Dual Injection Syringe for Ultrasound-Guided Musculoskeletal Injections
(Technical Paper)

The Triple Helix Model of Innovation and its Impact on Academic Entrepreneurship
(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

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Fall, 2020

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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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Prospectus

Double Barrel Syringe for Ultrasound Guided Musculoskeletal Injections
(Technical Topic)

The Triple Helix of Academia and its Impact on Academic Entrepreneurship
(STS Topic)

By

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November 5, 2020

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Introduction

Musculoskeletal injections guided by ultrasound are arduous procedures to administer and undergo because multiple syringes are needed to complete them, physicians can only use one hand to perform them, and patients experience discomfort at the injection site. My capstone project seeks to mitigate these effects by creating a double-barreled syringe that gives the physician full autonomy in both aspiration and injection which can be used with one hand while increasing patient comfort. My capstone advisor Dr. Jeremy Kent had mentioned that if he and my capstone group cannot obtain a patent for this device, he might want to just distribute it on a small scale with his peers. When he shared this, it made me think about what options and resources are available to those in academia that look to distribute individual pieces of innovation for non-commercial use. Building on this question, my STS research incorporates literature on academic entrepreneurship and "triple helix" models of relations between the government, academia, and industry. This research is established to understand programs that both advance and discourage academia-based innovation and commercialization.

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.[1] 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.

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.[2] 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%).[3] 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 Wittek notes, "musculoskeletal problems are common in primary care and often respond to injections containing both corticosteroids and short-acting anesthetics."[3] For use in sports medicine, the average age of patients is about 20 years old with the common cause of injury being overuse.[4] However, the majority of these injections are performed in family medicine and are applied to patients between the ages of 40 and 60.[4] 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).[4] 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.[5] 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.[6] 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.[7] 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.

STS Topic

Introduction

The interrelatedness between academic innovation, the government, and the economy has been well documented for decades. All three of these entities have been shown to shape the others, and their interactions can be best described by the Triple Helix Model of Innovation. Generally, government policy has been known to put in place laws and policies to incentivize university-based innovation, which in turn affects the overall economy. While that has been established in many studies, further investigation is needed to determine how academic entrepreneurs pursue or bypass commercialization of their innovative research.

Background

Currently, there are numerous examples of how science and technology fueled innovation is limited or advanced by government driven policy. For example, a cohort of 166 individual studies outline the initiatives in place for ventures in academic entrepreneurship (Sandström, et al., 2018). On the one hand, there are many incentives in place to encourage academic entrepreneurship (AE) fueled by government policy with intentions of economic stimulation. These incentives allow certain stakeholders and entrepreneurs to facilitate their ideas into tangible innovation to be subjected to market pressure. Such a scenario is produced when policy provides a startup for entrepreneurship and the overall interests and capabilities of researchers align with the goal of the incentive, as shown in Figure 1.

