Novel Surgical Retractor for Thoracic Outlet Syndrome Surgery

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October 4, 2019

Background

Thoracic Outlet Syndrome, also known as TOS, is a group of disorders in which blood vessels or nerves are compressed at the thoracic outlet, between the first rib and the clavicle[1]. Due to the number of structures in the thoracic outlet area, TOS can also be classified by the compressed structure, and may be referred to as nervous, venous, and arterial TOS. Symptoms of TOS include pain, paresthesia, motor weakness, thrombosis, and edema, amongst others. While current statistics on the number of TOS cases are unknown due to the wide variety of symptoms and difficulty diagnosing, the National Institute of Health estimates that the incidence rate of TOS ranges from 3 to 80 cases per 1000 people[2], with the majority of cases occurring in women between the ages of 20 to 40 years old[3]. The majority of cases are resolved with physical therapy and medication, but a population of patients require surgery to alleviate symptoms. In a 50 year period at Baylor University Medical Center, over 25% of diagnosed TOS cases were resolved through surgery, with more than 10 percent requiring a second surgery to resolve symptoms[1]. Therefore, any innovative product for TOS surgery would share a similar market size as the rate of TOS surgery, with anywhere from 340,000 to 9,100,000 potential sales in the US alone. As surgeons continue to evolve the approach to TOS treatment, increased scrutiny has been placed on the techniques and equipment used in the surgery theatre. Due to the nature of the TOS, as well as the high rate of secondary surgery required to resolve symptoms, surgeon convenience is paramount in reducing complications.

Need Statement and Project Scope

In particular, it has been expressed by Dr. Robert Thompson that surgeons currently face problems during TOS surgery due to inadequate lighting and poorly sized surgical retractors, resulting in poor visibility and discomfort for surgeons in the surgical theatre. Therefore, there is a need for a new surgical retractor in order to minimize complications and increase TOS surgery success rates. A novel retractor specialized for thoracic outlet surgeons is proposed. In order to increase surgeon convenience and success rate while decreasing surgery time, the retractor will need to be size-adjustable while maintaining variable rigidity, and should implement a lighting solution to increase visibility during the procedure. Additionally, the retractor will need all parts integrated into a single unit, as well as to be single-use and disposable. The project will be considered completed when a working prototype that satisfies all client needs specified above has been created, and is adequate for mock surgery.

Design Requirements

To achieve size adjustability while maintaining some rigidity, the proposed novel surgery retractor will need to be circular in shape and made from a combination of flexible and semi-rigid materials such as rubber and plastic. The diameter range of the retractor depends on its design; if the retractor is self-retaining, the diameter range will need to be smaller than the incision length, while the retractor can be larger in size if it is an indirect supporting platform such as a wire retractor. The initial design will be decided upon on further discussion with Dr. Thompson and only a rough range of the retractor diameter can be given at this time. The diameter range is estimated to be a minimum of 2~6 cm and a maximum of 9~10 cm, given a typical incision length of 3~7 cm in thoracic outlet surgery.

Dr. Thompson requires the retractor lighting to be as bright as a smartphone flashlight, which is typically around 100 lumens. Since the retractor is expected to hold not more than 10 to 15 led lights, the brightness of the LED in need is in the range of 6.7 lumens/led~10 lumens/led. The Bright White Adafruit 5mm LED (Adafruit Industries) has brightness range of 6 to 10 lumens/led and is used for other LED metric specifications in the product design. Since a single Adafruit LED is able to produce around 10 lumens using 3 V standard battery and 20 mA current (0.06 W/led), the expected battery performance for the retractor is around 1W ~ 3W to power at least 10~15 LEDs for about 4~5 hours.

In order to ensure the safety of the patient, the operating temperature of the retractor shall not exceed 40 °C over the duration of the surgery. Adafruit LED light with similar specification has maximum operating temperature of 25 °C, safe to use in the retractor. The shelf life of the retractor shall be longer than 2 years to preserve the structural integrity of the retractor. The total weight will be between 300 and 500 grams in order to avoid unnecessary stress on body tissue trapped below the retractor.

