Extraction Device for Non-metallic Intraocular Foreign Bodies: Product Design Specification (PDS)

Client: Dr. Leslie A. Wei

Advisor: John Webster

Team: Amy Kim
Ngoc (Ruby) Phung
Carly Hildebrandt
Adam Strebel

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Function:

Traumatic intraocular foreign bodies are becoming increasingly common and can be visually devastating. Smooth, round, non-metallic foreign bodies such as airsoft pellets are uniquely difficult to remove surgically. These pellets are approximately 6 mm in diameter, enter the eye with at high velocity, and cause significant damage such as globe rupture, retinal detachments, and cataracts. Such injuries are more prevalent in children and young adults. A need exists for an intraocular instrument that will easily grasp and remove such an object within the eye.

Ideally, the instrument ideally would be 1) low profile enough to enter the eye and manipulate the foreign body without damaging surrounding structures, 2) able to easily grasp round, smooth objects that conventional forceps are unable to grasp, and 3) enter and exit the sclera (eye wall) without enlarging the wound.

Client Requirements:

- Instrument must be sterilizable or disposable
- Minimize the damage of the retina
- Provide flexibility in handling for surgeons without changing hand position
- Easily grasp the object in its entirety

Design Requirements:

1. Physical and Operational Characteristics

a. Performance requirements: The instrument shall be able to reliably grasp and lock into place a smooth, non-metallic, and spherical Intraoclular Foreign Body (IOFB) of diameter

6.1 mm or less. It shall not enlarge the surgical wound site beyond the size of the IOFB. It shall be easily and independently operable by a surgeon.

b. Safety: The instrument shall be able to be effectively sterilized after each use. It shall not possess any features that could pose an increased risk to the patient or surgeon, including but not limited to loose fitting parts and sharp edges.

c. Accuracy and Reliability: The instrument shall be able to repetitively grasp an IOFB without the IOFB slipping from its grasp through the duration of the procedure. Once in use the instrument shall be one-hundred percent successful in the removal of IOFB.

d. Life in Service: The instrument shall be in service for fifteen years with proper care and usage. The client is also open to the idea of a single use disposable instrument. [1]

e. Shelf Life: The instrument shall be able to be held for ten years under sterile conditions or until its sterilization has been compromised due to environmental factors. [2]

f. Operating environment: While the device is being used, it will be in contact with the inner part of the eye. It will specifically contact the sclera, cilia body, aqueous body, retina and vitreous body. It must be operable in a high-pressurized eye state with an infusion rate of 30. A surgeon in a sterile surgical environment will handle the device.

g. Ergonomics: The device should open and close smoothly while providing flexibility for a surgeon. It should be able to deliver precise movements. It must be easily graspable by one hand. It should provide a stable handling for a surgeon. Surgeon should be able to rotate the device in his/her fingers without changing hand position.

h. Size: The device must be large enough to grasp an IOFB but small enough that it does widen the original wound. Its thickness should be close to that of the foreign body. Its length shall be 24 mm from tip to handle to provide a minimum operating distance for the surgeon. The grasping part of the handle should not be too thin to provide stable performance. The device should not exceed 7mm in diameter in order to minimize the enlargement of entrance wound.

i. Weight: The device should be minimized but not too light that the surgeon could hold it comfortably and securely during the full time of the surgery.

j. Materials: The device should be made of surgical tool materials. It should be constructed with materials that do not interfere with the internal body. The material should be lightweight in order to provide small weight. The texture should provide sufficient friction

for the device to not slip from a surgeon's hand. Materials should be autoclavable if will be reused. If materials are to be disposable, they should be gamma-sterilizable. [3]

k. *Aesthetics, Appearance, and Finish*: These factors will be determined upon the fabrication of the device. The device should have a smooth finish with rounded corners and no sharp edges that might damage tissue.

2. Production Characteristics

a. Quantity: One unit is needed per each time of the operation. Quantity demanded for production will be defined later in the process.

b. Target Product Cost: The cost of production should be targeted around $250 per unit. Cost-effective factor will be determined upon completion of the project for future work.

3. Miscellaneous

a. Standards and Specifications: FDA approval of the device is required.

b. Patient-related concerns: Materials must be non-toxic and biocompatible. Any metals used must be hypoallergenic. Must not cause any additional damage to the eye or expand the wound.

c. Customer: Ophthalmologists, hospital personnel, and the patients who require intraocular foreign body removal.

d. Competition: There is no direct competing device specific for the removal of intraocular non-metallic foreign bodies. Similar designs and current instruments include hooked prong forceps designed to remove stones, neurological surgical forceps and tweezers.

References

[1] *Selection of stainless steels for surgical instruments*. N.p.: British Stainless Steel Association. Retrieved February 10, 2014, from http://www.bssa.org.uk/topics.php?article=132

[2] An Online Continuing Education Activit. (2011). *Care and Handling of Surgical Instruments* (p. 27). N.p.: CareFusion. Retrieved February 10, 2014, from http://www.pfiedler.com/1096/files/assets/basic-html/page27.html

[3] R. Pell, (2006). Printing Equipments and Supplies.*Surgical Instruments: Converting from Metal to Plastic*, Retrieved from http://www.mddionline.com/article/surgical-instruments-converting-metal-plastic