Double Barrel Syringe for Musculoskeletal Injections via Ultrasound Guidance

(Technical Paper)

The Influence of Money on the Evolution of Sports Medicine

(STS Paper)

A Thesis Prospectus Submitted to the

Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements of the Degree

Bachelor of Science, School of Engineering

Nathanael Chase Zegarski

Fall, 2019

Technical Project Team Members

Nir Diskin

Trent Levy

Jacob Morris

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

Signature _____ Date _____

Nathanael Zegarski

Approved _____ Date _____

Jeremy B. Kent, MD, Department of Family Medicine, University of Virginia

Approved _____ Date _____

Sean Ferguson, Department of Engineering and Society

Introduction

Ultrasound-guided injections within the musculoskeletal system are common procedures in family and sports medicines clinics. Due to the need for precision, the physician must use an ultrasound with one hand, forcing them to administer the injectate with the other. These procedures require multiple syringes, resulting in an inefficiency for the physician as well as discomfort for the patient. Therefore, our capstone project aims to design and develop a multiple barrel syringe that can be operated with one hand and administer injectates individually or simultaneously. The proposed device should minimize the invasiveness of injection sites, thus improving patient comfort.

As the capstone project is focused on the improvement and efficiency of medical practices in sports medicine clinics, the STS portion of the thesis will analyze the evolution of sports medicine and its correlation with the influx of money in the sports industry over several decades. I plan to investigate the underlying reasons for the rapid evolution of sports medicine and the associated actors within this network; considering the infiltration of money into sports and its influence on the advancements of sports medicine and healthcare practices.

Technical Topic

Specific Aims

Musculoskeletal injections are a common tool in family and sports medicine to manage various musculoskeletal conditions. Anesthetics, regenerative solutions, and corticosteroids are injected into articular, periarticular, and soft tissue structures to relieve pain, reduce inflammation, and increase patient mobility (Stephens et al., 2008). Ultrasound-guided injection of the musculoskeletal system is a common injection technique and it requires separation of

multiple solutions prior to injection. Currently, musculoskeletal injections are conducted with the physician guiding the ultrasound probe in one hand while handling the syringe with the other hand. The physician must inject one substance with one syringe and then subsequently exchange the syringe with another. This exchange process is burdensome for both the physician and the patient as it causes less efficient procedures and more patient discomfort. Dr. Jeremy Kent has envisioned a medical device that can be described as a "double-barreled syringe." We believe this device would be a viable option to improve the experience of the procedure for both the physician and the patient. Therefore, the goal of this year's work is to develop a patented injection device that can be used with one hand, exhibit autonomy in injecting different volumes of different liquids, and improve clinical outcomes and experiences.

Aim 1: Develop an ergonomic one-hand-operated injection device

1.1. Design and construct a device on Fusion360 and 3D print model that is able to function in four injection modes: injection of one solution, injection of an alternative solution, simultaneous injection of both solutions, and injection of no solution.

1.2. Design and construct a device in Fusion360 and 3D print model that is able to function in four aspiration modes: aspiration of fluid into one syringe lumen, aspiration of fluid into alternative syringe lumen, simultaneous aspiration of fluid into both lumens.

Aim 2: Improve clinical outcome/experience for patients and physicians

2.1. *Assess physician comfort using the device:* After successful prototyping, practicing physicians who perform ultrasound guided musculoskeletal injections will be asked to perform a multi injectate procedure on a cadaver from the Surgical Simulation and Fresh Tissue Cadaver

Training Laboratory. They will use a standard syringe and repeat the process using the prototyped device. Afterwards, participants will be surveyed on their experience. The responses will provide a metric of qualitative assessment.

2.2. *Assess device effect on overall procedural efficiency:* The aforementioned procedure will be timed. A standard t-test will be performed for each participant's results to determine which method, if either, is significantly faster. Procedural time will be used as a metric to represent procedural efficiency.

2.3. *Assess patient comfort with device:* Patients who have undergone ultrasound guided musculoskeletal injections will be surveyed on their experiences. Specific feedback will be requested as to how the procedure could be made more comfortable. Their responses will provide a qualitative metric of success to determine whether the device would improve the patient experience.

