Enhanced Safety and Visualization for Endoscopic Sinus Surgery

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Abstract

Currently, endoscopes used in sinus surgery present a fire hazard in the operating room (OR), as they can ignite patient drapes when set down unattended. Also, scope visibility is hindered by blood, condensation, and mucus, which coat the endoscope during use. A solution to this is the design of a scope caddy to house and clean the scope when idle and a sheath to protect it during nasal insertion. It is intended that both of these products may be patented and marketed together as a kit.

§ 1. Problem Statement

In endoscopic sinus surgery, the endoscope used presents a fire hazard in the operating room when left unattended. Also, inserting and extracting the scope from the nose frequently results in blood on the lens which obscures visibility. This project will attempt to address both of these problems with a scope holster containing an anti-fog solution, and a retractable sheath which will reduce contamination of the scope during insertion.

§ 2. Background Information

§ 2.1 Endoscopic Sinus Surgery

Sinusitis is a condition that afflicts 37 million Americans a year (Medtronic). The sinuses are composed of four cavities: the frontal, maxillary, ethmoid, and sphenoid sinuses (American). These sinuses allow for the proper drainage of mucus. Sinusitis results from an inflammation of the sinus membranes. Obstructions in these areas can block natural drainage and cause a risk for infection. This condition can be acute or chronic, the latter being less frequent and often requiring surgery.

Endoscopic sinus surgery was developed in the 1950's and has become increasingly popular throughout the years. This surgical technique was based on the theory that the best approach to obtaining healthy sinuses is to open up the pathways to the sinuses (American). The endoscope used is a very thin tube, inserted into the nose to visually examine the sinuses. The goals of endoscopic sinus surgery are to relieve nasal blockages, relieve facial pain, improve breathing, and improve the senses of smell and taste (eHealthMD). Endoscopic surgeries usually last one to four hours, depending on

the severity of the case and the surgeon. Because this surgery is minimally invasive, most surgeries can be performed as an outpatient procedure, or less frequently, as an overnight hospital stay.

During the surgery, the surgeon inserts a microdebrider into the nasal passageway to remove the obstructive tissue and polyps. The debrider has a dual edged blade that is usually set to oscillate. The tissue is sheared off and extracted by an attached suction device (Krouse). The endoscope is used to view the inside of the sinuses during this process. During the surgery, blood and sinus discharge is normal. This messy environment poses problems for the endoscopic lens. Vision through the lens can be obscured by this contamination several times throughout the surgery. The contrast between a clean lens and a bloodied lens is shown in Figure 1.

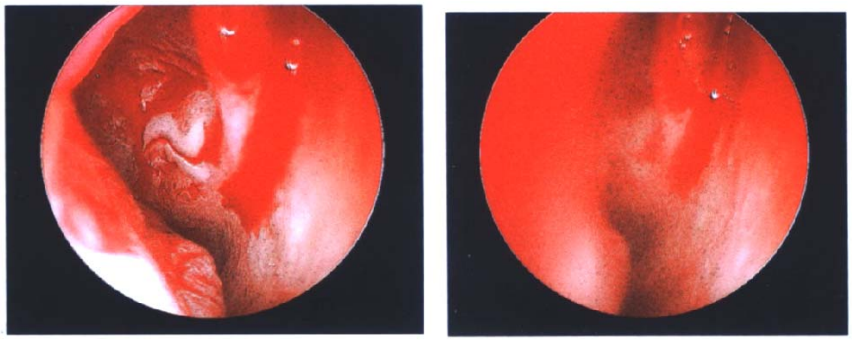

Figure 1. Clean lens (left) versus contaminated (right).

There are complications that can arise during surgery. The sinuses are in close proximity to the brain, eye, and major arteries. While severe complications are rare, injuries to the eye during surgery may result in double vision. Puncturing a hole in the brain can result in leakage of cerebrospinal fluid and serious complications (Medtronic). Due to this proximity, cases of chronic sinusitis, large polyps, or unusual nasal anatomy, utilize near 3D guided imagery. This imaging system combines tomographic scans of the

patient's head with infrared tracking of instrument position (Medical). Due to the expense of this equipment, it is utilized only in high-risk surgery.

§ 2.2 The Nose

The human nose is primarily composed of bone, cartilage, and fatty tissue. In endoscopic sinus surgery, the endoscope enters the nose through the nostril and proceeds past the nasal cartilaginous septum to reach the sinuses. This is shown in Figure 2. The blood vessels in the nose, especially those near the nasal septum, lie abnormally close to the surface of the nasal membrane. Accordingly, this region often bloodies the endoscope lens as it passes.

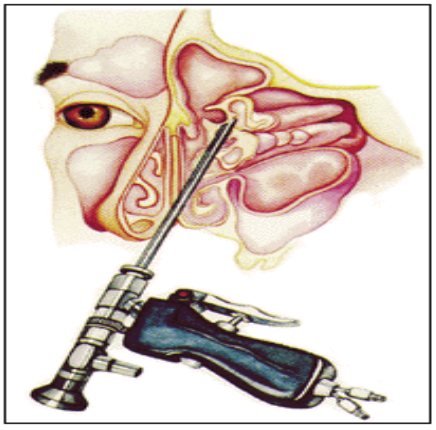

Figure 2. Endoscope in the nasal sinuses after passing through the nasal passageway.

