Graduated Bowman probe

BMEDesign: Preliminary Report

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Biomedical Engineering 301

Section 304

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Abstract

Nasolacrimal duct obstruction (NLDO) is a prevalent ophthalmologic condition affecting both infants and adults, often resulting in chronic tearing, infection, and decreased quality of life. Standard treatment frequently involves mechanical probing of the lacrimal drainage system using a Bowman probe to identify obstruction. However, commercially available Bowman probes lack graduated depth markings, requiring clinicians to estimate insertion distance within millimeter-scale anatomy. This reliance on estimation introduces variability in obstruction localization, and may increase the risk of false passage formation or incomplete treatment. To address this gap, four designs for graduated Bowman probes were compared against important criteria. Laser annealing was selected as the final design due to its ability to create precise millimeter-scale discoloration without removing material or altering surface smoothness, thereby preserving mechanical integrity and biocompatibility. Quantitative and qualitative validation will be used to assess the probe's appropriate implementation into the UW Hospital ophthalmological department.

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Introduction

A. Impact and Motivation

Nasolacrimal duct obstruction (NLDO) is a common ophthalmologic condition affecting both infants and adults, often leading to chronic tearing, infection, and decreased quality of life if not properly treated. Current standard Bowman probe devices lack graduated measurement markings, forcing clinicians to estimate insertion depth during probing procedures and increasing the risk of inaccurate obstruction localization, tissue trauma, and suboptimal treatment planning. Given the frequency of lacrimal procedures and the delicate anatomy of the nasolacrimal system, a graduated probe that provides precise, millimeter-scale depth feedback would reduce human error, improve diagnostic accuracy, and support more personalized and effective patient care across diverse age groups and clinical settings.

B. Existing Designs

There are currently no graduated Bowman's probes meant for clinical use available on the market. However, there are a few similar competitive designs that feature graduation and could become available for clinical usage. The Calibrated Bowman's Lacrimal probe from the All India Institute of Medical Sciences is a set of Bowman's probes that feature laser engraved numbers at varying millimeter intervals [1]. This design maintains ISO-10993-1 standards for biocompatibility and easily distinguishable millimeter markings for probe insertion depth into the nasolacrimal duct. This design does not exactly fit the criteria and function that has been requested by our client, as expanded upon in Background Section C: Design Specifications.

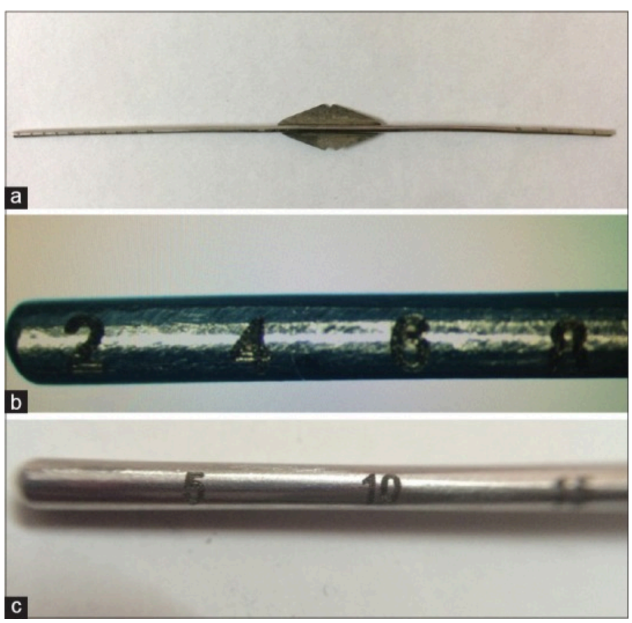


Figure 1: Calibrated Bowman's Lacrimal probe from the All India Institute of Medical Sciences [1]

C. Problem Statement

There are currently no available graduated Bowman's probes available for clinical use on the market. Consequently, doctors performing nasolacrimal duct obstruction procedures are required to estimate the probes insertion depth leading to large amounts of human error and inaccuracies in measurements. To provide a better method of insertion measurement acquisition, the creation of a set of clinically accessible graduated Bowman's probes is necessary. By creating an accurate device that features easy data collection, doctors will be able to ascertain the exact location of nasolacrimal duct obstructions and be able to provide more personalized treatment plans to patients. The device must be identical in dimensions to currently used Bowman's probes, feature distinguishable markings, and minimize any changes to surface texture in order to maximize measurement accuracy and patient safety.

Background

A. Relevant Biology and Physiology

The lacrimal drainage system is the anatomical pathway that removes tears from the ocular surface to the nasal cavity, starting with the puncta and continuing through the canaliculi, lacrimal sac, and nasolacrimal duct [2]. Blockages within this system are known as nasolacrimal duct obstructions, or more simply lacrimal obstructions, and can lead to an assortment of symptoms, such as epiphora and infection, which may result in the need for surgical intervention or manual probing [3]. During gestation, a cord of ectodermal tissue separates from the surface and enters grooves between the frontons and maxillary processes of the eye. This tissue eventually canalizes and forms the lacrimal sac and nasolacrimal duct of the lacrimal drainage system, fully developing by birth [4]. Incomplete canalization is the most common cause of nasolacrimal duct obstruction, where the puncta is clogged [5]. With age, inflammation, and injury, this tube can get even narrower which leads to the duct being obstructed resulting in the aforementioned symptomology. To both treat and assess the issue, doctors will use a Bowman probe to gauge where the obstruction is and either treat or assess what type of treatment and operations are required. For effective probing, an ophthalmologist must pass the probe through the bony nasolacrimal canal and perforate the embryological membrane without traumatizing other anatomical structures or creating a false passage which constitutes a micro level scale of the probe [6]. Nasolacrimal duct obstruction is an incredibly common disorder of the lacrimal system. Between 6 to 20 percent of newborns exhibit symptoms of duct obstruction [7]. The condition can be treated with several other methods including ointments, gentle massaging, and eye drops [8]. Commonly, however, symptomology continues to persist despite application of these known remedies, creating the necessity for a consistent solution in ophthalmological procedure. Bowman probes provide a solution that deals with the obstruction from the source, rather than coping with associating discomfort.

