Medication-Soaked Pledgets to Dilate Pupils for Cataract Surgery: How Fast Do They Work?

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ABSTRACT

Optimum conditions for cataract surgery require the pupil to be dilated to at least 6 mm. This objective has traditionally been achieved with medicated solutions instilled directly into the eye, but more recently, pledgets saturated with medication have been recommended. We studied 233 consecutive patients in our practice at the Lancaster General Health Campus Surgical Center to determine the optimum interval needed to achieve effective pupil mydriasis with the pledget technique.

A mydriatic formulation was prepared with gatifloxacin 0.3% (Zymar), cyclopentolate 1% (Cyclogyl), phenylephrine hydrochloride 2.5% (Mydfrin), and diclofenac 0.1% (Voltaren) eye solutions. Pledgets of Merocel® Polypore were soaked in the solution and then placed in each patient's operative eye for one of three specified intervals (dwell times): <45 min. (Group 1), 45-60 min. (Group 2), and >60 min. (Group 3). The pupil diameters were then measured.

There were no allergic reactions, ocular infections, corneal abrasions, or subjective patient complaints of discomfort associated with the use of pledget mydriasis. The median operative pupil size for all groups was 9 mm. There were no statistically significant differences in operative pupil size among the three Groups with different dwell times. A subgroup of Group 1 with 14 patients had a pledget dwell time < 30 minutes, and had a similar median operative pupil size, but the small sample size of this subgroup limits any statistical inference about the shorter dwell time.

Pledget mydriasis provides excellent pupillary dilation and improved patient comfort and convenience. The transition from multiple preoperative drops to the pledget technique maximized utilization of facilities and nursing staff, and positively impacted the efficiency of the Ambulatory Surgery Center.

INTRODUCTION

To facilitate uncomplicated cataract surgery, pupil size should equal or exceed 6 mm. Established methods of achieving optimum pupillary dilation involve administering intraocular medications in one of several traditional manners: as multiple timed topical drops, a topical viscous solution, or an intracameral epinephrine solution.

In 2000, Gills reported the use of pledgets soaked with medication for preoperative mydriasis,[1] and others have since confirmed the benefits of this technique.[2-5] In the present study, Gills' technique was modified to streamline preoperative administration of medications, by including antibiotic and anti-inflammatory medications in the solution used to soak the pledgets, as reported by Ong-Tone.[6]

Following Gills' initial report, we found that his technique provided excellent mydriasis without complications. Patients with a history of previous eye surgery with a different technique for mydriasis reported greater comfort with the pledget technique. The nursing staff and all 13 cataract surgeons at our center quickly adopted the use of pledgets, albeit with several individual formulations of the solution for soaking them.

It also became clear that various surgeons were leaving pledgets in place for different intervals ("dwell times"), usually on the basis of the time required to complete mydriasis with the earlier multiple drop technique. Moreover, no single dwell time or "soaking recipe" that assured maximum mydriasis was becoming prevalent. A review of the literature found only sparse data that could form the basis for either an optimum soaking solution or dwell time.[1-6]

To evaluate pledget dwell time as a single variable, we designed this prospective study to keep the other variable, the soaking solution, constant.

Figure 1:

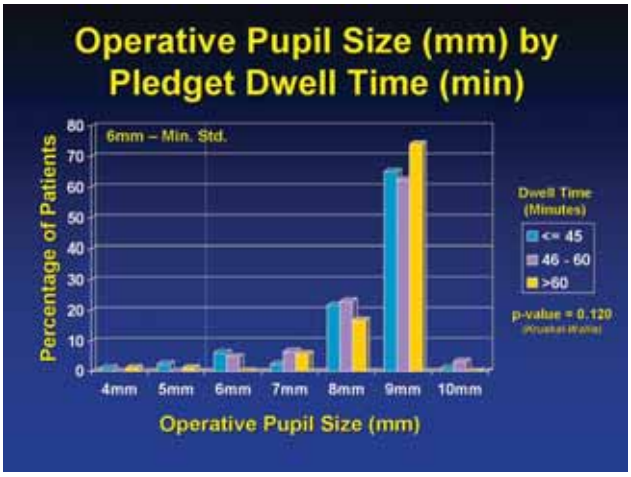
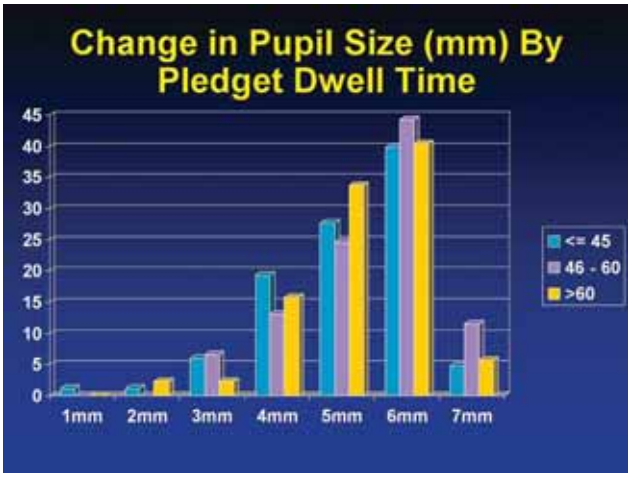


