Optimizing Current Delivery Methods of a Male Nonhormonal Contraceptive in the Form of a Hydrogel

(Technical Paper)

Gender Inequality in Reproductive Health and the Prolonged Development of Male Contraception

(STS Paper)

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Veda Raghu

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Technical Project Team Members

Abby Rieck

Abigail Myers

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Capstone Advisor: Timothy Allen, Ph.D., Department of Biomedical Engineering
STS Advisor: Richard D. Jacques, Ph.D., Department of Engineering & Society

General Research Problem

Due to recent changes in the political climate due to the overturning of Roe v. Wade, the discussion regarding potential options for male contraceptives has been rampant. Currently, there are numerous options on the market for female contraceptives, including many hormonal pills, as well as long-acting reversible contraceptives(LARCs). However, the only approved male contraceptive is sterilization. Though vasectomies are advertised as reversible, the rate of reversibility is relatively low, only 44% pregnancy rate 15 years after reversal(Patel & Smith, 2016). The surgical procedure for reversing vasectomies is very technical in nature, and only a minority of urologists are willing to perform(Patel & Smith, 2016). This operation is not covered by insurance as well, which poses a financial burden on the patient if they wish to conceive. Because of the risk of permanent sterilization, most parties opt to rely on the various methods of female contraceptives, which forces women to bear the burden of both pregnancy and contraceptive devices.

Contraline is a startup in Charlottesville that is currently developing a non-hormonal LARC. As the contraceptive device is non-hormonal, it provides birth control without carrying the physical and mental risks that many female contraceptive options carry. Contraline is currently developing Adam^{TM}, an injectable hydrogel that is designed to be reversed via a chemical dissolvent(*Contraline*, n.d.). It is marketed as being highly convenient and may prove to be the method of choice by couples around the world. Adam^{TM} is injected into the male reproductive system inside the vas deferens and induces a state of azoospermia in the body(*Contraline*, n.d.). Azoospermia is a condition in which the ejaculate contains no sperm(*Azoospermia (Sperm Production)*, n.d.). This prevents the conception of any children and therefore provides a valuable means for pregnancy prevention.

My technical topic will focus on working with Contraline to develop an in vitro model of the vas deferens to mimic the in vivo delivery of the non-hormonal contraceptive in the form of a hydrogel. The model will then be used to develop a device to identify the precise delivery of the hydrogel into the lumen of the vas deferens. My STS research will focus primarily on the gender inequity surrounding reproductive health.

Optimizing Current Delivery Methods of a Male Nonhormonal Contraceptive in the Form of a Hydrogel

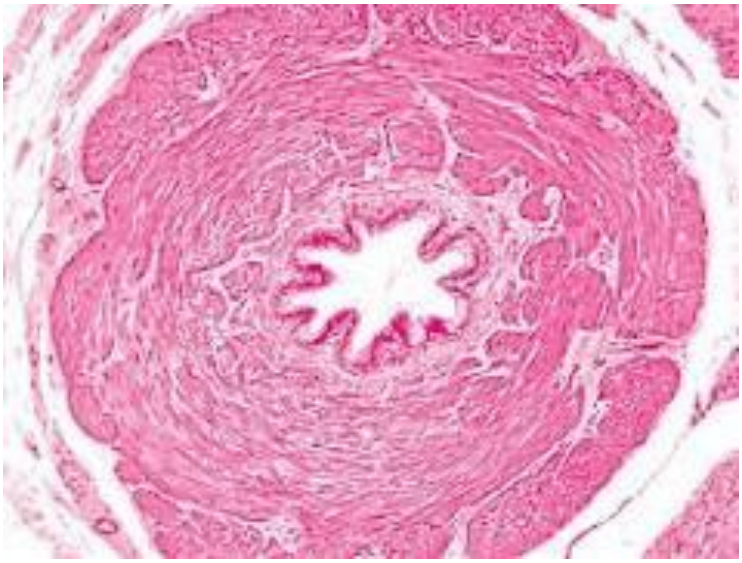
Numerous companies have attempted to develop methods for male contraception, including hormonal and non-hormonal methods. Contraline has developed an injectable hydrogel that acts as a physical barrier in the vas deferens that inhibits sperm from traveling through the male reproductive tract. This device allows the body to reach a state of azoospermia, as it provides similar results to vasectomies without needing as invasive of a procedure. A vasectomy requires manually cutting the vas deferens located in the scrotum. This procedure is conducted by isolating both vas deferentia from the spermatic cord in the scrotum, and then cutting and cauterizing both(Stormont & Deibert, 2022). The injectable hydrogel follows a similar methodology, however, instead of cutting and cauterizing, the vas deferens is cannulated using a catheter, and the hydrogel is injected into the lumen.

Contraline currently uses a model of the vas deferens for testing that is simply composed of silicone tubing. This results in highly inaccurate results of cannulation as it does not accurately model in vivo delivery of the implant. The first phase of my Capstone project revolves around developing a mechanically accurate in vitro model of the vas deferens to accurately mimic in vivo implantation. This requires a working knowledge of different materials as well as

using 3D modeling and printing. Information on modeling the male reproductive system is not widely available as more money has been invested in research on the female reproductive

e system. Therefore, trial and error will be required to identify the mechanical accuracy of our system. This will require histology analysis as well as, tensile strength and strain analysis.