B. Client Information

The client, Dr. James Law, is an oculofacial plastic surgery fellow in the UW Madison Department of Ophthalmology and Visual Sciences. The alternate client, Dr. Suzanne van Landingham, is an associate professor & oculoplastic surgeon in the UW Madison Department of Ophthalmology and Visual Sciences. They are interested in getting access to a probe that will allow quantitative characterization of lacrimal duct obstruction depth during procedure.

C. Design Specifications

The client has requested a set of graduated Bowman's probes that accurately measure a probes insertion depth into the nasolacrimal duct, and allows doctors to easily obtain the measurements. The device must comply with ISO-13485:2016 and ISO-10993-1 which requires manufacturing uniformity across prototypes and maintains biocompatibility standards respectively [9]. The final design must feature visible markings up to 35 millimeters at 5 millimeter intervals without changes to the surface texture as requested by the client. Furthermore, the markings must be within a 5% range of the correct nasolacrimal duct obstruction length. The device must also be able to withstand repeated autoclave cycles with an environment of 135 ℃ and 15-20 psi [10]. The prototyped set must match the dimensions of a standard Bowman's probe set with lengths ranging from 130 - 150 millimeters, a target weight of 45 grams, and diameters ranging from 0.4 to 1.8 millimeters [11]. The client has given us a flexible budget of $100 to design & fabricate our device.

Preliminary Designs

A. Laser Engraving

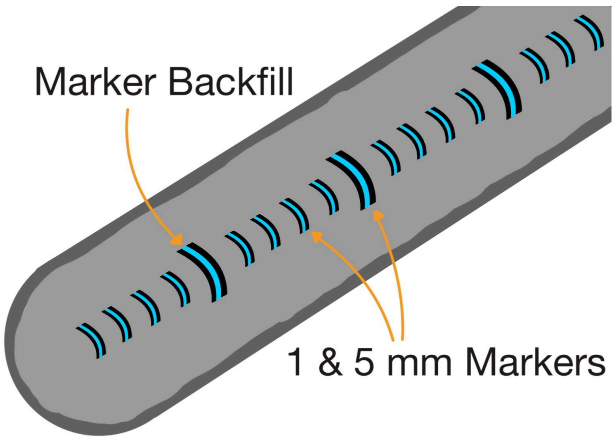


Figure 2: Laser engraving design

The first design brings laser engravings to the Bowman probe. Small hashes or dots will mark every 2 millimeters on the probe, which will be made by using a laser to engrave on the probes. The markings will not penetrate far into the probe so there is no harm to the structural integrity. The largest concern with this specific design is the engravings, when used during a procedure, could pull on the inner tissues of the nasolacrimal cavities causing more complications for the surgery and possible injury to the patient. To eliminate this issue, these engravings will be filled with a similar material with multiple of the same properties to smoothen the surface out. This version of the device will be much easier to fabricate and provide the real time feedback the client desires.

B. Laser Annealing

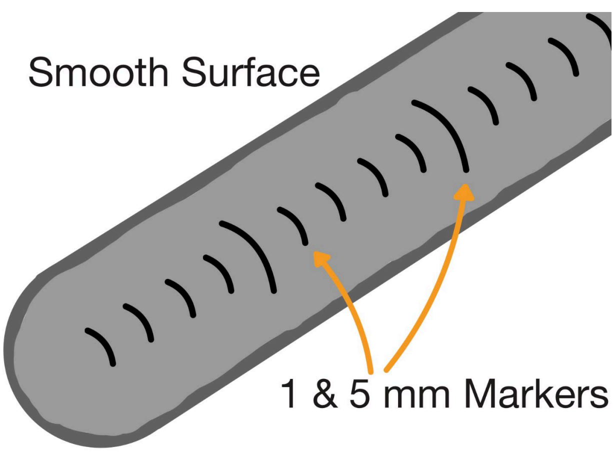


Figure 3: Laser annealing design

The second design considered uses laser annealing as a means to create line markers across the Bowman's probes surface. Laser annealing is similar to laser engraving as they both use a laser to change the appearance of a chosen surface. However, unlike laser engraving in which the surface material is removed, laser annealing maintains the original surface chemistry and texture while discoloring the surface. This difference is because laser engraving uses a higher powered laser relative to laser annealing. By focusing a low energy laser on the surface at 1 and 5 millimeter intervals, an oxidation layer will form causing discoloration at the accurate line markings [12]. This process will provide easily distinguishable line markers for doctors to reference during nasolacrimal duct obstruction probing procedures.

