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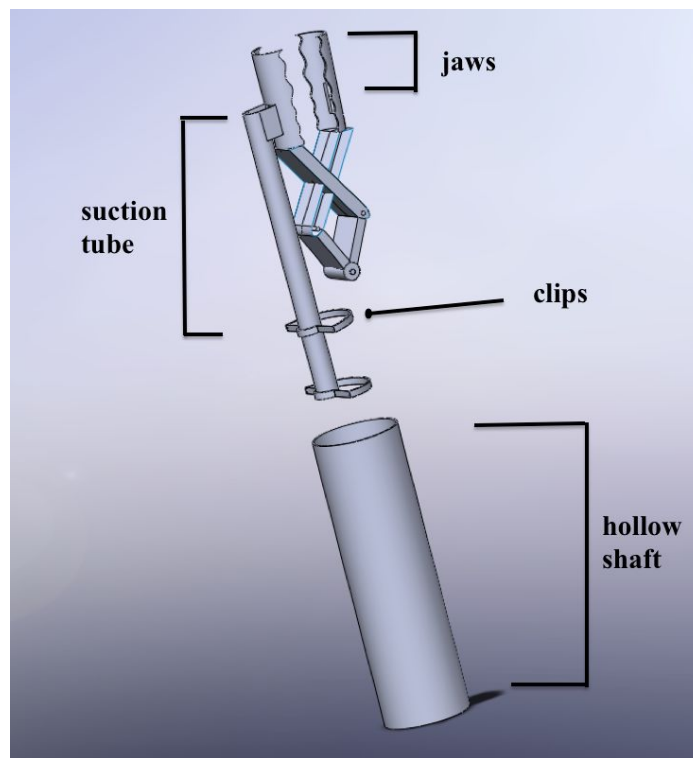
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A Revolutionary Approach to Transsphenoidal Surgery: The PEDG

By: Lavonia Duncan, Giselle Perkowski, Ren Garcia, and Paidia Ewing

March 26, 2020



A. Background:

A1. Pituitary Tumors

The pituitary gland is considered to be the master gland, as it secretes hormones as a communication mechanism to send messages to other endocrine glands to stimulate or inhibit a gland's hormone production [1] (Figure 1). When a tumor develops in the pituitary gland it affects the gland's function by either sending an excess of hormones that usually regulate the function of other glands or decrease hormone levels (Figure 2). While some tumors can go unnoticed, others can cause a variety of symptoms, depending on the hormones affected. For example, one can experience increased levels of fatigue, unexplained weight loss or weight gain, caused by an overproduction of specific hormones.

Pituitary tumors are adenomas which are characterized as non-cancerous growths confined to the pituitary gland and surrounding tissue. Therefore, they do not spread to other parts of the body [2]. The tumor location may also be a factor that increases the effect of symptoms due to the small space in which it grows. The resulting pressure of the tumor acting on surrounding neural structures can also cause headaches and even a loss of vision [3].

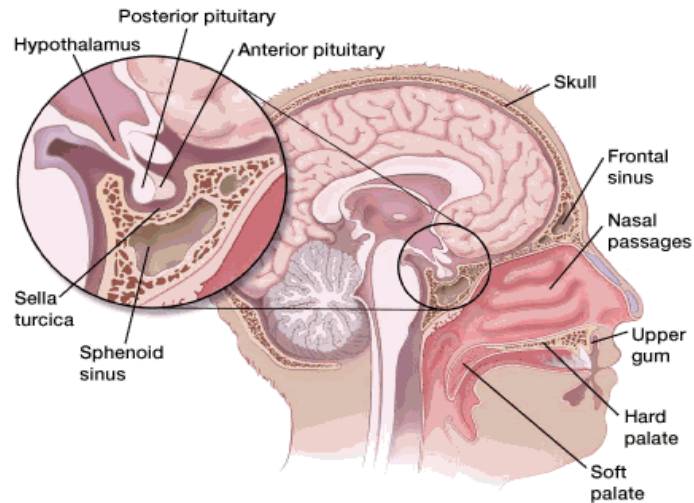


Figure 1: The pituitary gland and nasal passage [4]

There are two different sizes of pituitary tumors: macroadenomas which are 10 mm or greater and microadenomas which are generally less than 10 mm in diameter [3]. Pituitary tumors also have three different types of texture: soft, medium, or tough. Soft textured tumors have a liquid-like consistency enclosed in a loose membrane and tough textured tumors resemble a soft, rubber texture. Medium tumors have a texture ranging between tough and soft textured tumors [3].

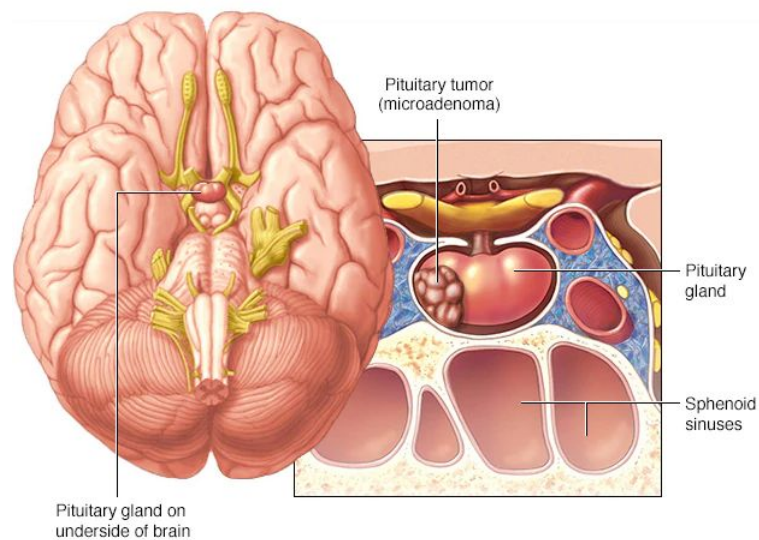


Figure 2: The location of the pituitary gland [5]

A2. Transsphenoidal History

Most pituitary tumors are removed depending on the size and how the tumor has grown in the brain. There are many surgical reasons for removing a pituitary tumor, particularly if it is pressing on the optic nerve or signaling the overproduction of hormones. Two of the most popular techniques to remove pituitary tumors include Transsphenoidal Surgery or more traditionally a Craniotomy. If surgery is not necessary, the tumor is typically treated with radiation therapy and medication [2].

