

Project Title: The role of bandage contact lens in post-operative patients undergoing Fasanella Servat ptosis repair

Short Project Title: Bandage contact lens in post operative ptosis patients

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Project Summary

Ptosis (eye lid drooping) can be corrected surgically via a procedure called Fasanella servat. As eyelid tissue is cut and existing edges sutured back together, the sutures can cause some irritation to the eye. Bandage contact lenses are used with the idea that it will protect the cornea by providing a protective layer from the sutures (Fontana, 1978). A study conducted by Awan *et al.* suggests that soft contact lenses may be a beneficial choice in surgeries involving the upper eyelid (Awan, 2009). To truly see any benefits in patients, studying the effects of bandage contact lenses in patients with ptosis surgery is important. Patients who require ptosis surgery on both eyes will be part of the study and one eye will be randomized to receive the bandage contact lens and the other eye will not. Pain/discomfort and blurred vision will be compared between the 2 eyes and the results will help us determine if the use of bandage contact lenses is warranted in ptosis eye surgery. If the lens is found to be unneeded, this can provide significant healthcare cost savings and prevent unnecessary resource utilization. Moreover in terms of the patient experience, if the lens is unneeded, this can provide a more comfortable recovery period (no hassles with keeping the lens in place) and any unnecessary complications by having a lens on the eye (i.e. blurred vision, foreign body sensation, etc.). Bandage contact lenses have been demonstrated to have reduced discomfort; however, patients had a preference not to wear them during the later parts of their recovery time as they did not experience much in terms of blurred vision and discomfort (Ahmed et al, 2001). Moreover, in a study by Shimazi *et al.* with corneal transplantation, it was concluded that no significant benefits were observed through the use of bandage contact lenses in their patients (Shimazi et al, 2016). Based on the above, it is hypothesized that the bandage contact lenses will not have a major impact on the pain/discomfort that the patient experiences and likely will not need to be routinely used.

Methods

Participants: The study population will include patients who have bilateral ptosis (drooping eyelids) and will require surgery to correct this, patients in this study will have no other eye related pathologies. In general, patients are older than 50 years old and from any demographic.

Design and Procedure: In this randomized control trial, 30 patients requiring surgery (Fasanella Servat procedure) with bilateral ptosis will have one eye randomized to receive a bandage contact lens whereas the other eye will not after their surgery. Participants will have a random number assigned in order to anonymize data and protect patient identity. We will place a contact lens on both eyes and immediately take it off from one (this will be the sham lens eye). Randomization of the lens placement will be determined by a flip of a coin (heads – keep lens on right eye. Tails – keep lens on left eye). Investigator will randomly generate for each patient whether the contact lens will be kept on right or left eye, sham contact lens will be placed on other eye, placing it and immediately removing it. Therefore, the patient will not know which eye has a lens. Follow up will occur in one week after their surgery where the outcomes will be obtained through questionnaires. Upon 1 week follow up, the person administering the questionnaire is also blinded as they will not know which eye was randomized to have the lens placed. The primary outcome that will be obtained during the study is the patient's pain/discomfort. This will be obtained using the Eye Sensations Scale where the patient can select a box from None, Mild, Moderate, Severe, to Extreme. The secondary outcome that will be obtained is to determine if the patient has experienced blurry vision. This will be measured using one question from the Ocular Surface Disease Index (OSDI), with a scale from 0 (none of the time) to 4 (all of the time).

Statistics and Analysis

This randomized controlled trial will enroll consecutive patients and randomizing one eye to control treatment and the other eye to the experimental treatment. Assuming a mean pain score of 3.5 with standard deviation of 1.6 for control treatment, we need to enroll 30 patients and randomize one eye to control and one to experimental treatment to detect a mean difference of one score in pain with beta of 0.1 (90% power) and alpha of 0.05 (significance level of 0.05) if the null hypothesis of no difference in population means is true.

Baseline characteristics will be summarized as frequencies and relative frequencies for categorical data and mean and standard deviation for continuous data. Paired t-test will be used to compare the pain score between control and experimental eye and mean difference with 95% confidence interval will be reported as treatment effect. For categorical outcome measure, McNemar test will be used for comparison between control and experimental eye and proportions will be reported. A p-value of 0.05 will be set for statistical significance.

Ethics

Informed consent will be obtained from patients by the staff Ophthalmologists and the consent form will be signed by the patient. In terms of any risks to the patient, the intervention being studied is currently the standard of care for many clinicians. Thus, participants in this study are not being exposed to any additional risk at all as a result of this study. The only risks faced by participants are those risks inherent to the surgical procedure that they will consent to undergo and these risks are the same for the treatment and control group.

Timescale

This project is ready to begin as soon as possible and will be conducted for 6 months.

References:

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