AC 2009-2431: REACHING OUT TO A NONTRADITIONAL CAPSTONE SPONSOR: DESIGN OF A UNIVERSAL EYE SPECULUM WITH VIBRATIONAL ANESTHESIA

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Reaching out to a Non-Traditional Capstone Sponsor: Design of a Universal Eye Speculum with Vibrational Anesthesia

Abstract

In these days of universities encouraging interaction between students and the community, faculty members sometimes need look no further than their own personal lives to find such opportunities. This professor was undergoing a simple ophthalmological procedure when she noticed the discomfort related not to the procedure itself, but to the eye speculum used to hold back her lashes during the procedure.

Discussions began immediately with the ophthalmologist regarding the causes of the discomfort and other limitations of what appeared to be a simple, mechanical device; from these discussions a senior capstone design project was proposed. The goal of the project was to design a universal eye speculum that could be used with a wide variety of eye shapes. Vibrational anesthesia was also incorporated into the speculum.

The majority of discomfort was found to occur while the eye speculum was being actuated. To alleviate this problem, a universal eye speculum was designed to incorporate product benefits such as enhanced ergonomic motion and vibrational anesthesia, with a special focus on variable eye shapes. The speculum was divided into major components that were individually analyzed. Key items, such as effectiveness, ergonomics, cost, and manufacturability were weighed and analyzed for all of the major components. These analyses then produced a final design which combined the best component features. A vibrational component was also introduced into the design to be used as anesthesia. The use of vibrational anesthesia is innovative in the field of ophthalmology. Finite element analyses were conducted on each portion of the design for structural strength and fundamental vibration frequency determination. The final design prompted the university to investigate possible patents, resulting in three patentable features. However, market analyses indicated that the cost of pursuing these patents would be more than potential earnings.

Three students enthusiastically volunteered to work together on this project. During the semester the students were guided by their faculty advisor in weekly meetings, but all design and analysis was conducted independently by the students. The student learning outcomes were assessed via performance criteria using (a) grades from the paper, poster and presentation; and (b) professor evaluation. Additional indirect assessments were obtained through student surveys and peer reviews. All assessment techniques indicated that the students met and exceeded both course expectations and the performance of other student groups enrolled in the capstone design course.

Seeking Significant and Interesting Topics for Senior Capstone Design Courses

As anyone who teaches and advises undergraduate senior capstone design courses will attest, seeking undergraduate topics with the appropriate amount of depth and design is an unending process. For universities with graduate programs and significant research endeavors, senior capstone topics can often be identified as those that, although have merit, are perhaps not large enough in scope for a graduate student. Regardless the size of a school's research activities, local industries can be a wonderful source of design topics. It's a win-win situation since you can get a terrific topic for your students and they can get free engineering; but sometimes it can be difficult for a faculty member to meet these engineers and tap their design problems, especially if the faculty member is new to the area.

Perhaps the best way to contact the industries is through the program advisory boards, but beyond that it definitely requires polishing of networking skills. We can get involved with local professional societies, or contact the engineers who supervise our students while they work in co-op or internship positions. Beyond the traditional locations, however, if you keep your eyes open, you might be surprised where you're able to find an interesting and substantial project.

A few years ago I had bilateral LASIK (Laser-Assisted In Situ Keratomileusis) corrective eye surgery, conducted by David Malitz, M.D. Much to my surprise, significant discomfort was not caused by the cutting or laser, but simply when the doctor used an eye speculum to open and restrain my eyelids. I soon learned that my discomfort was very common, and through initially casual conversations with the doctor, I discovered that he was frustrated by his futile search to find a speculum that did not cause such discomfort. With the search for quality senior capstone design projects always in the back of my mind, I quickly realized that this topic had potential, and we met to formally discuss the possibility of developing a senior project to improve this device.

Student Learning Outcomes

As with any senior capstone project, I had to assure that it met the learning objectives of the course. At the University of Southern Indiana (USI), we offer a recently accredited BSE degree and do not have a graduate program. We offer specialties in civil, electrical, industrial, mechatronic and mechanical engineering. ENGR 491, *Senior Design*, is the capstone design course offered commonly for each specialty. Students are advised by faculty members in their discipline. In the mechanical engineering specialty, we commonly have two students per project, but when appropriate, as in this project, we will have three students. The student learning outcomes, associated ABET outcomes, and performance criteria for the course are listed in Table 1. In addition to fulfilling the departmental objectives, this course also incorporates the following university core curriculum (UCC) objectives:

A. Enhancement of Cognitive Abilities- composition, speech, and math,
B. Enhancement of Individual Development- ethics,
C. Enhancement of Cultural and Natural Awareness - environmental, economic, health and safety, sustainability aspects of projects, as well as science (usually physics and/or chemistry) applications, and contemporary problems.

Background – Eye Speculum

The eye speculum holds the eyelids open and restrains the eye lashes during various ophthalmologic procedures. It is used for all ages and many applications. An eye speculum consists of three major components: blades, arms/frame, and a pivot mechanism as shown in

Table 1: Learning Outcomes and Criteria

Student Learning Outcomes	ABET Outcome	Performance Criterion
1. Students will have an ability to design a system, component or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability and sustainability.	C	Design a system, process, or component.
2. Students will have an ability to apply knowledge of mathematics, science and engineering.	A	Identify and solve a practical engineering problem.
3. Students will have an ability to communicate effectively.	G	Produce a professional report showing the process, analyses and design conducted to complete the project. Present a professional quality 20-minute presentation before faculty, industry representatives and guests.
4. Students will have an ability to use techniques, skills and modern tools necessary for engineering practice.	K	Recognize the tools necessary to function effectively in engineering practice.
5. Students will have an understanding of professional and ethical responsibility	F	Gain a further recognition of professional responsibility and ethics.
6. Students will have the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental and societal context.	H	Recognize the importance of a broad education and the global aspect of engineering practice.
7. Students will have recognition of the need for and the ability to engage in life-long learning.	I	Recognize the importance of life-long learning in the engineering profession.