A craniotomy is performed for large and more complex tumors (Figure 3). The procedure incorporates a 3-D neuronavigation system and previously performed MRI's and CT scans for better visualization of the structure and tumor location on the gland. The incision is made over the tumor location, a piece of the skull is removed, and the dura is cut to access the tumor for removal [6]. After the surgery is completed, the surgeon closes the dura, reattaches the skull with titanium screws and plates, and closes the scalp with sutures and staples. This surgery is completed in two and a half hours. Similar to other surgical procedures, there are many complications that may occur. For a craniotomy, there is the possibility of suffering from strokes and seizures, bleeding, infections, blood clots, swelling in the brain, nerve damage, cerebrospinal fluid leakage, and even the loss of some mental function [6].

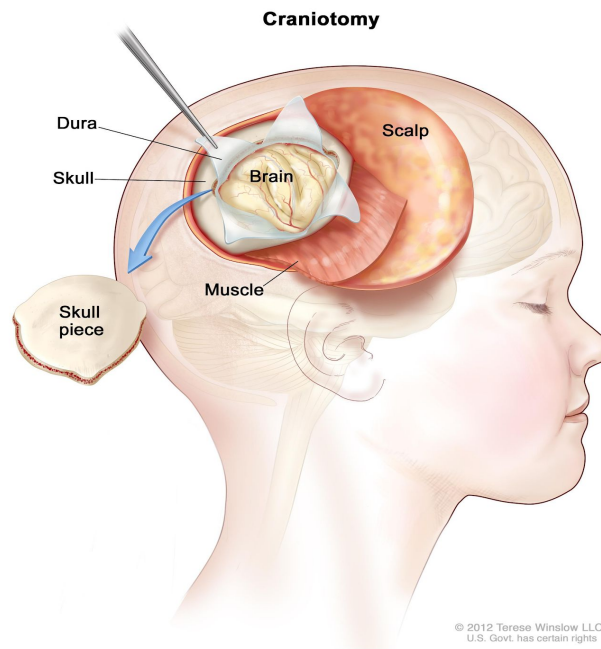


Figure 3: Crainitomy, a surgical procedure previously used to remove tumors from the brain and associated with dangerous complications [7]

The less invasive and safer method of removing pituitary tumors is Endoscopic Transsphenoidal Surgery (Figure 4). This surgical procedure is performed to safely remove most tumors and therefore, is the desired method of tumor removal. The surgery is performed by making a small incision along the nasal septum, removing the sella which is the bone positioned between the sinus and the brain, and removing the tumor. Then, a packing material is placed into the nasal cavity to stop any bleeding caused from the incision [8]. This surgical procedure can take up to three to six hours to complete, but it has less postoperative complications. Some of the risks of this surgery include cerebrospinal fluid leakage, meningitis, damage to the pituitary gland, hematomas, and vision problems [8].

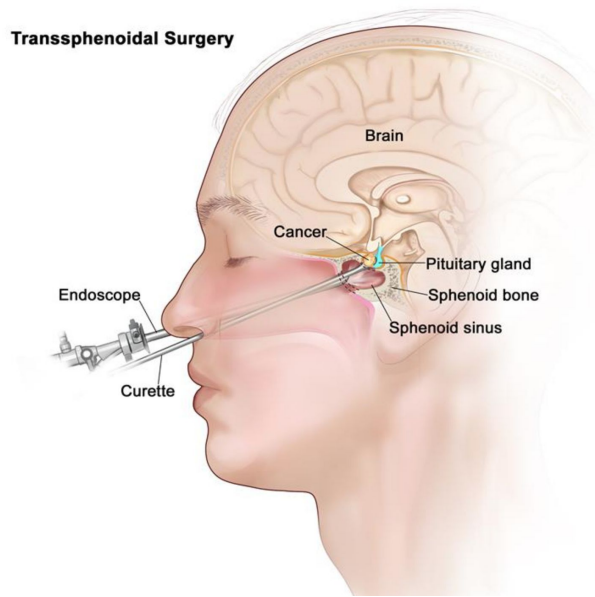


Figure 4: Transsphenoidal Surgery, a current popular surgical procedure used for the removal of pituitary tumors [9]

In both surgeries, many tools are used throughout the procedure to gain access to the brain and to remove the tumor. An aspirator is used during a craniotomy to break the tumor apart and collect the pieces through suctioning [6]. Forceps can be used to grip the tumor and a scalpel can be used for cutting. The tools used in Transsphenoidal Surgery are similar to those used in a craniotomy. For tumor removal, however, nasal forceps are more commonly used instead of regular forceps for grasping a tumor. A suction machine is then used for tumor collection [8]. In both surgeries, an endoscope is used for the surgeon's visualization to examine the tumor inside the brain and to avoid any surgical complications [6, 8].

Currently, there are many instruments in the market that are designed for Transsphenoidal surgery as well as general sinusoidal surgeries. The Evans 360 Rotatable features a 360 rotatable tip with varying tip options and improved gripping capabilities (Figure

5). However, even with this improved tool, the surgical time is still lengthy for effective tumor removal and therefore needs refinement.



Figure 5: The Evans 360 Rotatable Forceps [10]

A3. Patents

Additionally, there are many patents that have similar aspects and mechanisms to Transsphenoidal surgical instruments. The patent shown in Figure 6 is an endoscope with a removable suction tube [11]. This device features a suction tube which attaches to the endoscope via a circular connector (#40 in Figure 6), with an identical shape and size to the suction tube. The suction tube runs along the length of the endoscope, avoiding any interference with the pinching mechanisms occurring inside of the shaft (Figure 7).

