pressure. At pressures above this critical pressure, the SPS cannot regulate the pressure at the human-socket interface. Figure 11 shows the normal load as a function of the Instron extension.

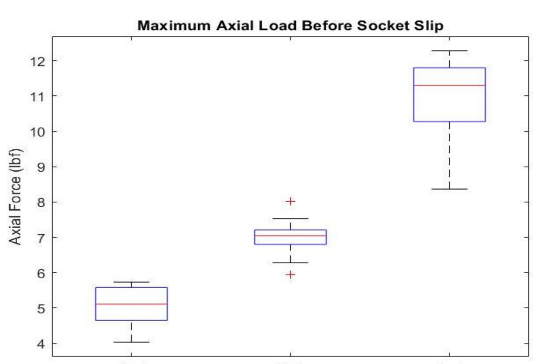

Figure 10. Maximum axial loads the SPS could withstand before slipping relative to the replica forearm.

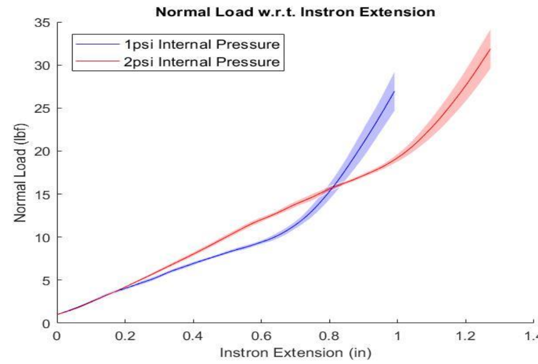

Figure 11. Normal load as a function of the Instron extension. Notice the change in slope of the curves corresponding to the maximum load the socket can withstand while regulating the human-socket pressure.

The next test conducted on the SPS was designed to determine the maximum torque the SPS can withstand before slipping on the forearm. For these tests, the forearm model was again transversely grounded to the static clevis of the Instron machine and the socket was being torqued using the moveable Instron clevis. To convert the force from the Instron to a torque applied to the SPS, cord, and fabric wrapped around the SPS was attached to the moveable head of the Instron. The torque applied to the socket was calculated from multiplying the force read by the Instron by the perpendicular distance from the axis of the forearm to the location of the applied load. Figure 12 shows the maximum torque the SPS withstood at internal pressures of 1, 2, and 4psi. Again, ten trials were recorded for each specific internal pressure. The maximum torque the socket was able to support with an internal pressure of 4psi was 39.2±1.7lb-in.

Lastly, the SPS was tested to characterize how it accommodates growth or volume changes in the forearm. To

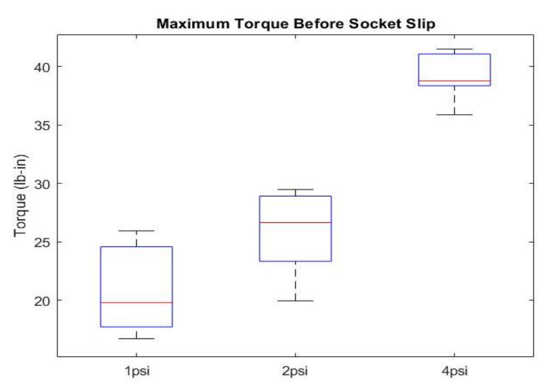

Figure 12. Maximum torques the SPS can withstand before slipping relative to the replica forearm.

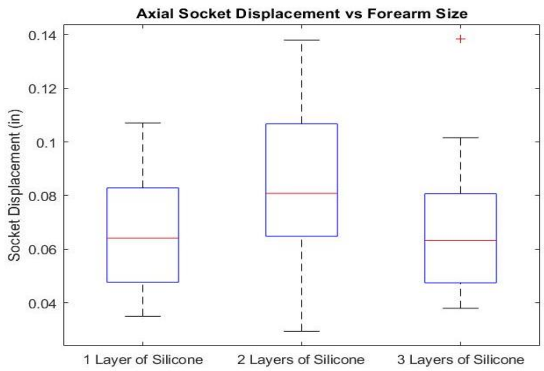

Figure 13. SPS displacements after loaded to 5lb. Comparison between different forearm sizes.

simulate users' appendage volume changes, layers of Ecoflex 00-30 were added between the plastic forearm and the synthetic leather of the replica forearm. Each layer was about 0.25in thick, therefore each layer added 0.5in to the diameter of the forearm. To determine the effect of the growth on the performance of the SPS, the socket was axially loaded and unloaded to a maximum axial force of 5lbs. These tests were run with a relatively slow rate of extension (0.1in/min) to minimize the increasing hysteresis of adding more layers of soft material. Eight trials were recorded for each forearm size. The displacement of the Instron at the end of the test was subtracted from the initial position of the Instron clevis to get the socket displacement.