C. Electroplating

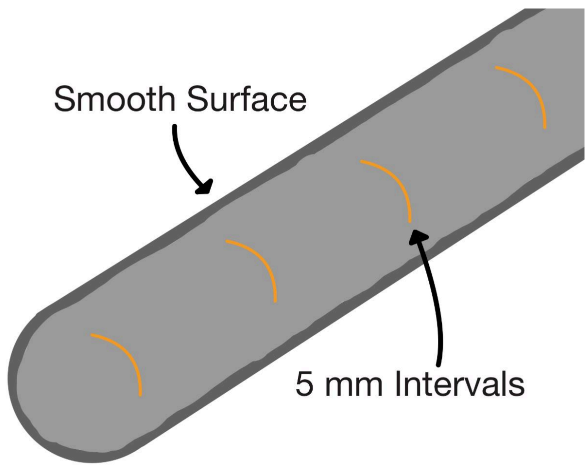


Figure 4: Electroplating design

The third design consideration is electroplating. Electroplating is the process of producing a metal coating on a solid substrate through the reduction of cations of the chosen metal via an electrical current. The two chosen substrates in this case would be the stainless steel Bowman probe, acting as the anode, and a secondary, separate colored metal, such as a dark titanium, as the cathode [13]. Using electroplating, tiny strips of metal coating would be plated onto the Bowman probe in specific locations through controlled masking with tape or wax. These tiny strips would indicate millimeter measurement markings along the shaft of the probe, providing a visible graduation for live, clinical use during ophthalmological procedure.

D. Thermochromism

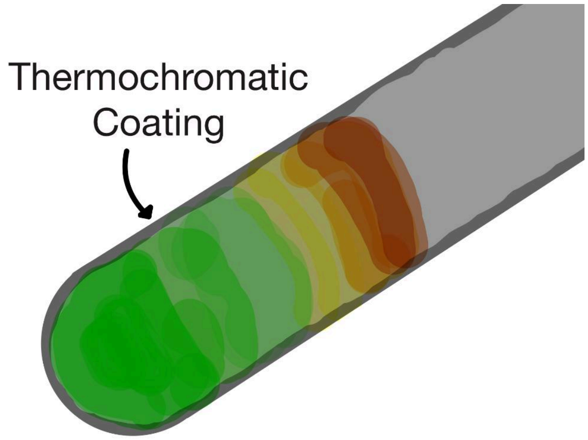


Figure 5: Thermochromism design

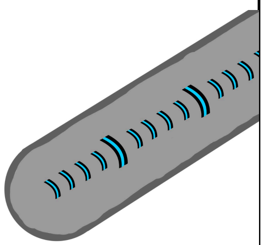
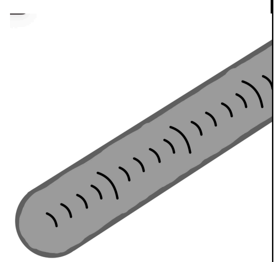
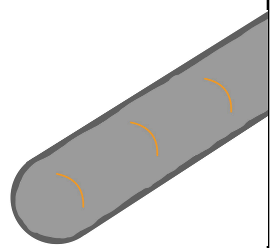
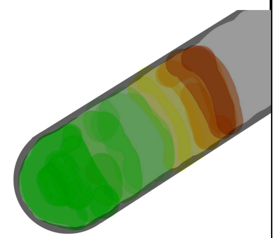
The final design features a thermochromatic coating that is intended to change the probe's color depending on the insertion depth into the human body. Thermochromic coatings have microcapsules that contain encapsulation agents and pigments such as urea-formaldehyde and leuco dyes respectively. When heated, the solvent inside the capsules melts which allows the weak acids to interact with the leuco dyes. This process changes the capsule's chemical composition and results in the probe's surface changing color [14]. Upon use, this design would require doctors to maintain nasolacrimal duct probe insertion until the thermochromic coating activates and changes the probe's appearance. After the probes change in color, the doctor would need to measure the range of color manually with a measuring tool.

Preliminary Design Evaluation

A. Design Matrix

The most critical design specifications were considered when creating the design matrix. Criteria are weighted and ordered based on importance. The winning design was Laser Annealing.

Table 1: Design Matrix

		Laser Engraving		**Laser Annealing**		**Electroplating**		**Thermochromism**	
									
Criteria	**Weight**	**Score**	**Weighted Score**	**Score**	**Weighted Score**	**Score**	**Weighted Score**	**Score**	**Weighted Score**
Accuracy	25	5/5	25	5/5	25	5/5	25	3/5	15
Patient Safety	25	3/5	15	4/5	20	4/5	20	2/5	10
Ease of Data Acquisition	20	5/5	20	4/5	15	3/5	12	2/5	10
Durability	15	2/5	6	5/5	15	5/5	15	5/5	15
Ease of Fabrication	10	4/5	8	2/5	4	2/5	4	3/5	6
Affordability	5	5/5	5	2/5	2	2/5	2	2/5	2
Total	**100**	SUM	**79**	SUM	**81**	SUM	**78**	SUM	**58**

B. Determination of Criteria and Justification of Scores

Accuracy - This criteria refers to the probes ability to accurately measure the depth of the probe that has been inserted into the nasolacrimal duct. Markings must be made at the correct depths, and must have the marking be easily discernible so the user reports the correct value. Accuracy is of critical importance (25%) to ensure the user is able to make accurate measurements of the depths of blockages to inform treatment. Laser Engraving and Electroplating both scored 5/5 in accuracy, due to their precision of machining, and clearly marked depths. Thermochromism received the lowest score of 3/5 due to the less direct nature of the measurement. There are a number of factors that might influence the accuracy of the Thermochromism measurement, including diverse internal temperatures, length of exposure, and difference in how color is measured between clinicians, ultimately decreasing the accuracy of the design.

