Enhanced Safety and Visualization for Endoscopic Sinus Surgery

Leah Brandon (Corresponding Author)
University of Wisconsin-Madison, Department of Biomedical Engineering
Phone: (608) 406-0529 Email: ljbrandon@wisc.edu

Adam J. Budde
University of Wisconsin-Madison, Department of Biomedical Engineering

Tom Knight
University of Wisconsin-Madison, Department of Biomedical Engineering

Kieran Sweeney
University of Wisconsin-Madison, Department of Biomedical Engineering

Sara Worzella
University of Wisconsin-Madison, Department of Biomedical Engineering

Abstract

Currently, endoscopes used in sinus surgery present a fire hazard in the operating room, as they can ignite patient drapes if placed upon them. Also, scope visibility is hindered by blood, condensation, and mucus, which coat the endoscope during use. A solution to this is the design of an endoscope holster to house and defog the scope when idle, and to provide for ease of cleaning the endoscope's lens upon removal. During testing, the prototype acted as a heat sink to reduce the fire hazard and allowed for easy entry when the endoscope is placed in it. This device has the potential to increase both surgery speed and operating room safety when used during endoscopic surgery.

Keywords: endoscope, operating room safety, surgery efficiency, biomedical engineering

Background

Sinusitis, resulting from inflammation of the sinus membranes, is a condition that afflicts 37 million Americans a year. In addition, an estimated 1% to 2% of adults in the U.S. have lost their sense of smell and taste to a significant degree. Endoscopic sinus surgery is a prevalent method of treatment for these conditions.

The sinuses are composed of four cavities: the frontal, maxillary, ethmoid, and sphenoid sinuses which allow proper drainage of mucus. Obstructions in these areas can block natural drainage and be at risk for infection. This condition can be acute or chronic, the latter being less common and often requiring surgery.

Endoscopic sinus surgery was developed in the 1960s but did not become widely used in the United States until the 1980s. The goals of endoscopic sinus surgery are to relieve nasal blockages or facial pain and to improve breathing and sense of smell by correcting deviated septums or sinusitis [1]. The endoscope is a thin metal tube attached to a light source with a lens at one end. It works much like a telescope to give surgeons a view of the sinuses. This facilitates minimally invasive modes of surgery which results in faster, more efficient procedures that induce less stress on patients.

The endoscope, which utilizes fiber-optic technology, allows doctors to see inside the sinuses without cutting the face, and makes it possible to see parts of the sinuses that were formerly difficult to reach. A xenon light source is used in conjunction with the endoscope and has resulted in reports of patient skin burns and ignition of paper patient drapes [2,3]. The highest temperature recorded at the lens end of an endoscope attached to a xenon light source was 95ºC while the opposite end of the fiber optic light cables could reach 225ºC in 15s. The maximum temperature of the endoscope was reached within 10 minutes the remained relatively level throughout a 30 minute study [2].

Such incidents of patient burns or drape fires can occur when then endoscope is temporarily not in use and placed on the patient drapes. Currently, no device exists that provides a means of storage during surgery for the endoscope when not in use. The Association of Perioperative Registered Nurses (AORN) suggests that when electrosurgical instrumentation is not being used it should be placed in holsters to protect from fires or burns. Similarly, illuminated endoscopic cords need to be kept away from drapes, patient's skin, personnel's skin, and other flammable material [4]. The development of an endoscope holster provides an efficient way of addressing these safety concerns.

Other complications that occur when using the endoscope include decreased visibility due to blood or fog formation on the lens. During the surgery, blood and sinus discharge is common, which diminishes visibility multiple times throughout surgery. Currently this is resolved with a cleaning solution and defogging solution placed on pads atop the patient. Since these pads are not restrained well, often folding or moving while in use, they do not provide an efficient way of cleaning or defogging resulting in a source of undue frustration for many surgeons.