Aim 3: Develop a patent for aforementioned device for submission to USPTO*:*

3.1. The device history will be recorded, and a preliminary search of prior art will be conducted. After the preliminary search has been completed, a patent application will be drafted, edited, and finalized for the injection device.

3.1.1. While the patent application is being constructed, the necessary funds for the filing and examination of the patent will be acquired. An application for approval and funding from the UVA Licensing & Venture group will be filed to support the patent application process.

3.1.2. Pending funding, the patent application will be filed with the United States Patent and Trademark Office (USPTO). Once filed, an examination request will be made

with the USPTO. Responses to the examiner will be made with respect to the objections they have made, and the patent will then be granted.

Significance

The current single syringe and needle method is inadequate for performing and undergoing musculoskeletal injections for doctors and patients respectively. Currently, musculoskeletal injections of therapeutic substances into joints or ligaments constitute nearly 50,000 procedures annually (United States Bone and Joint Initiative, 2014). In a study from the Mayo Clinic GIM Musculoskeletal Injection Clinic, the three most commonly injected sites found were the knee (208 injections, 37%), greater trochanteric bursa or hip (197 injections, 35%), and glenohumeral joint or shoulder (96 injections, 17%) (Wittich et al., 2009). The application of these injections range widely in age and demographic. However, we will analyze and focus our attention to the importance of this procedure in the context of general practice medicine, including sports medicine and family medicine. As Wittich notes, "musculoskeletal problems are common in primary care and often respond to injections containing both corticosteroids and short-acting anesthetics," (Wittich et al., 2009). For use in sports medicine, the average age of patients is about 20 years old with the common cause of injury being overuse. However, the majority of these injections are performed in family medicine and are applied to patients between the ages of 40 and 60 (Kent, J. Personal Interview. (13 October, 2020).). These injections are used for treating ailments such as arthritis, which is associated with sedentary lifestyles and comorbidities like obesity. Specific to our project, concerning ultrasound (US) guided musculoskeletal injections, a significant barrier to progress arises from prior art due to the fact that similar devices have been proposed for other disciplines of medicine, such as dentistry

and veterinary medicine. This ultimately limits the scalability and generalizability of such a device long-term.

With the introduction of a double-barreled syringe, the field of musculoskeletal injections would be greatly impacted. The ability of a single device to inject and aspirate with full autonomy using one hand would allow physicians to do more with a single device. Technically, it would give physicians freedom to inject and aspirate freely without having to follow a predetermined sequence of separate injections or aspirations. Moreover, many musculoskeletal injections are guided by ultrasound, require two injections to carry out the procedure, and require a physician to hold and manipulate a US probe and syringe simultaneously. When using multiple syringes to perform multiple injections, patients experience discomfort at the injection site(s) because one syringe is switched out with another and the needle is left in the patient. Clinically, a dual injection system would increase the efficiency of injection procedures for physicians and better overall patient experience. These goals of increased efficiency and patient comfort would be accomplished by not requiring an exchange of syringes mid-procedure, effectively streamlining the process for the physician, and simultaneously entailing only one injection site, lowering patient discomfort. As previously mentioned, around 50,000 injections of therapeutic substances into joints or ligaments occur a year. It is estimated that using a dual injection device would save 40 seconds per procedure, equating to roughly 555 hours a year (23 days) (Kent, J. Personal Interview. (13 October, 2020).). An additional technical capability required to improve clinical outcome is a compact device that allows maneuverability at the skin so that an injection can be made almost parallel to the skin interface.

If the aforementioned proposed aims are achieved, the field will be given the choice to adopt this new device. It can be used for the vast majority of procedures that require multiple injections or aspirations. A byproduct of this change would be improvements in terms of time per procedure and improvements in terms of patient satisfaction per procedure.

