Pilot Trial of Loteprednol Etabonate Gel 0.5% at BID Dosing in Cataract Surgery Patients

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Introduction

- The new loteprednol etabonate ophthalmic gel 0.5% (Lotemax®) formulation confers benefits to the dose uniformity and pharmacokinetic profile which may enhance the efficacy to control inflammation
- The standard regimen at Brandon Eye Associates has been the use of loteprednol etabonate ophthalmic suspension 0.5% QID in conjunction with an NSAID in post cataract patients with excellent results

Introduction

- The objective for this study was to evaluate the efficacy of the loteprednol etabonate 0.5% gel formulation administered BID to control pain and inflammation in post cataract patients

Methods

Inclusion Criteria:

- Subjects with cataracts grade 1-3 and some PSC variety

Exclusion Criteria:

- Subjects were excluded from the trial if they could not afford the study medications
- Crystalens subjects were also excluded (Toric or Tecnis Multifocal subjects were not excluded).

Procedure:

- Standard cataract surgery 2.7mm incision
- Alcon Infinity machine

Methods

- Subjects were started on loteprednol etabonate gel 0.5% and besifloxacin ophthalmic suspension 0.6% (Besivance®) BID 2 days prior to surgery
  - Subjects were instructed to instill loteprednol etabonate gel first in the eye followed by Besivance
- Postop Day#1, subjects resumed administration of loteprednol etabonate gel and besifloxacin at BID dosing
- Subjects continued to instill besifloxacin for one week after surgery, and loteprednol etabonate gel for 4 weeks after surgery
- No NSAID was used in this study before or after surgery

Methods

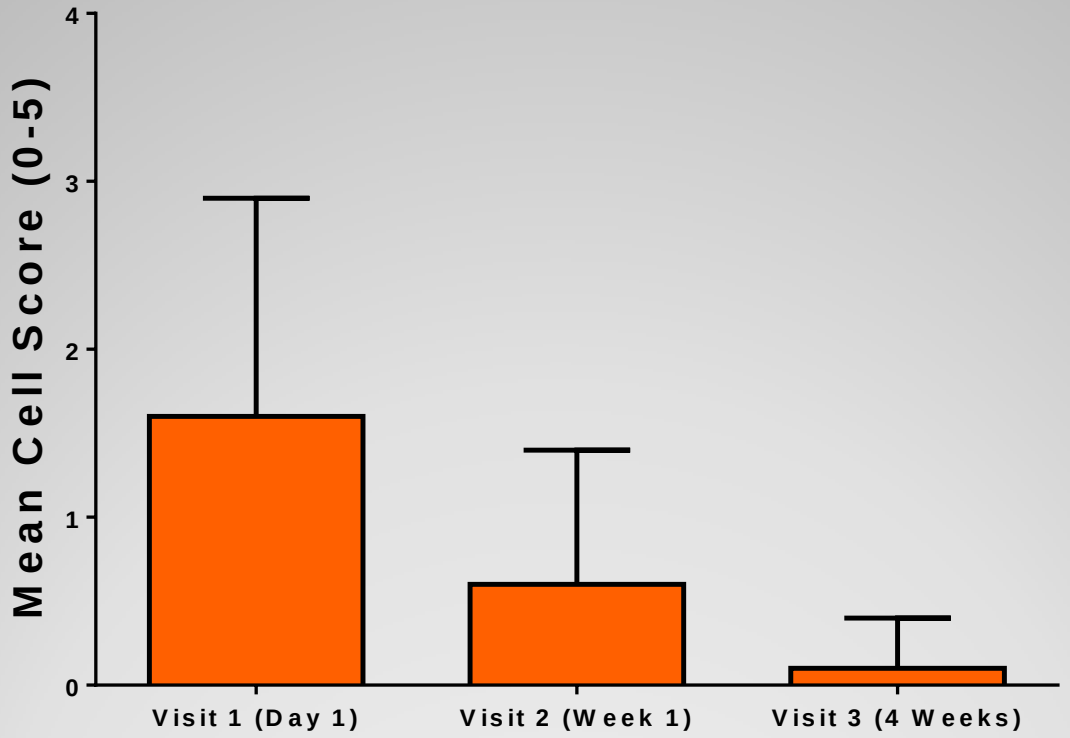
- Study endpoints were assessed at 3 visits after surgery: day 1, ~week 1 and after ~4 weeks. Control of anterior chamber inflammation
  - Cell Assessment Grading System
    - 0: No cells
    - 1: Rare (<5 cells per hpf)
    - 2: 5-10 cells per hpf (1+)
    - 3: 11-20 cells per hpf (2+)
    - 4: 21-30 cells per hpf (3+)
    - 5: >30 cells per hpf (4+)
- Pain/discomfort (as reported by patients)
- Safety: pressure rise and any other adverse events