Design

The primary function of this device is to enhance patient safety during endoscopic procedures. This is achieved through reducing heat buildup on the endoscope and providing a safe and secure location for its storage. There are a variety of laparoscopic devices that may

ignite patient drapes and each may attain different temperatures depending on their duration of use [5]. The endoscope holster must be constructed of an FDA approved material that can withstand these temperatures. This design is intended for single use and must be appropriate for inexpensive mass production.

Temperature differentials also contribute to fog accumulation on the endoscope lens. The holster houses a reservoir of glutaraldehyde defogging solution used to clean and defog the lens. This solution acts as a heat sink to reduce endoscope temperature, which it must tolerate without evaporation. This should not be a significant issue as these solutions are typically 1-2% glutaraldehyde in water and have a boiling point of 100°C [6]. The endoscope may be wiped off on cleaning pads located on the flat top of the holster. These cleaning pads must be easily attached and replaced.

The operating room is often a busy, cluttered environment and the endoscope holster cannot exacerbate this problem. The holster will attach to the drapes via standard surgical clips that pass through 15.88mm holes in its cleaning pad tray. The holster should have a minimal size footprint and an articulating hinge between the tube that holds the endoscope and the cleaning pad tray. This allows for a versatile, unobtrusive device that may easily positioned at the surgeon's convenience. The holster's tube should be tapered to funnel the endoscope into position in the defogging solution.

An initial prototype of an endoscope holster was developed to address the requirements of the design problem. As seen in Figure 1, the device combined a long cylindrical reservoir to house the endoscope, a funneled entrance for easy insertion, and flat platform to support an adhesive cleaning pad. The reservoir was designed to contain a defogging solution to treat the endoscope during storage. This solution also provides a heat sink to protect the holster from heat-induced failure. The holster was designed to be clipped onto a patient's sheets through the holes in the flat platform such that the hinge allows the funnel and cylinder to bend over the shoulder.

Figure 1: Initial endoscope holster prototype made of acrylonitrile butadiene styrene (ABS) plastic.

Acrylonitrile butadiene styrene (ABS) plastic was selected as the material for producing the prototype. ABS was chosen for its low cost and its ability to be easily machined. Due to the brittle nature of ABS, the prototype could not be produced as a single object due to its inability to hinge at the funnel-platform interface. The necessity to produce the reservoir and funnel separately as well as utilizing a separate hinge to combine the elements limits the ability for the design to become a marketable product both economically and in terms of durability.

An improved prototype was created to permit the device to be produced as a single-unit, offering the ability to bend at the hinge. The shape has been modified to offer a 3-dimensional funnel in place of the original 2-dimensional design. This allows the surgeon to insert the endoscope with minimal effort and from any orientation. A cutout in the funnel permits the endoscope to completely enter the reservoir by providing space for the fiber optic cable connected at the endoscope base. Figure 2 shows a model for the modified endoscope holster design. Full measurements of the design can be seen in Appendix A. In addition, the overall dimensions of the holster device have been minimized to reduce weight, the cost of materials, and overall bulkiness.

