THESIS PROJECT PORTFOLIO

Ring Device to Induce Hemostasis

(Technical Report)

The Delayed Diagnosis and Poor Prognosis of Melanoma in People of Color

(STS Research Paper)

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PROSPECTUS Technical Advisor: Dr. William Guilford, Department of Biomedical Engineering STS advisor: Benjamin Laguelli, Department of Engineering and Society How can Americans mitigate the consequences of a skin cancer diagnosis? In the United States, skin cancer is the most commonly diagnosed form of cancer, with an estimated 1 in 5 Americans estimated to develop skin cancer over their lifetime. Mohs Micrographic Surgery (MMS) is the gold standard in removing the two most common skin cancers: basal cell carcinomas and squamous cell carcinomas. When the procedure is performed on areas of the body that are prone to higher levels of bleeding, such as the head or the forearm, the surgeon's ability to control blood flow, also called creating hemostasis, is challenged. A difficulty in achieving hemostasis may induce patient and physician anxiety, frustration, and a compromised surgical experience. Further, it may cause an adverse health event such as increased scarring, postoperative bleeding, and increased risk of hematoma formation. Thus, a need exists for a "hemostatic ring" to create hemostasis during MMS to lessen the burden of excessive bleeding. Melanoma is the deadliest form of skin cancer because of its ability to spread, or metastasize, to other parts of the body.

Although people of color (POC) are less likely to be diagnosed with melanoma, their prognosis is significantly worse than their white counterparts. Despite the introduction of new technologies such as immunotherapies and targeted therapies, the discrepancy in diagnosis and consequent prognosis is only getting worse. The consequences of a melanoma diagnosis are far more severe for POC, warranting a better understanding of this discrepancy in order to mitigate it.

A device that allows for hemostasis surrounding the incision in MMS can allow clinicians to prevent excessive bleeding events. Various hemostatic ring designs were analyzed in Autodesk Fusion 360 and presented to Mohs surgeons in order to select the best design. Two designs were printed in stainless steel using direct metal laser sintering (DMLS). Post-machining processes were necessary to achieve a usable device. The rings of the hemostatic ring were dipped in insulation to ensure compatibility with an electrosurgical pen. The final device was tested on a silicone model of the cheek and forehead with a simulated blood vessel and wound to emulate how it stops blood flow. Applied force values were compared to that of the finite element analysis on Autodesk Fusion. Both final hemostatic rings were able to induce hemostasis in the silicone physical model in the estimated force range (5-15N). Since all proof of concept tests were performed, next steps would be to obtain IRB approval and begin clinical trials.

Actor-network theory (ANT) was used as a framework to analyze the disparity in diagnosis and prognosis for POC. ANT attempts to "open the black box' of science and technology by tracing the complex relationships that exist between governments, technologies, knowledge, texts, money and people." Actors were divided into three categories with various subcategories; Biological actors included melanocytes and anatomical location, socioeconomic actors included melanoma education, access, and income and insurance, cultural actors included clinical trial representation, physician awareness, and patient-physician interactions. Although it is more difficult to diagnose melanoma in POC due to biological actors, socioeconomic and cultural actors exacerbate the discrepancy in care. As the positive feedback loops between biological, socioeconomic, and cultural actors increase, the effects of disparities in any of these categories are compounded. Therefore, instead of tackling the actor that is most prevalent, future work should include minimizing the positive feedback loop that these actors present. Progressive strides in socioeconomic and cultural actor categories must be made.

Together these projects resulted in a better understanding of skin cancer treatment and the associated disparities. The technical project of creating the hemostatic ring was hugely successful in that stainless steel prototypes were made and tested on physical models of the skin. The "trifecta" of proof of concept was achieved by producing a finite element analysis, a physical model analysis, and stainless steel prototypes. Lack of assessment on actual patients

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was a major limitation of this project. Future work should include obtaining IRB approval for a clinical trial so that patients can actually benefit from this device. The socio-technical project of investigating the disparity in melanoma diagnosis and prognosis in POC illuminated weak points in our healthcare system. Socioeconomic and cultural actors were identified as targets for action in the effort to mitigate this disparity. It was also recognized that minimizing one factor helps to minimize others in the network, effectively showing that positive and negative actions have compounded effects. Future work should include identifying and creating actionable items that address the actors in the socioeconomic and cultural contexts. Other actors should be added to the network in order to create a comprehensive depiction of the disparity.

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