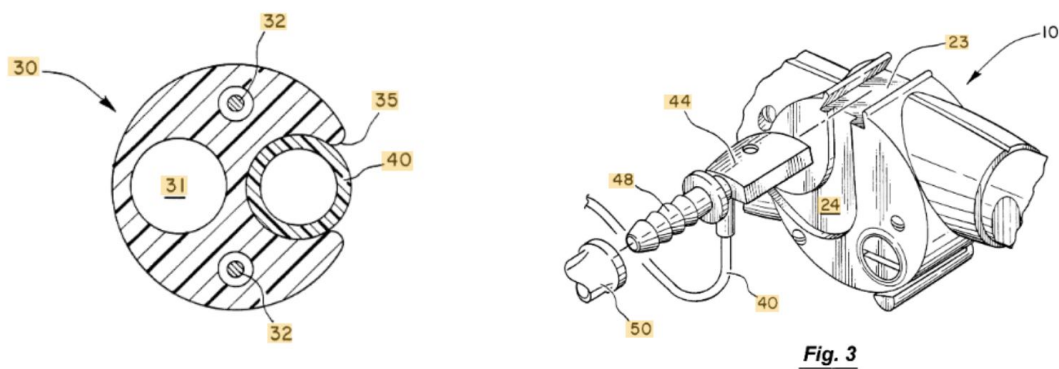


Figure 6: The Endoscope device with a removable suction tube. These drawings show where and how the suction tube would fit next to the endoscope, including an exploded view of the suction tube connector [11].

A removable suction element has many benefits to a stationary suction element, as it poses a lower risk of infection for the patients and is more efficient, as it can be more easily sterilized or disposed if needed.

Another relevant patent which incorporates a suction device is the Suction and Irrigation Sealing Grasper [12]. This patent incorporates a suction tube by inserting the tube through the handle, and running it through the shaft to the tip (Figure 7, 8).

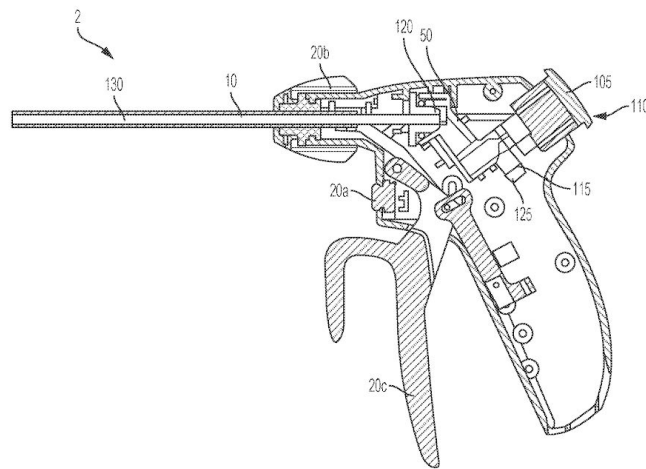


Figure 7: The cross sectional view of the Suction and Irrigation Sealing Grasper showing the inside mechanisms of the device and how the different components are connected [12].

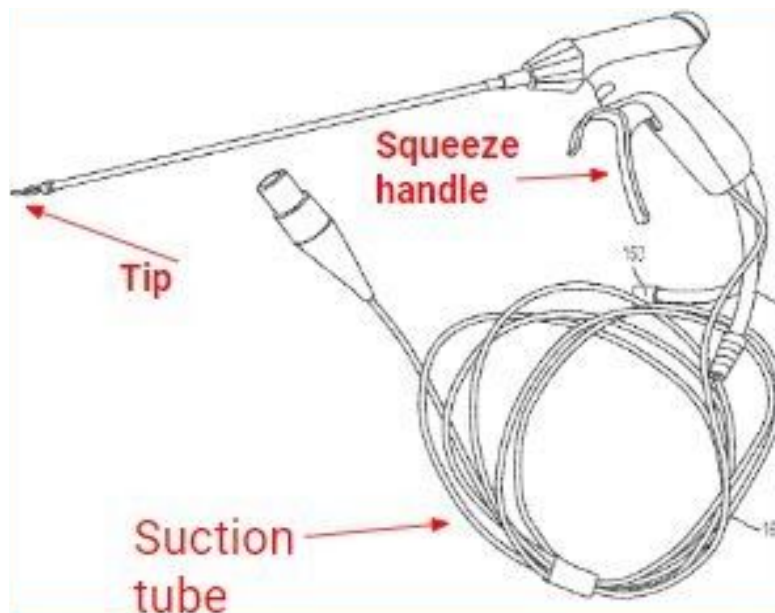


Figure 8: The entire device, including the suction device connected and the squeezable handle [12].

The tip has jagged ends but is hollow inside, which allows for the suction tube to be secure in the tip, without interfering with the grasping mechanism or puncturing the tube (Figure 9). This tip design has jagged teeth present on the interior edge of the tip to easily grasp a tumor while avoiding damage to the surrounding tissue (Figure 9).

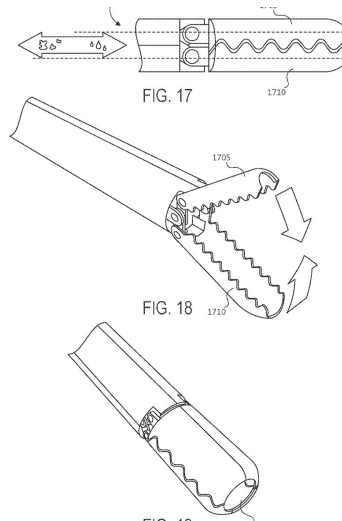


Figure 9: A close up view of the tip mechanism of the device, which includes a hollow portion for the suction tube [12].

The hollow circle in the middle of the tip allows for connection of the suction component to the tip, where it can draw in tumor fragments as the tip grasps at the tumor (Figure 8) [12]. The squeezing type handle mechanism is more convenient, easier to handle, and more comfortable for the surgeon [12].