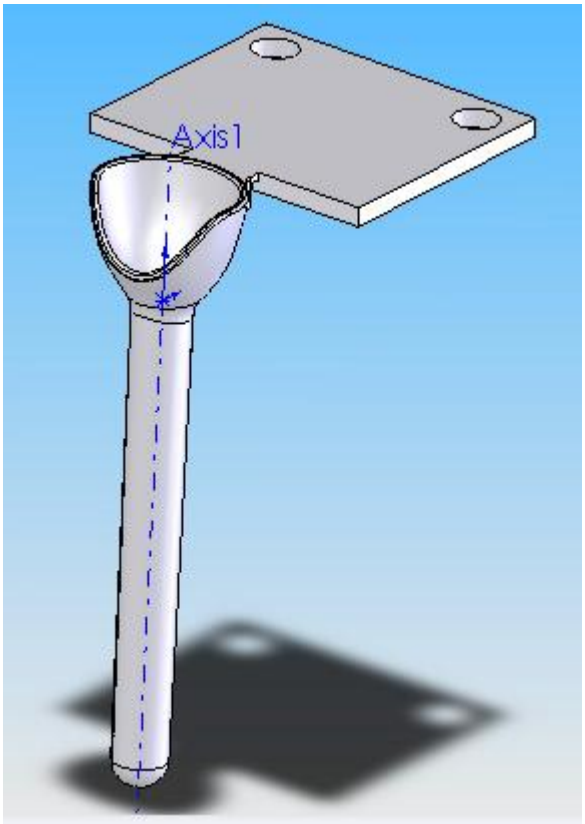

Figure 2: Modified Design for Endoscope Holster

Rapid prototyping technologies must be utilized to achieve the delicate contours and specificity of the design in place of hand milling processes. *Design Prototype Technologies* provides such services and offers a material known as DSM 9120. This polypropylene-like material offers robust durability, good chemical resistance, sufficient heat capacity, and in-use stability. Prototyping with this material is accomplished through a process known as

stereolithography (SLA) in which a liquid polymer is systematically cured through ultraviolet light [7].

Testing

The material used in the testing of the prototype was DSM 9120 polypropylene-like material. This material was found to be too brittle, as it broke at the platform piece at the hinge connection to the holster.

In preliminary testing, two tests were performed: cold start and hot start thermal testing. The cold start test started when the endoscope was initially attached to a cold light source. The endoscope was placed inside of the holster containing 8cc of glutaraldehyde-based defogging solution. Temperature readings from the solution were taken in five minute intervals over a thirty minute time period. In the hot start test, the endoscope was connected to the light source for an hour before an initial reading was taken. The one hour time period was chosen based upon current clinical procedures. At completion of testing, there was a gradual increase of 1.8ºC in the hot start thermal testing compared to 1.5ºC in cold start thermal testing as shown in Figure 3. After the thirty-minute test period of the hot start test, 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. This testing showed that the use of the holster with defogging solution will decrease the potential fire and burn hazard previously associated with the endoscope.

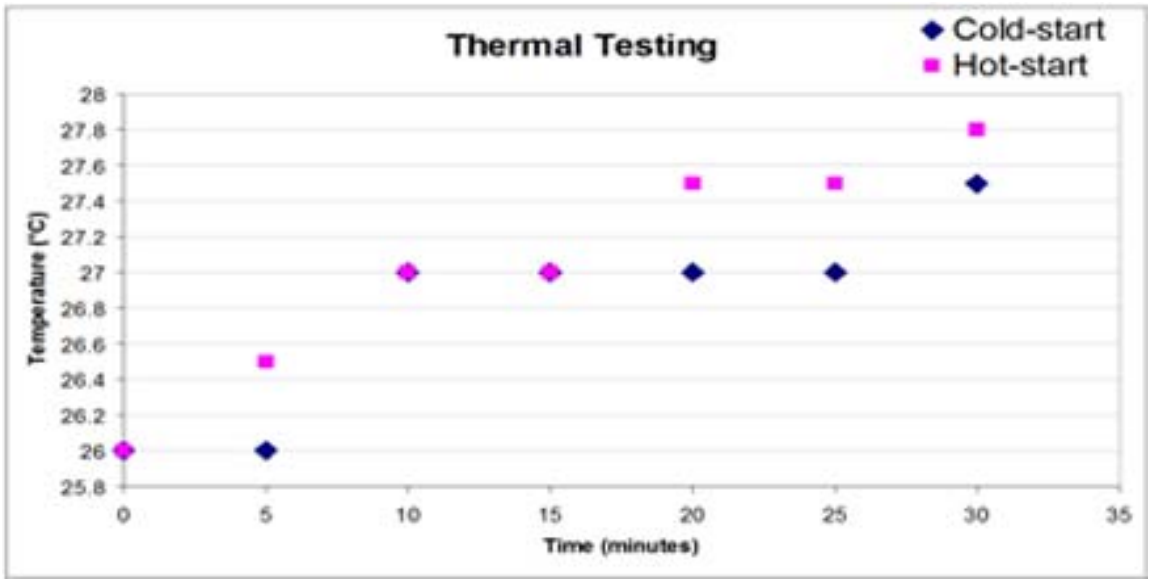

Figure 3. The thermal testing results of both beginning with a previously unused, cool light source and a previously used, hot light source.

