The development of the one-handed knee aspiration mechanism to aid in arthrocentesis

(Technical Paper)

The importance of users in prosthetics design process

(STS Paper)

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

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Introduction

Osteoarthritis (OA) is a form of arthritis that typically affects the hands, hips and knees. In fact, of the 32.5 million U.S. adults 90% of those people with knee OA receive arthrocentesis procedures (Maricar et al., 2016; *Osteoarthritis (OA) | Arthritis | CDC*, 2020). Arthrocentesis, also known as joint aspiration, is a clinical procedure that involves extracting synovial fluid via a syringe from a joint in order to alleviate pain and assist in recovery by reducing the fluid pressure in the joint. This procedure is most commonly performed on knees, but it can also be done on elbows, ankles, hips, and shoulders. Knee aspiration procedures involve two hands. One hand is used to squeeze the knee which is commonly referred to as "milking the knee" while the other hand is used to hold and retract the syringe plunger. Currently, extending a syringe plunger with one hand is a cumbersome and difficult process that requires a large amount of force. The large force and the awkward hand positioning are often compensated by temporarily using two hands to hold and extend the syringe plunger, which prevents the physician from continuously milking the knee. The purpose of my technical project is to develop a one-handed knee aspiration mechanism that can assist physicians by allowing them to perform the procedure in a more comfortable manner that also frees the second hand to milk the knee for the duration of the entire procedure.

My technical and STS project both relate to the ever-changing medical device industry. As our understanding for the pathology of illnesses has improved over the past century, we have seen an increase in human life expectancy. However, as humans live longer, the medical device industry has had to focus on longer term solutions to medical conditions, not solved by semi-functional replacements, but evolving medical devices that improve the quality of life and longevity of use for patients. My thesis will explore how the orthopedic industry has shifted from

creating prosthetics that are exclusively functional to devices that also improve the comfort and quality of life for patients living a variety of lifestyles and into their older ages. I plan to narrow in on a single company that is at the leading edge of prosthetic designs and evaluate how they understand, interpret, and collect data from their users in order to create these innovative approaches into their design process that focus on quality of life and functionality for their users.

Technical Topic

My technical project is to develop a mechanism that will assist physicians during arthrocentesis procedures of the knee allowing them to comfortably extend a 60cc syringe with a single hand, thus freeing the second hand to milk the knee during the entire procedure. My team consists of two BME undergraduates and two advisors associated with the Department of Orthopedics at the University of Virginia School of Medicine Hospital. The knee aspirator project consists of three objectives.

For objective one, we plan to develop a CAD model in Autodesk Fusion 360 for the knee aspiration mechanism that effectively fits the design specifications. For this objective to be successful, the mechanism design must be able to house a 60cc syringe that is 6” long and 1.25” in diameter. The design must be constructed to ensure stability and control for the physician. This will be controlled by constructing a handle for the mechanism that wraps around the barrel of the syringe that ensures that the operator has optimal control of the needle. The design must be comfortable for the user. The design will be ergonomic emphasizing its ability to have natural finger and hand placement for users with varying hand sizes and grip strengths.

For objective two, we plan to build a physical prototype that can test the effectiveness of the above design parameters from objective one in a lab and clinical setting. The physical prototype must be able to operate on mechanical components alone, ideally utilizing a linear

track to extend the syringe plunger with an option to temporarily unretract if the needle is obstructed by soft tissue. The physical prototype must be able to withstand the large force required to extend the plunger without breaking due to material failure. The prototype must be made from easily sterilized materials that allow it to be used more than one time in a clinical setting. First, the physical protype will be tested in a lab setting. After successful insertion of the 60cc syringe, the device will be tested by a variety of increasing viscous fluids to determine its point of failure. Starting with an artificial synovial fluid that models the same density and viscosity of the fluid, the device will be trialed with increasingly viscous fluids. A force will be measured for each fluid and the mechanism will be evaluated for any breaking after each trial. Second, the physical prototype will be evaluated in a clinical setting. A cohort of physicians will rank hand comfort, difficulty to operate, and ability to free their second hand without the device and with the device.

For objective three, our team will apply for a provisional patent application assisted by the UVA Patent and Licensing Clinic. A provisional patent will streamline the process for FDA approval, which will lead to the device being commercially available to clinics around the world.

