Project Design Specifications for BME 200/300 Group 10: Blinking Orbital Prosthesis

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Problem Statement:

When a patient has an orbital exenteration the large cavity is restored with an acrylic eye surrounded by a detailed but static silicone rubber restoration of the soft tissues (lids, etc). The PMMA eye is incorporated into the silicone part and the patient just places the entire unit in each day. It is retained with adhesive, osseointegrated percutaneous fixtures or by gentle anatomical fit. There seems to be adequate volume in a well lined cavity to house the needed mechanism for animation. The goal is to fabricate a patient simulator model with prosthesis that blinks, and a mechanism developed that would synchronize blinking with the working eye.

Client Requirements:

- Actuating mechanism is self – contained
- Contained sagittally between the lacrimal and the zygomatic bone and transversely between the maxilla and frontal bone[1]
- Mimics a typical spontaneous blink
- Not noticeably audible (less than 15 dB)
- Safe for use within orbital cavity
- Adequate budget available

Design Requirements:

1. *Performance Requirements*: Mimic a typical spontaneous blink, where a "typical spontaneous blink" is defined by a change in amplitude of the eyelid of 10-mm at a velocity between 150 mm/sec and 350 mm/sec (1700°/sec)[2]
2. *Safety*: Must be safely contained in orbital cavity with no exposed wires or other materials that would interfere with existing human processes and a magnetic field strength of less than 3 mG[3]

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[1] Bones of the Human Cranium and Face. 2008. Ivy Rose Holistic Health and the Human Body.12 October 2008. <http://www.ivy-rose.co.uk/Topics/Bones_CranialandFacial. htm>.

[2] Guitton, Daniel, Raymond Simard and François Codère. "Upper Eyelid Movements Measured with a Search Coil During Blinks and Vertical Saccades." Investigative Ophthalmology &Visual Science. Vol 32, No.13, Decmber 1991: 3298-3305.

3. *Accuracy and Reliability*: Produce a blinking motion that is 0.16-0.4 seconds in duration when prompted
4. *Life in Service*: Functional with single power supply for a full 15-hour day
5. *Shelf life*: The device should have a shelf life of 1 year
6. *Operating Environment*: Should be able to operate within orbital cavity while exposed to fluctuating conditions within and around the human body, including temperatures between -29° and 49°C
7. *Ergonomics*: The device should be manufactured to fit comfortably within the orbital cavity.
8. *Size*: Volume of orbital cavity varies between patients so device should be as small as possible in order to fit in a range of cavities, but should be no more than 3 cm in diameter.
9. *Mass*: The device should be no more than 60 grams, but additional weight may be added if external components are included (i.e. eyeglasses).
10. *Materials*: The portion of the device in contact with the skin is primarily composed of silicone and should not cause irritation, as shouldn't the other materials comprising the device.
11. *Aesthetics, Appearance and Finish*: The device should mimic as closely as possible a normal human eye.

Product Characteristics

1. *Quantity*: Only one prototype required, but should have the ability to be included in custom made orbital prostheses.
2. *Target Product Cost*: Less than $2,000.

Miscellaneous

1. *Standards and Specifications*: FDA approval is required
2. *Customer*: Customer would like a comfortable, non-invasive device
3. *Competition*: There is little to no competition, as no current patents exist and no attempts are being made for non-invasive methods

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[3] Are EMF's Hazardous to our Health?. Mercola.com Natural Health Newsletter. 12 October 2008. <http://www.mercola.com/article/emf/emf_dangers.htm>.