Figure 1: Histology of the Vas Deferens



This figure shows a histology slide of a cross-section of the vas deferens. The lumen is shown in the center, as compared the vessel wall(*Histology at SIU*, n.d.).

The anatomy of the vas deferens is incredibly unique. It differs from many other anatomical tubes as it has a large ratio of wall thickness to the lumen. As shown in the histology slide in Figure 1, the vas deferens does not take the form of normal tubing, it is highly unsymmetrical. The efficacy of the hydrogel is reliant on the ability to accurately deliver the hydrogel into the lumen of the vas, which is challenging as the lumen is incredibly insignificant in terms of size(see Figure 1). As the lumen is indistinguishable through current delivery methods, it can be difficult for urologists to identify whether they have successfully inserted the

catheter. Therefore, the development of an accurate model of the vas deferens is essential to progress the development of current delivery methods.

The second phase of my Capstone project involves using the anatomically accurate model we created in the first phase to develop a device or method to ascertain that the hydrogel has been successfully delivered. This requires a working knowledge of the current device used for implantation. Due to the nature of the delivery system, it is essential that the device developed is easily reproduced, is cost-efficient, and allows urologists to maintain motor control of the cannulation device as well. As my project is being led by a company, my technical advisor is Timothy Allen, the current Capstone professor.

Gender Inequality in Reproductive Health and the Prolonged Development of Male Contraception

The inequality in reproductive health has become exceedingly prominent as the overturning of Roe v. Wade has altered the current perception of contraceptives. As of 2019, there are 922 million women of reproductive age who use some form of contraception(United Nations, 2019). This includes short-term contraceptives, such as male or female condoms, and long-acting methods, such as sterilization and any form of intrauterine devices(IUD) or implants. Women bear the burden of reproductive health, as 43.2% of individuals who use contraceptives are on long-acting methods, and only 2% of this demographic are men(United Nations, 2019). Male sterilization is the only long-acting method of contraception available on the market. This social inequality promotes the construction of the feminine identity, revolving around motherhood. The lack of investment in male contraceptive methods has proved to have social

impacts on the social, economic, and cultural circumstances regarding reproductive health(Szasz, 1993)

Societal norms have an incredible amount of power over the thoughts and behaviors of individuals. Due to the idea that women are responsible for contraceptives as well as the upbringing of children, the idea that men may maintain extramarital sexual activity is tolerated, whereas, women must repress their sexual needs and desires for fear they may conceive(Szasz, 1993). The exclusive focus on female contraceptive technology has forced the idea that women must be responsible for the consequences of sexual acts(Szasz, 1993). This enforcement of societal standards has also led to a power imbalance, as women are more vulnerable to violence and sexually transmitted diseases. As abortion rights are being severely limited in various states, this has perpetuated the fear of childbirth in women who are unmarried or unprepared for bearing children. The financial and social burden of children falls directly on many single mothers. The lack of contraceptive methods in the market has a direct impact on the well-being of women around the world.

Women are the primary consumers of contraceptives available on the market. However, there is a growing desire for the development of male contraceptives. Although many pharmaceutical companies have no interest in developing such technologies due to profitability assessments, it is evident that male interest and responsibility in family planning are growing. More than 500,000 vasectomies are performed annually in the United States, which shows that men are interested in contraception(Wallach et al., 1977). Women are not alone in their inclination to limit family sizes. Approximately 90% of men feel that family planning services should be more available(Wallach et al., 1977). In a recent survey, 70% of men responded positively toward using a potential male contraceptive if it were available and

inexpensive(Wallach et al., 1977). The development of female contraceptive methods and the always ultimately the main reason why male contraception wasn't pursued. As rates of interest in male contraceptive technology are increasing, the development of such methods is promising. Most female contraceptive methods are hormonal, and this poses a great risk to individuals as they may have a variety of psychological and physical effects(Wallach et al., 1977). The development of a male non-hormonal contraceptive device may solve this problem by reducing the need for female contraceptives. This may also allow for a change in public perception of reproductive health and parenthood.

Nearly half of the pregnancies in the United States are unintended(Murdoch & Goldberg, 2014). There are no safe and fully reversible methods of contraceptives available for men(Murdoch & Goldberg, 2014). Women are now suffering from the lack of abortion and contraceptive access, which leads to a growing need for male contraception. By reducing the availability of abortion and contraceptive access, women are at risk. Unplanned pregnancies are incredibly common, and the societal norms exacted on women force them to suffer the dire consequences, emotionally and financially, of having children.

Conclusion

The impact of gender inequality in the field of reproductive health has many implications for the social well-being of women. As female contraceptive methods have dominated the market, there has been little progress in the development of male contraceptive methods. This forces women to bear the burden of reproductive health and employs a cultural norm that women are responsible for the prevention of unplanned pregnancies. The proposed project aims to assist

with the development of a non-hormonal long-acting male contraceptive to mitigate this disparity in contraceptive method options.

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