BME 400:
Preliminary Product Design Specification

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Function:

During endocrine surgery, specifically during thyroidectomies and related procedures, surgeons must retract the thyroid gland medially in order to gain access to the recurrent laryngeal nerve and parathyroid glands. Depending on the procedure, they must then dissect the thyroid gland from vascular attachments, and possibly the parathyroid glands. Surgeons use stainless steel forceps with a piece of gauze clamped at the tip, referred to as a "peanut" to retract and hold the thyroid gland in place, without rupturing it. However, due to the single point of contact, the thyroid gland can often be too large to be held in place by this method. The function of the device is to assist surgeons in retracting and holding the thyroid gland in place from multiple contact points.

Client Requirements

The client requires a surgical instrument to aid in the medial retraction of the thyroid and parathyroid glands during surgery. The device should have a single handle similar to standard forceps, but with two prongs to retract the thyroid gland from multiple contact points. Each prong should be capable of clamping and holding a surgical peanut sponge, a small sponge used to reduce the forces on the thyroid. The handle of the device should have some sort of ratcheting system to be able to adjust the distance between the two prongs. Additionally, the ratchet should allow for the device to be held in place for a period of time without having to manually hold the clamps shut.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:*

    The device should be able to assist in completing the tedious dissection of the thyroid without causing harm, such as excessive bleeding, nerve or tissue damage. It should be reusable, auto-clampable and have blunt ends that act as clamps. It must function as one instrument that has tissue-contacting surfaces at the end opposite of the handle. The device must be capable of adjusting the width between the peanuts, and locking into the desired conformation. Finally, the device must be capable of withstanding all forces that are applied to it, both by the surgeon and the areas of the body it is acting on. The 95th percentile for human grip strength in right-handed men is around 500 N [1], and the device handle must be able to withstand this force. As the average adult's thyroid weighs between 20 and 30 grams [2], the forces applied by the thyroid are negligible in comparison to those applied by the surgeon.

b. *Safety:*

The only people allowed to operate with and use the device on a live patient will be trained medical professionals, as to keep the safety of the patient at the utmost importance. Computational and physical testing of the device's ability to endure forces of the hand applying pressure during surgery will be conducted. These tests laid out will ensure the safety of the surgeons using the device, as the device will be tested to make sure it won't break while in use. The device is not required to be permanently biocompatible, because it will only be in contact with the patient temporarily. However, the device must not be toxic, or susceptible to leaching of potentially harmful chemicals into the body. Finally, blunt edges and ends should be preferred over sharp edges, so as to avoid any unintended perforation or trauma caused by the device.

c. *Accuracy and Reliability:*

The device must reliably be capable of performing the task it is designed for. It must not puncture or cause trauma to the thyroid or other areas of the body when in contact. The ratcheting and latching mechanisms must not jam or lock when unintended. The clamping mechanisms must be capable of holding onto a peanut for the length of surgery without risk of the peanut detaching and entering the body.

d. *Life in Service:*

Long service lives should be expected from stainless steel surgical instruments. The client's current device has a shelf life of a few years. The device should be able to last at least a few years with sterilization and being reused by autoclaving [3]. The device should be reusable and autoclavable until wear and tear begins to occur. If there are signs of device damage or material corrosion, the device should be replaced.

e. Shelf Life:

The device will be made out of surgical grade stainless steel. Due to the mechanical properties of stainless steel, the shelf life for the device will be rather long. The average lifetime of stainless steel products ranges from 15-25 years[4].

f. Operating Environment:

The device will be used in a surgical setting. The likely temperature that the device will be in is somewhere between room and body temperature, depending on the point in the procedure. This gives an operating temperature between 22° C and 37° C [5]. For pressure, the likely pressure the device will be experiencing is around 1 atmosphere [5]. From a biochemical standpoint, this device must be able to withstand corrosion of blood and fluid. The device will be used by surgical staff so it is important for the staff to receive adequate device training. Increased temperature and pressure will occur during autoclave sterilization. Autoclaving is a physical method of disinfectant and sterilization that uses steam, pressure, and time. Under autoclaving procedures, the temperature can reach up to 121° C, and 1 atmosphere, which the device must be able to withstand[AA]. Autoclaving will only be for the reusable portion of the device, manufactured from a material capable of withstanding the conditions.

g. Ergonomics:

The device should be relatively simple to use by a trained user in an operational setting. The device should have a handle that is easy and comfortable to grip and is able to be held by one hand. The device should feature a ratchet that can vary the distance between the prongs so it does not have to be manually held to a certain distance. The

device should not hinder the surgical staff during the operation, and ideally increases the ease of the procedure. Finally, the device should be able to accommodate 95% of hand sizes.

h. Size:

The current device being used is a clamping forceps with a small "peanut" sponge to contact the tissue and reduce surface forces. This device is approximately 8" in length [6]. Typical forceps and retractors used in surgery range from 8 to 12 cm. The device should be similar in length to these devices currently in use, so as to be easily adopted by surgeons utilizing other methods of thyroid retraction. Thyroids are anywhere from 4-6 cm and the device should have the two prongs 2-3 cm apart on average, with an adjustable range spanning from 1-4 cm, so that it may be used on a variety of patients and thyroid sizes. Measurements will be taken on current surgical forceps and retractors to determine accurate dimensions. Adult human hand anthropometry will be taken into account when designing the device, as well as when testing the device for ergonomics with surgeons.

i. *Weight:*

The weight of the device should be close to that of the weight of the forceps used with the peanut currently, or typical surgical forceps and retractors, at around 40.82 grams [7]. A small increase of weight will be allowed due to the addition of the second prong and tissue-contacting area, although the device should not be sufficiently heavy as to be difficult to operate by a surgeon. Measurements will be taken of a standard Weitlaner retractor to determine an accurate target weight for the device.

j. Materials:

The device will be made of stainless steel, as the current device and most modern surgical instruments are. In the medical device industry, stainless steel grade 316 is commonly used for medical grade surgical devices due to their high levels of nickel and chromium. These levels of nickel and chromium allow for endurance through sterilization procedures, as well as tolerance of corrosive material like bodily fluids. Stainless steel provides greater durability because it is anti-bacterial, non-corrosive and rust-resistant. It is also autoclavable, which allows it to be sterilized quickly and repeatedly. The durable stainless steel construction means the device will last and remain dependable for medical use [6].

k. Aesthetics, Appearance, and Finish:

The medical device should have the appearance of a typical surgical instrument. The device should have a highly polished, or mirror finish in order to prevent potential staining [8]. Also, the device should have a satin finish to prevent any bio-contaminants from residing in any ridges that may be present without a satin finish. Other than this requirement, aesthetics are less critical to the design than other relevant criteria.

2. Production Characteristics

a. *Quantity:*

Only one device will be produced for the full project, but it will be reusable since it is made of stainless steel. In the future, if this kind of device is proved to be beneficial to the procedure, more can be produced.

b. Target Product Cost:

The target cost of this device should be comparable to typical surgical forceps, although this cost varies greatly. Depending on the supplier and website, retail prices for surgical forceps and retractors can range from $5.00 to around $50 from medical supply companies [9]. For this design, the target cost of production will be between $5.00 and $10.00 per single thyroid retractor. Flexibility of cost will be taken into account to accommodate for the extra forceps incorporated into the device. Additionally, this is the final target cost of production, without development or prototyping taken into account.

3. Miscellaneous

a. *Standards and Specifications:*

The device falls under the category of a Class II medical device as it is substantially equivalent to another similar legally marketed device that already has FDA clearance [10]. This product will need to be FDA cleared in order for surgeon and patient use and is protected under FDA regulation 21 CFR Part 807. The device and the surgery must comply with CDC regulation regarding sterile procedures. During testing and clinical trials, the device must be tested under IRB regulations at the university level, and FDA regulation at the federal level.

b. *Customer:*

Our client has requested a two pronged, adjustable thyroid retractor. This device should ease common complications endured with just one prong, such as those associated with larger thyroids. Ultimately this device may suit other customers beyond our client, including other surgeons at UW and/or beyond.

c. *Patient-related concerns:*

To ease any patients' concerns, the device will be treated and used like any surgical device in the operating room. The device will be used by a trained professional, and cleaned thoroughly between uses.

d. *Competition:*

Currently, a Rochester-Pean forceps and "peanut" sponge are used to retract the thyroid medially. However, the single tissue-contacting area of the peanut does not provide enough traction or surface area of contact and causes the thyroid to fold. To solve this problem, two Rochester-Pean forceps are sometimes used to increase contact area and traction. This method also proves to be problematic, due to the difficulty of maneuvering two forceps with one hand. Other surgeons may use alternative methods to medially retract the thyroid.

References

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