

Redesigning the Loop Connector for Patients of Size

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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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Abstract

Over the course of the past few decades, obesity and its comorbidities have quickly risen to the top of the global causes of death, necessitating a medical shift towards the widespread treatment and accommodation of individuals suffering from this disease. One key problem unique to obese individuals is how weight limits can lead to the removal of certain supplementary technologies that cannot accommodate their body weight. One such supplement is called the Loop Connector, which provides comfort and mobility to larger patients that cannot move themselves. I pursued several solutions to the inadequate current loop connector design, which could only accommodate 330 pounds. At first, I modeled several potential iterations of the loop connector that could be constructed from recycled materials, though these did not pass finite element analysis. Pivoting, my advisor and I reached out to known textile experts to find potential materials that would pass a weight limit of 1000 pounds. We eventually settled on one model, a sewn rope loop, that successfully passed all testing and will be implemented into the UVA Health System as soon as possible. Moving forward, both my advisor and I believe that longer-term communication with manufacturers could be key in obtaining more testable materials. We would also like to test these materials to failure, and potentially shorten them down to better fit the purpose of the loop connector.

Keywords: Obesity, weight limits, comfort, mobility, finite element analysis, weight testing

Introduction

Significance

It is unacceptable in today's medical environment for a load-bearing component of any device to have a weight restriction that cannot support patients of significant size. One such component is the Liko™ Extension Loop, manufactured by Hill-Rom. Although intended as a small fabric loop used to enhance patient comfort and maneuverability when using repositioning sheets, slings, or similar patient-moving devices, this extension loop has a maximum weight capacity of only 330 lbs. for both of its available sizes¹. Considering that repositioning sheets, such as the Hoversling Repositioning Sheet favored by UVA Health, can handle weights up to 1000 lbs., the loop connectors that attach these sheets to the medical lifts used for patient transfer become the system's vulnerability². For companies like Hill-Rom, this might not appear to be a problem, as 330 lbs. considerably exceeds the average weight of patients, even those with mobility issues for whom this product is designed. However, the challenge lies in the evolving trend of increasing average patient weights over time. By the year 2030, it is anticipated that 25% or more of the population will be classified as severely obese³. Looking ahead, a 330 lbs. capacity no

longer seems adequate to guarantee the safety of all patients.

The primary concern related to this component is that its failure would almost certainly cause a patient, particularly one with severe obesity, to fall either to the floor or back onto their hospital bed. It is worth noting that upwards of 30% of falls occurring in hospitals result in injury, without accounting for the patient's weight or other contributing factors⁵. While a patient's obesity may not affect the severity of injuries sustained during a fall, it significantly increases their likelihood of falling due to the greater weight causing instability⁶. Even with an estimated injury rate of just 30%, the malfunction of these loop connectors poses a liability not only for the patient but also for the healthcare facility that employs them. A patient who has fallen, even if they remain uninjured, could choose to file a premises liability lawsuit against the hospital where they are staying, alleging the use of faulty equipment for their transfer⁷. Therefore, ensuring patient safety should be a primary concern for hospitals, and their utilization of potentially unsafe products could also lead to damage to their reputation.

Regarding their design, most loop connectors share a similar appearance as flexible fabric loops [Fig. 1]. However, there is limited published information detailing



Fig. 1. HillRom's Liko Extension Loop. This polyester and nylon loop is used in tandem with repositioning sheets, and has a weight limit of 330 lbs. before fracture.

the specific design process of these loops. In fact, there is a general scarcity of literature focusing on loop connectors. The information that does exist is primarily found within user manuals, which provide minimal detail about the loop itself, focusing instead on its proper usage. Beyond their similar aesthetical and practical appearances, another commonly held characteristic of loop connectors is their material composition. Both the Liko™ Extension Loop and the Handicare AdjustmentLoop are constructed from polyester, with little additional information provided about their precise makeup, despite their differing weight capacities of 330 lbs. and 660 lbs., respectively^{1,4}. Consequently, the testing methods, design procedures, and material compositions remain largely undisclosed to the public. The field of patient transfer predominantly emphasizes repositioning sheets, slings, or comparable devices, with less focus on the seemingly minor loop connectors that serve only as supplementary components. A significant aim of this project is to clarify this design process, which the industry currently considers unremarkable.