Innovation

The conception of a one-handed, double-barrel syringe for ultrasound-guided, musculoskeletal injections stands to streamline targeted injection procedures for physicians and improve the associated patient experience. Many designs of multi-injection syringes currently exist; however, none are viable for use in ultrasound-guided, musculoskeletal injections. Most variations in this category of syringe succeed in developing a lumen capable of storing multiple medicines while preventing mixing between them. They also provide a needle through which the multiple medicines can be injected at a single site, both of these being critical metrics of success. However, most of these syringes fail to meet the injective control requirements necessary for the proposed usage. These types of syringes, such as the Pizzino (1986) "Dual Syringe," utilize preloaded lumens, meaning they are incapable of aspiration, and the volumes and types of medicine to be injected are restricted to only what is sold by the supplier (U.S. Patent No. 4,610,666, 1986). Additionally, many of these models can only inject the medicines in a predetermined order. These traits institute severe limitations on their applicability across the numerous forms of ultrasound-guided musculoskeletal injections: procedures which vary in their usage of types and quantities of medicine. While the Kozam-series of multi-barrel syringes circumvents many of these issues, they still fail to meet optimal injection related design specifications. The 1978 version boasts aspiration capabilities and an individual lumen injection control, enabling the physician to aspirate their own volumes of medicine (Park, n.d.). However,

this design utilizes a one-way valve which forces the user to completely inject the contents of one lumen before being able to inject the other. This introduces another limitation for physicians in the process of aspirating syringe volumes and substantially reduces their level of control during procedures. This valve also prevents the simultaneous injection of the contents of both lumens, a critical design goal of the project. The 1983 version removes this valve, restoring mid-procedural control, yet the new design still prevents simultaneous injection (U.S. Patent No. 4,367,737, 1983). The goal for this project is a multi-barrel syringe viable for ultrasound-guided, musculoskeletal injections with complete, individual lumen control, aspiration capabilities, and an ergonomic design compatible with one-handed usage.

The proposed device approaches a novel solution for the purpose of musculoskeletal injections by overcoming the shortcomings of previous concepts. Physicians will have the ability to aspirate the desired amount of injectate into the desired barrel prior to administration. This capability gives the physician control over the volume of medicine that is to be injected into the patient. Multiple injection capabilities will allow for the administration of fluid successively or simultaneously. This feature allows the administrator to control and change the injection process at any given time during the procedure should they require making a change in the order or volume of injections. Furthermore, the device will feature an ergonomic design conducive to one-handed use, allowing the physician to guide and manipulate the needle comfortably while visualizing the procedure with an ultrasound probe operated by their other hand.

The Approach Section for the Technical Topic has not yet been written. It will be added upon completion.

STS Topic

In 2019, it was estimated that over one hundred different global sports franchises were valued at more than one billion dollars (*Major Sports Leagues All Make a Lot of Money, Here's How They Do It*, 2019). These franchises are highly valued as a result of the entertainment that they provide to fans. The signing of elite athletes to these teams provides the ability to grow and develop their fanbase; it becomes evident that keeping these superstars on the field will maximize their revenue. In order to ensure this, athletes must remain healthy, demonstrating a reliance on sports medicine. I plan to explore whether this infiltration of money into the sports world resulted in sports medicine evolving, or are these two actors unrelated and just a result of a natural cycle.

Advancement of Sports Medicine

Over the course of the last decade, the field of sports medicine has increased significantly. It is reported that the members of the American Medical Society for Sports Medicine (AMSSM) have tripled in size. Asif (2018) states that "the growth in our specialty… which has been targeted to be the premier educational venue for the sports medicine physician." The desire to enhance medical knowledge as well as the increase in sports medicine physicians demonstrates the advancement of the field of sports medicine. This evolution has provided a better understanding in diagnosing and treating athletes' injuries, as well as injury prevention, thus allowing for more efficient treatments and faster recoveries.

Ethics in Sports Medicine and the Associated Actor Network

Testoni (2013) introduces the concept of ethics in sports medicines with respect to the conflict of interests between groups. Within sports organizations, there exists a struggle between the decision's players, coaches, owners, and team physicians make with respect to the team.

Team physicians have an obligation to serving the athletes as well as remaining loyal to their employer. The obligations of the team physicians provide an ethical issue within the field as they must decide to better serve the player's individual needs or the team (Testoni et al., 2013). The discussion of who should decide a player's availability to play becomes increasingly difficult to make when considering the athlete's health, and the organization's revenue and fanbase. Calandrillo (2005) further expands on this ethical conflict by discussing the relationship between coaches, players and medical physicians; he exemplifies this by using a former team physician's story discussing "who should remain within the team and who is expendable." This comes to question the ethics involved within sports medicine and a player's value to an organization. Ultimately, it's the decisions made by these parties that provide a struggle in the politics that either best serve the team or the players. Tom Coughlin, former National Football League coach, is reported saying that he would willingly "exert as much pressure on the player and the doctors to get the player [back] on the field," (Calandrillo, 2005). Testoni and Calandrillo both present conflicts within the sports medicine field, using the claims of power and competing priorities within organizations to demonstrate these ethical issues.