The extent of this problem is related to the initial size of the patient's nasal passageway. Narrow nasal passages necessitate repeated cleaning of the endoscope lens during surgery. This involves removing the endoscope from the nose, cleaning the lens, and then reinserting the endoscope. To increase the efficiency of these procedures, a device or method to allow the endoscope to pass into the sinuses without contacting the nasal membrane is needed.

§ 2.3 The Operating Room

The current operating room setup for the endoscopic sinus surgery procedure creates a traffic jam of equipment within a limited amount of space. During the surgery,

the operating table is kept horizontal and the surgeon stands adjacent to the patient's head. Other personnel crowd the room such as the scrub tech, circulating nurse, and the anesthesiologist.

The types of equipment necessary for this procedure fall into three categories: handheld equipment, video equipment, and standard operating room equipment. During the procedure, the surgeon is primarily utilizing two instruments: the endoscope and the debrider with suction. This set up is shown in Figure 3. There are two video monitors directly across from the surgeon, displaying the view from the endoscope lens and the near 3D mapping system. Additionally, the scrub tech tray, anesthesia equipment, IV lines, and items crowd the limited space.

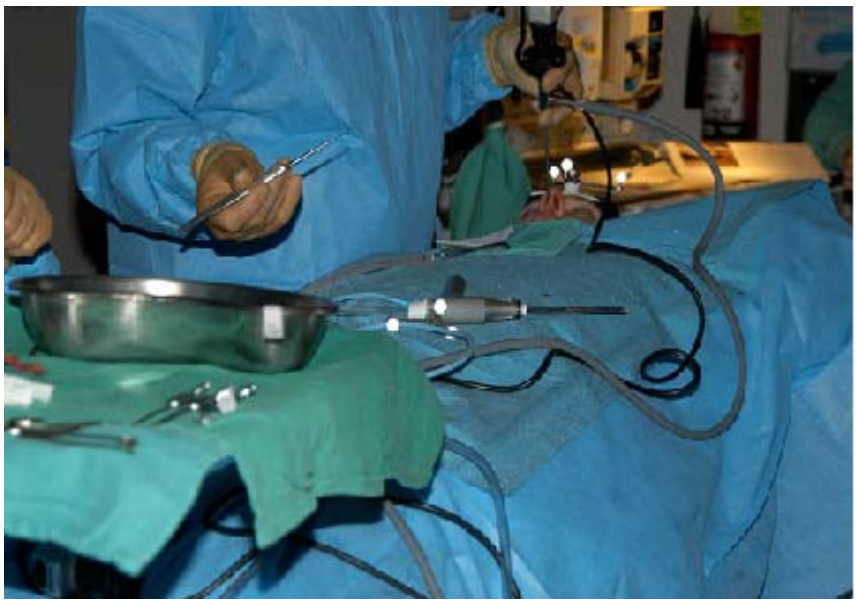

Figure 3. Typical set-up of an operating room.

This clutter of equipment presents a variety of concerns. The endoscope is often set idly on the drapes when unneeded. While not a frequent occurrence, the endoscope has ignited the drapes after prolonged contact. Furthermore, ergonomic issues exist concerning the frequent cleaning of the endoscope lens. The endoscope is typically cleaned by swiping the lens across a cleaning pad with defogging solution. This cleaning pad is placed freely on the drapes near the patient's head. It is unanchored, and

unintentionally moves around when the surgeon attempts to wipe the scope. Lastly, the large amounts of equipment tubes and cables can become entangled and obstruct the operating space. When surgical complications occur, organization is vital as every second counts. Disorder can be dangerous, time consuming, and expensive (Anderson).

§ 2.4 Design Constraints and Client Requirements

The main goal of the project is to enhance the safety and efficiency of the endoscopic equipment and surgical procedure. Primarily, the design needs to reduce the fire hazard associated with the endoscope. It should also expedite the cleaning and defogging of the endoscope lens and keep it clean during nasal insertion. The reduction of wire clutter is secondary concern. Any design should address, and may not exacerbate, the current problem.

The design should be consistent with the anatomical constraints of the nose. Specifically, if a nasal expander is used, considerations for the elastic deformation of hyaline cartilage (5MPa), the main cartilaginous component of the nose, must be incorporated into the design (Spahn et.al). Also the dimensions of the nasal passageways must be considered. The nasal septum is generally 2.6 ± 0.3 cm x 3.1 ± 0.4 cm and the nostril openings 2.5cm antero-posteriorly x 1.25cm transversely (Mowlavi et.al). The variability of nasal parameters across various age and ethnic groups must be accommodated.

The design must be cheaply mass-produced, disposable, and easily incorporated into the operating room. Additional design constraints can be found in the attached Product Design Specification (Appendix C).

§ 3. Design Alternatives

§ 3.1a Horizontal Shelf Design

Overview

The horizontal shelf design alleviates many of the same problems as the vertical shelf design (discussed later). However, it would store the endoscope and debrider on a horizontal shelf when not in use. It can be seen in Figure 4. Aside from reducing the fire hazard, it would feature cleaning and defogging pads placed vertically near where the endoscope lens is placed. One passing swipe of the endoscope could simultaneously clean and defog the lens. The method would be most beneficial when the endoscope is picked up from the tray, as the lens could be cleaned and defogged with minimal effort.