From a clinical standpoint, the ultimate objective of this project was to establish a safety standard for all patients, regardless of characteristics such as size. Designing an alternative loop connector that offers a comparable level of adjustability to the current products available on the market, while also accommodating the higher end of the weight spectrum for nearly all patients, specifically up to 1000 lbs., represents a fundamental aspect of this standard.

Loop connectors are an obscure, Class I medical device, with such infrequent utilization that the University of Virginia currently possesses only five, according to advisor Leslie Wood¹. Their limited use and Class I designation do not alter the fact that, like every other weight-bearing device utilized in healthcare, they must be prepared to handle patients with increasing body weights as the obesity epidemic continues.

Innovation

Given the somewhat limited market for loop connectors, a redesign of the product could either significantly alter the design approaches of various medical device manufacturers or potentially go unnoticed entirely. Currently, there is a scarcity of published material concerning the design or production of loop connectors available for purchase, placing any innovation in this area in a unique position. It is still impossible to know how any changes to this product will be viewed in the field. One aspect to consider is the material composition of the loop connector, which companies like Hill-Rom and others simply identify as "polyester" in their self-reporting^{1,4}. Further details regarding their material makeup are scarce. Another element for consideration is the design process, which involves utilizing CAD software for the fabric loop before any physical prototype is created. This ensures that only designs vetted through this digital process undergo physical testing.

Despite the limited information available on the design of the polyester fabric used in commercially available loop connectors, considerable research has been conducted on the broader topic of polyester construction and enhancement. Notably, several research groups have explored incorporating natural fibers to augment synthetic polymers, achieving surprisingly effective results. For instance, when pineapple leaf fibers (PALF) constituted 30% of the composition of one polyester material, the tensile strength was found to increase by over 300%⁸. Similarly, the inclusion of ramie fibers, derived from vegetables, in comparable proportions also resulted in a 300% increase in tensile strength⁹. While these findings regarding the combination of synthetic and natural fibers are intriguing, they fell outside the scope of this particular project. I took a different approach for the material aspect of the project. Driven by both a lack of time and a lack of adequate fabrication resources, my advisor and I elected to order pre-fabricated loops, recommended by consulted textile experts, made of materials that were assured to easily surpass a weight limit of 1000 lbs. The material we

finally decided on in interest of time was the 7mm Sewn Prusik Rope from the company Sterling Rope. This woven nylon rope, intended for climbing, had never seen use in a medical setting, making its potential application there an innovation in itself.

While not strictly an innovation in itself, the application of CAD software in the development of the redesigned loop connector represents a novel approach according to the available literature on this device category. Across all research conducted on existing loop connectors, regardless of the various names under which supportive device companies market them, there has been no mention of the product development process, let alone the existence of CAD designs for these products. By ensuring that different loop connector designs, utilizing materials such as polyester and nylon, are thoroughly tested using CAD, the cost-effectiveness of evaluating various preliminary designs is significantly enhanced. This approach avoids the expenditure of materials, money, and time that would be required to physically create and test these designs. Employing this digital testing method also allows for the elimination of flawed designs from the production process before resources are wasted on discovering their inadequacies.

The design process undertaken in this capstone project was not entirely groundbreaking. It draws inspiration from existing technologies and practices in nearly all aspects, from the design specifications to the implementation of methodologies. However, the primary distinction between this project and its predecessors lies in the thoroughness of documentation throughout the design process itself. The design will undergo testing in CAD software, whereas others are often merely represented in engineering sketches. This novel loop connector aims not only to establish a safety standard for Class I devices but also to provide a more in-depth examination of the design process for otherwise unremarkable Class I products.

