ADAPTER FOR THE HOHMANN AND WEITLANER RETRACTORS FOR POSTEROLATERAL ANKLE FRACTURE FIXATION

INTEGRATING SOCIAL AND TECHNICAL DIMENSIONS IN MEDICAL DEVICE INNOVATION: A SOCIAL CONSTRUCTION OF TECHNOLOGY (SCOT) ANALYSIS

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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:

Among the most common injuries that orthopedic trauma surgeons treat are ankle fractures, with an incidence of about 187 per 100,000 people annually (Hermena & Slane, 2024). A standard treatment for displaced and unstable ankle fractures is the open reduction and internal fixation (ORIF) operation, which restores anatomic alignment and stability (Talbot et al., 2005). The posterolateral approach, in which the fracture is accessed through the side and toward the back of the foot, is commonly used for ORIF of ankle fractures involving the fibula and posterior malleolus of the tibia (Schultz et al., 2021).

During the posterolateral approach, the patient's skin, soft tissue, and peroneal muscles are retracted to expose the fracture site. This is accomplished by using hand-held retractors like the Hohmann retractor (for deep tissue retraction) and the Weitlaner retractor (for superficial tissue retraction) (Rouse, 2023; Zhong et al., 2017). However, to increase operational efficiency, surgeons aim to perform such tissue retraction *without* the need of assistants to continually hold retractors in place. Thus, it is necessary to design new technical devices, such as instrument adapters, to address this limitation. To accomplish this goal, I propose the development of a 3D printed adapter to dock the Hohmann retractor onto the Weitlaner retractor, resulting in hands–free tissue retraction and allowing for the surgical team to focus on securing an anatomic reduction and fixation of the fracture (Rouse, 2023).

The development of this adapter necessitates consideration of the interactions between technical and social factors that impact its design and implementation. To gain insight into such factors, I will draw on the Social Construction of Technology (SCOT) framework, developed by scholars Wiebe Bijker, Ronald Kline, and Trevor Pinch, as it provides a valuable lens through which to analyze these interactions (Bijker & Pinch, 1987). By applying this framework to analyze the failure of the modular titanium alloy neck adapter (MTANA) used in hip replacements, I aim to identify potential barriers and facilitators in the development and implementation of the proposed orthopedic adapter, ensuring it meets the needs of its stakeholders (Castagnini et al., 2023; Grupp et al., 2010). Specifically, I will investigate how social and technical factors, like the design of the MTANA, regulatory decisions, and market demands contributed to the device's failure.

Assuming that the proposed adapter for the Hohmann and Weitlaner retractors is isolated from its sociotechnical context comprises the adapter's effectiveness, inevitably lead to the design's failure. Therefore, because the goal of improving surgical efficiency is sociotechnical in nature, it requires attending to both its technical and social aspects to accomplish successfully. In what follows, I set out two related research proposals: a technical proposal for developing an adapter for the Hohmann and Weitlaner retractors and an STS project proposal for examining the interconnections among technical failures, regulatory decisions, and market demands at the time of the MTANA's design failure. This approach will help me develop a strategy that better accounts for the diverse sociotechnical factors necessary for a device's success.

Technical Project Proposal:

In the realm of orthopedic trauma surgery, the posterolateral approach for ORIF of ankle fractures presents a significant technical challenge. This procedure requires precise exposure of the fibula and posterior malleolus (see Figure 1), necessitating the use of retractors to hold back structures such as skin, soft tissue, and peroneal muscles (Mair et al., 2023). Currently, this task demands manual assistance from medical professionals, which can limit surgical efficiency, increase the workload, and impact the quality of the procedure. The development of a 3D-printed adapter that facilitates hands-free retraction of both superficial and deep tissues addresses these challenges.