Patient Safety - Patient safety refers to the probes ability to not harm or negatively affect the patient during standard use. To ensure safety, designs must have a smooth exterior that can not get caught on anything when inserted into the nasolacrimal duct. Additionally, the probe and alterations to the probe must be biocompatible, ensuring that it has no negative effects due to chemicals or materials used. Patient Safety is tied for the highest weighting, 25%, as the probe must be safe to be a beneficial improvement to standard Bowman probes. Electroplating scored the highest score of 4/5 due to having smooth markings that can't catch on anything in patients. The second highest score of 3/5 was awarded to Laser Engraving, slightly lower than Electroplating, due to having engravings that could possibly catch during use. Thermochromism scored 2/5, the lowest score in this category. This is due to the use of weak acids and encapsulation agents such as urea-formaldehyde, which could have potential biocompatibility issues, especially if the surface of the probe is broken in some way.

Ease of Data Acquisition - This criterion refers to the simplicity of probe measurement. Specifically, this category assesses how easy the nasolacrimal duct insertion depth can be determined from the design. This category is quite important as the user's ability to easily ascertain depth insertion is of importance, hence its weighting of 20%. The laser engraving design earned the highest score of 5/5 due to its brightly colored line markings at 1 mm & 5 mm offering simple direct measuring capabilities. The laser annealing design ranked second in this category with a score of ⅘ as it offers distinguishable line markings at 1 & 5 millimeters. Unlike the laser engraving design, which features brightly colored backfill in the engravings, the laser annealing method scored slightly lower as it doesn't feature this color distinction. The electroplating design placed third in the rankings at ⅗ due to its infrequent line markings. While this design features accurate line markers at 5 mm intervals, the exact measurement would prove difficult to gauge and would rely on the user's estimation. The final design featuring thermochromatic coatings scored a ⅖ in this category, the lowest of the 3 chosen designs. The rationale behind this decision is because of the lack of markings on the probe. While this design features a non-surface-penetrating method of graduation, the inverse effect is that doctors must measure the range of color change using their own measurement tools, ultimately making data acquisition more difficult.

Durability - This criterion is relatively straight forward and highlights the physical properties of the different designs of these probes. While the probes must be strong enough to prevent any form of breakage during the procedure, they must also be flexible enough to navigate the different canals in the nasolacrimal pathways.

Durability also relates to the changes made from the different forms of ‘graduating’ these probes. The laser engraving design scored the lowest because the probe’s properties and structure are being manipulated. While re-coating it with a new material to smoothen out the edges seems like a good option, a new material introduced into the probe could cause its structure to behave differently to what an ophthalmologist is used to; it could be too stiff or too flexible, which is why it scored the lowest. The other two prototypes' physical structure is not being manipulated at all, meaning that no change will be made to their properties, resulting in them earning the highest score for this criteria.

Ease of Fabrication - The ease of fabrication criterion refers to both the general feasibility and technical finesse required for the consistent execution of the described fabrication method. This criteria provides insight into what design ideas are realistic answers to the problem at hand, and what design ideas are built on a hypothetical solution. The design that scored highest in this criterion was the laser engraving design, earring a ⅘ . The group has experience with laser engraving and therefore understand the fundamental process associated with the specific fabrication method. Laser engraving would eliminate the human error associated with fine measurement graduation and therefore provide consistent, precise results that could be feasibly accomplished in the given time frame. The other designs, laser annealing, electroplating, and thermochromism, scored lower, with respective scores of ⅖, ⅖ and ⅗. All of these design ideas introduce technical practices the group is unfamiliar with which grows the opportunity for error during the fabrication process. Similarly, the electroplating and thermochromism fabrication practices require a strong chemical intuition that again may very easily introduce inaccuracy.

Affordability - The affordability criterion refers to the cost associated with the execution of each design idea. The design should desirably be cost effective in both a singular instance, and over repeated fabrications. The design that scored the highest was design 1, laser engraving. All the design requires is use of the laser at the Wendt Commons Makerspace, as well as potentially a biocompatible resin to fill in the engraving incisions to prevent tissue compromisation. The other designs each received a ⅖ score, as they would require either continuous purchase of multiple coating and fabrication materials or expensive fabrication equipment not necessarily available for free use for the group.

B. Proposed Final Design

Laser annealing is the best and most efficient approach to graduating these Bowman probes. The key aspects about this design is that it removes no material from the probe, but it adds a small oxidative layer creating a color change on the surface. This design scored the highest in accuracy solely due to the fact that a machine would be making these markings on the probe and reducing potential human error. It will be easily programmable to ensure that these markings are within 5% of a millimeter of each other. For patient safety, this design again scored the highest due to the fact that no material is being added or subtracted from the probe. It will maintain all qualities that ophthalmologists are used to working with in practice and adds now concerns relating to pulling on the tissues inside the nasolacrimal canals. For the next criteria, Ease of data acquisition, it scored the second highest solely because of the potential of the graduation fading during the autoclave process. Multiple testing trials will be conducted to ensure that the graduation will fade, but still, this possibility should be considered. For durability, this design scored the highest again because no material was removed from the probes and they will maintain all physical properties they had previously. This design scored the lowest for ease of fabrication solely based on the materials present for the design team. If the specific laser annealing machine is not available, another route will have to be considered for graduation. Finally cost, annealing scored the lowest again since it is a little more expensive than laser engraving. Overall, this design, although a little more expensive than others, will provide the safest approach and easiest to replicate for graduating Bowan probes.

