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The Use of an Artificial Cornea for Validation of a Novel Intraocular Pressure Measurement Device

Avinash Laha^{1,2}, Aravind Srinath^{1,2}, Frank E. Talke^{1,2}

¹University of California, San Diego, CA, USA ²Center for Memory and Recording Research, San Diego, CA, USA

Outline

- Introduction to Glaucoma Screening
- State of the Art
- Design solution Handheld 3-in-1 Device
 - Structural Description
 - Prototype Implementation
- Artificial Cornea Models
 - Design Considerations
 - Methods of Fabrication
 - Simulation of Intraocular Pressure
- Performance Testing with Tonometers
- Summary

Introduction to Glaucoma

- Primary cause of irreversible blindness in the world
- Risk Factors
 - Old age, physical + mental health, genetics
 - Elevated intraocular pressure (IOP) causing pressure on optic nerve
- Causes slow deterioration of vision field
- Often not self-diagnosed and surgical cure at later stages proven ineffective



Comprehensive Screening

Standard Eye Examinations



- Comprehensive exams for glaucoma can be time consuming and costly
 - Patients may not be able to travel or perform routine tests regularly
 - Post-surgery examinations required to screen for complications
- Need to develop easy-to-use, self-examining devices for glaucoma screening

Proposed Solution

Design and **Rapid Prototyping** of a portable ophthalmic device that combines:

- **Slit-lamp** examination
- Visual acuity screener
- Non-contact tonometer

 \rightarrow The device should be easy-to-use, internet-enabled and allow self-examination

First Prototype Implementation



Tonometry and Calibration Standards

- IOP fluctuation is the biggest risk factor for glaucoma and related diseases
 - Tonometers essential for early detection
- However, high variability between different tonometers
 - Some use adjusted "bIOP" calculations to account for cornea thickness, curvature, etc.
- Calibration needed to ensure reliable IOP readings at varying eye pressures
- Controlled using manometer chamber filled with water/other fluid
 - Excised cornea samples (ex-vivo)
 - Cannulated samples (in-vivo)
 - Artificial Cornea Models



Excised Cornea



Artificial Cornea



Cannulated Cornea

Artificial Cornea Design Considerations

- Goal: To validate working principle and calibrate the tonometer system
- Important to capture:
 - Geometrical dimensions of human cornea
 - Variance in some can create inaccurate tonometer readings
 - Mechanical behavior similar to human cornea in response to elevated IOP



Methods of Fabrication

- CAD Model designed using human corneal dimensions in literature
- Silicone Molding Process
 - 3D printed custom two-part molds developed with this geometry
 - Three silicone materials chosen with documented Young's moduli within human corneal range
 - Silicone mixed and cured for 24 hrs @ room temperature to obtain samples



Materials Selection - Tensile Testing

- Coupon tensile testing performed to confirm uniaxial test data and Young's modulus values
- Coupons molded using 3D printed mold (ASTM D638-14)
- Uniaxial testing and DIC performed on all chosen materials



Simulation of Intraocular Pressure

- Silicone corneas clamped and connected to a manometer water column
- Height can be adjusted to simulate varying range of IOP

$$P_2 = \rho g(h_2 - h_1) = \rho g \Delta h$$

Manometer Pressure (mmHg)	0	10	20	30	40
Column Height, Δh (cm)	0	13.60	27.21	40.81	54.42



Materials Characterization - Inflation Tests

- Corneal response under elevation of IOP can be studied to reveal similarities and differences with human cornea
- Corneal setup tested between 0-120 mmHg
- Results
 - DS10 linear up to 120 mmHg
 - ECO45-NC linear up to 55 mmHg
 - ECO30 nonlinear after 25 mmHg
- DS10 closest to human cornea apical displacement
 - Up to 40 mmHg



Performance Testing - Commercial Tonometer

- iCare TonoVet Plus Rebound Tonometer
 - Measures speed of miniature probe rebounding off the corneal surface to calculate IOP
- Tested on rabbit setting → similar corneal thickness to humans
- Testing to validate all developed cornea samples at different IOP
- Results
 - Linear increase with increasing IOP
 - \circ Higher stiffness \rightarrow Higher reading range





Performance Testing - 3-in-1 Device

- Air jet pulse mechanically applanates the cornea while recording movement of projected placido rings
- MATLAB filtering algorithms employed to analyze change in ring centroid displacement
- Results
 - Inverse relationship between IOP and placido ring deformation
 - Stiffer samples \rightarrow lower range of deformation



Summary

- Successful rapid prototyping of a portable ophthalmic device that allows self-examination of the eye
- Artificial cornea with tunable geometry and material properties
- Pre-clinical validation shown by linear relationship with changing IOP and prospect of calibration

Future Work:

- Exploration of composite materials to imitate strain-stiffening in corneas
- Follow-up testing with accurate human tonometers and excised corneas
- Making the device more user-friendly for higher patient variance
- Planning first clinical tests and further research development

Thank You!