Overall, the team is aiming to bring the manufacturing cost of the retractor to under $500 per unit, taking advantage of the low costs of acquiring key materials such as plastic and rubber. Given the existence of flawed but widely used current retractors, the low manufacturing cost will help in competitively pricing the novel retractor.

Existing Solutions

The search for pre-existing solutions was divided into three main areas: general surgical retractors, size-adjustability, and compact lighting solutions, which combined comprise the team's proposed novel retractor's "secret sauce".

A patent[4] for a size adjustable surgical retractor has been filed as early as 1995, with the patent proposing a "radially expandable tubular body" controlled by a pull wire. A more recent patent[5] in 2008 has proposed a size adjustable retractor with a fiber optic lighting solution as seen in **Figure 1**, but its design seems cumbersome to use and poorly thought out.

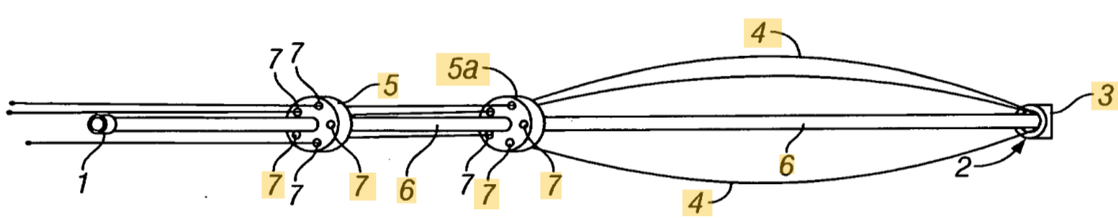

Figure 1. Proposed Size Adjustable Retractor with Fiber Optic Lighting[3]. The central rod provides lighting via fiber optics, and the retractor's size is controlled by expanding the flexible wings labeled "4". The overall design will likely interfere with a surgeon's mobility.

The most relevant patent[6] has been filed only recently by Chinese inventors and was published on February 28th, 2019. It proposes a belt-shaped retractor utilizing a locking mechanism via ratchet, as seen in **Figure 2A** and **2B**. While this design is in line to the team's initial proposed design, some design flaws can be found in the locking mechanism. First, the lack of counter-facing ratchets means the retractor will contract in size under contractive pressure exerted by the body, failing to securely lock the retractor in place. Second, the locking mechanism itself seems highly unstable, as the ratchets are only held in place by fitting into the side slits, and are likely to be pushed out of the slits under contractive body pressure. Third, the overly long spacing between each ratchet prevents detailed size adjustments. Therefore, there are still plenty of improvements to be made to the locking mechanism.

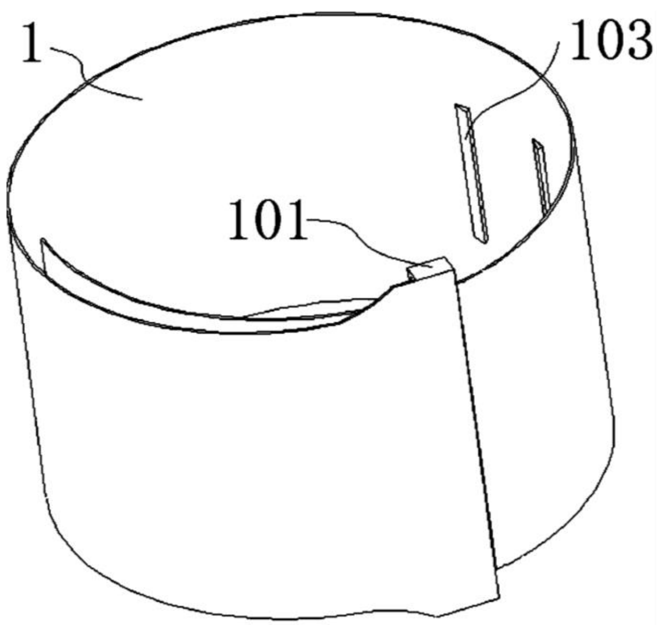

Figure 2A. Overview of Belt-Shaped Retractor[4] with Ratchet Locking Mechanism. The retractor is made of a flexible material and functions like a belt to adjust size.

