Graduated Bowman's Probes for Nasolacrimal Duct Obstructions

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Problem Statement

- Currently no graduated Bowman's probes are available on the market
- Current measurement methods rely on estimation or with use of an external measurement apparatus
- Inaccuracies in measurements lead to diagnostic error and inefficient treatment plans
- A graduated Bowman's probe is necessary for easier, accurate measurement acquisition

Background & Motivation

Client Background

- 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 easy quantitative characterization of lacrimal duct measurements during procedure

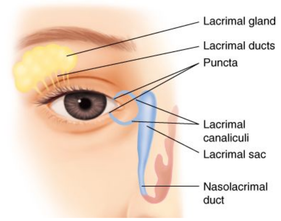

Figure 1: Diagram of the lacrimal drainage system [2]

Lacrimal Drainage System

- The anatomical pathway that removes tears from the ocular surface to the nasal cavity [1]
- Consists of the lacrimal puncta, inferior and superior canaliculi, common canaliculus, lacrimal sac, and nasolacrimal duct

Nasolacrimal Duct Obstruction (NLDO)

- Blockages in the lacrimal system which lead to symptoms such as epiphora (excessive tearing) and infection, which may result in the need for surgical intervention [3]
- Can be caused by canalization during gestation or develop with age due to narrowing of the duct
- Bowman probes used to find the depth of obstruction

Figure 2: Nasolacrimal duct obstruction causing a buildup of fluid in an infant child [4]

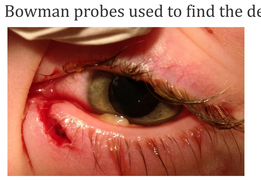

Figure 3: Canalicular laceration resulting from trauma to the lower eyelid [5]

Canalicular Laceration

- A traumatic tear of the eye's tear-drainage system often caused by eyelid trauma, accidents, or dog bites [6]
- Involves intense pain, risk of infection, and potential for scarring and stenosis, which in turn may cause epiphora
- Bowman probes used to find the point of laceration

Current Probes

- No visible graduation
- Clinical 'gold standard' procedure involves the use of an external measuring apparatus
- Introduces a greater chance of diagnostic inaccuracy
- Leads to inefficient procedure plans

Figure 4: Unmarked Bowman's probe

Design Criteria

- Allow easy measurement of a probes insertion depth into the lacrimal system
- Feature visible markings up to 35 millimeters at evenly spaced millimeter intervals without significant change to the surface texture
- Comply with ISO-13485:2016 and ISO-10993-1 which requires manufacturing uniformity across prototypes and maintains biocompatibility standards respectively [7]
- Have the markings be within a 5% range of the correct desired measurement length
- Be able to withstand repeated autoclave sterilization with an environment of 121 ℃ and 15-20 psi [8]
- Fabricate a full set that matches the dimensions of a standard Bowman 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 [9]

Final Design

Sample Holder

- Fabricated out of Aluminum
- Allow for each probe to be placed in the same orientation under the focal point of the laser
- Holds 3 Bowman probes during fabrication
- Vertical Channels to straighten each probe and hold in place
- Horizontal Channels to align the ends of the probe 2.5 millimeters away from the first marking

Graduated Probes

- 2.5 millimeter markings up to a total marked length of 35 millimeters
- Graduation fabricated with a LasX industrial 200 watt laser tracing a vector file
- Set of six probes each containing a different diameter on the ends ranging from 0.5 millimeters to 1.8 millimeters
- Probes will be applied to all the same procedures as ungraduated probes

Figure 5: Sample Holder

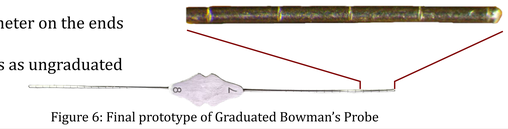

Figure 6: Final prototype of Graduated Bowman's Probe

Testing

Cadaveric Testing

- 5 cadaveric specimens
- Left eye lower and right eye upper canalicular lacerations equating to 10 measurements for each participant
- Free estimate, regular probe, regular probe with ruler and graduated probe measurements
- Dr. Law and 2 medical residents participating
- Using ruler measurements as the gold standard and observing accuracy of graduated probe outright and in comparison to the nongraduated probe

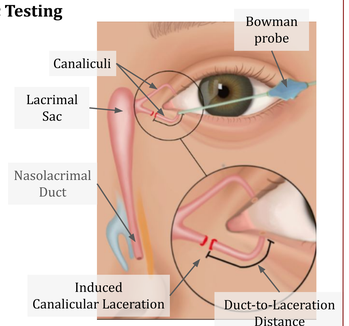

Figure 7: Diagram of a canalicular laceration in the nasolacrimal drainage pathway

