Redesigning and Prototyping Microscissors for Autologous Breast Reconstruction Surgery

Investigating the Source of the Public Funding Gap in Women's Health
(STS Project)

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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:

Throughout many parts of history gender gaps have existed, in wages, in leadership, in education, in healthcare, all based on the archaic social construct of women being the "lesser" gender. This dates back to the third century BCE Greece, when women were "medically defined as faulty, defective, deficient" due to their anatomical and biological differences from men (*Medical Myths About Gender Roles Go Back to Ancient Greece. Women are Still Paying the Price Today*, 2021). Considering that we are now in the 21st century, almost 2800 years later, it is surprising that these gaps related to gender still exist. Yet they do and specifically, the gaps that exist in research regarding women's health and the funding for women's health remain a large problem.

It wasn't until 1993 that the National Institute of Health began to accept women and other minorities in clinical and research studies (*History of Women's Participation in Clinical Research*, n.d.). Any woman with child-bearing capabilities had previously been excluded due to the risk of potential unknown effects on a woman's ability to have a child. This exclusion criteria contributed to years of missing research in many diseases - not just those exclusive to women. In 2022, the NIH spent $45 billion on biomedical research (Smith, 2023). An applied mathematician, Dr. Arthur Mirin, conducted a study on the distribution of funding based on the classification of diseases by the NIH after his daughter was diagnosed with chronic fatigue syndrome (ME/CFS). He was inspired to look further into this when he learned that (ME/CFS) is a female-dominant disease, yet severely underfunded. Mirin used the number of years of healthy life that are lost from disability, disease, and premature death to determine the burden of the disease on a patient. Mirin determined that the ratio of burden to funding for ME/CFS is 0.04

compared to that of HIV/AIDS being 15.6 (Smith, 2023). He discovered that this is a common trend among diseases that disproportionately affect women.

Women's health funding isn't the only subject that needs improving. Microscissors are important surgical tools for any surgery involving reconstruction with a patient's own tissue. In this case specifically, they are used to create a clean cut in veins attached to tissues that are to be used for breast reconstruction after mastectomy. This clean cut is especially important to prevent thrombosis of the anastomosis. When the diameter of the venous anastomosis is less than 2.5mm in diameter, research has shown that patients have a much higher risk of vein thrombosis which leads to loss of the tissue used for breast reconstruction. Breast reconstruction failure is traumatic for patients and surgeon alike and increases health care costs for both hospitals and patients. Microinstruments like micro-scissors play a vital part in these technically challenging cases.

The goal of this technical project is to redesign microscissors that are easy for surgical use and increase vein circumference to allow larger diameter vein anastomosis to improve surgical outcomes and reconstructive success. In addition, I will examine the STS question: why is it so difficult for research focusing on women's health to obtain the public and federal funding it needs close this existent gender deficit?

Technical Topic:

From a database of breast cancer patients who underwent mastectomy immediately following breast reconstruction between the years 2009 to 2016, over 16% of women had an autologous procedure (Berlin et al., 2020). An autologous procedure involves attaching a harvested tissue flap to rebuild the breast shape. It typically costs over $29,226 and is often chosen due to a 23% decreased likelihood of infection post-operation (Sawyer et al., 2022).

However, thrombosis or blot clotting from poor attachment of veins is the main cause of a failed autologous reconstruction and results in skin or flap necrosis (Nikolis et al. 2003). Necrosis from thrombosis occurs when the blood supply to the newly attached skin flap is no longer secure and the tissue does not receive the oxygen it needs to survive, leading to loss of the harvested tissue.

Microscissors are important surgical tools for any surgery involving reconstruction with a patient's own tissue by creating a clean, precise cut in veins attached to harvested tissue. When the edge of the venous anastomosis is ragged due to dull scissor blades and the vein diameter is less than 2.5mm, surgical precision decreases and research has shown that patients have a much higher risk of thrombosis. Therefore, the goal of this project is to redesign and prototype microscissors to have a blade that indicates when it is no longer sharp to ensure durability and maximize usable tissue around the vein circumference in its cut. By testing the efficacy of the modifications in each prototype, the final design will improve cutting and therefore reconstructive success.

We plan to meet this goal by achieving two specific aims: Aim 1, research prior art and literature and develop a prototype of a microscissor that is both durable and creates a clean-cut using CAD software. Aim 2, Test the efficacy of microscissor prototypes through Finite Element analysis (FEA) and conduct experimental trials to assess durability and precision of the cut. Aim 1 will be completed in three steps. First, we will research literature to understand the key components of the microscissor and how previous microscissors were constructed. Researching literature can also influence the design process to discover where areas of error may lie and how design improvements can be made. Second, we will use the information collected from literature research to CAD in Auto360/SolidWorks a microscissor prototype that uses materials that are biocompatible, durable, sterile and comfortable for the user. Lastly, we are printing a prototype

using a 3D printer and assembling the printed pieces using a pivot screw in order to evaluate the preliminary size and movement of the redesigned blade and scissor shaft.