Figure 2:



PATIENTS AND METHODS

All patients had appropriate indications for cataract surgery, were fully informed of the study's details, and provided written informed consent for topical anesthesia, small incision clear corneal cataract extraction, and lens implantation. Pregnant women were excluded from the study, which was approved by the Lancaster General Hospital IRB.

PATIENT GROUPS

We assigned 233 consecutive cataract surgery patients from May to July 2006 to three groups with different pledget dwell times: <45 minutes (Gr. 1), 45-60 minutes (Gr. 2), and >60 minutes (Gr. 3). We estimated that 60 patients would be needed in each Group to determine with adequate statistical power if there was a difference in pupil dilation based on pledget dwell time. A description of the dwell time groups and patient characteristics is shown in Table 1.

SURGICAL TECHNIQUE

Merocel® Polypore sponges (Medtronic, Inc.) were cut into 3 × 5 mm pieces with sterile technique, placed in a sterile container, and dated. One nurse cut all sponges for the study, and they were discarded after 1 month.

A pledget soak solution was prepared daily with equal amounts of gatifloxacin 0.3% (Zymar), cyclopentolate 1% (Cyclogyl), phenylephrine HCL 2.5% (Mydfrin), and diclofenac 0.1% (Voltaren).

Twenty drops of each medication were mixed in a sterile cup, and precut sponges were then added. Each pledget absorbed 0.3 ml of the mixture. The preparing nurse

TABLE 1. CHARACTERISTICS OF PATIENTS BY PLEDGET DWELL TIME.

	Group 1 ≤45 min n(%)	Group 2 46-60 min n(%)	Group 3 >60 min n(%)	Total n(%)	P value*
Number	83	61	89	233	
Female	56 (67.5)	36 (59)	44 (49.4)	136 (58.4)	0.056
Male	27 (32.5)	25 (41)	45 (50.6)	97 (41.6)	
Right Eye	41 (49.4)	29 (47.5)	46 (51.7)	116 (49.8)	0.880
Left Eye	42 (50.6)	32 (52.5)	43 (48.3)	117 (50.2)	
Age (Mean Years)	73.4	72.8	73.4	73.2	0.936

*P value for differences between Groups in the designated parameter (Kruskal-Wallis test). There were no significant differences.

signed each pledget solution cup and noted on the label the time and date of preparation, and the contents. The mixtures were discarded 4 hours after preparation. Mydfrin was refrigerated, and opened bottles of all drops were discarded at the end of each week.

The pre-dilation baseline pupil size was measured and recorded. One drop of tetracaine 0.5 % was placed in the marked operative eye. After 5 minutes, another drop of tetracaine was inserted and the pledget was placed in the fornix of the eye with a sterile forceps. The pledget was removed after an interval determined by the study's randomization process, and another drop of tetracaine was placed in the eye. The pupil size was again measured and recorded.

Patients were randomly assigned to one of the three dwell time study groups as noted earlier. Due to common circumstances in a busy ambulatory surgical environment, there were significant deviations from assigned dwell times due to unexpected availability of operating facilities earlier or later than scheduled. When such a deviation occurred, it superseded the patient's randomized allocation to a Group, and the patient was reclassified to the appropriate Group based on actual rather than assigned dwell time, Primary analyses of the data were performed and reported on the basis of actual dwell time. We also performed intention-to-treat (ITT) analyses, with patients grouped according to their originally assigned group regardless of actual dwell time; and per-protocol (PP) analyses, which included only patients with actual dwell times that matched their intended randomization group.

RESULTS

Two hundred thirty three patients were randomized. The median, minimum and maximum operative pupil sizes were calculated for each Group at baseline and at operation, and the medians were compared using the Kruskal-Wallis test, a non-parametric, one-way analysis of variance among two or more groups. There were no statistically significant differences in median baseline or operative pupil sizes among the three Groups (Tables 1 and 2).

The median change in pupil size from baseline was 5 mm in Group 1 and Group 3, and 5.5 mm in Group 2, with a maximum change of 7 mm in all three Groups. There were no statistically significant differences between the Groups (Table 2).

In the ITT analyses, there were no statistically significant differences in the median operative pupil sizes. There was a statistically significant difference in median change in pupil size (Table 3). As noted above, this difference did not exist when analyzed by actual dwell time.

TABLE 2. ANALYSIS PER ACTUAL DWELL TIME GROUPING.