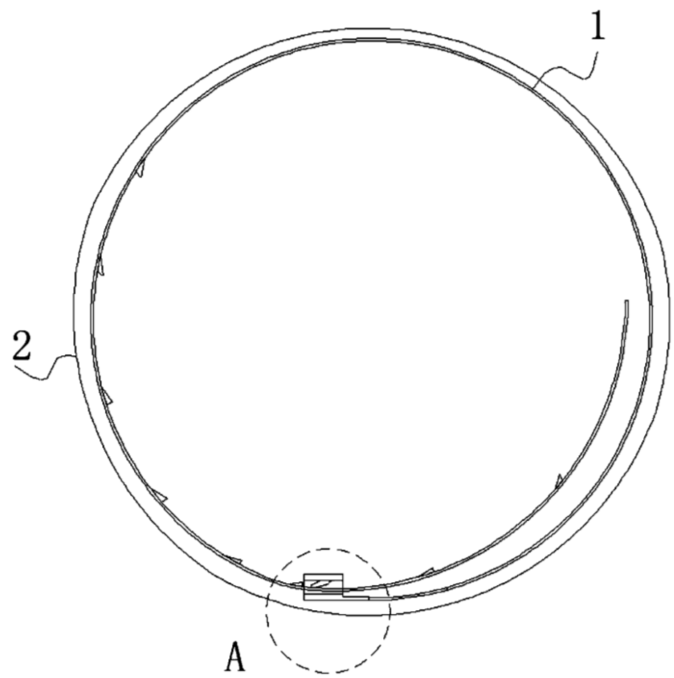

Figure 2B. Ratchet Locking Mechanism of Belt-Shaped Retractor. The retractor's size is locked by ratchets on the inner side of the retractor that fit into slits on the retractor wall. Several problems exist with this design.

Size adjustability in devices has potentially infinite ways to be applied, but the medical device community has currently focused on a select few mechanisms. Primarily, medical devices that require size adjustability have implemented a ratcheted system in order to maintain size during operations. This can be seen implemented in a multitude of patents applied for devices such as needle holders[7], forceps[8], as well as both belt shaped[6] and bladed wound retractors[9], seen in **Figure 3**. As the shortcomings of the belt shaped retractor have been addressed, a more detailed look at the other device must be made. In the case of holders, forceps, and the bladed wound retractors, seen in Figure 3, these devices the restrictive power of springs or other mechanisms locking mechanisms in order to provide pressure on the ratchet position and hold the devices in place. Unfortunately, the retraction of these devices is based on a toothed metal bar of mild curvature. Given the diameter sizing found in the device metrics, the current solution seems to require additional engineering in order to accomodate the curvature necessary, as metal with the correct thickness to maintain the retraction may be unable to accommodate the change in arc due to size adjustment.

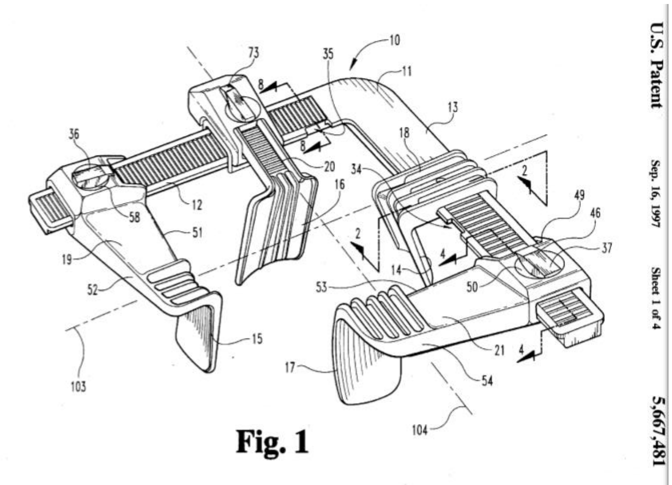

Figure 3: Ratcheting system of a bladed surgical retractor with rigid toothed bars for size adjustment.