A one-way analysis of variance (ANOVA) was calculated on these three sets of data to determine if any set has a different mean than the others. The resultant p-value is 0.35, indicating that there is no significant difference between the displacement of the SPS when varying forearm sizes. The SPS displacements for different size forearms are shown in Fig. 13.

C. *Underactuated Donning Mechanism (UDM) Testing*

The UDM was tested to determine its successful donning rate. The UDM successfully merged the hook and look of the SPS 30 out of 30 times. For these 30 trials, the SPS was placed in the same location on the UDM before the donning process took place. The SPS was then inflated to 2psi and loaded axially until the socket slipped on the replica forearm. To determine the effect of using the UDM on the performance of the SPS, the maximum axial loads of these 30 trials were compared to the maximum axial loads the SPS withstood when donned by hand. Figure 13 shows the comparison

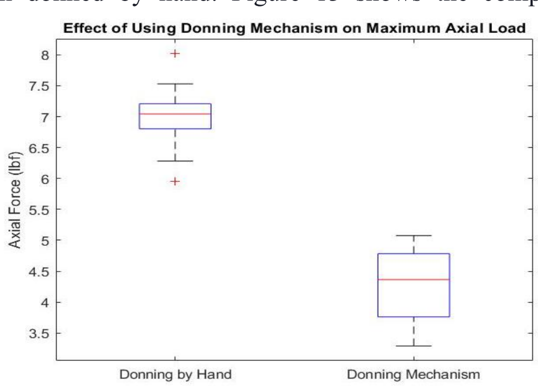

Figure 14. Maximum axial loads the SPS can withstand before slipping relative to the replica forearm. Comparison between donning methods.

between the trials donned by hand and the trials donned with the UDM.

A one-way ANOVA was used to determine if there is a significant difference between the means of the two data sets and the resulting p-value much less than 0.05. This indicates that the means are significantly different. This difference probably stems from the donning mechanism more loosely wrapping the SPS around the replica forearm than when the SPS was tightly donned by hand. Even with this discrepancy, the SPS supports enough load for the user to lift a 4lb object when their forearm is pointing toward the ground.

V. CONCLUSION

This paper presents a socket that is safe for a user to wear when inflated at pressures lower than 1psi for long-term use and pressures up to 4psi for relatively short durations (<1hr). The accompanying donning mechanism can safely and reliably don the socket onto a user's forearm. The socket can regulate the human-socket interface pressure at pressures up to 4psi, even when the socket is loaded. The testing of the SPS shows that the socket can support loads that correspond with everyday tasks, such as opening doors, holding bags, etc. At 4psi of internal pressure, the SPS can hold 10.8 ± 1.3lbf of axial load before the socket slips on the replica forearm. The SPS also can regulate the pressure exerted on the user when the normal load imparts a pressure less than the internal pressure of the socket. The SPS was able to hold 19.3 ± 0.1lbf while maintaining an internal pressure of 2psi. The torque testing showed that the SPS was able to hold 39.2 ± 1.7lb-in of torque before the socket slipped on the forearm replica when inflated to 4psi.

However, there are limitations of the SPS and UDM designs. One limitation of the SPS is the ability to regulate local pressures at the human-socket interface. By not allowing the human-socket interface to support different pressures, the socket tends to compress and decompress when loads are applied to it. This movement could inhibit the user from performing precise tasks, so future designs of the SPS should include multiple bladders with independent control systems. Additionally, future SPS designs will incorporate a pressure sensor array to more accurately determine the pressures that are imparted on the user. Future designs of the SPS will also include strain limiting components to the neoprene shell of the SPS to reduce the loss of pressure imparted on the user when the cross-section of the bladder compartments become more circular during expansion. Future iterations of the UDM design will incorporate some method for more tightly wrapping the SPS around the user's limb to minimize the SPS performance decrease seen when using the UDM. The implementation of a closed-loop control system may help the UDM achieve this goal. After these design changes are made to the SPS and the UDM, human subject testing will be performed to determine the perceived comfortable and functionality of the SPS as well as the reliability and functionality of the UDM.

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