Actual dwell time	n	Median operative pupil size	Median change in pupil size
Group 1: ≤45 minutes	83	9	5
Group 2: 46-60 minutes	61	9	5.5
Group 3: >60 minutes	89	9	5
p-value (Kruskal-Wallis)		0.120	0.217
Total n = 233			

TABLE 3. INTENTION-TO-TREAT (ITT) ANALYSIS OF PATIENTS WITHIN THEIR RANDOMIZED GROUP REGARDLESS OF DWELL TIME.

Randomized group: targeted dwell time	n	Median operative pupil size	Median change in pupil size
Group 1: ≤45 minutes	83	9	5
Group 2: 46-60 minutes	70	8.5	5.5
Group 3: >60 minutes	78	9	5
p-value (Kruskal-Wallis)		0.467	0.010
Total n = 231: There were 2 patients where a random group number was missing.			

TABLE 4. PER-PROTOCOL ANALYSIS ONLY OF PATIENTS WITH ACTUAL DWELL TIMES THAT MATCHED THEIR RANDOMIZATION GROUP.

Randomized group: targeted dwell time	n	Median operative pupil size	Median change in pupil size
Group 1: ≤45 minutes	57	9	5
Group 2: 46-60 minutes	23	8.5	5.5
Group 3: >60 minutes	46	9	5
p-value (Kruskal-Wallis)		0.245	0.135
Total n = 126			

In the PP analyses, there were no statistically significant differences in the median operative pupil sizes or changes in pupil sizes (Table 4).

Five patients (2.1%) failed to achieve pupil dilation to 6 mm and underwent surgery nonetheless. This study did not have the statistical power to determine the significance of the small inter-group differences in this phenomenon. McCormick reported that 2 of 25 patients (8%) failed to reach 6 mm dilation. Ong-Tone observed 3.6% of trial patients had poorly dilated pupils, but did not discuss the criterion used to determine "adequate" dilation.[6]

The interval between mixing the solution and inserting the pledget (mix to insertion time), and the pledget removal to surgery time, were reviewed to determine if they had an effect on pupil dilation. The mix to insertion time was limited to 4 hours because of the policy of discarding the solution 4 hours after mixing. The median time from mix to insertion was 2 hours (120 minutes). There was no statistically significant difference in median operative pupil size if the mixture to insertion time was greater or less than 120 minutes.

The median time from pledget removal to surgery was 30 minutes. There were no statistically significant differences in the median operative pupil size for pledget removal to surgery time whether it was greater than or less than 30 minutes.

The study was designed to identify potential complications associated with pledget use; corneal opacity or abrasion, conjunctival irritation, ocular allergic reaction or infection. All corneas were graded as clear and there were no instances of irritation, allergy or infection.

A subgroup of patients with a pledget dwell time of 30 minutes or less occurred due to process factors in the Day Surgery area. Sub-group analysis demonstrated no statistically significant difference in median operative pupil size when compared to pledget times greater than 30 minutes.

DISCUSSION

With the medication solution we used, pledget mydriasis improved patient comfort and convenience, while providing excellent mydriasis that was reliable and safe. Because the pledget technique is faster and more consistent than traditional methods of mydriasis, it increases nursing efficiency in the surgery center and maximizes utilization of beds and nursing staff.

In addition to demonstrating that there are no differences in pupillary dilation between pledget dwell times of 30 to 60 minutes, this study also indicates that the minimum dwell time needed for optimum surgical mydriasis has not yet been determined.

The second phase of this project, review of pledget dwell times less than 30 minutes, is currently in progress.

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REFERENCES

1. Gills JP. Consultation Section. *Journal of Cataract and Refractive Surgery* 2000;26:955.

2. McCormick A, Srinivasan S, Harun S, Watts M. Pupil Dilation using a pledget sponge: a randomized controlled trial. *Clinical and Experimental Ophthalmology* 2006;34:545-549.

3. Dubois V, Wittles N, Lamont M, Madge S, Luck J. Randomized controlled single-blind study of conventional versus depot mydriatic drug delivery prior to cataract surgery. *BMC Ophthalmology* 2006;6:36.

4. Mouly S, Mahe I, Haouchine B, Sanson-le-Pors MJ, Blain P, Tillet Y, Dewailly J, Mongold JJ, Bergman JF. *Basic & Clinical Pharmacology & Toxicology* 2006;98(6):547-54.

5. Patel CK, Bui TA, Gregariou G, Pereira S, Chopdar A, McLeod BK. A pre-operative mydriatic regimen using a single application of tropicamide novel ophthalmic delivery system and guttae phenylephrine 10%. *Eye* 1995;9:337-340.

6. Ong-Tone L. Use of a wick to deliver preoperative mydriatics for cataract surgery. *J Cataract Refract Surg* 2003;29:2060-2062.

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