Figure 1. The blades contact the eyelids, restraining the lids and lashes during surgical ophthalmologic procedures. The arms connect the blades to the pivot mechanism, allowing the surgeon to manipulate the blades a safe distance from the eye. The pivot mechanism allows the blades to hold the eyelashes in place without interfering with the surgical area. Pivot mechanisms can be as simple as a bend or loop in a wire, or more complex with the inclusion of a hinge mechanism. Various designs of each component exist.

The eye specula are used for many common ophthalmologic surgeries including LASIK, PTK/PRK (Photo-Therapeutic Keratectomy), and Cataract surgery. Specula are occasionally used in clinical examinations as well. The wide applicability of the speculum necessitates a

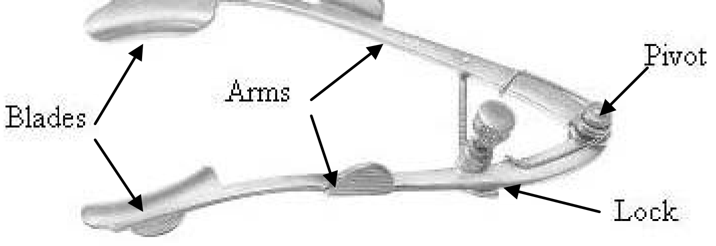

Figure 1: Basic Speculum Components

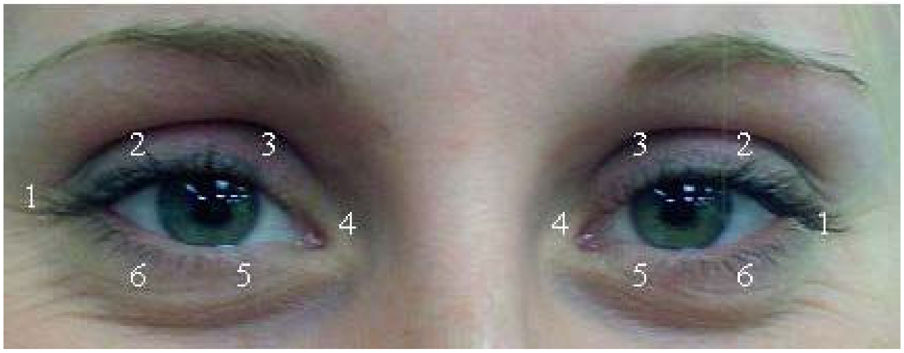

Figure 2: Pain Localization Points[2]

universal design. The ophthalmologic procedures may vary, but the function of the speculum to restrain the eyelids, remains constant among them. Surgical procedures are constantly being improved; consequently, surgeons gain better results, faster recovery time, and more effective use of their time. However, specula deficiencies prevent additional surgical advances[1].

Due to the growing field of ophthalmologic surgical vision correction, the necessity for simpler, more effective specula has arisen[1]. Today there are many types of specula on the market. Different designs for various components have been combined and improved to create new specula, but despite progress in ophthalmology procedures, specula shortcomings still exist.

Patients claim that the speculum is the most uncomfortable portion of the LASIK procedure[1]. This pain has been shown to affect Caucasian[2] and Asian[3] persons; both adults and even premature babies[4] have been found to be uncomfortable while the eye speculum was used on them. Details of these studies follow.

During their senior project, Elpers, et. al., developed a pain intensity survey that was conducted by Dr. David Malitz at his offices in Evansville, Indiana, and Las Vegas, Nevada. Twenty patients were evaluated: all were Caucasian, six were male, and ages ranged from 22 to 69. The survey was administered in procedures when the current specula are first administered. The survey began with Dr. Malitz asking the patient if they feel any discomfort. If pain was present, Dr. Malitz assisted the patient in localizing their discomfort by applying gentle pressure at the locations described above. The patients were then asked to evaluate the pain intensity on a scale of one to five, where one represents the lowest amount of pain and five the highest amount. Dr. Malitz identified the pain locations following the localization points shown in Figure 2. Results from the survey show that patients feel intense pain most frequently at the outer corner of the eye. This is due to the speculum pulling the corner of the eye away from its natural position. The pain is distributed with a diminishing intensity from the outside corner to the inside corner. Due to the anatomy of the eyelid and the elasticity of the surrounding skin, the lower lid shows slightly more pain presence than the upper lid.

Cheng, et. al., studied fifty consecutive Chinese patients undergoing simultaneous bilateral LASIK. They were randomly allocated to have either the right or left eye operated first. The pain scores for each eye at speculum placement, microkeratome cut, laser ablation, and at 15, 30, and 45 minutes after the procedure were recorded. In addition, an overall score for the whole operation was evaluated immediately after the procedure for each eye. They found that the second eye was significantly more painful than the first eye at the stage of speculum placement and microkeratome pass ($P < 0.001$). Laser ablation was the least painful stage for both eyes. There were no statistical differences in pain scores for the postoperative period. They concluded that higher pain scores were associated with the stages involving eyelid manipulation. Further, they recommended supplementary anesthesia when excessive stretching of the eyelid structures was anticipated.

P. Gal, et. al., have noted that even using a topical anesthetic, neonates born at < or = 30 weeks' gestation also exhibited pain associated with the use of an eye speculum during their exams of retinopathy of prematurity (ROP). Pain was measured using the Premature Infant Pain Profile (PIPP) scoring system, which measures both physical and physiologic measures of pain, and the scores were simultaneously assessed by 2 study nurses, and the same ophthalmologist performed all eye examinations. PIPP scores were recorded 1 and 5 minutes before and after the eye examination and during initial placement of the eye speculum. The authors hypothesized that procedural pain could be lessened by adding 24% sucrose to the topical anesthetic. For 3 of the 5 definitions of pain response, patients experienced significantly less pain at speculum insertion with sucrose than with placebo. After the ROP examination, pain responses were similar with either sucrose or placebo. The authors concluded that oral sucrose may reduce the immediate pain response in premature infants undergoing eye examination for ROP.