While ratcheting devices make up the majority of existing size adjustment in medical devices, there are some more novel solutions. In particular, mitral valve rings for annuloplasty have been patented to be size adjustable based on external energy transfer into the device using an electrode[10]. While this solution seems to be inefficient in terms of project scope, further research must be conducted in order to rule out the process.

To solve the problem of poor visibility inside the retracted wound, there exists a patented product called “Surgical retractor with light”[11] as a possible solution. As seen in **Figure 4**, the surgical retractor is composed of a main metal ring for support and integral retractor blades embedded with LED lights. Although the existing product provides some useful aspects in improving TOC surgery, it is insufficient and lacks specific standards. The LED lights are products of Philips Lumileds Lighting Co and expected to produce 90 to 180 lumens combined (7.5 lm/led ~ 15 lm/led). The lumen range matches the desired range specified in the project scope, but LEDs in the product relies on external power source. The product falls short in integrating the parts as a single unit (desirable in improving TOC surgery). Although the lighting source and retractors are integral parts, the power source, support ring, and retractor blades are separate parts.

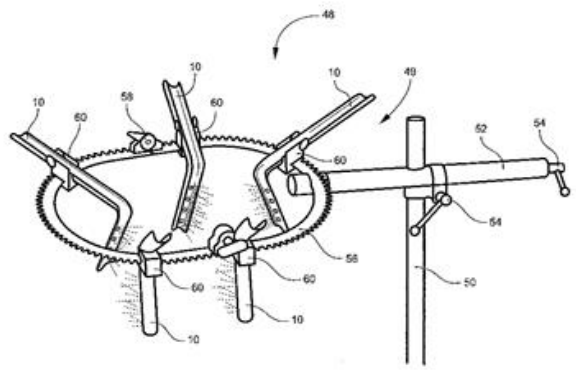

Figure 4. Surgical Retractor with Light. The retractor is comprised of retractor blades with LED lights embedded and main ring for support.

Based on the preliminary research of currently existing products, the team is confident that a novel surgery retractor incorporating an improved size adjusting mechanism and a lighting solution will have a large market impact and still be eligible for a potential patent filing.

Preliminary Schedule and Team Responsibilities

In order to properly conduct each stage of device creation, careful planning of the required tasks during the design, creation and validation phases must be completed. After assessing the tasks and due dates, the team believes that the Gantt chart below will allow for proper time to complete all tasks. As this project is in the preliminary phase, this timescale of events is a rough estimate, and may be subject to changes.

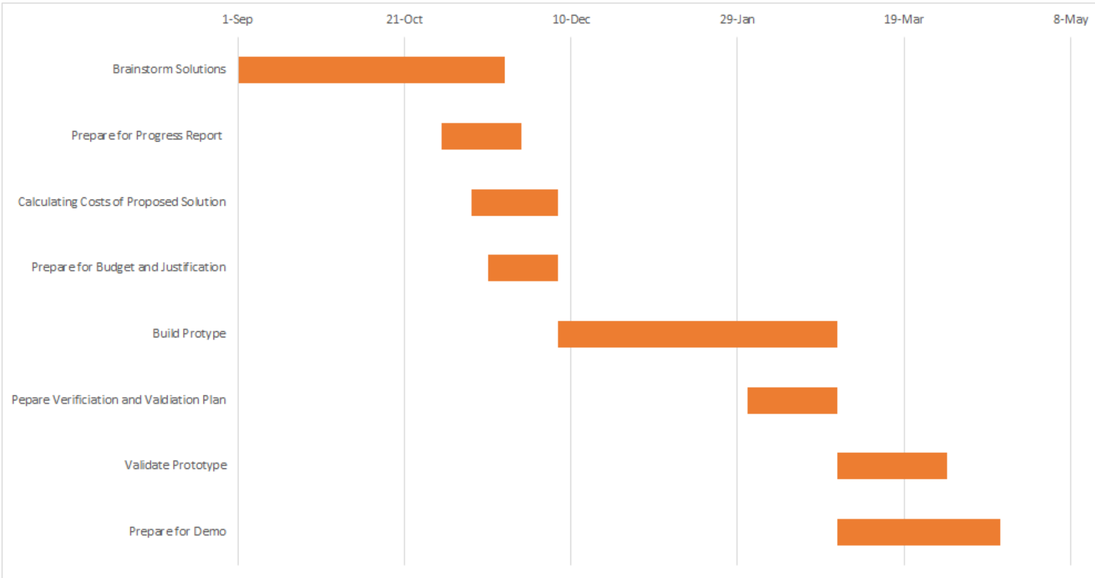

Figure 5. Gantt Chart of Proposed Timelines for Activities in Capstone Design.