In addition to temperature testing, the ease of use of the holster for the surgeon was evaluated. The prototype allowed a 70 degree wide angle of entry, a significant improvement over the previous prototype.

Conclusions

The failure of the rigidity testing was in direct contrast to the advertised properties of the prototype's material. A defect or mistake in the type of material used for the prototype likely caused this result.

The thermal testing of the prototype showed that the prototype with defogging solution only increased several degrees during testing. The reason for this behavior was that the holster with defogging solution acted as a heat sink, thus cooling the endoscope as heat was transferred from the endoscope to the surrounding glutaraldehyde environment. This shows that our prototype is more than adequate at reducing the fire risk that endoscopic surgery presents.

In addition, future rigidity testing will be performed with the polypropylene prototype. One of the main concerns for the durability of this product is the hinge area which failed using DSM 9120 polypropylene-like material. Thus, the hinge of this design will go through bending rigidity testing. The bending rigidity will be examined in terms of the load vs. deflection plot. There are two extremes to avoid: if the material is too rigid, it will crack instead of bend. Conversely, if the material is too flexible, it will not be stable enough to hold the endoscope. The hinge will theoretically only be bent a few times throughout its use, thus not needing to withstand excessive bending. It should, however, be rigid enough to support the weight of the endoscope while attached to the drapes. We intend for the mass-produced model to be made of polypropylene, which is very capable of creating the living hinge we desire. This type of living hinge can be seen on common objects such as a polypropylene Tic-Tac® box and so should not hinder the design's efficacy.

After satisfactory thermal and rigidity testing, trial runs of the prototype will be performed in an operating environment during sinus surgery procedures. During these trial runs, the temperature of the defogging solution will be recorded at regular time intervals throughout the surgery and ergonomic conditions, ease of use, and incorporation into the OR setting will be qualitatively noted from the surgeon's perspective.

Manufacturing and Marketability

A third party manufacturer will be contracted for the mass production of the holster. Injection molding with polypropylene will be used for this mass production. Several of the reasons for choosing this plastic relate directly to its use in the operating room. In addition to having chemical resistance and being non-toxic, it is also autoclavable. Due to the hinge design, this material was also chosen for its favorable mechanical features. Polypropylene is resistant to stress and cracking, meaning it has a high tensile and compressive strength. Additionally, this material is suitable for contact with the heat of the endoscope. It has a deflection temperature of 107-121ºC [8]. In previous research, the hottest endoscope tested reached its final maximum temperature in 10 minutes at 95ºC, which is below our deflection temperature [6]. This means that the material choice has a wide range of applicability to all endoscopes in all types of surgery. Additionally, every time the endoscope is placed in the holster, it will be cooled off by the defogging solution.

This device will ultimately be packaged in a 'Endoscopic Sinus Surgery' kit. The kit contents will include the scope caddy, cleaning pad with a sticky backing, two alligator clips and a container of defogging solution. This kit will be suitable for the needs of an ENT surgeon. Alternate kits can also be created for use in different types of endoscopic surgeries.

A patent will be pursued based on the current prototype design. Whether to pursue the patent through the Wisconsin Alumni Research Foundation or individually is yet to be determined. Additionally, since this device must be FDA approved for OR use, there are baseline requirements that apply to all medical devices for marketing, proper labeling and monitoring the device's performance once it reaches the market [9].