Background – Vibrational Anesthesia

Improved speculum design could minimize the pharmacological interventions mentioned in the pain examples above, but another way to minimize pain could be to involve the use of vibrational anesthesia. Vibration is used in both dentistry and dermatology as a mild anesthetic, however in ophthalmology; the use of vibration has not been explored. The vibration does not typically alleviate the pain completely but it makes it more tolerable. For example, in 2004, vibration was used clinically as anesthetic in dermatology applications where patients were in excessive pain or had an aversion to needles; the study reports favorable results, the patients felt less pain[1]. Additionally, in 2005, a pilot study using vibration as an anesthetic was evaluated for dental applications at injection sites[5]. Another study in 1997 combined the use of vibration and topical anesthesia; this combination yielded significantly lower pain ratings[6]. Based on these promising results, vibration is a feasible anesthetic.

Aside from clinical success, one of the most prominent theories supporting vibration as a viable option for anesthetic purposes is the Gate Control Theory. This theory, proposed by Ronald Melzack and Patrick Wall, states that pain signals are blocked because of the differentiation between nerve fibers and stimulation of the touch signal. The basic theory states that when pain is felt in a particular part of the body, rubbing or massaging that region stimulates large nerve fibers. These fibers overpower the small nerve fibers that are carrying the pain signal.

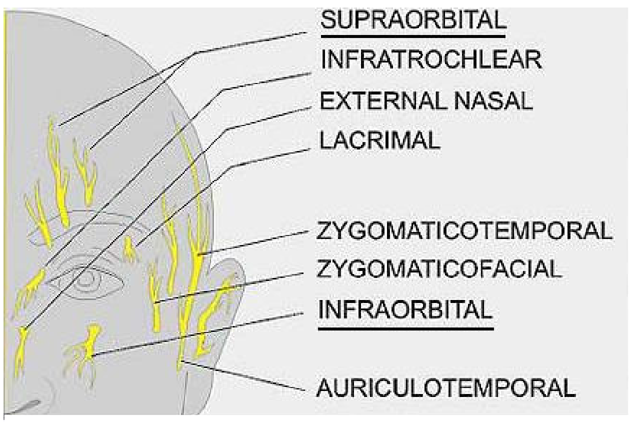

Figure 3: Nerve Locations

The large nerve fibers carry the touch signal so the brain is ‘distracted’ by the predominant incoming signals, and perceives the pain as being less[7,8].

The ophthalmologic application of vibration anesthesia would involve applying the vibration to the primary sensory nerves in the upper face, the supraorbital and infraorbital nerves. The insertion of the supraorbital nerve through the orbital bone is near where the forehead meets the bridge of the nose. These locations are shown in Figure 3[9]. The vibration is applied to the face in proximity to these nerves. Additionally, the bone structure that surrounds the eye, the orbital bone, effectively transmits the vibration to the nerve endings.
Aside from reducing the discomfort of the speculum, vibration used as an anesthetic has many benefits. Compared with other types of anesthesia, vibration has no risk of allergy, which also alleviates the possibility of complications from such reactions. Additionally, vibration can be used in conjunction with topical anesthetic to further reduce the discomfort. Vibration is much less invasive than eye drops and it could possibly be more effective, since it is applied directly to the nerves—clinical testing is necessary to verify these suggestions.

Pedagogical Aspects of the Literature Review

As the faculty advisor, I helped the students initiate their literature review by introducing them to relevant library staff members and discussing the quality of information. Today’s students are very familiar with information searches through the internet, but I found that my team did not fully appreciate the differences in information quality. This lead to discussions comparing search engines to which the library subscribes, such as COMPENDEX, to free search engines such as Google Scholar, Google, and Wikipedia. I encouraged the students to use the former whenever possible, and required them to identify the search engine used if it was not through the library.

After completing much of their literature review, it was soon realized by both advisor and students that additional pain data were needed, so they developed a pain survey to be used by the consulting ophthalmologist, David Malitz. The initial survey that the students presented to me wasn’t very easy to read, so I helped them understand that the nursing staff would be surveying the patients while the procedures were taking place, so it needed to be as simple as possible. After that discussion, the students decided to include a photo with numbered pain locations that helped the patients quickly identify the specific locations of their pain, as shown in Figure 2. Dr. Malitz agreed to use this convenient survey in both of his office locations, and from it valuable data were collected.

Project Goals

Based on the literature described above, additional design suggestions from Dr. Malitz, and guidance from the faculty advisor, the students established the following goals for the final design of the speculum:

- Design a universal eye speculum more compatible with multiple patient eye shapes and types
- Design a speculum that optimizes the following benefits: aspiration, single-handed use, stability, comfortable blades, contour around eye, reusable, and restrains lashes—many of

- these benefits are singly available in separate specula, but there is not one universal speculum on the market that encompasses all of these characteristics
- Introduce vibration component to the speculum for local anesthesia
- Accomplish design while maintaining similar economic value, compared to current models
- Complete design in preparation for construction of prototypes

Component Optimization

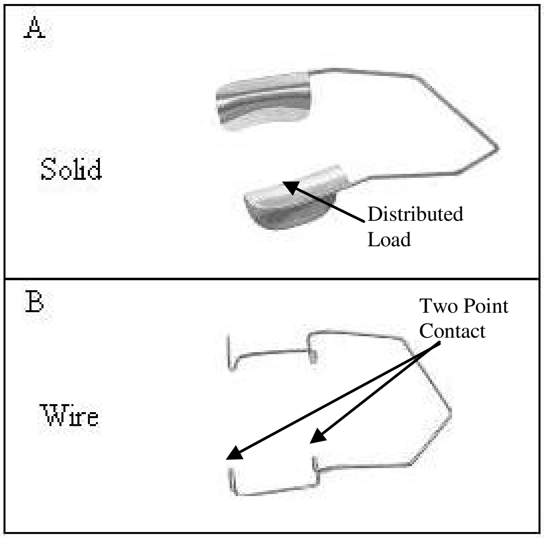

Figure 4: Common Blade Types

To create a universal eye speculum, each component was evaluated independently to obtain the best possible combination of elements. The following component designs will be described in detail: blades, blade translation mechanism, and vibrational mechanism. Aspiration and a vibration-resistant, single-handed-use locking mechanisms were also designed, but will not be described here. The faculty advisor was available to answer questions and assist in project management, but the students worked as a team to develop all major designs.