Another patent found was the Development of a Suction-Irrigation-Grasper Multi-Tool for a Miniature Surgical Robot, which contains a tip with jagged ends and a hollow space in the middle of the shaft used for a vacuum device (Figure 10) [13]. This component is electrically controlled, which has improved surgical control and functionality.

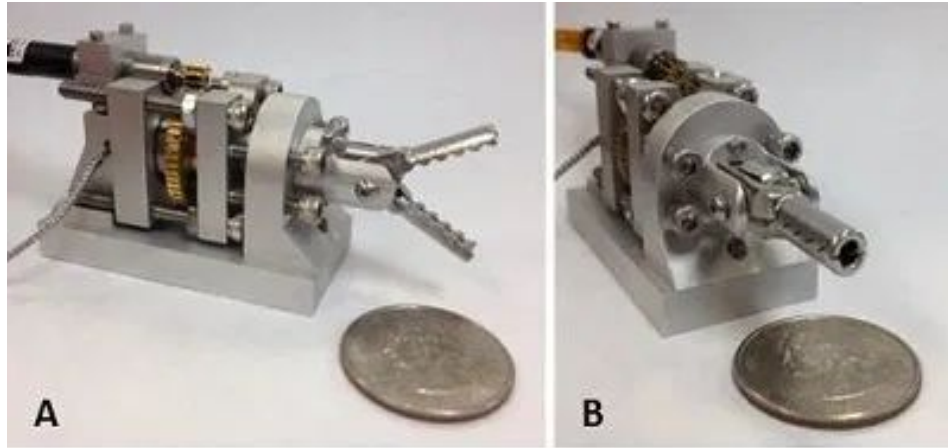


Figure 10: Development of a Suction-Irrigation-Grasper Multi-Tool for a Miniature Surgical Robot , which features a mechanically controlled tip with a space for the suction device in the center of the device [13]

B. Problem Statement:

Transsphenoidal Surgery is a minimally invasive endoscopic procedure done to remove pituitary microadenomas, which are generally smaller than 10 mm in diameter and are characterized by three texture types; soft, medium, and tough [14]. Soft textured microadenomas are typically more easily removed by aspiration with a suction cannula, whereas medium and tough textured tumors are much more difficult to aspirate, especially as a whole tumor. Surgeons often face difficulty using surgical instruments to segment and extract each piece of a tough tumor and the location of pituitary tumors is a significant hindrance on surgical efficiency, due to its close proximity to the optic nerve and carotid artery [14]. **About 1500 pituitary tumors diagnosed each year are tough textured microadenomas found mainly in patients aging from 55-80. Improving the tools used for extraction will allow for better control and precision during the procedure to ensure that tough textured tumors are completely removed from the pituitary gland and that surgical time is reduced.**

C. Design Objectives:

We generated three main objectives for our design, including efficiency, marketability, and safety, based on the needs of the patient and surgeon. We weighted these objectives to determine their relative importance in the design. Efficiency and marketability were weighted with the highest design emphasis, as safety is a given objective in the medical field. Under the efficiency objective, we created time saving and multifunctional, as these objectives correspond with the main purpose of our design, which is to shorten surgical time. The multifunctional objective includes designing a multi-faceted instrument used in sinusoidal surgery and transsphenoidal surgery, including but not limited to the removal of pituitary tumors. These multiple design elements will help ensure that tissue is properly dismantled and removed. It is critical to design a time saving device to improve upon surgical efficiency, as previous instruments require repeated removal of the instrument during the procedure with each obtained tumor fragment. Therefore, we wanted to design an instrument that can remain inside of the nasal cavity throughout the entire surgical duration to reduce the risks of surgical complications as well as to reduce procedural costs.

Under the marketability objective, affordability, durability, user-friendly, and easy to manufacture are all sub-objectives for this device design. We also added an additional generalizable sub-objective under marketability after meeting with Dr. Leapman, an ENT surgeon at AMC. Approximately 600,000 patients undergo some form of ambulatory sinusoidal surgery each year in the United States, which is a significantly larger number than the 1500 patients diagnosed with a tough textured tumor and treated in a year [15]. We

decided to proceed with designing a more general instrument that can be used for multiple types of sinusoidal procedures, including Transphenoidal surgery, as this would apply to a greater number of patients.

These objectives are essential given our time available for prototyping, the design budget, and access to materials. We wanted our instrument to be user-friendly, specifically fitting under the “one-handed method,” for a surgeon, meaning that all the desired mechanisms of the instruments can be accomplished with one hand. We also wanted our instrument to have a design that is substantially equivalent to other market approved medical instruments, yet still incorporating an innovative design. Lastly, the safety objective includes the instrument to be biocompatible and sterilizable. The portion of the instrument inserted into the body would be made of a biocompatible and sterilizable material. The biocompatibility of the instrument corresponds to the types of materials used and how they interact with a biological environment, such as inducing an inflammatory response in the body (Table 1, Appendix A1).

Table 1. Design Objectives

Efficient	Marketable	Safe
Time Saving	Affordable	Biocompatible
Multifunctional	Durable	Sterilizability
	User Friendly	
	Easy to Manufacture	
	Similar to current technology	
	Intuitive for Surgeon	
	Generalizable	

D. Device Functions and Specifications:

The goal of the design is to create an all encompassing device that can perform multiple functions at once. All functions were considered to ensure efficiency of the procedure and ease of use for the surgeon. The components that we focused on the most are the device's handle and tip which we altered for better handling and ease (Table 2). From the time that these functions were put together to the present design stage, there have been many changes made to scope of the project. Initially, the main use of the device was solely for the removal of tough textured tumor pieces in Transsphenoidal surgery, but after meeting with our mentor, it was concluded that the device could also be applied to general sinus surgery. The main purpose of the device still stands, which is to allow for the ease of removal of fibrous tissue pieces from the nasal canal that cannot be extracted easily with a suction cannula.