Sismondo (2010) presents Actor Network Theory (ANT) as an approach to social theory where everything's relationship with one another forms a dynamic network. Actors within these networks are defined as any human or object that has some form of association with one another. It is these associations that provide a framework to uncover the influence of actors in a network and further investigate how their own self-interest can drive change in this interaction network (Sismondo, 2010). ANT will provide the ability in exploring the actors within the sports medicine field. Dunn (2007) identifies advertising and emerging technologies as other actors within the sports medicine network. Physicians will consult and advertise biomedical companies'

products, and treat their athletes with these products as they can gain a share of the profit from the company (Dunn et al., 2007). This brings technology/treatment options, medical sales, and biomedical companies into the network, further complicating the relationship between physician, player, and organization.

Sismondo's ANT concept of a dynamic and shifting network of actors will provide an explanation for the rise of innovation in sports medicine and the role in which money has affected it. This network will allow for the exploration of the political economy between players, teams, and sports medicine. Analysis of the cause of sports medicine innovation will determine whether it is a result of money infiltration into sports, or rather just the natural cycle of medical practices. It's evident that a conflict exists within organizations as every actor is acting in self-interest, thus resulting in a continuously changing network.

Next Steps

It has become evident that sports medicine has evolved in the last decade and that value is the primary motive for sports organizations. I plan to investigate the revenue streams for these organizations and how they invest their money; additionally, analyzing player contracts, their associated clauses and performance bonuses. Further exploration of the ethics in physician decision making will provide evidence in treatment practices and question how money has affected these decisions. The network that which these actors affect will provide evidence on how the infiltration of money has evolved sports medicine.

References

Asif, I. M. (2018). Celebrating the Advancement of Science in Sports Medicine: A 10-Year Collaboration Between Sports Health and the AMSSM. *Sports Health*, *10*(2), 110–112. https://doi.org/10.1177/1941738118756067

Calandrillo, S. P. (2005). Sports Medicine Conflicts: Team Physicians vs. Athlete-Patients Symposium. *Saint Louis University Law Journal*, *50*(1), 185–210.

Dunn, W. R., George, M. S., Churchill, L., & Spindler, K. P. (2007). Ethics in Sports Medicine. *The American Journal of Sports Medicine*, *35*(5), 840–844. https://doi.org/10.1177/0363546506295177

Kent, J. Personal Interview. (13 October, 2020).

Kozam. G., Romanelli, P. (1983). *U.S. Patent No. 4,367,737.* Washington, DC: U.S. Patent and Trademark Office.

Major sports leagues all make a lot of money, here's how they do it: (2019, March 7). Global Sport Matters. https://globalsportmatters.com/business/2019/03/07/tv-is-biggest-driver-in-global-sport-league-revenue/

Park, H. (n.d.). *(76) Inventors: George Kozam, Tenafly; Pat*. 7.

Pizzino, J. L. (1986). *U.S. Patent No. 4,610,666.* Washington, DC: U.S. Patent and Trademark Office.

Sismondo, S. (2010). *An introduction to science and technology studies* (2nd ed). Wiley-Blackwell.

Stephens, M. B., Beutler, A., & O'Connor, F. G. (2008). Musculoskeletal Injections: A Review of the Evidence. *American Family Physician*, *78*(8), 971–976.

Testoni, D., Hornik, C. P., Smith, P. B., Benjamin, D. K., & McKinney, R. E. (2013). Sports Medicine and Ethics. *The American Journal of Bioethics : AJOB*, *13*(10), 4–12. https://doi.org/10.1080/15265161.2013.828114

United States Bone and Joint Initiative: The Burden of Musculoskeletal Diseases in the United States (BMUS), Third Edition, 2014. Rosemont, IL. Available at http://www.boneandjointburden.org. Accessed on (Oct. 19, 2020).

Wittich, C. M., Ficalora, R. D., Mason, T. G., & Beckman, T. J. (2009). Musculoskeletal Injection. *Mayo Clinic Proceedings*, *84*(9), 831–837.