Currently, there are few US patents for any device or mechanism that retracts a syringe, thus making our device have a novel design and function. However, there are similar mechanisms that exist. The aspiration biopsy syringe gun uses a gun-shaped hand positioning that uses the index finger to pull back a linear track which extends the syringe plunger (Minho Kim et al., 2009). The hand positioning used on this device is suboptimal because it is located far from the needle, thus leading to more instability. In addition, this device has no capability to move the syringe forward to unblock the needle. The one-handed knee aspiration device improves this hand positioning by creating a handle that encompasses around the barrel of the

syringe, thus providing more stability and control of the needle during the aspiration procedure. Another similar device is the pencil-grip fine needle aspiration syringe holder; this mechanism can be aspirated at user speed, but the hand positioning is not ergonomic (Tao, 1998). In addition, it is designed for biopsy procedures, which use smaller 10cc fine needle syringes that cannot be used for knee aspiration procedures. Lastly, it limits the movement of the plunger, preventing it from its fully extended position. The one-handed knee aspiration device 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.

As a member of this team, I am responsible for coworking on objectives one, two, and three with two other BME undergraduates. We plan to spend equal time developing a CAD model of the mechanism, building and testing a physical prototype, and filing for a provisional patent. So far, we have an initial working prototype that we hope to finalize by mid-November before we begin the testing phases in objective two.

STS Topic

The medical device industry has shifted from creating solutions that are solely functional to solutions that focus on functionality and improving the quality of life for patients. I plan to investigate the prosthetics industry and show how the industry evolved to create new prosthetics that support people of varying lifestyles and ages via their methods of collecting user data and involving users in their design process. Össur is a world leader in the protistic device industry. Össur claims to "focus its efforts and experience on helping people be confident, safe and mobile, regardless of injuries or conditions that could compromise their quality of life"(*Össur. Life Without Limitations. Ossur.Com*, n.d.). There is a reason that companies like Össur become so successful. They properly sought out after user data to improve their products to properly

improve quality of life for their users. In my thesis, I will show why Össur became the leading edge of prosthetic designs and evaluate how it understands, interprets, and collects data from its users in order to create these innovative approaches into its design process that focus on quality of life and functionality for its users.

The use of wooden limb prosthetics has been dated back to as far as the era of the ancient Egyptians, who used dried reed stalks to fixture limbs (Marin et al., 2020). These prosthetics were often temporary and uncomfortable to wear. There was no purpose to develop a more comfortable and durable device because the majority of amputees died after a short period of time due to septic shock and hemorrhaging. By the mid-nineteenth century, the survival rate increased largely due to the use of aseptic techniques and general anesthesia (Sachs et al., 1999). At this time, the American Civil War created a demand and need for a new take on limb prosthetics. Companies like the Salem Leg Company took advantage of this new market and sold durable and comfortably padded leg prosthetics that mimicked the shape and movement of a real leg because the inventor himself, Professor George B. Jewett, personally knew from user experience that wooden fitted legs alone would not be sufficient to a lifelong use (*The Salem Leg: Under the Patronage of the United States Government*, 1864). In this particular case, Professor Jewett was the user and the designer. He used his user experience from uncomfortable wooden sockets to create a far superior design that suited the user better. The prosthetics industry boomed and took a turn focusing on user feedback to create new designs that have advanced to incorporate a variety of activities and lifestyles that we see today such as running, bicycling, swimming, or skiing.

Hyysalo et al.in the chapter titled *User Representation* discusses the need and importance of incorporating users into the design process. This process of user representation can be

exhibited in several fashions, whether it be from surveying or direct user design input. Users help to interpret how a product may be viewed prior to its release, which helps mature the design process to a point where it is maximally impacting the user group. Different sources of user representation can change how designers approach a project. In addition, the designers need to be mindful of users that are affected by the design but might not be directly using the product. There is a new focus on users being viewed not as subjects but as valuable members to the design process, now labeled as design participants. This scholarly work highlights the main framework for how I plan to show how the orthopedic companies are creating new dynamic designs for the prosthetic industry. They have changed their focus on how to incorporate design input from their users. Surveys, commentary, and user feedback all used by the companies to develop the shift in static prosthetics that were merely functional to ones that are now adaptive to different lifestyles and activities (Hyysalo et al., 2016).