Fabrication

A. Materials

For fabrication of the graduated Bowman probe, a set of medical grade stainless steel probes will be modified through a precise laser annealing process. Stainless steel is the standard material of application for Bowman probes, and most surgical equipment, due to its set of valuable and unique characteristics. Stainless steel has intensely high biocompatibility, durability, and malleability, something specifically important for delicate navigation through the lacrimal duct [15]. Additionally, when doped with a layer of chromium oxide, the steel becomes highly corrosive-resistant, significantly increasing its life span and improving its ability to be sterilized [16]. Bowman probes are semi-invasive and are required to be sterilized through autoclave after each use, making this sterilization quality necessary. The laser annealing process will only be modifying the existing stainless steel on the probe and will not be adding any additional material.

B. Methods

Laser annealing is the process of slowly heating the surface of a material until chemically oxidized in order to generate a darkened color shift on the material surface. It neither takes nor adds any additional material to the item of interest, preserving the surface finish common with the rest of the item and preventing bacterial build up within the minor grooves generated in laser engraving [17]. When annealed, the layer of chromium oxide that is promoting corrosion resistance of the steel is melted off, but is quickly restored through spontaneous passivation, preserving this necessary quality [18]. Commonly used for barcodes and branding, laser annealing is a precise design method that utilizes computer generated vector files for output of a precise and clean design. A vector file, which can be developed in most common software, will provide the mathematical accuracy for a laser finish that is needed for the millimeter graduation desired for the probe.

C. Final Prototype

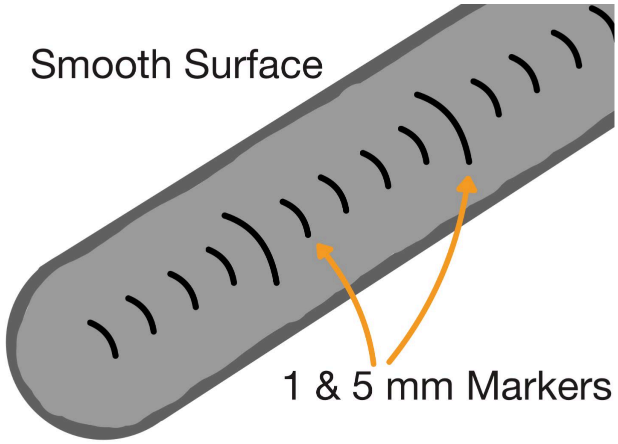


Figure 6: Proposed Final Prototype

Testing and Results

A. Testing Plan

In order to test that the fabricated Bowman probe design satisfies all necessary PDS and client requirements, a series of both quantitative and qualitative assessments have been curated. These testing procedures include the following: a human cadaveric laceration assessment; bioreactor and autoclave material deposition observations; and a subjective nasolacrimal probing evaluation.

Quantitative

Human Cadaveric Laceration Assessment

The human cadaveric laceration assessment will have Dr. Law and Dr. Landingham surgically induce a defined length laceration in and around the lacrimal duct area of several cadaveric specimens. These lacerations will then be observed and attempted to be measured by several medical school residents utilizing a Bowman probe. Half of the students will be randomly assigned the use of a standard, current market, Bowman probe and the other half assigned the fabricated, graduated Bowman probe. Using the probes, the residents will report an estimated measurement for the laceration which will be recorded. The results will be examined for accuracy relative to the defined length induced by Dr. Law and Dr. Landingham, and subsequently put under statistical analysis to determine if there is an improvement in the residents ability to define the length of the laceration. An improved ability can then be translationally applied for determination of obstruction depth within the duct itself, therefore providing evidence for the improvement of the practitioner's ability to quantitatively characterize the nasolacrimal obstruction being dealt with.

Bioreactor & Autoclave Material Deposition

In order to fulfill necessary biocompatibility and autoclave endurance parameters defined within the PDS, the fabricated probe must endure extensive material deposition tests to ensure the integrity of the probe's safety moving towards actual ophthalmological implementation. In these tests, a control group, a set of regular commercial-grade probes and a test group, an associating set of fabricated graduated probes, will be put through ten rounds of either, a pH and temperature controlled bioreactor environment for an approximate procedure time, one minute, or through an autoclave sterilization. Each probe will have their mass weighed with a calibrated scale prior to, between, and following the trials. If material deposition occurs, a drop in weight following the test as compared to prior will make this to be identifiable. The before and after recorded probe masses will be tracked and compared between the control and test group and then statistically analyzed for significant difference. Any observable damage or impact, including to the graduation marks, that the testing environments generated on the probes will also be tracked and evaluated.

Qualitative

Subjective Nasolacrimal Probing

As per client request, the graduated Bowman probe should not alter the current standard nasolacrimal duct obstruction procedure involving probe usage. In order to ensure that the fabricated design does not do so, a qualitative evaluation of the similarity between procedure with a normal, commercial-grade probe and a fabricated, graduated probe must be conducted. For this, Dr. Law, Dr. Landingham, and other medical school residents will perform a duct obstruction procedure with the graduated probe. The practitioners will then be asked a series of questions about how the procedure went with the graduated probe, and if there were any significant ergonomic or procedural alterations that were made to routine operation as a result of the probe. The responses given to the questions will then be evaluated and associating modifications will be made to limit any level of adjustment. A result of no procedural change will confirm the probe's theoretical implementation.