Autoclave Testing

- Weighed each probe prior to and after autoclaving
- A full set of 6 probes were tested to account for the differences in diameter
- 3, 1 hour autoclave cycles
- Testing for material degradation during the autoclave environment through weight loss or observable erosion

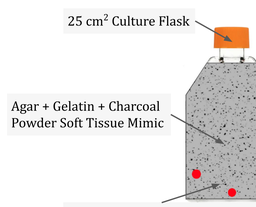

Figure 8: Tissue pull soft tissue mimic setup

Tissue Pull Testing

- 5 agar with gelatin and charcoal soft tissue mimic samples
- 5 different probe sizes used: 1, 2, 4, 7, 8
- 3 trials of probing for each size, both graduated and ungraduated
- Overlaying before and after probe pictures to find percent disruption of the charcoal using a python algorithm
- Comparing binary percent disruption in a region of interest of graduated versus graduated to determine tissue pull

Figure 9: Charcoal-gelatin soft tissue mimic with binary difference in R.O.I. overlayed

Uniformity Testing

- Leica MZ95 stereomicroscope used to capture images of manufactured probes
- 28 probes of varying sizes measured
- ImageJ used to measure marker width, interval length, and length of probe end to first marker
- Comparison of probe dimensions to ensure uniformity across manufacturing process

Figure 10: Uniformity Testing Measurements

Accelerated Life Testing

- Artificial tear solution
- 4 probes left in solution in sterile incubator at 37 ℃
- Probes stored in incubator for 48 hours equalling 2,880 procedural uses
- Leica MZ95 stereomicroscope used to observe changes in color and marking visibility

Figure 11: Accelerated Life Testing Setup

Results & Discussion

Tissue Pull Test

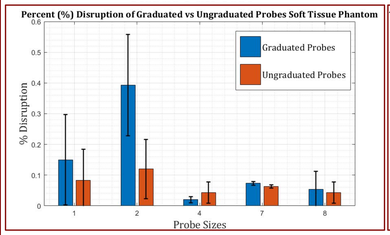

Figure 12: Comparison of graduated and ungraduated probes % disruption of an agar, gelatin and charcoal soft tissue phantom to display change in chance of tissue pull

- Probe sizes 1, 4, 7, and 8 had no significant difference in % disruption between the probe types
- Trend suggests that inclusion of graduation does not increase chance of tissue pull or snag while in use

Cadaveric Test

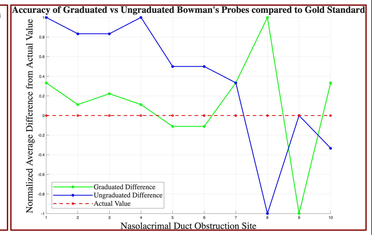

Figure 13: Comparison of average graduated vs non graduated laceration depth estimation in reference to the gold standard, ruler measured, length

- Data provided no statistical significance between the gold standard and graduated probe measurements
- Average graduated error was consistently less than average ungraduated error

Uniformity Test

- Probes showed desired consistency in interval length and marking width
- Interval Error: 3.71%
- Width Error: 15.35%

Accelerated Life Test

- Probes showed slight discoloration following 48 hour incubation
- Markers remained unchanged in both clarity and form

Autoclave Test

- There was no visible deformation to the marks
- There is no statistical significance of the mass before and after autoclaving

Figure 14: Top: Graduated Bowman probe, Bottom: Graduated Bowman probe after accelerated life testing

Discussion

- The graduated probes succeeded in providing an alternative method to determine nasolacrimal measurements other than the standard ungraduated probe + ruler method
- There was no statistical difference between the use of the graduated Bowman probes and the gold standard procedure
- A survey from the residents and fellow confirmed that during usage there was no change in technique required for the graduated probe, and mentioned no concern related to the graduation pulling on the inner tissue
- Professional opinions from Dr. Van Landingham and Dr. Law mentioned that they prefer the graduated version over using a ruler to determine the depth
- It is important to note that testing these probes on cadavers is different than their performance during a surgery on a live person, since there will be other biological factors like blood and swelling that are not accounted for

Future Work

- Redesign of probes with 1 millimeter marking intervals and entire circumference graduation
- Live patient testing
- Universal laser manufacturing & machining process to increase uniformity & ease of reproduction
- Reproduce prototypes & conduct testing with expensive probes

Acknowledgements

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