Table 2. Initial device functions

Handle Functions	Tip Functions
Handle can control tip sufficiently	Removes tough tumors in large chunks
Handle has additional knob for rotation control	Maneuvers through the nasal canal with ease
Handle has a gripping surface for surgeon's comfort	Collects and compresses tumor fragments to be suctioned
Handle has a squeezing function	Tool end can rotate at multiple angles to properly access tough tumors
Usable with one hand	Tool allows a clear field of view for operation
	Contains a suction element

We opted for a squeeze handle function instead of the traditional “scissor” function currently used in the laparoscopic forceps (Figure 11). The squeeze function allows for better control and for more mechanisms to be included to control the tip, such as a rotating knob, without compromising the device’s functionality with one hand.

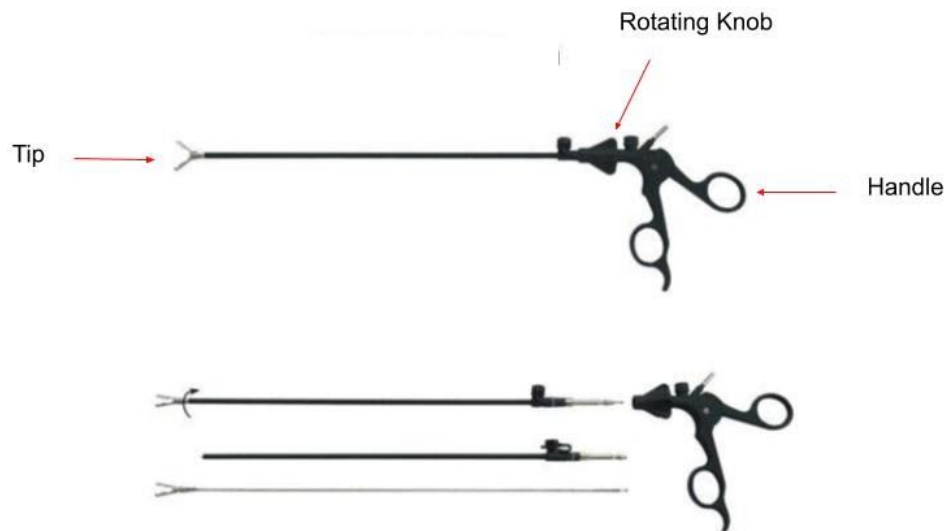


Figure 11. Laparoscopic forceps with scissor handle [15]

The tips that are currently used for Transsphenoidal forceps simply grip and tear off pieces of tumor tissue. The volume of tissue that is gripped is often very small; if large pieces are torn off they cannot be extracted easily through the narrow canal. As a result, the surgeon must continually insert and retract the forceps as they remove miniscule pieces one at a time. This is both tedious and time consuming for the surgeon. Our device’s tip functions aim to avoid this issue. The main function is to include a suction element that will extract fragments without complete removal of the device. The ideal suction force is 525 mmHg and the tube is designed to

fit within a tip of diameter of 4 mm [17]. Another function of the tip is to compress large pieces so that they can be suctioned more efficiently. The rotation aspect also relates to the function of the tip which will allow for better control and can reach surrounding areas in the nasal cavity.

E. Design Requirements:

The requirements of this design fall under three main categories which include: the tip's gripping volume capacity, the vacuum's suction force, and the handle mechanism.

E1. Gripping Volume Capacity

The tip should be capable of gripping tissue pieces and simultaneously tearing off sufficient fragments to fit inside the compressed tip. Given that the diameter of this tip is 4 mm and approximating that the tip is hemisphere in nature, the volume of tissue it can hold is approximately 33.5 mm^3 . This is a very rough estimation as it is dependent on the shape of the tip and the varying textures of the tumors. The tip function will be tested independently from the suction to ensure that it performs well at tearing the pieces before they are suctioned.

E2. Suction Force

The suction ability of the device is crucial to improve the overall efficiency of the procedure as it allows for faster extraction of tissue fragments. As mentioned earlier, the ideal suction force is 525 mmHg. This value, however, only indicates the strength of the suction pump. Our device will have a suction tube with a diameter less than 4 mm. This will affect both the force of suction and the size limit of the tumor fragments that can be extracted without getting trapped in the suction tube. The suction force should be sufficient enough to transport a

tumor fragment with a volume equal to 33.5 mm^3 or less, in order to meet the desired requirements.

E3. Handle Mechanism

We opted for a squeeze mechanism as the desired function for the handle because it will make the device more comfortable and easier to operate. The main goal is to provide the surgeon with enough control over the amount of force transferred to the tip, and this can be done more intuitively when the device is held between the palm and four fingers, instead of being held with two fingers and the thumb, as used in the traditional scissor handle. If the handle is capable of transferring adequate gripping force to the tip, then it will meet the desired requirements. The strength used to squeeze the handle should be proportional to the grip of the tip.

Another important feature of the device is that it can be utilized with only one hand. The pinching mechanism and the rotation are both controlled on the handle by the surgeon. In current devices, the rotation knob is located between the end of the shaft and the beginning of the handle (Figure 11). This means the surgeon must use their second hand to twist the knob for rotation. The squeeze mechanism would allow the surgeon the freedom to, instead, use their thumb to rotate the knob, when the knob is located in the correct position. The user should be able to comfortably use their thumb to rotate the knob for at least 10 full rotations.

F. Documentation of the Proposed Design:

Our device, the PEDG, works to effectively grasp and remove any sinusoidal tissue fragments as well as additionally functioning to remove tough textured pituitary tumors through the nasal passage. This design works in a two step fashion to first grasp at given tissue and then aspirate the dislodged fragments and other debris with an incorporated suction device (Figure 12). This device is inserted through the nasal passage, runs through the sinus regions, and reaches the pituitary area of the brain. The long, slim shaft allows for easy nasal insertion with a removable suction device securely clipped along the shaft's exterior. The distal portion of the suction tube is inserted through the outer surface of the jaws to rest in the hollow space between the jaws to be situated in a location allowing for proper suctioning. The other end of the shaft connects to a star-shaped rotational knob which mechanically controls the rotation of the shaft and the tip of the tool. The knob is located at the back of the handle. The handle utilizes a squeezing mechanism to control the opening and closing of the jaws for gripping tissue. After the device is inserted through the nasal cavity, the handle is squeezed to control the tip and can be rotated by using an individual's thumb to move the star-shaped piece right or left in a dial-like motion. This mechanically controls the rotation in incremental amounts. The suction component, which rests between the two jaws at the tip end, vacuums the dislodged tissue fragments and any other debris accumulating in the jaw space into a collection container outside of the body for easy discarding.