Project Aims and Predictions

The ultimate goal of this capstone design project was to engineer and assess an alternative loop connector model that moves beyond potentially unreliable methodologies to guarantee the safety of severely obese patients during its use. The primary aim involved the design and testing of a replacement loop connector capable of safely accommodating all patients utilizing HoverTech's Hoversling repositioning sheet. The first sub-aim involved testing potential designs within a 3D modeling program,

Autodesk Fusion 360, which can simulate finite element analysis (FEA) for weight testing. Subsequently, these designs will be applied to prototype products, undergoing weight testing using provided repositioning sheets to simulate severely obese patients and evaluate the effectiveness of the prototypes. This testing will be conducted using a UVA Health medical lift. The second sub-aim directed that the design must maintain a similar outward appearance and operational functionality to the current product. This includes adhering roughly to the existing dimensions of 22 cm in length and 3 cm in width, as well as utilizing more durable materials to align with the aesthetic design of the Loop Extender model. Finally, the third aim dictated that the design must meet the cost requirements specified by the interested party, with the understanding that the current Hill-Rom model costs \$33 per unit. Our group's initial hypothesis was that at least three of the potential CAD designs would be successfully applied to prototypes for testing, while the thickest of these three designs would pass the desired weight limit of 1000 lbs. successfully.

The second aim focused on verifying the legality of redesigning specific components of licensed products to enhance patient safety. The first sub-aim involved preliminary research into patent law and its application to individual parts of larger products. Specifically, the legality of redesigning components such as the loop connector for use in medical settings will be verified. Any points of contention that HoverTech or related parties may have regarding the new design and its use as a replacement for the original product will be cataloged and addressed individually. As a secondary sub-aim, any relevant medical codes pertaining to the loop connector and its associated repositioning sheet will be examined and documented. Given that the loop connector is most commonly utilized in hospital and physical therapy environments, adhering to established medical doctrines to ensure patient safety is of paramount importance. This will be achieved through further comprehensive research into the loop connector and any related codes. For this aim, our group hypothesized that there would be no pressing legal matters or codes that would prevent the implementation of the new loop connector design in healthcare, primarily due to its insignificant and often overlooked nature.

Materials and Methods

Materials

Repositioning Sheet

The first major material utilized in this project was the Hoversling Repositioning Sheet that my advisor provided me very early on into the design process. This repositioning sheet, comprised of three different variable mixtures of polyester and nylon, was easily capable of holding 1000 lbs. without fracture. These three textile mixtures were present in the three primary parts of its design. The first, and weakest, comprised the ballooning cover of the repositioning sheet that could be inflated with air to provide more comfort to patients. This material, thinner and more malleable than the other two, was considered the weakest of the three. The second material comprised the bottom of the repositioning sheet, below the first material, served as the backbone of the product. It was not as easily torn, though still proved fairly easy to maneuver and did not appear of great tensile strength. The third, and most promising material, was found in the straps around the outside of the repositioning sheet, used in direct contact with the medical lift. These straps, however, did not have much material on a per-loop basis. Initially, these three materials were approximated utilizing three different strength variations of Nylon present in Autodesk Fusion 360.

7 mm Sewn Prusik

Sterling Rope's 7mm thick Sewn Prusik Rope (Figure 2) was the second major material utilized in this project, and was the most important in project success. Though not many details about the physical makeup of this rope is known, what is apparent from the parent site's product

description is that the rope is made of carefully, thinly woven nylon. This red nylon rope, which measured 19 inches in length and 7 mm in thickness, was a good deal larger than the loop connectors used currently. The connection between the different side of the ropes was held between a combination of tight sewing and sealing within a small plastic sleeve. This material was tested through both FEA and physical testing for its efficacy.

Methods

CAD Work

CAD analysis of the materials was performed using the Autodesk Fusion 360 software, which was acquired using a temporary license from the University of Virginia Department of Engineering. The models were constructed in as close an approximation as possible to the products measured in real life, with exact dimensions and as close as possible of an approximation to their applicable states. FEA was performed using the software's force simulation program, which analyzed the force and subsequent deformation on every part of the product to the best of its computing ability. Forces of 330, 500, 750, and 1000 lbs. were applied to the loop connector models, with their passes or failures being recorded as they finished simulating. The testing data of these simulations was not recorded definitively, as the success or failure of each loop mattered much more than how much and where they failed.