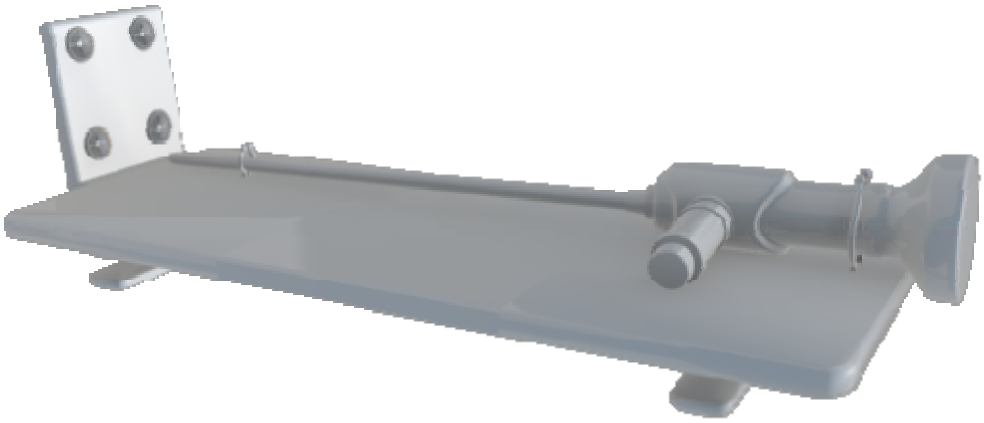

Figure 4. The horizontal shelf design, which stores the endoscope and debrider on a tray while they are not in use. This would attach to a nearby, solidly anchored tray.

The device would likely be made of an easily sterilized solid plastic. It could be made for one-time use, eliminating the need to sterilize, or could be made from metal that tolerates sterilization and would allow for reuse of the product. The tray would have elevated holders to secure the endoscope and debrider. This would allow for easy

gripping of the tools by the surgeon. The tray would attach to a nearby, solidly anchored tray via two large clamps. This would limit placement options but would avoid the clutter introduced when adding another table.

Advantages

The horizontal tray would be a fireproof device and would eliminate the need to place the endoscope on the patient. The endoscope would be conveniently picked up from and set down on the tray. The placement of the defogging and cleaning pads would hasten cleaning of the endoscope lens.

Disadvantages

The horizontal shelf would need to be placed farther away from the patient's nose, and so the time needed to move the endoscope from the nose to where it is stored would be slightly increased, especially compared to the holster design. How the shelf is attached might be an issue, as the shelf is rather large, and so would only add more clutter to the surgeon's environment. In order to be feasible, the shelf would likely need to be made of metal and therefore would need to be reusable to be cost effective, but it is the client's wish that the device be a one time use package.

§ 3.1b Endoscope Holster

Overview

The second proposal for an endoscope holder is the endoscope holster. Generally modeled after a pistol holster, this device supports the endoscope with the lens aimed

downwards as shown in Figure 5. This orientation not only provides a natural, ergonomic means for storage, but is also the basis for the defogging process.

Figure 5. Endoscopic holster design with passive angle, shown here at 90°.

An already available defogging solution is stored in the cylindrical reservoir that houses the extended portion of the endoscope. This hollow cylinder need only be filled with enough liquid to sufficiently submerge the lens. A small sponge will be placed at the reservoir bottom to further clean the lens and reduce splashing if the holster were to be bumped. The defogging solution also provides a liquid heat sink to cool the endoscope. A funneled entrance to the cylindrical reservoir helps channel the endoscope into the defogging solution. This allows quicker and more carefree use by the surgeon. It also serves as platform that accommodates the larger and heavier portion of the endoscope.

Attached to the funneled entrance is another platform that hosts the lens-cleaning pad. These pads, like the defogging solution, are common and are provided for all endoscopic procedures. The pads are currently kept loose and will move during use. The holster design affixes them to the platform and so keeps them steady during use. A thin line of coincidence provides an articulating connecting between the platform and funnel entrance. This allows the use ratcheting clips to attach the platform to the patient's shoulder at a horizontal angle. The bend would allow the funnel entrance and cylindrical reservoir to point downwards and gravity would keep the endoscope and cleaning solution within the cylindrical reservoir.

Advantages

There are many advantages to the holster design. Storing the endoscope reduces the risk of fire, which the heat sink effect of the defogging solution should further minimize. Defogging solution yields an improved image quality over the present method of wiping the lens with a loose defogging cloth. The defogging requires no additional effort by the user as it is automatically accomplished upon storage. The attached cleaning pad makes wiping the lens quicker and less frustrating. The use of standard cleaning pads reduces the need for proprietary device peripherals.

The ratcheting clips allow the surgeon to choose a convenient location for the holster. The holster is designed to hang off of either shoulder, depending on the dominant hand of the surgeon and orientation of the patient. In addition, the passive bend between the platform and funneled entrance allows for various patient sizes and storage angles. It may be oriented anywhere between 0°-90° relative to the horizontal plane. This permits the production of a cheap and convenient "one size fits all" design. The holster shall be designed to fit the largest typical endoscopes to facilitate use in other surgical procedures.

The simplicity of the device is a key advantage. With no moving parts or electronics, the passive design has a low possibility of failure. Proper material selection should allow for mass production with low-cost injection molding techniques.

Disadvantages

The primary design advantage is the possibility of heat damage to plastic. Prolonged endoscope storage could result in excessive heat build up and the plastic may deform or puncture. Although unlikely, this could result in leaked defogging solution, possibly onto the sterile operating environment, and a damaged endoscope. Proper material selection and product testing could mitigate such effects.

The double-stick tape used to adhere the cleaning pad to the platform does not allow for the cleaning pad replacement during a long procedure. It also prevents one from using both sides of the cleaning pad.