Figure 12: SolidWorks of the PEDG, showing the overall design of the device.

F1. Tip Function

The purpose of the tip of the device is to grasp and tear the tumor in order to remove it from the pituitary gland (Figure 13). The tip mechanism of most current devices is simple in which the tip mechanism utilizes only one connection. However, our device uses two connector pieces to properly connect the tip mechanism to the shaft in order to be controlled by the handle. The tips of current devices are also not sharp enough, which makes it harder to tear the tumor in pieces for removal. The tip designed for this instrument has jagged edges that are sharp enough for tearing at the tumor, yet do not damage surrounding structures. At the front of the tip, there is a round smooth edge, that was designed to avoid cutting any other important parts of the pituitary gland and surrounding structures. The jagged edges are important to easily tear off pieces, rather than cutting the tumor, and their interior

positioning avoids inflicting damage to other structures. When the tip is closed, there is a hollow hole in the surface of one of the jaws in which the suction tube can be inserted (Figure 14). This allows for the suction tube to be used as part of the larger instrument.



Figure 13: 3D printed tip showing the jaws and the hole where the suction is inserted

The mechanism used to control the tip was adapted from the Bissinger Laparoscopic Bipolar Forceps (Figure 11). The mechanism is scissor-like and has two sets of connectors. One set of connectors is directly fastened to the jaws, while the other set is connected to the wire which is controlled by the handle. The connectors are attached to each other and this creates a scissors mechanism which controls the open and closing of the jaws when acted upon by the handle. When the handle is squeezed, a wire pulls down on one set of connectors which then pulls down on the other, thus controlling the jaws.

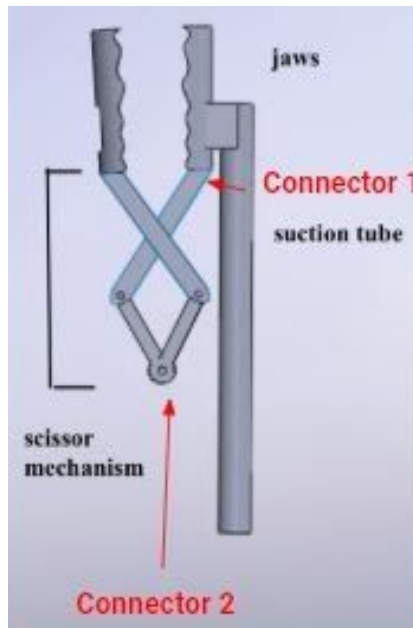


Figure 14: SolidWorks of the tip function with the suction connected to the shaft exterior

F2. Rotation

The rotational mechanism is mechanically controlled by the user. It is a star shaped knob piece with a hole placed in the center of the shaft that connects to the handle of the device (Figure 15). The spaces between each star point is where a finger can be placed to control equal amounts of rotation of the shaft and tip. This works by using an individual's finger to push the triangular point left or right, which in turn rotates the shaft and tip of the device for improved tissue removal. This type of mechanical mechanism allows for easy and controlled rotation, without requiring the user to remove their hand from the handle during a procedure. This makes for a convenient device, used with only one hand and leaves the other hand free to control the endoscope, which is necessary for surgical visualization.

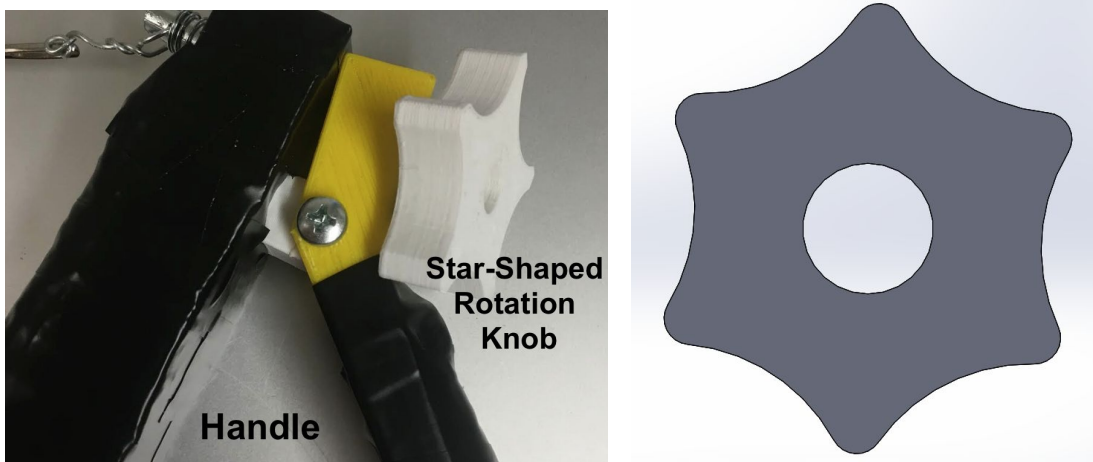


Figure 15: The handle (left) and star shaped rotating knob (right) for our prototype.

F3. Handle

The primary goal of the handle portion of this device was to be comfortable for the surgeon during long surgical procedures. This was accomplished by including a squeeze mechanism into the design, which is an easier motion to perform over alternative mechanisms used in current tools. The mechanism commonly seen in current technology is a “scissor-like mechanism,” which can be seen in the Bissinger Laparoscopic Bipolar Forceps (Figure 11). The squeeze mechanism controls the tip by having a wire affixed to one end of a connector which pulls the jaws of the tip closed. Near the handle, this wire is joined to the handle using a tip connector which is affixed to a metal piece that moves back and forth upon when the handle is squeezed (Figures 15, 16). Everytime the handle is squeezed, the jaws of the device close, respectively. The handle is also padded with a foam material for surgical comfort. Without cushioning, due to the hand placement, a surgeon will often experience muscle fatigue after a long surgery.