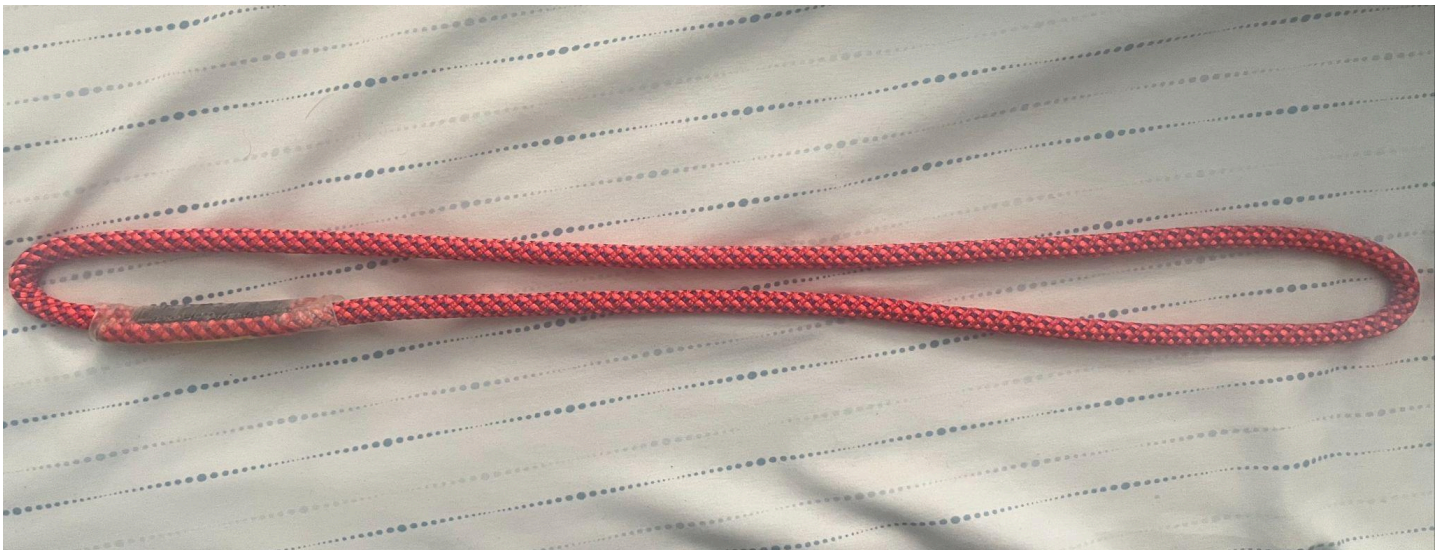


Fig. 2. One of the four 7 mm Sewn Prusik Ropes from Sterling Rope. This rope was used in the physical testing of the product.

Weight Testing

Weight testing was performed in the University of Virginia Hospital Underground, utilizing 950 lbs. of weight provided by the hospital for this test. To accurately test the Prusik rope's efficacy, it was tied to the loops of the repositioning sheet in the exact same fashion as the current loop connector design. Sets of hundred pound weights were placed in the center of the sheet, then lifted off of the ground using the medical lift that these ropes were attached to. As the hospital could only provide 950 lbs. total of weights, this was the maximum value of testing used at this stage.

Results

Design Constraints

The design of the new loop connector had only three primary design constraints from my capstone advisor. First, the design must be of a reasonable thickness and length to fulfill the same performative duties as the current loop connector. These values are specified as 22 cm in length and 3 cm in thickness. Secondly, the design must be within a reasonable price range compared to the current design, costing less than \$50 ideally. Finally, most importantly, the design must accommodate 1000 lbs. in tandem with a repositioning sheet without permanent deformation or fracture. Other than this, the materials, design, and appearance of the new loop connector were up to me. These specifications came directly from my advisor, thus did not require further justification as I moved forward through the design process.

3D Modeling

Initial Finite Element Analysis

To begin the 3D-modeling of the novel loop connector, I was first tasked with deciding which CAD software would provide the most accurate and economical analysis of the shapes I was looking for. As a result of its "free" nature and my own experience previously working in the software, I chose Autodesk Fusion 360 moving forward. In this software, I modeled nine different potential shapes based off of the Liko Extension Loop design pictured in Figure 1. The modeling process can be found under the Methods section. As for testing, this was done using the engine's built-in Finite Element Analysis (FEA) simulator, where a load of 330, 500, 750, and 1000 lbs. was tested against the rigid plastic designs. Figure 2, pictured to the

left, depicts one such test on Model 2 (First Material, Second Thickness). The force used in testing was applied to the opposite side of the loop as the locked point in order