With consideration to the tasks shown in **Figure 5**, responsibilities have been assigned to team members based upon their proficiencies. In the case of the four presentations spaced throughout the year, the team has agreed to have all members lead at least one report and resulting presentation. For the first presentation, the preliminary report, Chang Hi Lee will lead the creation of the report and present to the grader. The second progress report will be led by Luke Belusko, and the third budgeting and justification report will be led by Tommy Ahn. The fourth report has been agreed upon by the team to be led by Chang Hi Lee, with additional crafting of the report done by Luke Belusko and Tommy Ahn.

The team has also assigned leadership roles in the creation of the prototype and communication of project details with clients. Tommy Ahn will be in leading the creation of the CAD designs and necessary printing during the prototype creation phase. Luke Belusko will be in charge of creating the team website and maintaining all relevant documents on the site. Chang Hi Lee will be in charge of communication between the team and the client and any material or part suppliers, as well as officially documenting group meetings.

Overall, the team believes that the assignments of these roles will provide the best result throughout the course of the solution creation, prototyping, and validation seen in the Gantt chart in **Figure 5**.

In conclusion, the group believes that the creation of a novel retractor for TOS surgery is feasible and the completion of the design can be accomplished by unique means that can be patented and improved upon. To do so, the group will follow the specifications given by Dr. Robert Thompsons, as well as the corresponding metrics associated with current solutions, in order to create an ideal solution. By following an organized, phase based approach and clearly differentiating roles, the group believes that this project can be completed on time and within budget.

References

1. Urschel, Harold C, and Harry Kourlis. “Thoracic Outlet Syndrome: a 50-Year Experience at Baylor University Medical Center.” *Proceedings (Baylor University. Medical Center)*, Baylor Health Care System, Apr. 2007, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1849872/.
2. Genetic and Rare Diseases Information Center. “Thoracic Outlet Syndromes.” *Genetic and Rare Diseases Information Center*, National Center for Advancing Translational Sciences, June 2017, https://rarediseases.info.nih.gov/diseases/7759/thoracic-outlet-syndromes.
3. Mayo Clinic. “Thoracic Outlet Syndrome.” *Mayo Clinic*, Mayo Foundation for Medical Education and Research, Sept. 2019, http://www.mayoclinic.org/diseases-conditions/thoracic-outlet-syndrome/symptoms-causes/syc-20353988.
4. Hammerslag, Julius G. Adjustable surgical retractor. Hemodynamics Inc, assignee. Patent US5460170A. 1995.
5. Chu, David. Expandable surgical retractor for internal body spaces approached with minimally invasive incisions or through existing orifices. City of Hope National Medical Center, assignee. Patent US20040236186A1. 2008.
6. 郭思栋, 王锐, 王晓东, 莫小慧, and 钟旭飘. Surgical incision retractor. N/A, assignee. Patent WO2019037505A1. 2019.
7. Shoichi Nakamura. Surgical needle holder. Nippon CPC Corporation, assignee. Patent JP3087968U. 2002

8. Liu Huining. Object holding forceps and cerclage strip for endoscopes. Shijiazhuang Mandien Biotechnology Co. Ltd, assignee. Patent CN204394620U. 2015
9. Villalta, Josue. Four bladed medical retractor. Metro Plasic Technologies Inc, assignee. Patent US5667481A. 1995
10. Le Le. Adjustable annuloplasty ring and activation system. Micardia Corp., assignee. Patent US20130197313A1. 2008
11. Shaw P. Wan. Surgical retractor with light . Patent US2013O197313A1. 2013