Figure 16: Another example of the handle mechanism. This was used in an earlier prototype and was a model for our current handle.

F4. Suction

This suction mechanism of the device is used to aspirate tissue or tumor fragments and other debris. We designed connectors to attach the suction tube to the outside of the shaft portion of the device. Therefore, this allows the surgeon the freedom to decide if a suction device is needed for that given procedure, as this feature can simply be added by attaching the suction tube to the outside of the device. For our prototype, we used a baby aspirator to mimic a suction device typically used in a hospital setting. We connected a longer tube to the head of the aspirator, attached the tube to the outside shaft, and then situated the tube between the jaws of the tip. When turning on the baby aspirator, this device will vacuum any tissue pieces or unwanted debris (Figure 17).



Figure 17. Graco Baby Nasal Aspirator [18]

G. Validation of Design

In order to verify that the PEDG meets the satisfactory design specifications, tests were designed to validate the device's suction capability, surgical efficiency, gripping strength, and rotational feasibility. Tough textured tumors were modeled using clay pieces for each test. In each test, certain variables were quantified for further analysis to prove that the PEDG improves tissue and tumor removal. Unfortunately, due to time constraints, the tests were not completed.

G1. Suction Capability

An integral part of removing tough textured tumors is incorporating a high vacuum force that aspirates tumor fragments from the pituitary gland to an outside storage compartment. The vacuum force would be tested using suction tubes made of a polymeric material, all with

different diameters. We hoped to measure the suction force by tracking the time needed for the tumor to travel from the instrument's tip to the storage compartment. We want to verify if the diameter of the suction tube affects the aspiration rate from the tip to the storage compartment. We predict that a smaller diameter for the suction tube may require a higher suction force since friction from the tube may inhibit the velocity of the tumor fragments. The tumor's velocity would be recorded using a camera with a slow motion option, such as the *Tracker* application. Additionally, the same measurements would be performed for tumor fragments in two types of vacuum devices that have varying amounts of force: a baby nasal aspirator as well as a car vacuum cleaner. The car vacuum cleaner could be used for later testing as it provides a much stronger suction force, which may be needed in the device to remove tissue from the surgical space.



Figure 18. Car Vacuum Cleaner [19]

G2. Surgical Efficiency

Reducing surgical time is an essential component to the design. This is accomplished by incorporating the suction mechanism as this eliminates the need to frequently insert and retract the instrument from the nasal passage. For this test, we would represent a tough textured tumor using playdoh since it has a similar texture. Therefore, the surgical time would be tested by timing the entire tumor extraction process including the time it takes to complete the grasping, suction, and rotation mechanisms for the removal of one playdoh piece less than 10 mm in diameter. Since the PEDG is scaled up by 4 times of a traditional Transsphenoidal tumor removal instrument, the diameters of the playdoh would be scaled up by 4 times as well. This test would be repeated for five different diameters of playdoh, measuring 7, 14, 21, 28, and 35 mm.

G3. Gripping Strength

The instrument would be tested on materials of various textures to see how effectively it can tear pieces from the samples, which include raw chicken meat, donut pieces, playdoh, and jello. The test would determine the range of gripping strength, since these materials have different textures, ranging from tough to soft, respectively. The tougher textures would require a greater gripping strength whereas softer materials would require less strength. These results correspond to the material strength of sinusoidal tissues extracted during surgical procedures, including pituitary tumors. This will provide a general idea of the strength of sinusoidal tissues and the required gripping strength of the PEDG's tip to remove these varying materials.

G4. Rotation Efficiency

The rotational mechanism is essential in removing tough textured tumors because it allows for the instrument's tip to have a full range of motion, up to 360 degrees. In order to verify that the instrument's rotation handle is comfortable and easy to use, 20 participants would be selected to rotate the star-like shaped knob on the PEDG and rate the efficiency of rotation in 2 sub-categories: comfort and ease of use. Each participant would be asked to rate each category based on a score from 0 to 4 (0=very poor, 1=poor, 2=good, 3=very good, and 4 =excellent). Similarly, participants would be asked to rate the laparoscope rotating knob, since it is similar to the design of currently used Transsphenoidal and Sinus Surgical Instruments. The mean rating for both the laparoscope rotating piece and the PEDG's rotating piece would be calculated separately, for further comparison and analysis. This would ultimately determine which instrument is more comfortable for a user in terms of the rotational knob.

H. Anticipated Regulatory Pathway

Although our device may not yet be incorporated in hospitals, it is still necessary to understand how our device can be cleared by the FDA. Therefore, a similar device to the PEDG is analyzed below, that has already received 510 (k) pre-market approval. The Captura Disposable Bronchoscope Biopsy Forceps was recently approved in 2018 as a Class II device by the FDA.

For FDA approval, the device must satisfy four requirements before submission. The first consists of proper classification (Class I, II, and III) and understanding the safety threats to its users [20]. For example, the PEDG is a Class II device that is invasive and poses moderate to high risks to patients, as it accesses the pituitary gland through the nasal passage and may disrupt neighboring structures, including the optic nerve [2]. Additionally, the device should be submitted for 510k premarket notification since it is a Class II instrument and it is “substantially equivalent” to a sinus and transsphenoidal surgical instruments on the market [20]. Once the PEDG has been submitted for 510k premarket approval, the FDA will conduct administrative and interactive review. Lastly, the PEDG should comply with regulatory controls to ensure that it is safe and effective for use [21].