Discussion

A. Ethical Considerations

The biggest ethical consideration related to the graduated Bowman probes is its behavior during the procedure inside the body. After multiple different testing procedures to determine the compatibility of the design, the design itself will need to be submitted for an IRB for more detailed data acquisition in a controlled environment. The IRB will evaluate this design further to ensure ethical compliance and minimal risk to users. The important thing to note is that Bowman probes being used are already approved and used regularly in practice and the probes being modified will be the same. The method of graduation method does not damage the integrity or change the mechanics of the probes, however, it is a new product and the changes should be considered. As mentioned by Dr. Law, if any risk is brought upon the patient from these probes, it would be due to error caused by the ophthalmologist performing the procedure. Since these probes are not changing mechanically and only visually, the concern should be minimal.

B. Future Work

Following prototype completion, the graduated Bowman probes will be submitted for an institutional review board to ensure that the design is safe for use in practice. This new design of the probe will make diagnosis of nasolacrimal blockages more accurate at determining the exact location of obstruction inside the nasolacrimal canals. No changes to the procedures using the probe will be necessary since the probes themselves are not physically changing. Once approved by the IRB, these probes will continue to be tested in practice by residents as a trial period. After this trial period, the probes will be implemented into the hospital's regular usage. Potential causes for error are during production of the probes where the millimeter hash markings are not accurately spaced between each other resulting in inaccurate measurements. This problem should be easily avoided however, since the machine being used to apply this graduation method will apply these markings which have less likelihood of creating error related to spacing than a human wood. Another error that will need to be accounted for is that during the annealing process, some of the material gets obstructed or frayed and begins to wear off. Assuring that the probe is smooth on all sides is critical to maintain patient safety.

Conclusions

Nasolacrimal duct obstruction is a common condition that requires precise probing to accurately locate and treat blockages within the lacrimal drainage system, yet the current Bowman probe lacks graduated depth markings, forcing clinicians to estimate insertion distance. To address this limitation, multiple fabrication strategies to create graduations were assessed on important criteria. The fabrication strategies evaluated included laser engraving, laser annealing, electroplating, and thermochromic coating, each presenting different trade-offs in surface modification and material integrity. These designs were compared using a weighted set of criteria including accuracy, patient safety, ease of data acquisition, durability, ease of fabrication, and affordability to balance the priorities of the project. This process led us to select laser annealing, a technique that produces precise millimeter-scale discoloration without removing material or altering the probe's smooth surface, as it offered the best balance of accuracy, safety, and durability. Moving forward, the team will design multiple prototypes based on the proposed final design. The prototype's accuracy and usefulness will be assessed through quantitative validation, ensuring the probe accurately reports the correct depth. Additionally, biocompatibility and Autoclave Sterilization compatibility will be assessed to ensure the probe is compatible in the expected operating environment.

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Appendix A: Product Design Specifications

Graduated Bowman probe

BMEDesign: Product Design Specification

February 5, 2026

Biomedical Engineering 301

Section 304

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Function

Bowman probes are the standard instrument used in interrogation of the nasolacrimal (tear duct) system in Ophthalmology. They are available in various sizes and provide tactile feedback to the surgeon when probing the canalicular/nasolacrimal system, allowing them to assess for strictures, discontinuities, obstruction, or other abnormality within its lumen. Probing is typically performed prior to the passage of implants such as nasolacrimal stents (eg. Crawford, Lacriflow, Nunchucku, Monoka), to confirm patency of the nasolacrimal system. There are currently no available graduated Bowman's probes available for clinical use on the market. Consequently, doctors performing nasolacrimal duct obstruction procedures are required to estimate the probes insertion depth leading to large amounts of human error and inaccuracies in measurements. To provide a better method of insertion measurement acquisition, the creation of a set of clinically accessible graduated Bowman's probes is necessary. By creating an accurate device that features easy data collection, doctors will be able to ascertain the exact location of nasolacrimal duct obstructions and be able to provide more personalized treatment plans to patients. The device must be identical in dimensions to currently used Bowman's probes, feature distinguishable markings, and minimize any changes to surface texture in order to maximize measurement accuracy and patient safety.

Client requirements

- The design must feature accurate line markings that are easily recognizable during procedures
- Device must be smooth and shouldn't have any engravings that result in a rough-textured surface
- The device's material must be compositionally strong after addition of measurement markers
- The design must be able to withstand autoclaving and repeated sterilization
- The design should fit standard probe size guidelines

Design requirements

1. **Physical and Operational Characteristics**
   a. **Performance requirements -** The device should be able to accurately present the depth of nasolacrimal duct probe insertion in millimeters. The device must be similar in comfort to the user's previous probes to avoid discomfort and procedural-change. The device must also be able to undergo 1000 rounds of sterilization via autoclaving with proper care[1], and therefore must maintain structural and chemical integrity throughout high temperature exposure. Finally, the device must be able to withstand long-term usage without material degradation and/or mechanical failure.
   b. **Safety -** The selected design must comply with ISO-13485:2016 to uphold necessary safety and regulatory requirements[2]. This standard specifies the need for design risk assessment, product cleanliness, and

overall quality assurance for medical devices. Should the design feature laser engraved measurement markings per the client's request, it must be tested and held to ISO-13485:2016 standards to ensure material composition and therefore patient safety is not jeopardized. Furthermore, the design's strength should be tested through MTS compression testing to confirm material integrity after the addition of measurement markers. While the procedure has minimal operating times, with the device being implanted for less than one minute, the design must follow ISO-10993-1 which specifies necessary guidelines for biomaterial interactions with live tissue. A majority of design safety specifications are largely covered in sections 3a: Standards and Specifications and 3c: Patient Related Concerns.