Blades

Many factors come into question while making the decision of how to optimize the blades. Positioning the blades under the eyelid is a cumbersome task for the surgeon; hence, ease of positioning is an important factor to consider. Low profile blades slide under the eyelid more easily, making the installation less awkward. Two main types of blades are available, wire blades and solid blades. A visual comparison of these can be made in Figure 4. The forces on the eyelid caused by the speculum forcibly opening the eye are the source for discomfort. The main difference between blade types is the force distribution on the eyelid. Regardless of the blade configuration, the same magnitude of force is transferred to the eyelid, whether it is distributed over the length of the blade, or applied at the two points where the wires contact.

The shape of the blades is also critical. Ideally, the blade shape would account for differences in eye shape, eyelid curvature, and surgical equipment shapes. As illustrated in Figure 5, many specula are completely straight; this pulls the eyelids away from the eye surface creating unnecessary tension on the delicate parts of the eye.

Possible blade designs were judged by function - their ability to restrain the eyelashes, shape – how they conform to the eye shape, the ease at which the blades slide under the eyelid, durability, universal attachment, and ease of manufacturing.

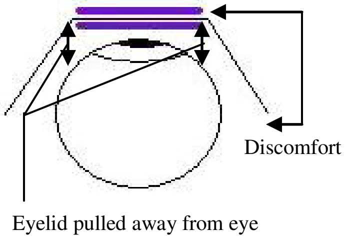

Figure 5: Straight Blade Discomfort

The blades of the final design are solid and curved in two planes to optimize comfortable fit and accommodate the suction ring. The final blade design is shown in Figure 6. The blades have convex curvature toward the eyelid at a radius of 18mm to gently curve the blades to help distribute the load and to keep the edges of the blades from cutting into the outer portions of the eyelid. This distance also allows of clearance for the suction ring, which has a diameter of 13mm, to fit on the eye between the blades.

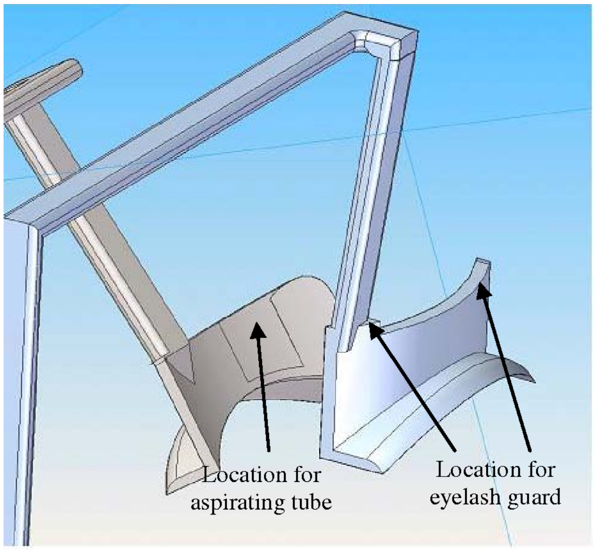

Figure 6: Final Design of Blades

By shaping the blades with two arcs on orthogonal planes, the curvature of both the eyeball and the eyelid are accommodated. With respect to the eye surface, the blades have a concave curvature at a radius of 16mm to match the curvature of the eye; this is to keep the eyelids from pulling up away from the eye surface. The concave curvature allows the blades to slide under the eyelids and into place without flattening the eyelid and putting extra tension on the inner and outer corners. This should give the application a more natural feel. The blades also have a tapered profile on the leading edge that slides under the eyelid to assist in positioning the blade under the eyelid without minimal discomfort. The blades are .75mm thick.

Another area of concern pertaining to the blades is the portion of the blade that restrains the eyelid and lashes. This is the part of the blade specified in Figure 6. It is important that the guard is mostly vertical and does not cause the eyelid to roll back upon itself, causing patient discomfort. The primary reason for this design specification is to cater to the narrow Asian eye shape. Traditional specula blades have a deep pocket to contain the eyelids. The top edge of the pocket puts excessive pressure on the top of the Asian eyelid, depicted at right in Figure 6. By utilizing a vertical blade profile, the pocket is eliminated. This should greatly reduce the pain incurred on the Asian patients. On the top edge of the blade there is a small lip to deflect the lashes. From this edge, the arms of the translation mechanism can easily be attached to the blades and formed as one piece allowing for greater ease of manufacturing.

The blades aspirate to keep the eye clear of fluids during surgery. The blade design accommodates the aspiration tubes by means of a channel cut on the outer bottom edge of the blade as shown in Figure 6. The stainless steel aspiration tubes, complete with tiny holes, are attached with epoxy into the channel providing aspiration along the entire width of the blades. Incorporating this feature requires one less tool during operation keeping the working area open and a free hand for the ophthalmologist.

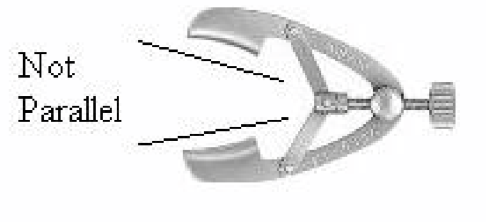

Figure 7: Initial Blade Translation

Blade Translation Mechanism

One component needing special attention is the method of translating the blades, the arms or translation mechanism. The translation mechanism dictates the path of motion of the blades; the ideal geometry of the arms keeps the blades as close to the surface of the eye as possible, following the curvature of the eye. The curved blade path keeps the eyelids from stretching. To prevent pain from sudden, jerky movements, movement of the speculum should also be smooth throughout its range of motion. It is crucial that the blades stay parallel throughout the entire range of motion; this keeps the inner portions of the eye from being stretched as displayed in Figure 7. If the blades are skewed one way or the other, the forces from the blades cause pressure points near the corners of the eye.

The main constraints on the design include a curved path of motion following the eye curvature, a way to keep the blades parallel throughout the entire range of motion, and a smooth operation. Additionally, a spring or resistance device needs to have attachment on the frame or pivot point to supply resistance to the movement.