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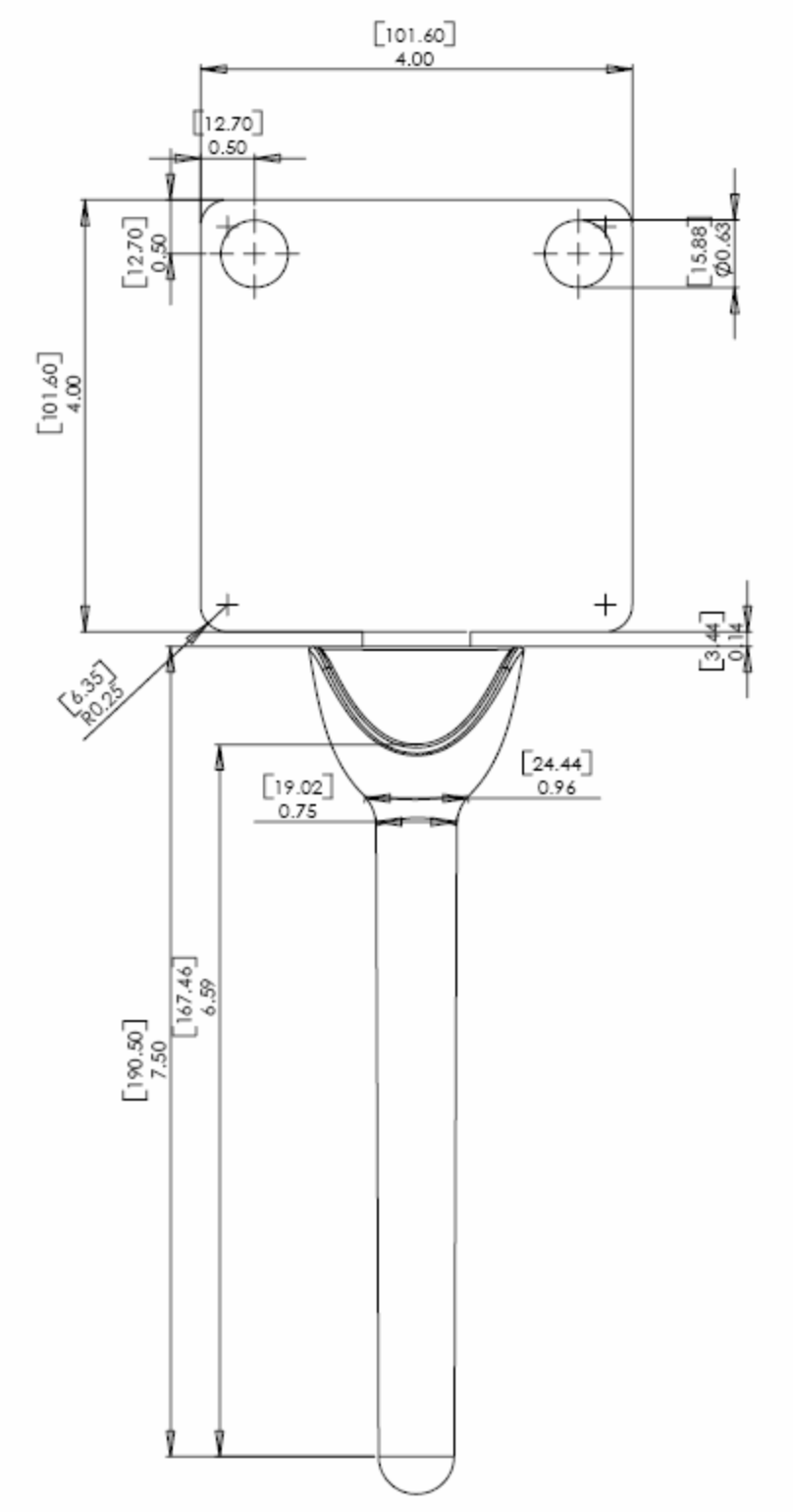
Appendix A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