c. **Accuracy and Reliability -** The design should have accurate markings every 5 millimeters along the probe as requested by the client, and feature inscribed bands corresponding to millimeter markings. The chosen device must also be within a normal range of standard commercial Bowman probes in terms of weight, length, and diameter to comply with standard procedural operation. The measured values must be within a 5% range of the correct nasolacrimal duct obstruction millimeter length.
d. **Life in Service-** The design must be reusable, withstanding 5-10 years of clinical use. In order to achieve this, the probe should be designed from a material significantly resistant to wear and corrosion, such as stainless steel. This is particularly important for the design, since wearing down of the markings could harm functionality of the probe or lead to incorrect measurements In addition, the probes must be capable of withstanding hundreds of sterilization cycles, typically performed via autoclaving[3]. Individual uses of probes last from seconds to a minute.
e. **Operating Environmen**t-The design must be able to withstand all qualities of a clinical environment, as well as the environment of the tear duct. Firstly, the probe must be able to withstand temperatures of up to 132-135 °C to withstand the autoclaving process[3]. The probe will not be subjected to significant pressure, and will be exposed to the moderate humidity of operating rooms, ranging from 20-60% RH[4]. Additionally, the probe will be exposed to increased moisture during autoclaving. While being used, the probe will be exposed to the fluids of the tear duct, including tears, blood, and mucous. Particular care must be used to ensure probes are not contaminated between uses.
f. **Ergonomics**-The probe will be designed for use by trained clinical personnel and Ophthalmologists, who are familiar with Bowman probes and how to handle clinical instruments. The probe must be designed to be comfortably and precisely controlled by gloved fingertips, typically achieved using a flat center. The probe must withstand minimal insertion force, up to 1 N[5], and the minimal torsion force caused by twisting. Fatigue is not a concern for this design, as they are intended to be used for a short duration. To ensure the safety of the patient, the probe should feature a rounded, atraumatic tip to prevent cutting. Finally, the design material should have a smooth, polished surface to prevent tissue trauma and improve tactile feedback. This extends to the graduated markings or engravings of the design.
g. **Size**- Bowman probes are available in sizes ranging from 0000-8. For the purposes of this project, the client is most concerned with sizes, 00, 0, and ½, representing 0.7 mm, 0.8mm and 1mm diameters, respectively. Additionally, probes are available in lengths ranging from 130-150mm. Finally, the probes come either curved or straight, however our client only uses straight probes.
h. **Weight**- These probes are typically very tiny and light to allow the ophthalmologist to be as precise as possible while performing the procedure to minimize error. Bowman probes weigh roughly 45 grams. If this weight were to be increased by using different material, the probe would be more likely to cause error by puncturing the walls of the nasolacrimal cavities. If it were to be lighter, the probe's structural integrity could be more likely to fail during the procedure and further complicate the procedure.
i. **Materials**- materials used to make probes must be organic metals that can be used in the body and minimize the risk of the patient creating some toxicity or allergy to it. The majority of the probes are made from stainless steel since the material combines strong structural integrity with flexibility [6]. The Bowman probe must also be able to withstand sterilization techniques, the most prominent of which being the autoclave (temperatures range from 121 to

134 degrees C). Finally, the material must be smooth and blunt to, again, minimize injury. A semi-sphere will be attached to the end of the probe to remove any sharp edges that could cause damage to the patient.

j. **Aesthetics, Appearance, and Finish**- probe will be thin, smooth, and be very forward looking about its usage. There should be no changes to probes already used in practice by ophthalmologists other than the changes to read measurements.

2. **Production Characteristics**
    a. **Quantity**- As a preliminary approximation, 10 probes should be made for testing, allowing for multiple trials testing the integrity of the measurement tactics used. Allowing for multiple probes will provide a good baseline for techniques that work and those that don't. Although 10 is an approximation, it is likely that more will be used during testing especially because of the teams lack of training when applying these probes. Multiple errors could be made during fabrication assuming that a specific technique would be used and the probes are built accordingly, but in reality, medical professionals use another resulting in these probes to break.
    b. **Target Product Cost**-the target product cost is $100 but can be changed depending on the progress made with the project. Depending on the materials used, the final product can be more expensive but the team will make it a priority to make the product as cost effective as possible. Most of the expense will most likely come from buying the actual probes to prototype on and test. When the device is fully functional, optimizations to the device will be made to further lower the cost to make it more widely available for anyone.
3. **Miscellaneous**
    a. **Standards and Specifications**
        i. ISO 10993-1 provides guidelines for toxicity testing of biomaterials in order to prepare for their interaction with living tissue. The evaluation is based on the specific materials used, how it contacts the body, and the duration of that contact. It provides an in-depth biological risk analysis, evaluation, and control procedure to allow for biocompatible confirmation of a material or device and is an internationally recognized biocompatibility assessment that is required for numerous regulatory applications [7]. The Bowman probe comes in direct contact with the lacrimal epithelium of the human body during operation and therefore falls under this guideline [8].
        ii. ISO 13402:2025 describes specific test methods to evaluate the resistance of stainless steel surgical instruments from autoclaving, corrosion, and thermal exposure. It outlines procedures specific to typical alloy compositions with each individual test evaluating the materials effective resistance against each of the three aforementioned qualities. [9] The Bowman probes used at the UW Hospital are sterilized via autoclave and must be corrosion-resistant to ensure long-term durability and to prevent alloy degradation and therefore should abide by this standard.
        iii. ISO 17664 specifies the appropriate procedure for cleaning, disinfecting, and sterilizing medical devices. It describes the characteristics an appropriate medical device must have which includes being easy to clean and sterilize as well as an associating proof of sterilization through formalized testing and data collection. It breaks down medical devices into three categories, critical, semi-critical, and non-critical, with surgical tools being deemed critical and therefore requiring the most attention as they pose the highest risk of infection [10]. Bowman probes are categorized as a surgical tool due to their vital role in ophthalmological procedure and therefore require high sterilization efforts.
        iv. ASTM B912 specifies the passivation of stainless steel alloys through electropolishing. It gives a detailed outline for the pre-treatment, electropolishing, and post-electropolishing processes for various grades of stainless steel [11]. The Bowman probes will be manufactured out of stainless steel and will require a surface restoration process following any modifications made to the probe in order to prevent alloy deposition and an associating inflammatory response [12].