Given the length of the cylinder and the bend created by the shoulder contour, it is possible that the endoscope could be knocked from the holster during an operation. The addition of a third ratcheting clip to create a triangle with the original two would reduce the likelihood of such an event by providing added stability.

These disadvantages will be further investigated through additional testing. Any necessary changes will be made for future prototypes in an effort to minimize potential problems. The present design supports many advantages and few disadvantages and has a high probability of functioning successfully.

§ 3.2a Shape Memory Polymer Design

Overview

The Shape Memory Polymer (SMP) design addresses the concern of decreased visibility due to contamination of the endoscope lens when entering the nasal passage. The SMP design is a nasal

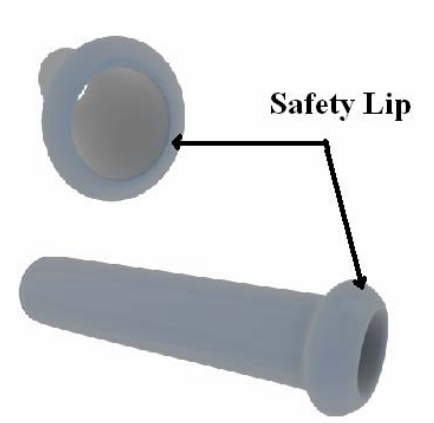

Figure 6. Frontal and lateral view of SMP nasal expander design

expander based on the use of thermal activated shape memory polymers.

Using thermal stimuli, shape memory polymers can change from a rigid polymer to an elastic state, then back to a rigid state again. In its elastic state, the polymer will recover its "memory" shape if left unrestrained. Ideally, this design would be fabricated to be slightly larger than the nasal cavity and have a low activation temperature. Therefore, the polymer will retain the manufactured 'memory' shape, as shown in Figure 6, yet be elastic enough for the surgeon to 'squish' the polymer, position it into the nasal cavity and release. It would then re-expand and stretch the nostrils to creating a large and protected passageway to the sinuses.

The SMP design is ergonomically modeled to fit the nasal passageway without producing unnecessary regional stress to the native tissue. It also has a 'safety lip' to allow easy removal following surgery as well as security in its placement.

Advantages

Shape memory polymers can be stretched, folded, and conformed while tolerating up to 200% elongation and still recover their 'memory' shape when unrestrained (Shape Memory Polymer Tutorial). The expansion property of the design should sufficiently open the nasal passage and provide extra maneuvering room for the surgeon. Also, the addition of a safety lip decreases concerns over removing the device while aiding in the proper placement of the device upon insertion.

It is important to note that shape memory polymers do allow for customizable thermal activation temperatures ranging from -30°C to 260 °C (Shape Memory Polymer Tutorial). This allows for a product that can be tailored to our specific design needs.

Disadvantages

The SMP design is highly customizable and the material is very specialized. Manufacturing of this design would require the cooperation of companies that could produce the material and fabricate the design. Since the material is so specialized, very few options exist for obtaining material. This results in costs that may be excessive given the disposable nature of the design.

Also, the design would have a maximum size that it can obtain. This limits the extent to which it can expand resulting in limited adaptability to extremes in nasal passage the size.

§ 3.2b Conic Plastic Expander

Overview

A conic expanded is another option for protecting the endoscope's passage through the lower regions of the nasal cavity. It can best be summarized as a tunnel that provides a barrier against contamination due to contact with the nose walls.

The design uses a plastic conic shell cut lengthwise to allow for changes in the interior diameter. The widest segment of the cone remains outside the nose with the narrower region funneled inside. To minimize the loss of space within the nose, the narrow portion has a slightly smaller diameter smaller than the wide portion. The split-cone design allows the surgeon to either curl the cone onto itself, reducing the interior diameter, or expand the cone for additional volume.

The conic plastic expanded is rolled tightly and placed into the nose. The plastic response of the materials will cause an outward expansive force within the nostril, thereby stretching the walls for additional workspace. Given the symmetry of the cone relative to its lengthwise axis, this expanding force will provide uniform pressure within the nose, for patient comfort. Forceps may be inserted into perforations in the cone. This allows the surgeon to further adjust cone volume and easily extract the expander. A slider, similar to a "zip-tie," may be used to lock the cone to a given volume and prevent unwanted expansion or contraction. This slider remains on the outside of the nostril for ease of use.

The expander will have a lip at the widest end to prevent it from completely entering the nasal passageway. This safety feature will assist extraction after surgery and improve adjustability. A single cone size could be adjusted for a wide variety of patients and thus few cone sizes would be necessary for the entire population, perhaps only adult, adolescent, and infant sizes.

Advantages

The main advantage of the conic expander is the simplicity of design and use. Made of plastic, the device could be inexpensively mass-produced via a molding process. In addition, the passive nature of the design offers little opportunity for failure or improper use. It can be inserted and removed from the nose with ease and speed. Once situated correctly in the nasal cavity it can be locked in place to prevent movement or accidental lodging.

Disadvantages

Although the conic shape allows for easy insertion and removal from the nose, there may also be a tendency for the device to become dislodged unintentionally. This would result in a loss of time for the surgeon or an inability to adequately protect the endoscope lens upon entry or removal.

Another drawback to the design is the need for outside tools for adjustments. The current proposal requires forceps to control cone diameter. While this tool is present in virtually any operating room, the device would optimally be a standalone product. Limitations on adjustability also necessitate the production of multiple cone sizes to accommodate all patients.