The final blade motion design has the following details. The arms keep the blades parallel by means of two right angles from the pivot point with the pivot axis going directly through the center of the eye, as shown in Figure 8. This setup allows the translation of the blades to stay parallel and to follow the curvature of the eye. To ensure one handed operation, the actuating levers of the arms come off the back side of the pivot point at forty-five degree angles to keep the actuating levers off the side of the face, as shown in the Figure 9. The actuating levers have thirty degree angle offsets to move the arms. By squeezing the actuating levers together, motion is transferred through the arms to displace the blades. When the blades open to the desired displacement, the locking mechanism is engaged and the speculum is ready to impart vibration. Originally, the two components were going to be symmetrical, but as the design developed it became evident that proper clearances and blade configurations would not allow for exact symmetry. The left arm fits slightly under the right arm; this is shown in Figure 9. The connection point for each of the arms is an 8mm circle with a 2mm diameter hole in the center. The hole facilitates the locking mechanism. The pivot point of the arms is anchored on the foot of the speculum, which acts as a base, resting on the lateral side of the orbital bone.

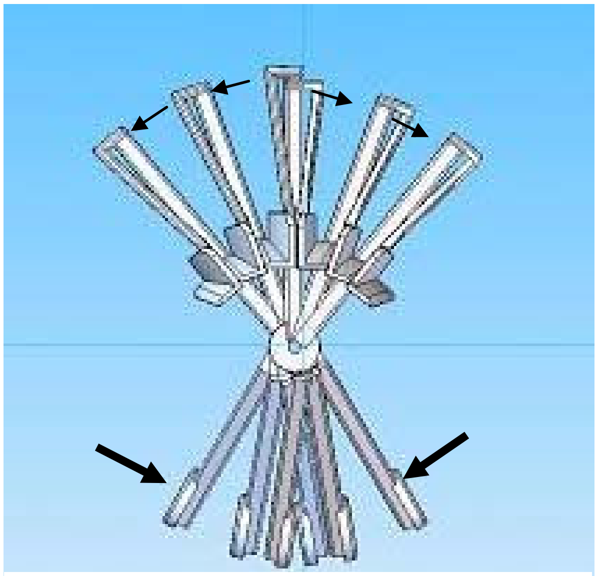
Figure 8: Arc Blade Path

Vibration Component

The vibration component was dependent on the final design of the speculum; so it was the last component to be developed. A major design consideration was whether the vibrating assembly should be incorporated into the frame of the speculum, or constructed as a completely separate structure. Additionally, the method of attaching or incorporating the vibration component was dependent on the final geometry and construction of the speculum.

The motor that creates the vibration needs to be removable for sterilization since the high temperature of the autoclave process would break the magnets inside the motor and render it inoperable. It is also necessary for the vibration component to be as minimized geometrically to compliment the delicate structure of the speculum.

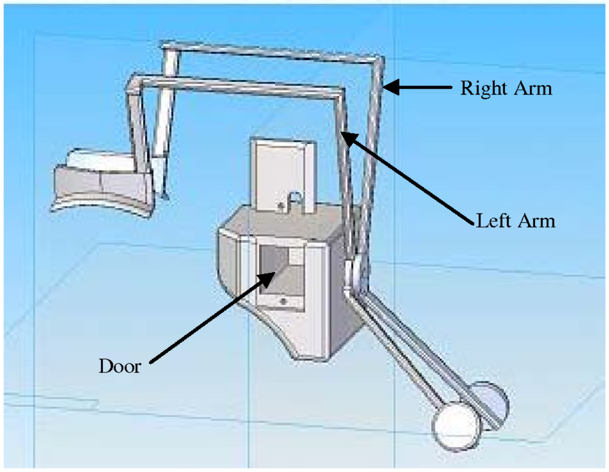

Figure 9: Complete Design of Speculum

A small direct current motor with an attached unbalanced mass on the shaft is used to create the desired vibration. This motor, shown in Figure 10, is similar to the type used in cellular phones for the silent-ring/vibration option. The motor is placed in a cavity in the "foot" of the speculum where it localizes the vibration to the lateral region of the orbital bone. The placement of the vibration is critical for the nerve reception; the receptor nerves travel through the orbital bone. Since bone transfers vibration effectively, this is the optimal location to impart the vibration. The foot is machined to follow the curvature of the face, as shown in Figure 9. It also acts as both a foundation and mounting base for the arms. The vibration is then transmitted from the foot to the critical nerves via the facial orbital bones[9].

Alternatively, a design was considered that included the vibration apparatus as a separate unit from the eye speculum. With the vibration apparatus as a separate device, ease of sterilization of the eye speculum is assured, but autoclaving the vibration apparatus still poses a great concern. One advantage of the vibration component constructed as a separate unit remains that it could be marketed as an accessory for current specula. However, the increase in marketability of the independent vibration component could diminish the marketability of the speculum; furthermore, it is noted that there are no current specula available that fit the design goals previously stated. Several parameters were evaluated using a design matrix such as: removable from frame, direct nerve application, adjustability, autoclave-ability, and ease of manufacturing.

The vibration incorporated into the speculum as a single device has advantages over construction of a two part system. The speculum including a vibration component would be an innovative idea introduced to ophthalmologic surgical tools. The eye speculum containing the vibration component gives a more compact design, opening up work space for the surgeon. Customarily, in current dentistry and dermatology applications, it is common practice to impart vibration directly to the pain site. However using the speculum with the included vibration component, the vibration is not only be transferred to the pain site at the eyelids, it is also directly transferred to the supraorbital and infraorbital nerves, through the orbital bone[10]. This inhibits pain messages from reaching the brain via the orbital nerves. Ultimately it was

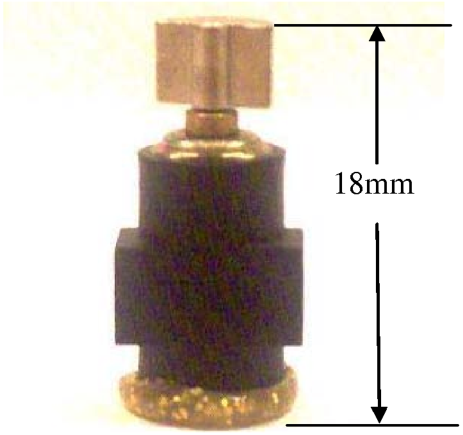

Figure 10: Vibration Component

decided to incorporate the vibration component into the eye speculum; since a speculum incorporating a built in vibration component better satisfies the overall goal of this design.