The Captura Disposable Bronchoscopic Biopsy Forcep (rigid) is a Class II approved for market release on February 21, 2018 [22]. The 510k application was submitted by Wilson-Cook Medical Inc., located at 4900 Bethania Station Road Winston-Salem, NC 27105. The 510k regulation number is 874.4680 and the product code is EOQ [22]. The applicant who submitted the 510k was Ashley Howard, a Regulatory Affairs Specialist I at Wilson-Cook Medical Inc.. Under the regulation number, a report was made describing the Identification and Classification details about the Bronchoscope forceps [22]. The Identification sector describes the components of the device that are to be reviewed by the FDA. The Captura Disposable Bronchoscope Forceps comes in a set with other Bronchoscopic accessories, including a bronchoscope with rigid and flexible curettes that have similar components and mechanisms to the PEDG. All components of the device and its accessories are made of stainless steel or flexible plastic. The

Classification of the device is Class II, Bronchoscope (flexible or rigid) and accessories 21 CFR 873.4680, as stated by the Regulation number [22].

The main purpose of the bronchoscope set is to examine the lungs and the bronchi through a biopsy in adult patients and is often used with fiber optic light to obtain better visualization of the larynx. The bronchoscope cages the bronchoscopy biopsy forceps during a procedure, to ensure that it is protected from neighboring tissue. The ENT controls the forceps by opening and closing the handle at the end of the forceps. The tips of the forceps are connected to the handle by a coiled spring that allows for the tips to open and close.

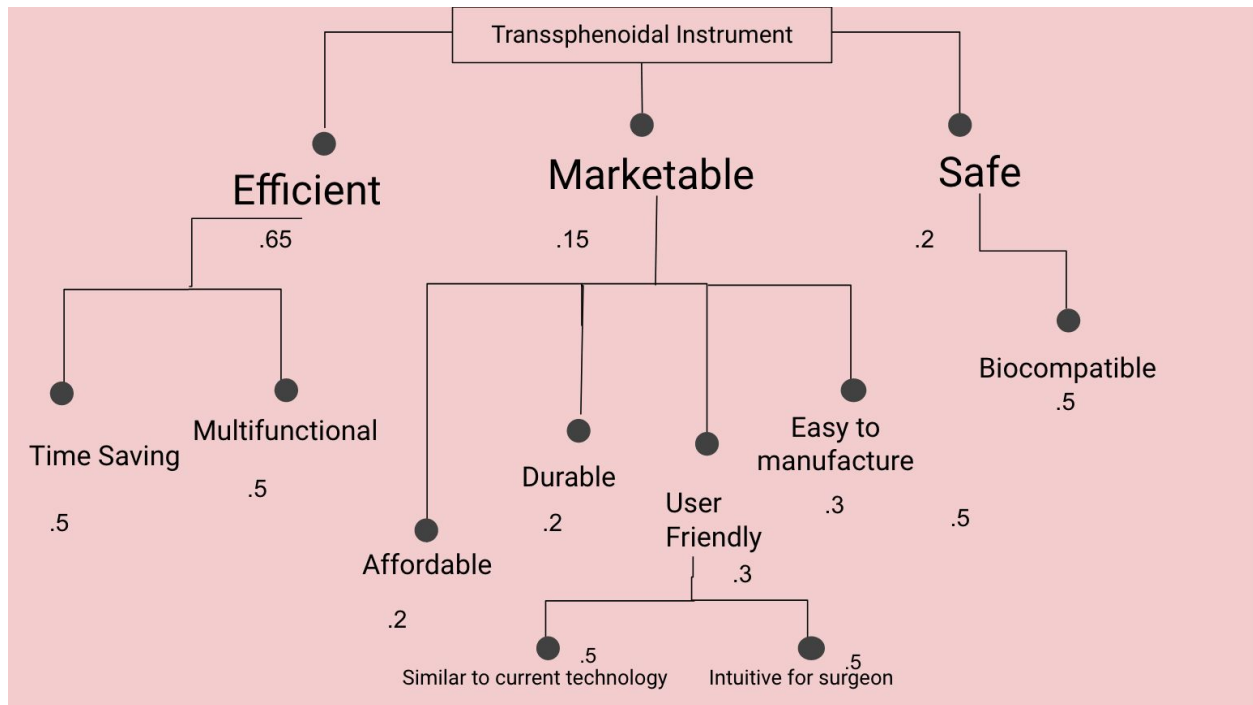
When the bronchoscope set was compared to other manufacturer products it was marked as “substantially equivalent” to other products, such as the Disposable Bronchoscope Biopsy Forceps that was cleared on November 18, 1992 (reference number: K923847) [22]. The significant difference between the disposable bronchoscope biopsy forceps and the Captura Bronchoscope Biopsy Forceps is the handle and changing the forcep tip; instead of a spiked tip, it is cupped. These changes were made to improve the strength of the forceps and to improve the procedure steps.

Additionally, non clinical testing was performed to confirm that the device validates its designs specifications. The design team performed flexure, fracture, and force tests, however, specific details about such tests were not described in the 510k notification clearance [22]. Tests were also performed for cytotoxicity, sensitization, irritation, acute toxicity, and material-mediated pyrogenicity, in accordance with the FDA “Biological evaluation of medical

devices- Part I Evaluation and testing within a risk management process,” guide [22]. The team also provided an instruction guide to be followed by the surgeons so that the device is only used for its intended functions. After the device was approved by the FDA for the 510k premarket status, the device was noticed to have various problems with its design including the tip, difficulty in removal, obstruction of flow, and cracks on the instrument [22].

The PEDG has comparable mechanisms to the Captura Bronchoscopy Biopsy Forceps. The PEDG and forceps are both required to internally access the body. Additionally, they are both simultaneously used during procedures with an endoscope. However, the PEDG does not require the endoscope to encompass it, as it enters the nasal passage, while the forceps require protection from the Endoscope. Additionally, the PEDG has jagged, sharp tips for tumor extraction, while the Captura Bronchoscopy Biopsy Forceps tip has a cup configuration.

Appendix A: Design Objective tree with the three main objectives: efficient, marketable, and safety, as well as lower level objectives.



Appendix B: References

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