The greatest disadvantage of the conic expander is the limited range to which contaminant protection is offered. Although most fluids are present in the lowest portion of the nostrils, no protection would be provided for the remaining pathway to the sinuses. Further modifications as well as clinical testing may assist in reducing this and other potential disadvantages.

§ 3.2c Sheath Design

Overview

The sheath design is a long cylinder that protects the lens of the endoscope as it is inserted into the nasal cavity. It can be seen in Figure 7. The device works by sliding forward on the endoscope so that it protects the lens from debris such as mucus, water, and blood as it is inserted into the nasal cavity. Once inserted, the sheath is pulled back using the ring finger of the surgeon's hand, which is on the endoscope.

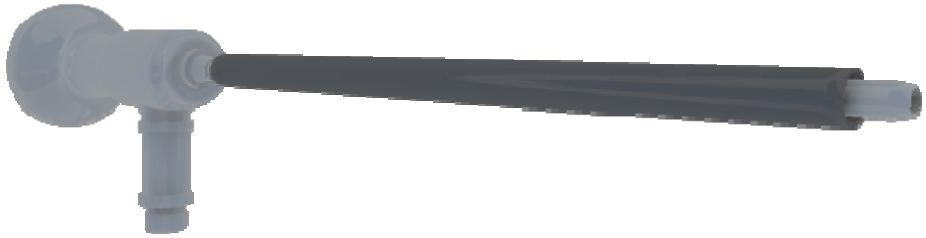

Figure 7. The sheath design extends over then lens during insertion into the nasal cavity, but then is pulled back by the surgeon for normal viewing through the endoscope.

This is very similar in design to how the surgeon used the Endosheath®, which can be seen in Figure 8. To use the Endosheath®, the client clipped off both ends of it, and used it the same way our sheath design is intended to be used.

Figure 8. The Endosheath®, which was used previously by the client with both ends cut off (Vision-Sciences, Inc.).

Advantages

The sheath is a straightforward design that speeds nasal endoscopic surgery not by making the cleaning and defogging go faster as in other designs, but by reducing the need to clean and defog the lens. It would be a very cheap design to produce, and if it did not need to be sterilized, would rival the cost of an ordinary drinking straw. This device would speed surgery by reducing the number of times the lens needs to be cleaned, and would therefore also save money.

Disadvantages

Some drawbacks of the design include the fact that the device may be somewhat difficult to manipulate during surgery. The surgeon would need to use his ring finger to operate it, and with so many distractions and more important tasks it may not be worthwhile to add another object that the surgeon needs to control. This product may not warrant the effort for the amount of good it does. Fogging of the lens would still be a problem, and the sheath likely would not do much to prevent it. Because of this, surgeons may feel that using this product is not worth the trouble.

§ 4. Design Decision Matrix

A design matrix was created to evaluate each alternative in order to select the best design. The matrices can be seen in Appendix A. The endoscopic holder and cover were compared in separate matrices, as they are solutions to two independent problem goals. The holder matrix compares the horizontal tray and holster. Each design was rated on a weighted scale for effectiveness in meeting design goals, including stability in an operating room, space consumption, cost, and ease of use. Using this system, the horizontal tray received a score of 44 out of a possible 60. Lack of stability, due to the patient mounted surgical setup, was this design's major flaw. The holster style was selected as the best alternative with a score of 58 out of 60.

Three designs were developed to cover the endoscope during insertion into the nasal cavity. They were compared in another design matrix with the categories: scope protection, ability to fit all patient types, size, preparation required, ease of use, and cost.

The memory shape polymer received the lowest overall score with 29 out of 50, because of its lack of adjustability and cost. The conic ranked second with a total of 42 because it could only protect the endoscope within a limited area. The sheath design received a perfect score of 50 because it is simple, fits all patients, and requires no preparation.

The design matrices, along with the discretion of the design team, determine that the holster and sheath were the two best designs. These designs will be developed in tandem and future work will focus on their optimization, construction, and implementation.

§ 5. Design Prototypes

§ 5.1 Endoscope Holster

Overview

The endoscopic holster was the best design for the housing and cleaning of the endoscope. After developing a final draft, a prototype was produced for testing and to provide a basis for further design improvements. The completed prototype is shown in Figure 9 and detailed design parameters can be found in Appendix B. It was originally intended that the design be created via injection molding or by rapid prototyping. This proved unfeasible, due to the costs associated with developing a mold and the unavailability of a rapid prototype machine. As a result, the initial prototype was manually mill from a ABS, plastic material.

Figure 9. Endoscope Holster prototype from 3 angles. The device was milled from ABS plastic.

The funnel entrance was hardest to mill. It was shaped from solid block of ABS plastic. The cylinder was developed as a separate piece and later attached to the funnel with epoxy. The platform, which hosts the cleaning pad, was machined from the same block of plastic as the funnel. The platform and funnel were attached by a piece of flexible plastic, as the ABS plastic was too brittle to bend as originally planned.

Although the piecewise creation of the prototype resulted in a working model of the endoscope holster, a uniform production method is desired in future versions. In addition to cost reduction, injection molding also reduces the time and effort needed to produce the device. Also, there remains some risk the sections to separate as they were formed separately and later bonded. Future efforts will investigate any design changes necessary for injection molding.

Materials

Initially, the scope caddy was to be fabricated with a rapid prototyping machine, but technical difficulties prevented this. Rapid prototyping uses acrylonitrile butadiene styrene (ABS). We constructed our prototype with ABS plastic because it is relatively easy to mill manually. It is a flame-retarding thermoplastic with an operational temperature range between –40 C and 71 C, though this varies with polybutadiene content.