v. 21 CFR Part 820 is a quality system regulation standard for medical devices which provides necessary details on the designing, manufacturing, storage, and application of medical devices specific for human use. The criteria for this standard lie in tandem with the FDA and therefore provide a good basis for qualification of an appropriate medical device [13]. This standard could become extremely important for the graduated Bowman probe depending on the extent of development that is done within the project sphere.

b. **Customer**

i. The users of the device will be Dr. James Law and Dr. Sarah van Landingham as well as other clinical practitioners in the ophthalmology department at the UW Hospital. They desire the implementation of the device to be a seamless process that swaps the current Bowman probes for the modified devices, where no alteration to the methodology or step-wise process of the operation is required.

c. **Patient-related concerns**

i. For medical patients whose operation will be completed with the modified device, all relevant concerns with the procedure both relating to and not relating to the modified Bowman probe will have been approved and cleared by numerous medical professionals prior to the operation [14]. This includes all anesthetic, pain-related and biological safety concerns for the procedure. The device will be sterilized with an autoclave prior to and after each use and therefore must be tested for continued autoclave sterilization with no signs of damage or degradation.

ii. Potential exposure of alloy particulates to the epithelial-lined conduit of the nasolacrimal duct from laser engraving could cause an unintended inflammatory response within the eye and long term development of scar tissue [15]. The probe must undergo a surface restoration process in order to prevent this response from occurring, such as electropolishing. [16]. The graduated probes will be implemented into the congenital nasolacrimal duct obstruction procedure. This process involves perforating a thin epithelial membrane and is a relatively brief and concise operation, approximately 1 minute in total invasive time for adult patients . This brevity decreases the opportunity of particle deposition from these engravings and prevents intense chemical breakdown from the moist, protein rich environment of lacrimal mucosa [17].

iii. Because of the generation of microscopic burrs and sharp edges during the engraving process, there is an increased chance of prominent friction between the probe edge and the epithelial lining it contacts [17]. Since lacrimal epithelium is thin and delicate, there is potential for abrasion and damage to the surrounding tissue [18]. Thus, damage to the lacrimal tissue within the duct leading to small scale hemorrhage and the development of scar tissue within the lining, further closing the duct, poses a potential concern [19]. Similar to alloy deposition, surface restoration processes such as electropolishing are necessary to diminish the probability of this occurring.

d. **Competition**

Sklar Surgical Instruments

i. Sklar Bowman probes are the most monetarily prolific brand in the market, bought in bulk by hospitals and other medical facilities [20]. They are known for reliability and quality and offer probe customization with various sizes and material options including stainless steel and silver [21].

ii. The probes are thin malleable rods with a rounded end used for clearing of the nasolacrimal duct, as well as other general procedures involving the lacrimal system. The device is double ended with distinct probe sizes on each end of a singular instrument.

iii. All probes offered by Sklar are bought non-sterile, reusable, and absent of any latex material helping prevent common anaphylaxis [21]. They are not graduated and therefore though medically acceptable, are not as quantitatively precise as desired by the client.

Calibrated Bowman's lacrimal probe from Indian journal of ophthalmology.

i. These Bowman probes were individually manufactured with numbered engraving to improve the diagnostic and therapeutic utility of the Bowman probe in relevant ophthalmological procedures. The numbers have been engraved on the millimeter scale on either side of the probe using laser engraving [22].

ii. The graduated probes are made of stainless steel and feature the exact same size range as standard probes. They are double sided, contain a central metal plate for grip, and are reusable and sterilizable.

iii. The engravings provide nominal size references rather than specific discrete measurement points. The markings provide general guides for the distance of probe insertion into the lacrimal duct but no high level specificity.

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any quantitative information without references came directly from the client, Dr. Law

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Appendix B: Expense Sheet

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Set of Bowman's probes	A set of unmarked Bowman's probes used in duct procedures for the team to practice fabrication and testing	Premium Instruments	B0777N38SV	2/25/26	3	$16.99	$50.97	Link
Component 2								
Component 3								
TOTAL:								**$50.97**