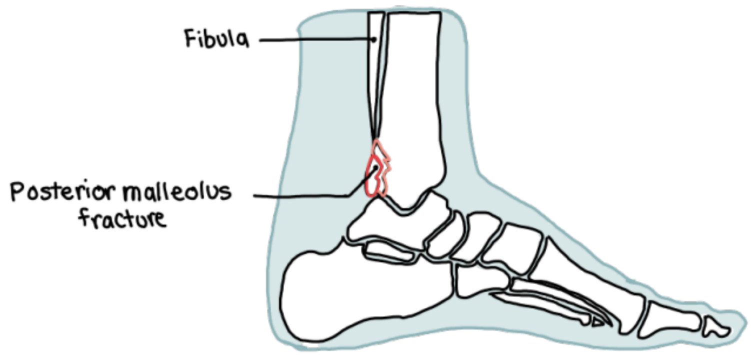

Figure 1. A Lateral View of the Lower Leg and Ankle. The figure displays a posterior malleolus fracture. The fibula is labeled, showing its position above the fracture site. The fracture is located at the back of the tibia, near the ankle joint, and is marked in red to indicate the area of injury.

Existing retractor systems, such as the Dodson Modular Retractor and the Galaxy II Retractor, have attempted to address such challenges, but many limitations continue to exist. The Dodson Modular Retractor offers a customizable modular design that allows surgeons to adjust the angle of retraction according to the surgical site's characteristics (Dodson, 2014). While this kind of retraction can provide flexibility for physicians, it can be cumbersome and time–consuming to set up and adjust during surgery. Similarly, the Galaxy II Retractor features a self-retaining mechanism designed for tissue retraction, reducing the need for manual assistance from surgical staff (Spang, 2023). However, its reliance on a complex system of hooks can pose challenges with ease of use and quick adjustment during surgery. Additionally, the Galaxy II

Retractor may require frequent repositioning and careful handling to avoid issues such as tissue damage or improper retraction(Boese et al., 2022). Moreover, it is important to note that both designs do not integrate with the existing surgical tools (such as the Weitlaner and Hohmann retractors), leading to inefficiencies, requirements for additional training, and even potential compatibility issues in the operating room. Therefore, despite the innovations of these existing approaches, many limitations still exist.

The solution that I am proposing is a 3D–printed adapter designed to connect the Hohmann and Weitlaner retractors, facilitating hands–free tissue retraction. Its design should be adopted by orthopedic surgeons and hospitals because it offers a cost–efficient, and easily integrable solution to the many challenges of surgical exposure and staff allocation during the procedure. By improving retraction capabilities without requiring additional manual assistance, the adapter enhances the overall efficiency of the surgical procedure. Additionally, the adapter's design takes advantage of existing surgical tools, making it an attractive option for surgical teams seeking to optimize their workflow without additional investment in training or new surgical equipment.

The development and refinement of this design will require engineering knowledge, skills in computer-aided design, and 3D–printing technologies. The process will utilize iterative prototyping in order to optimize the adapter's functionality, durability, and compatibility with existing variations of surgical retractors. Important engineering methods for this proposed project include finite element analysis to assess the mechanical performance of the adapter and to ensure that it can withstand the forces exerted on it during surgery.

In order to prove the value of this proposed adapter design, data will be collected through a series of tests and evaluations. This includes quantitative data, such as measurements of assembly time and retraction force during cadaveric studies to assess the adapter's effectiveness in tissue retraction. Additionally, qualitative feedback will be gathered from orthopedic physicians on the adapter's ease of use and integration into the surgical workflow. This feedback will inform design improvements and ensure that the adapter meets the needs of its users. Lastly, material testing will also be conducted so I can evaluate different 3D–printing materials for biocompatibility, sterilization resistance, and mechanical strength. Overall, results from these quantitative and qualitative measurements will ensure that the adapter is safe and durable for use in the surgical environment, ultimately facilitating its adoption during the posterolateral approach to ankle fracture ORIF.

Science, Technology, & Society (STS) Proposal:

The failure of the modular titanium alloy neck adapter (MTANA), used in hip replacements, serves as an important case study that aids in the understanding of the interplay between technical and social factors in medical device development. This study aims to answer the research question: "How did the interaction of technical and social factors contribute to the failure of the MTANA?" By exploring this question, I will aim to gain better insights that can help inform the development of my proposed technical design, ensuring that similar pitfalls are predicted and avoided.