ABS plastic is tough and impact resistant. These are desirable properties when one considers its use in a hectic operating room where objects are sometimes bumped and dropped. Unfortunately, it is a rigid material and cannot be properly bent to form an articulating joint. Furthermore, its temperature tolerance, while adequate for most situations, may not be sufficient for extreme situations where an endoscope is inadvertently left on in an empty scope caddy. It is likely that a different plastic will be chosen for subsequent prototypes and developments.

Expenses

Net expenditure for the project was $59.97. The primary cost was $40.48 for a 1 in x 12 in x 12 in sheet of ABS plastic. A 5 ft long ABS tube with a 0.75 in diameter was purchased for $15.00. A $4.49 bottle of epoxy was used to join the prototype's component parts. Much of the purchased plastic and epoxy was not used during fabrication but was necessary in case of damage during fabrication. These costs can be viewed in Table 1.

These development costs differ substantially from the production cost per unit were this to be mass-produced. Economies of scale, different materials, and automated production would reduce the unit cost substantially.

Table 1. Project expenditure on materials. ABS plastic was the primary cost.

	Unit Cost	Quantity	Total Price
ABS Rod	$3.00 per foot	5 ft	$15.00
ABS Sheet	$40.48 per unit	1 unit	$40.48
Epoxy	$4.49 per unit		$4.49
			$59.97

§ 5.2 Sheath Design

As discussed earlier, the sheath design is a long cylinder that that protects the lens of the endoscope as it is inserted into the nasal cavity. It can be seen in Figure 7. It works by sliding forward on the endoscope so that it protects the lens from debris such as mucus, water, and blood as it is inserted into the nasal cavity. Once inserted, the sheath is pulled back using the ring finger of the surgeon's hand, which is on the endoscope.

This device would be manufactured as a one time use product. The sheath would be made of a light weight plastic which would not need to have demanding mechanical properties, but would have to be non-irritating and easily sterilized. Current drinking straws are made from extruded polypropylene, which has the benefits of good dimensional stability, good chemical resistance, and can also be approved for human surgical contact and so we used a drinking straw as a basis for our prototype (Schueller).

The sheath will fit snugly around the endoscope, but should remain easy to slide. Dimensions can be seen in Figure 10. Upon consultation with the client, the cover that opens and closes will be removed, as he deemed it unnecessary. Also a grip for the ring finger to more easily manipulate the sheath during surgery should be added. For prototype construction, a common drinking straw, since it had appropriate diameter and was also made of polypropylene, was cut to length.

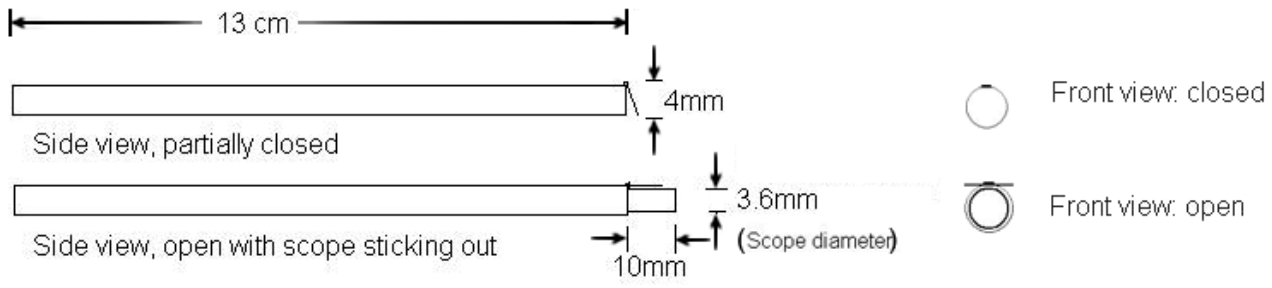

Figure 10. The sheath prototype's dimensions

§ 5.3 Testing

When in use, the light source for the endoscope can produce extreme heat which has the potential to set patient drapes on fire. Preliminary testing was done to determine how the holster design would be affected by the heat from the endoscope.

Testing was performed using 8cc of glutaraldehyde based defogging solution in the holster prototype with an operating room xenon based light source attached to the endoscope. This simulated the actual operating environment. Temperature readings from the solution in the holster were taken in five minute intervals over a thirty minute time period. The thirty minute time period was chosen based upon current clinical procedures. According to our client, it is reasonable to assume that the scope will not be left in the holster for longer than thirty minutes at a time.

The results from the testing are found below in Figure 11. Throughout testing the temperature of the solution changed less than 3ºC. The reason for this is that the holster with defogging solution acted as a heat sink, thus cooling the endoscope as heat is transferred from the endoscope to the surrounding glutaraldehyde environment.