Since the integration of the vibration component better suits the design goals of this project, the one piece design was chosen as the final design. The foot design allows the vibration component to be incorporated into the eye speculum, and provide a base for the pivot point on the arms and a housing for the vibration mechanism. The compartment for the vibration motor is a tight-fit with small clearances to help minimize unwanted vibration and noise within the motor compartment. Also, when the motor fits rigidly into the compartment, the majority of the vibration is transmitted to the foot. The foot provides a point of contact for the vibration to be applied to the bone structure adjacent to the eye. It rests on the lateral region of the orbital bone and send vibration, with little damping from the bone, through the bones to affect the entire area with vibration anesthesia.

The foot was designed to fit the contour of the orbital bone. Using clay molds to measure the contour of orbital regions, they measured and averaged the radii to come up with a contact radius of 38.1mm. This allows for a comfortable fit for the contact zone of the vibration. Adhesive pads can be placed on the contact zone of the foot to aid in stability, placement, and dampening effects, if necessary. The adhesive pads are disposable and are replaced between surgeries. The vibration intensity can be adjusted by using disposable adhesive pads of varying thicknesses. The adhesive pads act as dampers, and the thickness of the adhesive pad relates proportionally to the damping effect, which lessens the intensity of the vibration to accommodate for differences in patients' pain thresholds and vibration tolerance. The foot was designed with a door enclosing the motor cavity. The door engages the foot body with a sliding action, and is held closed with a thumbscrew. The sliding engagement and screw makes the door vibration resistant, securing the motor during operation. Additionally, the use of a thumb screw eases the process of removing the motor for autoclaving.

The arms should always be in the locked position when the vibration component is engaged;

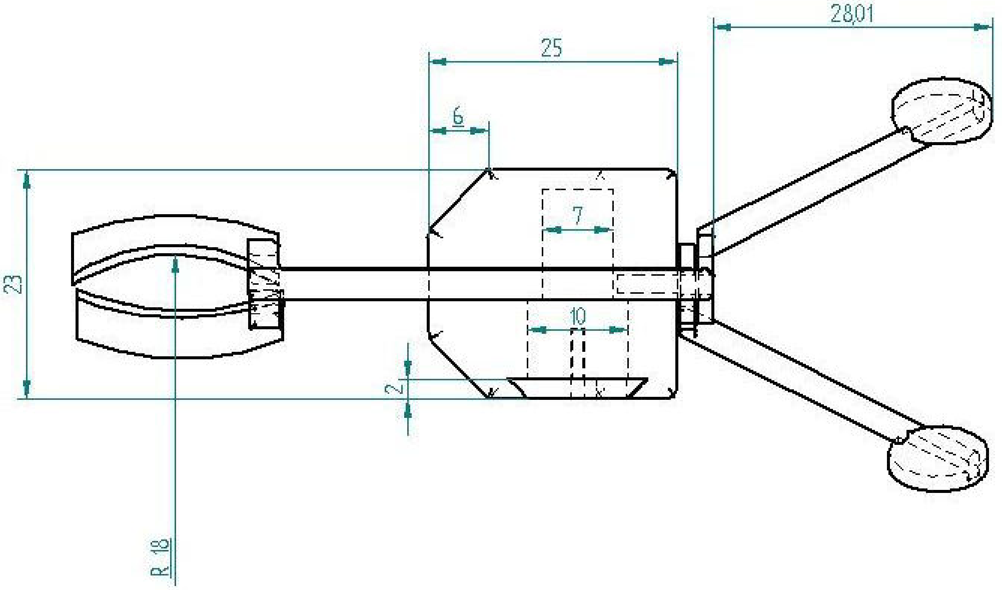

Figure 11: Final Design - Top View [mm]

creating a rigid interface between the components. The vibrating component is not engaged for the duration of the procedure since it could interfere with the procedure. Ultimately, the use of the vibration component will be at the discretion of the ophthalmologist.

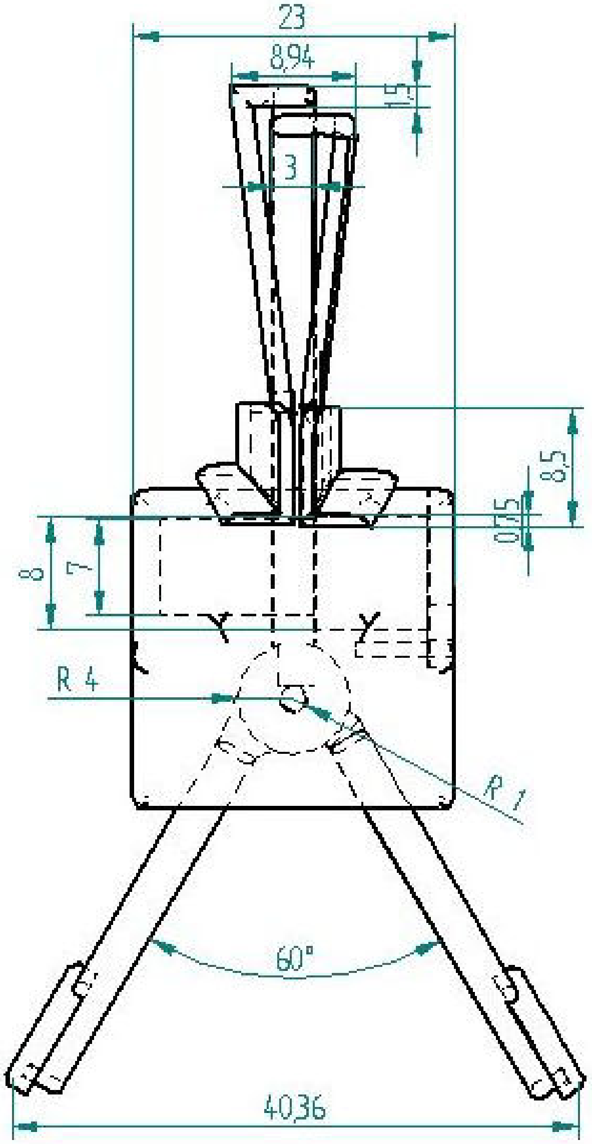

Figure 12: Final Design - Front View [mm]