Aim 2 is to be completed in two main steps. First, we will conduct FEA in Autodesk Fusion 360/SolidWorks with Titanium and other biocompatible metals in order to figure out which metal has the best durability and strength under tensile and compressive stresses felt by scissors when cutting into tissue. The most promising designs will then be constructed using metal from the results of the 3D printed prototypes and FEA. We will then conduct trials with multiple criteria such as ease of use, ease of manufacturing, clean cleaving of vein, surface area of usable tissue around vein circumference, and diameter size of vein once cleaved. The prototype will first be tested on tubing similar to the vein diameter sizes, and then tested on cadaverous veins provided by our advisor, Dr. Chris Campbell. The cleaved vein will be observed under a microscope to measure the amplitude of the microscopic ridges in the tissue after cutting using ImageJ. The closer the amplitude is to zero, the cleaner the cut of the blade is. The prototype that is tested will be evaluated after trial to assess how many repetitions the blade can withstand before passing marginal durability parameters.

By redesigning the blade and shaft of the microscissors used by surgeons in anastomosis procedures, we expect not only surgeon precision to be improved but vein diameter to be increased. By improving both of these factors, we believe this redesigned surgical tool can be used to improve surgical outcome and patient happiness not just in breast reconstructive procedures but any surgical operation that requires the use of microscissors.

STS Topic:

While surgical outcome and patient happiness can be improved through the redesign of a surgical tool, there are larger systematic issues that lie in the healthcare industry that have a downstream effect on innovations in surgery and healthcare. An article in *Nature*, a multidisciplinary scientific journal, comments on the universal lack of funding in women's health related research stating that, "funding for many conditions that exclusively or disproportionately affect women is lower than for those affecting men" ("Women's Health: End the Disparity in Funding", 2023). But what is the cause of this missing funding? More specifically, why is it so difficult for research focusing on women's health to obtain the public and federal funding it needs in order to close this gender deficit? By using this article as a starting point, I will expand upon this topic and argue that the answer to this question lies in three main points: the organization and management of funds within the National Institutes of Health (NIH) and other similar organizations, the existence of gender bias that persists in healthcare, and the classification of what is considered a "men's" health issue versus a "women's".

The NIH funding taxonomy doesn't classify women's health research in a way that allows researchers to access the information they need for grant funding or research. Researchers are then burdened with the daunting task of reading every grant that mentions the disease they're researching and manually add the numbers ("Women's Health: End the Disparity in Funding", 2023). In addition, of the people diseases such as autoimmune disorders affect, 80% of the population of patients are women, yet the funding distribution does not reflect this need for research ("It's about Time to Focus on Women's Health," 2023).

As stated above, gender bias within healthcare is still a large issue and contributes to the difficulty in obtaining women's health funding. Women coming into hospitals and eventually being diagnosed with non-communicable diseases (NCDs) like heart disease and cancer are often treated very differently by clinicians. A study was conducted, examining the interactions between clinicians and women with undiagnosed coronary heart disease that proved that women are asked fewer questions, receive fewer examinations and have fewer diagnostic tests ordered compared to men (Bonita & Beaglehole, 2014). Treatment of NCDs in women is not prioritized as highly as they are in men as determined by this study. This gender bias appears in funding allocations as the NCDs that disproportionately affect women and are neglected by clinicians are the same NCDs as those ignored in research.

Lastly, there exists an unconscious classification system in healthcare which causes certain diseases to be misclassified as a disease that affects "everyone" when there is a disproportionate effect on a certain population. Diseases such as breast cancer or osteoporosis are misclassified as women's health diseases and are therefore understudied and underfunded in men (Bird, 2022). Diseases such as migraines, which disproportionately affect women, are generally thought to affect both men and women equally. The effects and symptoms of migraines in women, which differ when compared to men, are therefore not prioritized in research. Most research focuses on the general symptoms found between men and women instead of focusing on the highly affected (Smith, 2023).

To help prove these three points, I will draw on Feminist STS theory to gain a better understanding of the social factors and implication of this topic. One of the basic tenets of Feminist STS is that due to the gendered differences in society and technology, we give different functions and purposes to society and technology separated purely on the basis of gender. The

healthcare system and how it allocates public funding is a very concrete system. Feminist STS theory will be used to examine how this system creates a women's health funding disparity at its foundation as examining this issue only at its surface is "contenting ourselves to simply patch existing failures" (Hicks, 2021).

In addition to taking points from Feminist STS, in order to determine the root cause of this shortcoming in women's health funding I will analyze case studies that have been conducted on the methods of funding by NIH and other similar institutions. By diving deeper into *Nature*'s article highlighting the disparity in women's health funding, I will investigate where these deficits originate and what continues their existence. I also plan to conduct interviews with researchers and activists in organizations such as "Women's Health Access Matters" (or WHAM for short) who advocate for equal funding and research of diseases that disproportionately affect women (*WHAM*, n.d.).

Conclusion:

In my technical project I will be working to redesign and prototype microscissors to have a blade that indicates when it is no longer sharp to ensure durability and maximize usable tissue around the vein circumference in its cut. In my STS research, I will investigate the source of the gap in public funding of women's health research. Women's health is an issue that affects everyone, not just women. By investigating the cause of the lack of public funding for women's health, I hope to raise awareness of this issue as well as highlight where systematic change should and needs to occur. In addition, by redesigning microscissors, I will aid in optimizing a surgical tool vital to not just breast reconstruction surgery, but any surgery that involves the cutting and reconfiguration of vascular tissue.

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