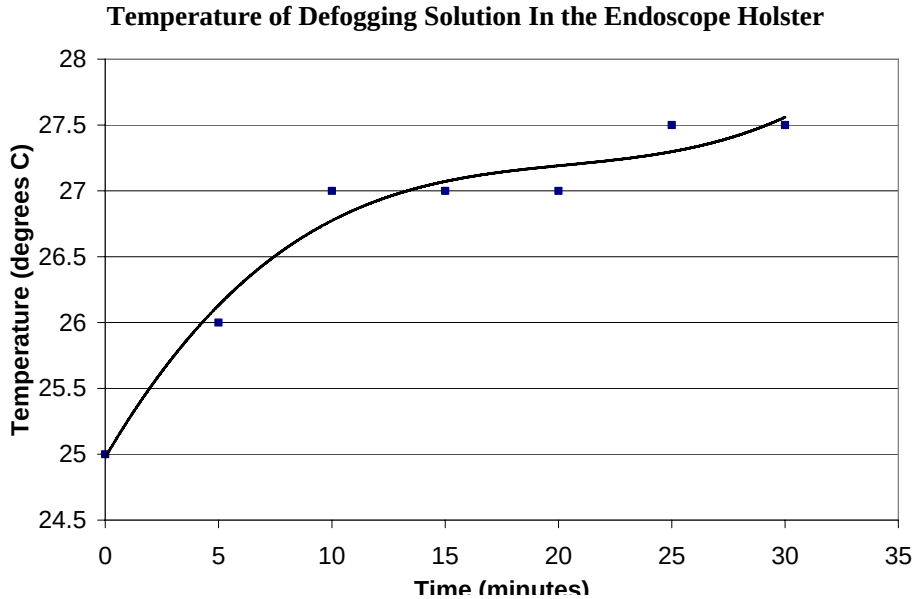

Figure 11: Results of preliminary thermal testing.

After the thirty-minute test period, the connection point of the endoscope to the light source was hot to the touch, while the portion of the endoscope that was in contact with the defogging solution remained cool.

The results from testing present a promising outlook for the design. This testing showed that use of the holster with defogging solution will decrease the potential fire and burn hazard previously associated with the endoscope. In the future, the other variables should also be considered in testing, such as allowing the endoscope to heat up first, and then testing the effects on the solution temperature over a longer time interval may provide useful information. Another parameter that should be considered is the affect of fluid volume over time. These results will inevitably help improve the holster design, specifically when the consideration the use of an alternative material.

§ 6. Ethical considerations

The endoscope holster and sheath are designed with full consideration for the safety and well-being of the human subjects involved.

The endoscope holster and the retractable sheath will be used in the operating environment. Thus, materials used must not endanger the patient or hospital personnel. Additionally, this device, specifically the sheath design, must be approved by the FDA for operating use.

§ 7. Future Work

Future work shall focus on incorporating the chosen designs into operating procedures. Improvements relating to material selection, manufacturing, and the overall design of the device need to be considered.

The current holster design was milled out of ABS plastic. During construction, the ABS was found to be too brittle for the initial design which hindered the incorporation of a hinge. This resulted in a multi-component device that required glued attachments. Ideally, the design incorporated a thinned section of plastic that can be bent to form a hinge. This would allow the entire design to be constructed as a single unit. Future considerations regarding mass production of the device will require researching a plastic appropriate for our design requirements.

The holster design should also be modified to a more conical shape that will provide a more secure encasement for the endoscope. This will allow for a worry-free placement of the endoscope and decrease concerns of the equipment possibly falling out of the holster.

Very little manufacturing was done on the endoscope sleeve device. Since the design itself is already very simple and functional the main focus of improvement for the sleeve design relates to its manufacturing and approval. Unlike the holster design, the sleeve will be entering the human body and there for will have additional FDA related considerations which need to be researched. With regards to manufacturing, research on ways to obtain a sterile, disposable plastic sleeve for testing purposes needs to be done.

In recognition of client aspirations, future work will also involve research into the mass production and patentability of the design. This will entail trial runs of the

prototype in an operating environment and subsequent testing of how heat from the scope will affect the plastic over time. Further modifications to the design will also be done to prepare it for injection molding and mass production. Finally, the possibility of producing an 'Endoscopic Sinus Surgery' kit with the incorporation of the device and any additional components, such as defogging solutions, will be investigated.

The future work described above will inevitably facilitate a smooth integration of the device into a hospital setting.

§ 8. Conclusions

The endoscope holster and retractable sheath designs adhere to the client requirements. The choice of incorporating the defogging solution and cleaning pad into the holster design provides the desired functionality components of protecting and cleaning the lens. The sheath reduces the frequency of insertions and extractions through the nasal passages. In addition to functionality, these designs ensure fire safety and proper incorporation into the operating room. The design team will focus next semester upon the selection of plastic, the design of the hinge, pursuing a patent, and creating a marketable surgical kit.

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Appendix A. Design Decision Matrices

Endoscope Holder

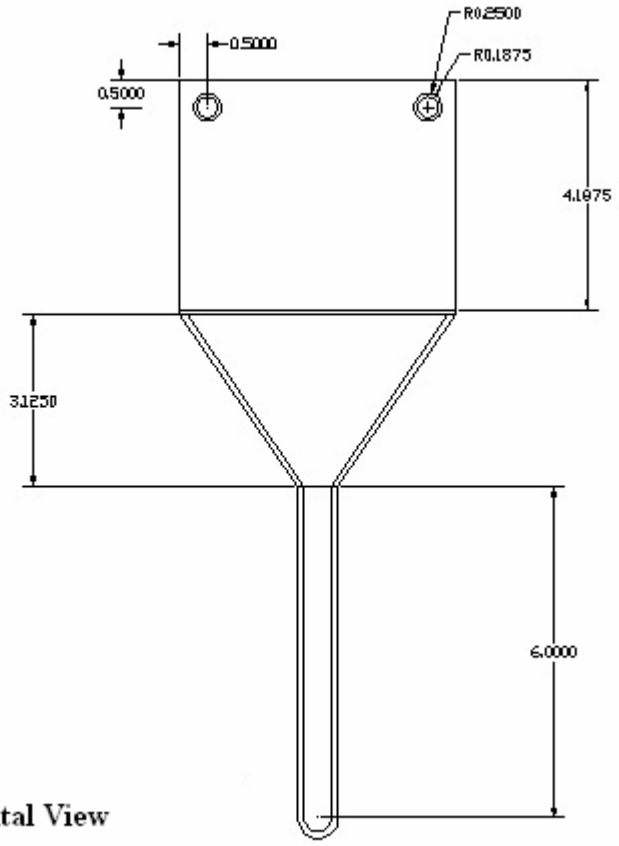
		Table Rack	Manual Holster
Light Protection	(10)	9	10
Cleaning ability	(10)	7	9
Defogging ability	(10)	7	10
Stability (on patient)	(8)	4	7
Ergonomics	(8)	6	8
Size and Weight	(6)	5	6
Preparation	(4)	2	4
Cost	(4)	4	4
Total	(60)	44	58