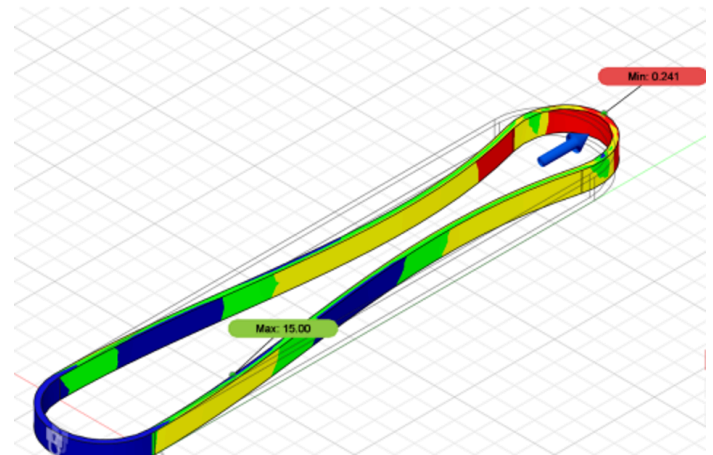


Fig. 3. Finite Element Analysis of Model 2. This 3D loop was modeled similarly to the other 8 used in the initial CAD work. It was 4 cm thick, 22 cm in length top to bottom, and used the material Nylon 6. It failed testing at 330 lbs.

to best emulate how the force would be applied during physical testing. Of the nine initial designs, only two passed the test at 330 lbs., Models 3 and 9. Though quite dire, this also posed an opportunity to experiment with different shapes in order to find which orientation or specifications would lead to a successful product. I used several similar shapes and materials to attempt to surpass the bare minimum 330 pound limit. These design changes included reducing the space in between the sides of the loops to better emulate how they would appear under absolute stress, utilizing different materials. Over the course of several months of this testing, however, I still found little recourse in the software and my designs. The metric of "success" was whether or not each design fractured under testing, which was quantified as having elements score below a 1 during the FEA simulation. In Figure 3, the weakest point of Model 2 scored a 0.241, meaning that part of the design would fracture under 330 lbs.

Further Modeling and FEA Analysis

As the design pivoted from self-manufactured prototypes to pre-manufactured ones, further modeling was performed to compare the efficacy of the recommended models against the attempted designs that barely passed. To much surprise, the rope model from Sterling Rope performed very well, as demonstrated in Figure 4 below. This model underwent FEA at all weights previously tested on the other models, using the same materials. The smallest

performance value associated with any part of the design was 1.577 under a tested weight of 1000 lbs., which is higher than the value of fracture and indicated a strong chance of the rope's success in physical testing. As we were unable to acquire samples of the other two recommended materials for testing and analysis were not

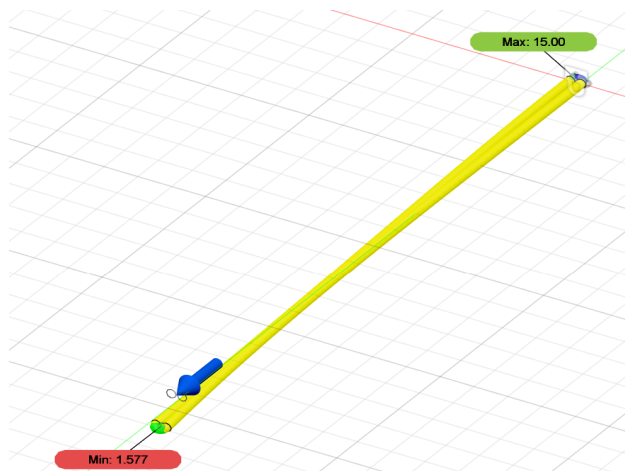


Fig. 4. Finite Element Analysis of Sterling Rope Model. This 3D loop was modeled after the 7mm Sewn Prusik Rope from Sterling Rope, and successfully passed FEA testing at 1000 lbs.

modeled. The materials constructing them were also not available for testing in Fusion 360, rendering CAD of their designs virtually impossible to distinguish from the other non-woven models.

