Design of a Capsularhexis Device for Cataract Surgery

Product Design Specifications
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Function: Approximately 1.5 million cataract surgeries are performed each year in the United States and millions more throughout the world. A precise mechanical device is looking to be developed that will be significantly more cost effective than the laser technique thus allowing for much broader access than is currently available with the laser technique. The purpose of this project is to construct a prototype to show the mechanism of the capsularhexis and test the suction method on cadaver eyeballs.

Client Requirements:

- Device must not create any microtears during surgery.
- Device must cut a precise 6 mm circle within 0.5-1 mm accuracy.
- Device must be sterilized before use.
- Device must not change the current protocol of surgery.

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device must safely enter the human eye through a 2.0 mm incision in the cornea, unfold inside the eye into a circular device that is then able to create a 6 mm circular opening in the capsular tissue of a human lens within 0.5-1 mm accuracy. Must then fold back up and be removed through same 2 mm incision. Device must be sterilized between uses or may be disposable. The design project will be constructed at a larger scale to show the mechanism in detail.

b. *Safety*: Device must be biocompatible with the eye. It cannot damage, harm or put the eye at greater risk during surgery. Must be sterilized to prevent infection during surgery. The design project will be constructed

at a larger scale, therefore safety considerations can be implemented when the device is scaled back down and constructed.

c. *Accuracy and Reliability*: Device must cut varying eye tissues of 15 micron in thickness. It must fit through an incision of 1.9-2.8 mm. No microtears are to be created during surgery. The opening must be within 0.5-1 mm. The design project will fit these requirements at a larger scale.

d. *Life in Service*: The design project will show the mechanism for multiple uses at a larger scale.

e. Ergonomics: Larger-scaled device must be easy to use during surgery. There is only one chance for the circular opening to be made; device must be easy to use with confidence that it will make the opening and not create any microtears.

h. Size: Device must operate in a space of 3-5mm (the vertical distance of the cornea to the lens). Must fit through an incision of 1.8-2.8 mm. The larger-scaled device will meet these requirements at a larger scale.

i. Materials: Device must be biocompatible. If reusable, must withstand autoclave.

2. Production Characteristics

a. *Quantity*: 1 device.

b*. Target Product Cost*: $200-$500.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval required before use in surgery.

b. *Customer*: Client liked the blade design of cylindrical shape with a lever that deploys a circular blade and then retracts after use.

c. *Patient-related concerns*: If device is reusable, must be sterilized between uses. Materials must be hypoallergenic.

d. Competition: Femtosecond Laser, Nottingham Cataract Device, Fugo Plasma Cutter.