Endoscope Contamination Protection

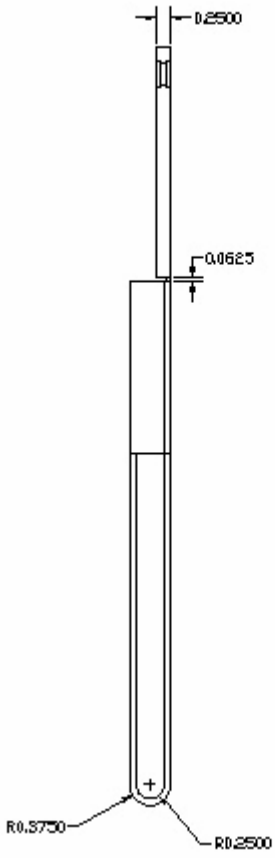
		Thermal Polymer	Conic Plastic	Retractable Sheath
Scope protection	(10)	8	8	10
Adjustability	(10)	0	8	10
Wall thickness	(10)	8	8	10
Preparation	(8)	4	7	8
Insertion/Extraction	(8)	7	7	8
Cost	(4)	2	4	4
Total	(50)	29	42	50

Appendix B.

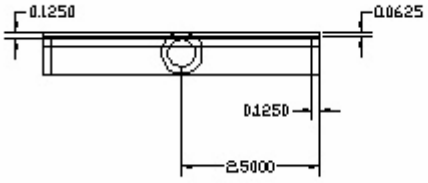
Holster Design Parameters (in cm)



Frontal View



Side View



Top view

Appendix C.

Enhanced Safety and Visualization for Endoscopic Sinus Surgery.
Project Design Specification (PDS)

Team Members: Leah Brandon, Adam Budde, Kieran Sweeney,
Tom Knight, Sara Worzella

Client: Dr. Ashley Anderson

Last updated: 12/04/06

Function: Currently endoscopic sinus surgery telescopes present a fire danger in the operating room, as they can ignite paper drapes. In addition, inserting and extracting the scope from the nose frequently results in blood on the lens. This project will attempt to address both those problems with a scope caddy containing defogging solution, and an alar (nose) opening retractor which will reduce contamination of the scope during insertion. In addition, other ergonomic and practical improvements to this procedure will be considered, including the possibility of incorporating an irrigation system into the retractor.

Client Requirements:
The client requires the design to:
- Enhance safety of endoscopic equipment
- Lens defogging and cleaning
- Reduce wire clutter
- Expand nasal passage

1. Physical and Operational Characteristics

a. *Performance requirements*: Disposable after single use. Design must be able to practically incorporate into hospital settings and current procedures.

b. *Safety*: Biocompatible with nasal environment if needed. Minimize heat and fire hazards. Chemical resistance to cleaning and defogging solutions.

c. *Accuracy and Reliability*: To the extent that is needed to maintain the safety and sterility of the operating environment.

d. *Life in Service*: One time use.

e. *Shelf Life*: Dependant upon the incorporation of cleaning and defogging solutions and their estimated shelf life. Overall, approximately one year prior to use.

f. *Operating Environment*: Operating room in a sterile field. Any endoscopic accessory devices may be exposed to biological and chemical fluids as well as heat from the scope. Most components will not be in direct contact with the patient

g. *Ergonomics:* Should incorporate into OR environment with accessibility and ease of use, including versatility to suit various endoscopic devices.

h. *Size*: Minimal size and footprint. The device should not detract, clutter, or interfere with the operating environment and procedures.

i. *Weight:* Minimal, comparable to size constraints.

j. *Materials:* Plastic materials are desired for ease of processing, size and weight constraints, and cost effectiveness.

k. *Aesthetics, Appearance, and Finish*: Secondary to safety and functionality. Simplicity is key, the design should be unassuming to the surrounding environment.

2. Production Characteristics

a. *Quantity*: Design should have to ability to be mass produced if desired by the client.

b. *Target Product Cost*: To be determined, but must be compatible with the disposable nature of the product.

3. Miscellaneous

a. *Standards and Specifications:* Must be FDA approved for OR use.

b. *Customer*: Product must not be time consuming or interfere in anyway with patient treatment to insure use of product by medical personnel specifically ENT surgeons.

c. *Patient-related concerns*: Materials, chemicals, or necessary electronics must not endanger patient.

d. C*ompetition*: Informed that no similar product is currently marketed. Previous patents existing for similar ideas include but may not be limited to the following: the Endosheath