Weight Testing

Utilizing the promising modeling predictions from FEA of the Sterling Rope, our group moved forward with physical testing after ordering four replicas of this 19-inch rope. Testing was performed in the UVA hospital underground, using 950 lbs. of weights divided into groups of 50 lbs. and 25 lbs. These were added in intervals of 100 lbs. groups, with the final group added only weighing 50 lbs. Throughout the testing process, the lift, repositioning sheet, and prusik ropes showed no signs of fracture, deformation, or any other damage. The lift successfully accommodated all weight levels both on and off of the ground, indicating a resounding success in replacement. This final weight test is pictured in Figure 5, which depicts the entire testing apparatus with maximum weight successfully lifting the weight off of the ground. Even when applied to the lift and repositioning sheet by someone with little experience, such as myself, the ropes were well capable of surpassing the desired weight limit.



Fig. 5. Hoversling Repositioning Sheet and Prusik Rope Holding 950 lbs. off the ground. This figure depicts the testing apparatus and loop connector replacement accommodating as much weight as the UVA hospital could provide for testing.

Figure 6 below further illustrates the difference in tensile strength and weight accommodation between the current and novel materials that can serve as loop connectors. Though there was no way of measuring the actual weight applied to each of the sewn prusik ropes, further weight above the 950 lbs. was applied by my own arm and likely surpassed well over 50 lbs. further of force. This, too, showed no deformation or fracture on the products. As such, I have made the assumption in Figure 6 that the ropes could accommodate 1000 lbs. at the least.

Discussion

Challenges and Adjustments

CAD Failures

The most pressing early hindrance of the design process was the failure of my initial CAD designs from surpassing

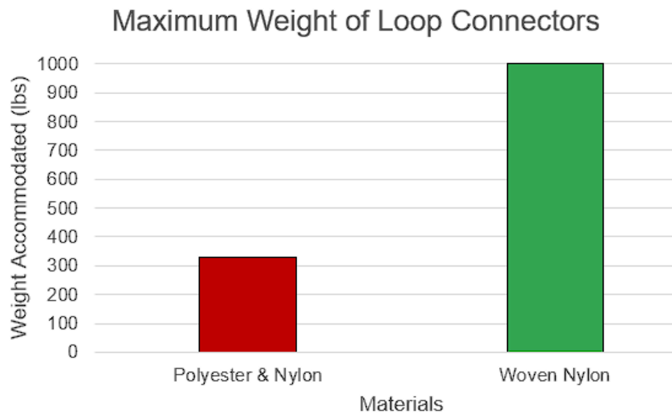


Fig. 6. Bar Chart with weight testing data. This figure depicts the difference in weight accommodation between the Liko Extension Loop and the Sewn Prusik Rope. As testing to failure could not be performed for the latter, the actual maximum load before fracture is unknown.

the 330 lbs. weight limit of the Liko Extension Loop model. Even the two models which did pass at 330 lbs. through FEA did not in turn pass when tested at 500 lbs., which was the bare minimum weight limit desired by my advisor to call the project a success. The reasons behind the failures of these designs is unknown, but several months of CAD adjustments were able to work out some of the kinks. One initial problem with the CAD was that the loops were modeled with too much internal space, which is apparent when comparing Figures 2 and 3. The loop connector only exhibits plastic behavior, which is tested in FEA, at its most rigid and outstretched form, meaning that the loops needed less space in between them. This, however, proved unable to reconcile the issue and did not create more effective designs. Another potential pitfall lay with the models' material composition, which was estimated based off of the limited options available in the Fusion 360 software. These materials, three variations of Nylon, appeared to have little difference when testing was performed, with FEA favoring thicker models regardless of composition. After testing different materials also present in the software, such as aluminum, iron, and even wood, these designs performed significantly better. However, it was evident that many of these materials were not fabrics and could not provide the mobility required with the product.

Lack of Technical Resources at UVA

To overcome the CAD difficulties of the design process, I contacted Dr. Emiel DenHartog, Head of the North Carolina State University Textile Engineering Department for advice regarding the CAD process for textiles, and whatever advice he may have for the actual technical

manufacturing process. This was the turning point of this project, as, while helpful, Dr. DenHartog's advice proved to invalidate much of the preliminary work I had done towards the design of the novel loop connector. He claimed it would be difficult for me, a student with no experience in the complicated world of textile manufacture, to create a small loop capable of holding 1000 lbs. This was especially true given UVA's lack of a textile engineering department, and lack of devices capable of emulating the conditions necessary for this production process. Dr. DenHartog then advised me to, rather than fabricate my own product completely from scratch, investigate different pre-manufactured materials capable of accommodating this immense weight.