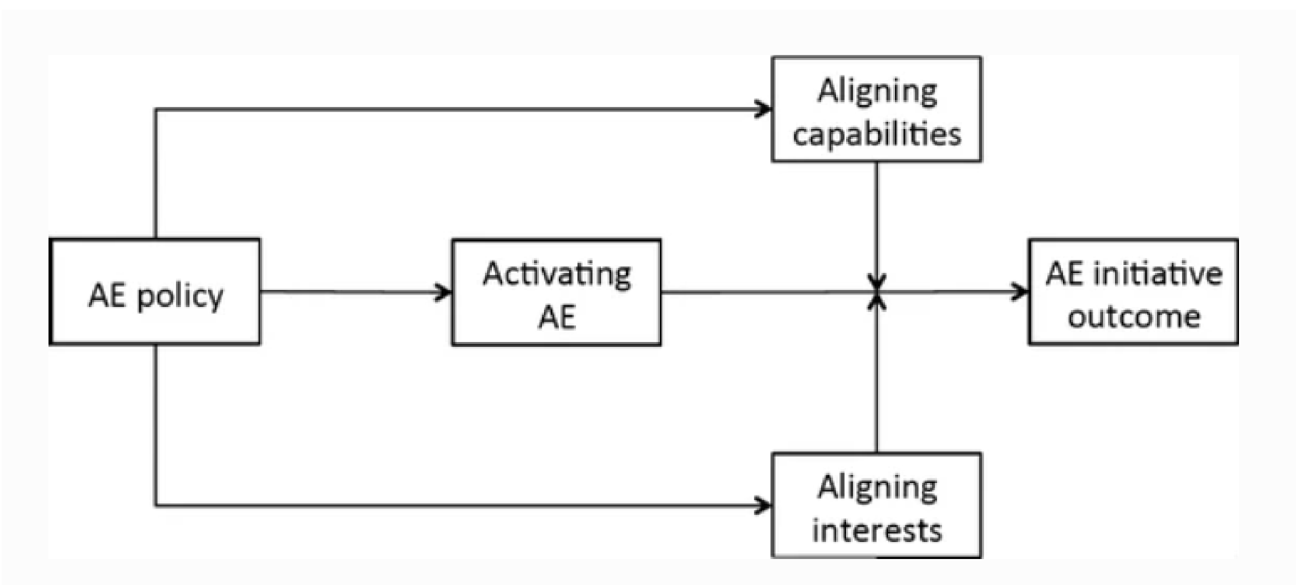

Figure 1. Model for effective Academic Entrepreneurship (AE) incentives

Alternatively, Sandström also notes that there are very few environments built to truly take advantage of these incentives and endure long term. For these initiatives to be most effective, researchers and their partners must be aligned with the intention of the incentive itself. However, oftentimes researchers in academia choose to remain focused on publishing papers, teaching, and conducting other research outside of their AE ventures. This conflict of interest can result in lower levels of productivity and could eliminate the possibility of commercialization, rendering the incentive ineffective. In fact, due to the instability around current initiatives, this study goes on to suggest that there could be alternative ways to facilitate the transfer of academic invention into societal goods and services.

Like lackluster incentives, as explained by Forsberg et al. (2018), the patent system presents its own obstacles to the academic community when attempting to foster academic innovation. For instance, there have been ethically based restrictions incorporated into patent legislation when regulating research in the field of biotechnology. These restrictions are in contrast to the ideals of the academic community, which tends to advocate for a more "open science" approach to promote discovery and innovation. This divide can lead to academic innovation being halted before it even has the chance to start. This friction has even prompted policy to be written in a confusing or misleading fashion, to further spite the academic community. This schism between the patent system and the academic community exemplifies another possible hurdle for academic entrepreneurs to jump, hindering the opportunity for their innovations to be funded and ultimately commercialized.

Framework

The Triple Helix Model of Innovation highlights the overarching relationships between academia, the government, and the economy. Since the 1960s, there has been international debate regarding how large of a role colleges and universities should take in the transfer of knowledge and generation of technology for the greater society (Etzkowitz & Leydesdorff, 2000). Some looked to the current system to quantify overall “market pull” or “technology push” in order to define such roles, but the current system at the time was deemed insufficient to adequately incorporate these parameters. It has been noted that academic publications and patents on marketable technology are produced from vastly different systems. In the United States, various programs were created to close this gap and incorporate both industry and academia via public policy. A powerful subset of these programs includes: Small Business Innovation Research program (SBIR) and the Small Business Technology Transfer Program (STTR), the Advanced Technology Program (ATP), and the Engineering Research Centers of the National Science Foundation (Etzkowitz & Leydesdorff, 2000).

Additionally, many ventures in science and technology have been seen as a valuable cog in the economy and have been thought to improve economic outcomes (Berman, 2014). For example, the America COMPETES Act of 2007 and a similar bill passed in 2010 were signed into law in order to “increase the economic competitiveness of the United States” and to “[develop] a globally competitive STEM workforce” (Berman, 2014). Yet, Berman points out that there is no sound evidence that the programs these policies create and the subsequent funding into them correlate to economic growth. In fact, this move towards economization of research and innovation can come at the expense of acquiring crucial knowledge, solving critical problems, and other societal benefits. The overall efficacy of these policies calls into question the efficacy of the Triple Helix Model itself.

Alternatively, rather than creating policies to make academic innovation more available and incentivized, some have argued to change the way that innovation is governed via the patent system. Parthasarathy (2020) argues that both patents and intellectual property should be more regularly subjected to political and policy-based discussion. By more closely controlling IP and policies that exist to regulate it, it is believed that innovation and discovery could be made optimal for societal benefit. Allowing researchers and academic entrepreneurs to more freely explore ways to contribute to the greater good could allow innovation to flourish. This can be accomplished through a refurbishment of the patent system which would eliminate systemic barriers to discovery, and possibly even benefit the economy.