Current discourse on the failure of the MTANA often highlights the technical issues such as material fatigue, fretting, and corrosion at the modular junctions (Pautasso et al., 2023). These technical failures were exacerbated by high mechanical loads and surface contamination, leading to device fractures (Grupp et al., 2010). On the other hand, social perspectives have examined the role of regulatory bodies and market pressures in the premature introduction of these devices, as well as the lack of thorough clinical testing prior to widespread use (Bartley & Lara, 2017). Nevertheless, these perspectives typically treat technical and social factors in isolation, and thus fail to adequately address how these elements interact. Technical literature tends to focus on material science and mechanical failures without considering the social context of a device's use, such as surgeon preferences or patient demographics. In contrast, social analyses may overlook the specific technical challenges that can contribute to a device's failure. Such isolated perspectives can lead to a superficial understanding of the factors that led to the MTANA's failure. This compartmentalization is a significant limitation to the existing analyses.

By continuing to adopt these isolated perspectives, scholars miss the opportunity to develop a more holistic understanding of how technical and social factors interact in the development and implementation of medical devices. This understanding is vital for designing devices that are not just technically sound but also socially viable. By integrating these perspectives, this study will offer a new understanding of the case, emphasizing the importance of considering the sociotechnical context in which medical devices operate.

The main argument in this study is that the failure of the MTANA was not solely due to technical flaws or social pressures, but rather a unique interaction between such factors. I propose that a new understanding of this failure can be achieved by examining how technical problems, like material fatigue and corrosion, were influenced by social factors like regulatory decisions and market demands. This integrated perspective can help guide the development of the proposed adapter for the Hohmann and Weitlaner retractors, ensuring that both technical and social dimensions are considered in the design process.

By applying the Social Construction of Technology (SCOT) framework to this study, I will explore how different stakeholders, including surgeons, regulatory bodies, and manufacturers, influenced the development and eventual failure of the MTANA. SCOT emphasizes that technological development is socially constructed as iterations of a technology address the priorities and concerns of various social groups involved in its design. Key sub-concepts from SCOT, such as relevant social groups, interpretive flexibility,

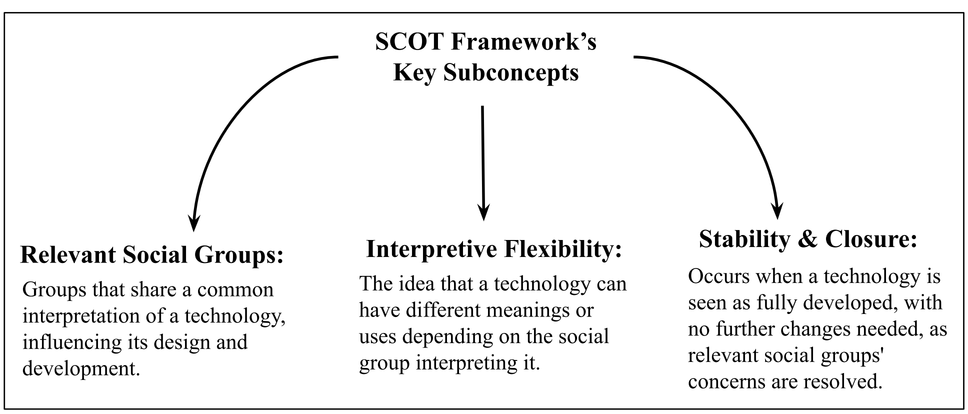

Figure 2. Three Key Subconcepts of the SCOT (Social Construction of Technology) Framework. SCOT, and the sub-concepts identified above highlight that the process of technological development is socially constructed as iterations of a technology address priorities and concerns of various social groups that have a stake in its design.

stabilization, and closure (see Figure 2), will be used to analyze the interactions between technical and social factors (Basu, 2023). Through this analysis, the study aims to provide a comprehensive understanding of the factors that led to the adapter's failure and offer guidance for the development of my technical project.

Conclusion:

To conclude, the challenges presented by the development of the proposed 3D printed adapter can be addressed by integrating both social and technical insights of product development. My technical project is focused on developing an adapter for the Hohmann and Weitlaner retractors, aiming to deliver a hands-free retraction system that improves surgical efficiency and reduces labor requirements. This design not only enhances workflow but also presents a cost-efficient and easily integratable solution to a problem present with existing surgical tools. The STS project provides a deeper understanding of the social factors that influence the development of medical devices. By using the SCOT framework to analyze the failure of the MTANA, I aim to gain deeper insight into how social dynamics, such as regulatory influences and market pressures, interact with technical aspects of design development and integration. These insights are valuable for considering how to predict and avoid similar pitfalls. Through the combination of these technical and social perspectives, I aim to ensure that the proposed adapter is both technically sound and socially viable. This will ultimately lead to efficiency in orthopedic trauma procedures while maintaining consideration for how different stakeholders – including surgeons, regulatory bodies, and manufacturers – can influence the development and implementation of this innovation.