Adjustment to Pre-Manufactured Loops

In order to find materials that would be suitable for holding 1000 lbs. without deformation or fracture, I utilized my connections through my advisor, Leslie Wood, to find biomedical design engineer, Kristin Bush, at UVA. Further through her, we contacted Gary Edwards, a high ranking textile engineer at private company Tsuga Textiles. Gary, who had much more experience than the rest of us in finding unique solutions to textile engineering problems, provided my advisor and I with three potential materials that he believed would easily surpass the 1000 lbs. weight limit our project desired. These materials were Tapecraft's Dyneema Nylon Webbing, Sturges' Dyneema Nylon Webbing, and Sterling's Sewn Prusik Rope. With these three materials, the project was able to progress forwards.

Corporate Communication and Rushed Solution

Despite now having three materials to select from and compare, this point in the project was far too late for delays in communication. They, of course, occurred regardless. After emailing and calling both Tapecraft and Sturges several times for estimates on the prices of ordering their webbings, I received no response. This lack of response continued well into the final stage of the project in April, and my advisor and I both decided it would be best to acquire the one product we could, the Sewn Prusik Rope, while leaving the other two materials for future BME Capstone projects to pursue. While not ideal, the Prusik Rope was cheaper than the current loop connector design (\$33 vs. \$22) and was supposedly much sturdier. Testing served to further reveal this efficacy and led to project success despite the delays.

Conclusions

The Loop Connector Project began as an effort to create a completely novel textile device, assisting nurses and other healthcare professionals in their daily mobility of patients, whether they be 100 lbs. or 1000. Unfortunately, this project, like many others, was hit by roadblock upon roadblock until the solution needed heavy simplification for, if nothing else, the sake of time. This, combined with the project being a solo endeavor, led to difficulty in completing every project aim. In the end, I elected to recycle a known alternative product from a different field into a successful alternative to the inadequate current loop. I do not believe this solution to be a cop-out, or an attempt at laziness on my own part. As time progressed, I merely ran out of options, and was forced to make a call. I chose project success, and an applicable solution to the problem, rather than the pursuit of a product I could patent and pursue as a professional work without definitively completing my project on time. Though simple, this solution worked. The sewn prusik rope, intended for use in climbing, was able to interface with the medical lift and repositioning sheet as easily as the Liko Extension Loop, and held 950 lbs. definitively for an extended period of time without deformation or fracture. This, more than any other aim, was essential. Though there is much room for improvement on this repurposed design, such as through shortening its length or testing it to definitive failure, I consider this project to be a success thanks to the solution's efficacy.

Broader Impacts and Future Work

There are few impacts of this project on the field of biomedical engineering, but its results could have a lot of potential in the field of healthcare ergonomics. While the CAD and manufacturing portions of the project did not see success, what did was the repurposing of an unrelated product to accomplish a goal that could take a group of engineers several years to complete in full. What's more, this product was acquired and tested within the span of under one month after its identification by a known expert. Most engineers seek to utilize their skills in producing replicable, unique products that they can acquire as intellectual property and sell for millions to those that need them. However, ultimately, our duty as engineers is to solve a problem. If this problem can be solved with ease by repurposing another product, making minor adjustments, and demonstrating its efficacy, is that not suitable enough? Perhaps, in some small way, this project

will demonstrate to other engineers that solutions to problems, big and small, can be found in the most unlikely of places.

In terms of the larger body of work, and what can be done to ensure a more thorough understanding of the loop connector and its alternatives, several projects could be pursued in the future. For one, a group could communicate earlier on with the now known companies that can produce webbing suitable for accommodating over 1000 lbs. In addition, by request of my advisor, they could pursue shorter options whose dimensions much more closely align with the loop connectors being used in UVA health today. Another potential expanding project would be to communicate earlier with the Textile Department at NC State, to investigate if they would be able to utilize their facilities for the fabrication of a novel, patentable loop connector.

Author Contributions and Notes

All work for and surrounding this paper was done by R. D. R., with assistance from his advisor, and several field experts mentioned in the acknowledgements.

The author declares no conflict of interest.

This article contains supporting information online.

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