Scope

Further research into the Triple Helix Model of Innovation and how it applies to academic entrepreneurs is needed to understand the impact it has on overall academic innovation. An investigation will take place to see how each helix ultimately enables or discourages academic innovation. It could be found that innovation is degraded because there is too much of a focus on commercialization and not enough on pure ideas to help others. On the other hand, marketability could be seen as a driving factor for innovation and motivate more researchers and professors to pursue such solutions. Both a deeper dive into existing literature and conducting interviews with essential stakeholders could shed light on this situation. For example, known academic entrepreneurs seeking to further their field of work via innovation could provide valuable insight into the current system. This could point towards these stakeholders leaving the Triple Helix network and collaborating with a third-party group to carry out business. Additionally, research into organizations, such as the Michigan State University Bioeconomy Institute, that serve as an example of larger bodies that help facilitate academic innovation into marketable products, will be conducted. Furthermore, the options presented towards academic inventors are more motivated to help others, rather than those looking to commercialize, will be explored: mainly, whether or not the same funding and encouragement would be provided.

Next Steps

- What US institutions do a good job of turning innovation into tangible goods and services (MSUBI)?
    - Is there something to learn/could be applied to the Triple Helix?
- Maybe look at academic innovation outside of United States?
    - European endeavors in academic entrepreneurship and how the EU is involved
        - Compare and contrast
            - If they do it "better" is there something to learn?
                - Could people be pushed to invest or innovate overseas to escape the current system?
- Are there alternative ways to share innovation outside of the patent system?
    - Is it more beneficial or detrimental to circumvent the patent system?
- What happens if you don't want to commercialize?
    - Is funding revoked or discouraged?
    - Are you pushed to seek commercialization anyway?

References

1. Stephens, M. B., Beutler, A. & O'Connor, F. G. Musculoskeletal Injections: A Review of the Evidence. *AFP* **78**, 971–976 (2008).D
2. The Burden of Musculoskeletal Diseases in the United States (BMUS) 3rd Edition (Dated 12.31.16).Pdf.D
3. Wittich, C. M.; Ficalora, R. D.; Mason, T. G.; Beckman, T. J. Musculoskeletal Injection. *Mayo Clin Proc* **2009**, *84* (9), 831–837.D
4. Kent, J. Personal Interview. (13 October, 2020).
5. Pizzino, J. L. (1986). U.S. Patent No. 4,610,666. Washington, DC: U.S. Patent and Trademark Office.
6. Kozam, G. (1978). U.S. Patent No. 4,109,653. Washington, DC: U.S. Patent and Trademark Office.
7. Kozam, G. (1983). U.S. Patent No. 4,367,737. Washington, DC: U.S. Patent and Trademark Office.
8. Sandström, C., Wennberg, K., Wallin, M. W., & Zherlygina, Y. (2018). Public policy for academic entrepreneurship initiatives: A review and critical discussion. *The Journal of Technology Transfer*, *43*(5), 1232–1256. https://doi.org/10.1007/s10961-016-9536-x
9. Forsberg, E.-M., Hanssen, A. B., Nielsen, H. M., & Olesen, I. (2018). Patent Ethics: The Misalignment of Views Between the Patent System and the Wider Society. *Science and Engineering Ethics*, *24*(5), 1551–1576. https://doi.org/10.1007/s11948-017-9956-5
10. Etzkowitz, H., & Leydesdorff, L. (2000). The dynamics of innovation: From National Systems and "Mode 2" to a Triple Helix of university–industry–

government relations. *Research Policy*, *29*(2), 109–123. https://doi.org/10.1016/S0048-7333(99)00055-4

11. Berman, E. P. (2014). Not Just Neoliberalism: Economization in US Science and Technology Policy. *Science, Technology, & Human Values*, *39*(3), 397–431. https://doi.org/10.1177/0162243913509123

12. Parthasarathy, S. (2020). Approaching intellectual property scholarship differently: A qualitative research review and agenda. *Science and Public Policy*. https://doi.org/10.1093/scipol/scaa010