I plan to analyze the prosthetics manufacturing company called Össur that has developed some of the most diverse and effective prosthetic designs of the modern-day market. Upon early research, Össur claims to "accumulate medical and biomechanical data during their development process" (*Össur 2019 Annual Report*, n.d.). This includes collecting data from users before the product is released and finalized. In fact, Össur "initiates and promotes clinical studies" in participation with scientists, users, and healthcare professionals (*Össur 2019 Annual Report*, n.d.). Often, a clinical trial is used to judge the safety and effectiveness of a design with the users' feedbacks having a large effect on the reevaluation of the original design in order to improve usability (Bitkina et al., 2020). An example of Össur involving users in the design process can be seen in the 2016 clinical test report for the RHEO KNEE, the mechanical knee component of Össur's lower limb prosthetics. Össur gathered user data from 13 participants and

used a combination of four different questionnaires to evaluate the new device. They used a six-minute walk test to evaluate a faster walking performance and a PEQ questionnaire to determine the users' overall perceived quality of life and experience to support the new device being more advantageous, less exertive, and natural for the users (*RHEO KNEE XC Clinical Test Report*, 2016). These tests specifically focused on quality of life for each user and gained feedback about how the new device compared to the existing prosthetics. Össur uses data to confirm the usability of its devices and improves them based off user data before they are released into the market. This confirms that Össur involves users in the design process. However, I plan to later find data from Össur that confirms that they process user feedback to either inspire a new device design or use it during the design process itself prior to manufacturing the first prototype, thus differentiating it from other prosthetics companies and contributing to its success as a company.

Next Steps

Moving forward, I plan to find examples online and contact Össur directly to see how it include users in its design process before the first prototype is created and tested. I also plan to research the different type of products that Össur has in development or have already made to increase the diversity of lifestyles that people with prosthetics can participate in. This will bring to light the importance of user involvement in the design process, specifically in the field of prosthetics but the same idea can be expanded into other fields. As for the technical project, a full-sized prototype is planned to be finished by mid-November. Once the prototype is complete, my group will begin the mechanical failure testing and collecting the physician user data through the end of this semester and continue until the end of February. At this point, we will begin a provisional patent application.

References

Bitkina, O. Vl., Kim, H. K., & Park, J. (2020). Usability and user experience of medical devices: An overview of the current state, analysis methodologies, and future challenges. *International Journal of Industrial Ergonomics*, *76*, 102932. https://doi.org/10.1016/j.ergon.2020.102932

Hyysalo, S., Jensen, T. E., Oudshoorn, N., Jensen, T. E., & Oudshoorn, N. (2016). *The New Production of Users: Changing Innovation Collectives and Involvement Strategies*. Routledge. https://doi.org/10.4324/9781315648088

Maricar, N., Callaghan, M. J., Parkes, M. J., Felson, D. T., & O'Neill, T. W. (2016). Clinical assessment of effusion in knee osteoarthritis—A systematic review. *Seminars in Arthritis and Rheumatism*, *45*(5), 556–563. https://doi.org/10.1016/j.semarthrit.2015.10.004

Marin, E., Boschetto, F., & Pezzotti, G. (2020). Biomaterials and biocompatibility: An historical overview. *Journal of Biomedical Materials Research Part A*, *108*(8), 1617–1633. https://doi.org/10.1002/jbm.a.36930

Minho Kim, Park Ki-Ha, & Taehyun Lee. (2009). *Aspiration Biopsy Syringe Gun* (Patent No. KR200443099Y1). https://patents.google.com/patent/KR200443099Y1/en?q=Aspiration+Biopsy+Syringe+Gun.&oq=Aspiration+Biopsy+Syringe+Gun.

Össur 2019 Annual Report. (n.d.). Retrieved November 1, 2020, from http://annual-report.ossur.com

Össur. Life Without Limitations. Ossur.com. (n.d.). Retrieved October 28, 2020, from https://www.ossur.com/en-us

Osteoarthritis (OA) | Arthritis | CDC. (2020, August 4). https://www.cdc.gov/arthritis/basics/osteoarthritis.htm

RHEO KNEE XC Clinical Test Report. (2016). Ossur. https://assets.ossur.com/library/36572/RHEO%20KNEE%20XC%20Comparison%20Study.pdf

Sachs, M., Bojunga, J., & Encke, A. (1999). Historical evolution of limb amputation. *World Journal of Surgery*, *23*(10), 1088–1093. https://doi.org/10.1007/s002689900628

Tao, L.-C. (1998). *Pencil-grip fine needle aspiration syringe holder* (United States Patent No. US5830152A). https://patents.google.com/patent/US5830152A/en?q=Pencil-Grip+Fine+Needle+Aspiration+Syringe+Holder&oq=Pencil-Grip+Fine+Needle+Aspiration+Syringe+Holder

The Salem leg: Under the patronage of the United States Government. (1864). United States Army and Navy; U.S. National Library of Medicine. https://collections.nlm.nih.gov/bookviewer?PID=nlm:nlmuid-25922360R-bk#page/8/mode/2up