Analysis

The students used Solid Edge to model the design in three dimensions, and from which a prototype was created using the Catalyst 3-D Rapid Prototyper. The students used NX 4.0 for finite element analysis, with some hand calculations to verify results. Vibration modes and structural integrity were examined. To accurately simulate the applications the speculum encounters clinically, measurements were taken to establish the amount of force a patient exerts when trying to forcefully close their eye. This was measured - under faculty advisor supervision - by putting a clip on a student volunteer and attaching a spring scale. The spring scale measured the force exerted by the individual while he was closing his eye. This experiment yielded results of 0.2N, however since this force could vary between individuals; a Safety Factor of 2 was added and a 0.4N force was entered into the computer software and used in the hand calculations. Additionally, the surgeon applies a small force on the actuating levers to open the speculum. This force opposes the torsion spring placed at the pivot point. The torsion spring causes the speculum to spring closed when it is not in use or in the locked position. Using a current speculum model with a spring, they measured the force exerted to operate the speculum at 1.9N. The newly designed speculum does not contain such a strong spring, but to remain conservative 1.9N was still used in the simulation.

Due to the symmetry, one arm needed to be modeled. To be conservative, the right arm was chosen because it has the same cross sectional area as the left arm but had slightly longer spans. This is conservative for the strength analysis since longer spans translates to larger bending moments, which is more detrimental to the structure. The right arm passed the strength analysis with a maximum stress of 37.2MPa. This value has a Safety Factor of 5.5 against yielding.

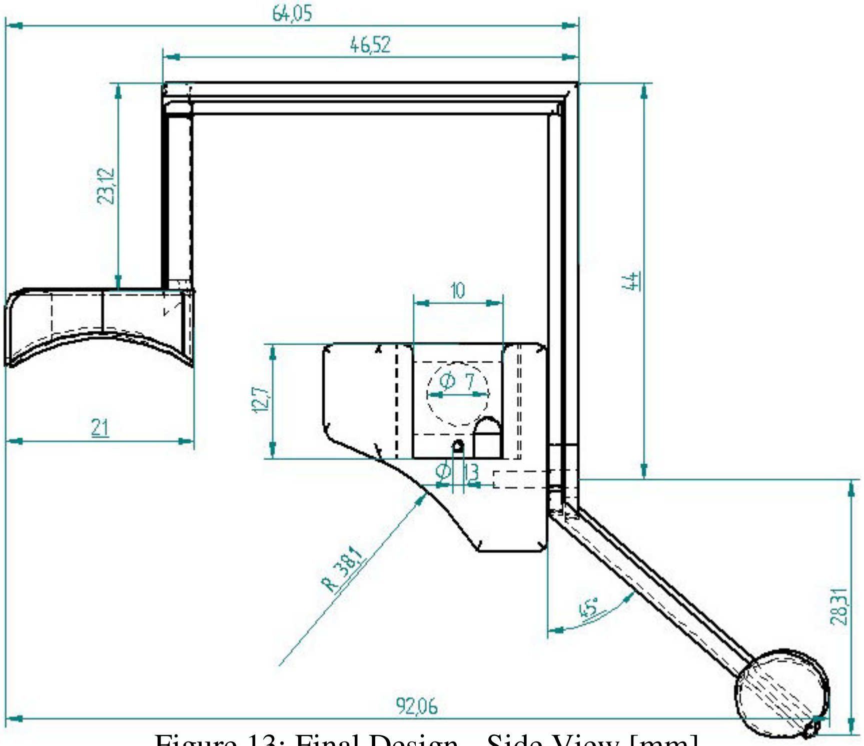

Figure 13: Final Design - Side View [mm]

Using the right arm is also conservative for the vibration analysis because ideally the natural frequencies of each part are higher, by at least 50%, than the forced vibration frequency. If the vibration motor is driven with a frequency at or near the fundamental frequency of the speculum, the frame would fail catastrophically. Ideally the part's natural frequency should be greater than 50% larger than the driven frequency, in this case 100Hz. The right arm was tested since it has longer arm spans that add a little mass and cause the structure to be less rigid, both of which would drive the natural frequency down. The design passed the natural frequency test since the FEA showed that the lowest natural frequency of the right arm was 170Hz, 70% greater than the driven frequency of 100Hz.

Summary – Final Design

The final design for the speculum pulls together all the optimized components mentioned above, plus the locking mechanism and aspiration, which are summarized below. An isometric view of the final design is shown in Figure 9. In addition, front, top, and side views in Figures 11-13 show the assembled speculum orthographically with dimensions labeled in millimeters.

- The blades are solid and curved in two planes to optimize comfortable fit and accommodate the suction ring.
- In the translation mechanism the left arm fits slightly under the right arm. The arms keep the blades parallel by means of two right angles from the pivot point with the pivot axis going directly through the center of the eye. To ensure one-handed operation, the actuating levers of the arms come off the back side of the pivot point at forty-five degree angles; this also prevents the actuating levers from contacting the face. The actuating levers have thirty degree angle offsets from the vertical plane to allow rotational range of motion for the arms.
- The locking mechanism consists of two rubber washers between the arms and the construct is locked down using a stepped thumbscrew.
- The blades allow aspiration via a channel on the outside edge of the blade for the stainless tube to ride in, and the tube has epoxy to hold it in the channel. Plastic tubes,

which attach to the stainless tubes, trace the shape of the arms to the pivot point. Adjacent to the pivot point they are bundled with the vibration power wires.

- The vibration component of the speculum uses a small DC motor with an attached unbalanced mass on the shaft to impart vibration. The motor is placed in a cavity in the foot of the speculum; the foot is machined to follow the curvature of the face and acts as a foundation and mounting base for the arms. The compartment for the motor is a tight fit with small clearances to help minimize vibration and noise within the motor compartment. The motor fits rigidly into the compartment and transmits the majority of the vibration to the foot.