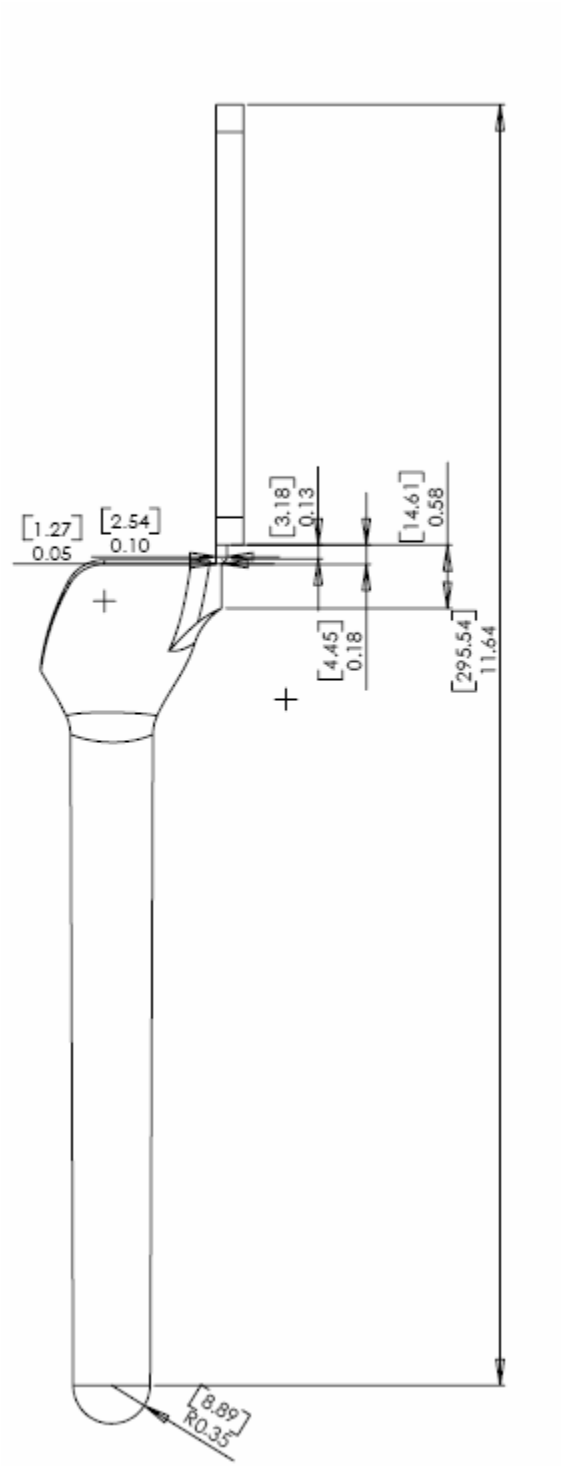
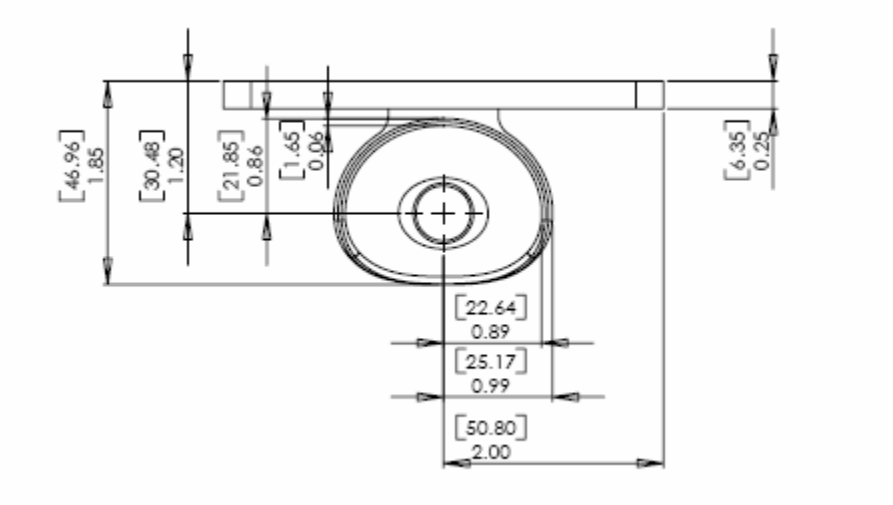


Appendix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