References:

Bartley, L., & Lara, J. (2017, December 21). "Billion Dollar Baby": Lawsuits over profit, pain and the hip implant some call "toxic." *ABC7 Los Angeles.* https://abc7.com/metal-hips-dupuy-orthopedics-hip-implants-on/2724100/

Basu, S. (2023). Three Decades of Social Construction of Technology: Dynamic Yet Fuzzy? The Methodological Conundrum. *Social Epistemology*, *37*(3), 259–275. https://doi.org/10.1080/02691728.2022.2120783

Bijker, W., & Pinch, T. (1987). The Social Construction of Facts and Artifacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other. In *Social Studies of Science* (Vol. 14, pp. 17–50).

Boese, A., Croner, R., & Wex, C. (2022). Concept for a retractor with force indicator for reduction of tissue trauma in abdominal surgery. *Current Directions in Biomedical Engineering*, *8*(2), 640–643. https://doi.org/10.1515/cdbme-2022-1163

Castagnini, F., Bordini, B., Lucchini, S., Cosentino, M., Tassinari, E., & Traina, F. (2023). Mid-term outcomes of revision hip arthroplasty due to titanium modular neck failure. *Archives of Orthopaedic and Trauma Surgery*, *143*(9), 5909–5918. https://doi.org/10.1007/s00402-023-04805-1

Dodson, M. A., & Individual. (2011, October 5). US20140073857A1 - *Modular Retractor and Related Method - Google Patents*. https://patents.google.com/patent/US20140073857A1/en

Grupp, T. M., Weik, T., Bloemer, W., & Knaebel, H.-P. (2010). Modular titanium alloy neck adapter failures in hip replacement—Failure mode analysis and influence of implant material. *BMC Musculoskeletal Disorders*, *11*(1), 3. https://doi.org/10.1186/1471-2474-11-3

Hermena, S., & Slane, V. H. (2023, August 8). *Ankle fractures*. StatPearls - NCBI Bookshelf. http://www.ncbi.nlm.nih.gov/books/NBK542324/

Mair, O., Pflüger, P., Hanschen, M., Biberthaler, P., & Crönlein, M. (2023). Treatment strategies for complex ankle fractures—Current developments summarized in a narrative review. *Annals of Translational Medicine*, *11*(11), Article 11. https://doi.org/10.21037/atm-23-1173

Pautasso, A., Bardellini, G., Stissi, P., & D'Angelo, F. (2023). Usefulness of modular neck adapter in partial hip revision. *Annals of Joint*, *8*(0), Article 0. https://doi.org/10.21037/aoj-23-22

Rouse, T. B. (2023). Weitlaner retractor. *British Journal of Surgery*, *110*(4), 409. https://doi.org/10.1093/bjs/znac357

Schultz, B. J., MD. (2024). Posterolateral Approach for Trimalleolar Ankle Fracture. *American Academy of Orthopaedic Surgeons.* https://www.aaos.org/videos/video-detail-page/23236__Videos

Spang, A. (2023). Graceful: Galaxy II Retrospective Safety and Effectiveness Follow Up Long-term Study–An Original Article. *MaplesPub*. https://www.maplespub.com/

Talbot, M., Steenblock, T. R., & Cole, P. A. (2005). Surgical technique: Posterolateral approach for open reduction and internal fixation of trimalleolar ankle fractures. *Canadian Journal of Surgery*, *48*(6), 487.

Zhong, S., Shen, L., Zhao, J. G., Chen, J., Xie, J. F., Shi, Q., Wu, Y. H., & Zeng, X. T. (2017). Comparison of Posteromedial Versus Posterolateral Approach for Posterior Malleolus Fixation in Trimalleolar Ankle Fractures. *Orthopaedic surgery*, *9*(1), 69–76. https://doi.org/10.1111/os.12308