Intellectual Property

Upon my recommendation and help from Sue Ellspermann, Ph.D. at the USI Center for Applied Research, it was decided that the innovations demonstrated in this device qualified it for an Intellectual Property Assessment, which was completed by Indiana University's Research and Technology Corporation. It was determined that three aspects of this project were patentable: blade design, blade translation mechanism and the vibrational component. Due to the high cost of acquiring patents, and what was perceived as the low potential volume of sales, patents were not granted. It was officially noted however, that due to the students adhering to a formal engineering design process, from synthesis through analysis to final design, a truly novel design was developed.

Pedagogical Considerations – Student Contribution

Three students enthusiastically volunteered to work together on this project, and they worked together remarkably well. As the faculty advisor, I met with them weekly and my contributions included:

- Introduced them to the project and facilitated meetings with ophthalmologist, David Malitz.
- Helped them get started with the literature review and then assisted with designing the pain surveys.
- Helped them narrow the project to identified project goals.
- Assisted with project management techniques including using Microsoft Project for developing Gantt charts and identifying dependencies within the tasks.
- Reviewed their designs, always trying to remind them that the simplest solutions are often the best ones.
- Reviewed the accuracy of their analysis.

Comparing this team to other groups that I have advised through the years, I was very impressed with the quality and quantity of their work, and how well they worked as a team.

Direct Assessment

The senior capstone design course, ENGR 491, the students have three deliverables: design papers, posters and the presentations to faculty and guests. Direct assessment is comprised of these deliverables as well as the faculty advisor's comparison of the deliverables to the Student Learning Objectives. Since this group divided the workload up evenly among themselves, they were each given the same grade. They earned A's on each deliverable, so their final grades were also A's.

My direct assessment of this project leads me back to the Student Learning Outcomes, so Table 1 has been expanded to include professor comments below in Table 2. It is shown that the students met and exceeded all Student Learning Outcomes with the exception of life-long learning. I will need to try to work on improving this in future semesters.

It should also be noted that the ophthalmologist who sponsored this project, David Malitz, was very pleased by his interaction with the students and often commented on their professionalism and thoroughness. Additionally he was very impressed and pleased with their design. Although USI will not be pursuing patents, Dr. Malitz is still considering pursuing this.

Table 2: Learning Outcomes – Direct Assessment

Student Learning Outcomes	**Performance Criterion**	**Assessment**
1. Students will have an ability to design a system, component or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability and sustainability. ABET OUTCOME C	Design a system, process, or component.	Very good. Multiple components were designed that had to work together as a system.
2. Students will have an ability to apply knowledge of mathematics, science and engineering. ABET OUTCOME A	Identify and solve a practical engineering problem.	Very good. Multiple engineering problems were identified and solved.
3. Students will have an ability to communicate effectively. ABET OUTCOME G	Produce a professional report showing the process, analyses and design conducted to complete the project. Present a professional quality 20-minute presentation before faculty, industry representatives and guests.	Very good. The report and presentation were excellent. Plus a presentation was given at a university-wide student research expo.
4. Students will have an ability to use techniques, skills and modern tools necessary for engineering practice. ABET OUTCOME K	Recognize the tools necessary to function effectively in engineering practice.	Very good. Used Solid Edge and NX 4.0
5. Students will have an understanding of professional and ethical responsibility ABET OUTCOME F	Gain a further recognition of professional responsibility and ethics.	Good. The students realized that this device would be used on public during surgery, and tried to keep focus on

		patient care.
6. Students will have the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental and societal context. ABET OUTCOME H	Recognize the importance of a broad education and the global aspect of engineering practice.	Good. This project definitely had a societal context. Patent search and results taught them an economic lesson.
7. Students will have recognition of the need for and the ability to engage in life-long learning. ABET OUTCOME I	Recognize the importance of life-long learning in the engineering profession.	Neutral.

Indirect Assessment

The Student Learning Outcomes and Performance Criteria are also evaluated in an indirect manner using student surveys that are completed after all deliverables are finished. Below in Table 3 the survey can be found with data averaged from the entire class of 14 students, including this three, compared to data averaged only from this team of three students. Note that the survey is from 1-5, with 5 being the best, and that the class metric, or goal, for each is 4.25.

Table 3: Indirect Assessment - Student Surveys

In ENGR 491- Senior Design – I have:	Overall Class	This Team
1. Improved my ability to analyze a complex design problem.	4.46	5.00
2. Improved my ability to design and conduct a practical engineering application.	4.61	5.00
3. Improved my ability to identify and solve a practical engineering application.	4.38	5.00
4. Improved my ability to communicate effectively through an engineering report.	4.46	5.00
5. Been able to give a professional 20-minute presentation before faculty.	4.61	5.00
6. Improved my ability to design an engineering system, component or process.	4.23	5.00
7. Recognized that I must have the tools necessary to function effectively in engineering practice.	4.53	5.00
8. Incorporated modern engineering practice into my solution of the design problem.	4.69	5.00
9. Gained a further recognition of the need for life-long learning.	4.38	4.67
10. Gained a further recognition of professional responsibility an engineering ethics.	4.53	5.00

Conclusion

Working at a university that does not have a graduate program and being new to the community and region of the university, I found a good senior capstone design project from my personal life during an uncomfortable elective surgery, LASIK. From that, three students were able to work on a senior project and their enthusiasm in the topic inspired them to work very hard.

Research showed that my discomfort during the procedure was common regardless of age or ethnicity. The project involved the development of an improved eye speculum that would be ergonomic and introduce the concept of vibrational anesthesia. Three aspects of the design were determined to be patentable, but the university decided not to pursue it further.

The course had seven Student Learning Outcomes. Direct assessments included student deliverables of design paper, poster and professional presentation. The students exceeded my expectations on all three deliverables and also divided the workload evenly among them; hence each student earned an A for all deliverables. Additional direct assessment included the faculty advisor's appraisal, which showed that the students met and exceeded all but one of the Student Learning Outcomes of the course, lifelong learning.

Indirect assessments included student surveys, and this team of three students was compared to the entire class of 14 for the spring of 2007. They exceeded the class average on every assessed item. It should be noted that the ophthalmologist was very pleased by his interaction with the students and often commented on their professionalism and thoroughness. Additionally he was very impressed and pleased with their design, and has pursued avenues to develop the design further.

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