Results

- Demographics:
  - 42 subjects enrolled (53 eyes evaluated)
    - 17 male (40%) / 25 female (60%)
    - Mean age (SD): 68.7 (10.8) years
    - Race/Ethnicity:
      - Caucasian – 29 (69%)
      - Asian – 5 (12%)
      - Hispanic – 4 (10%)
      - Black – 3 (7%)
      - Hawaiian – 1 (2%)

Results

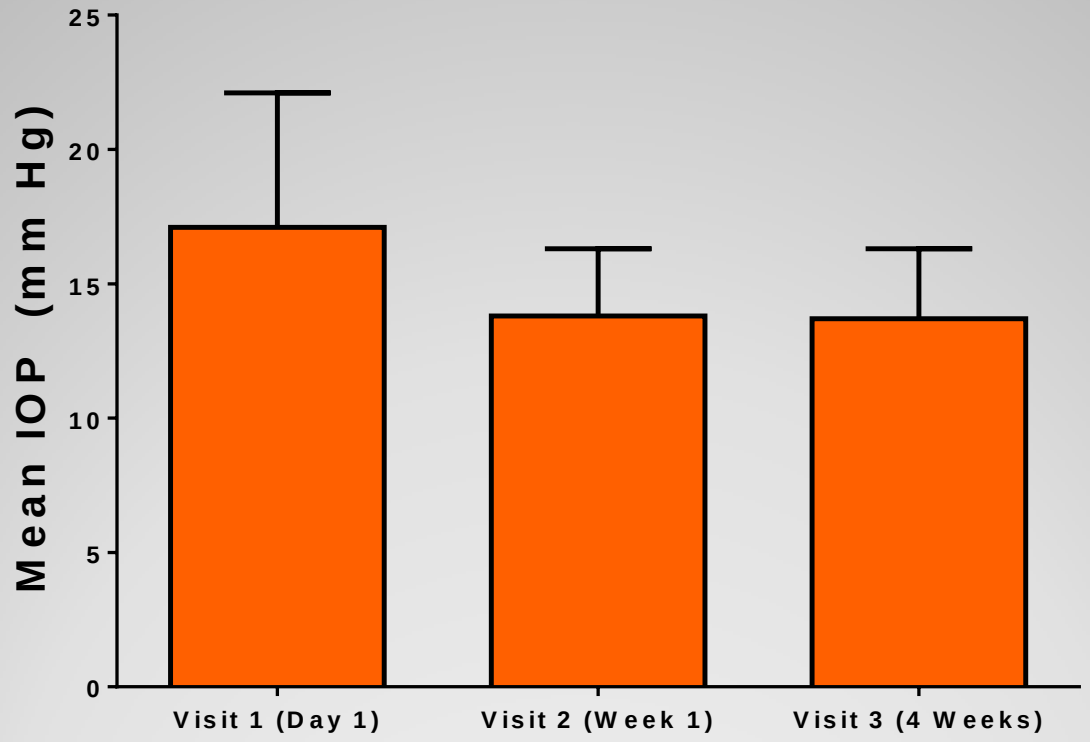
- Anterior Chamber Inflammation



  - Cell Score Range 0-5

Results

- Intraocular Pressure



  - IOP Range 8-35 mm Hg

Results

- Subjects reported loteprednol etabonate gel to be comfortable
- All subjects reported satisfaction with the BID dosing regimen
- No IOP rises were recorded

Results/Safety

- Pain/Discomfort
  - Visit 1: 3 instances (5.7%) of subject reported pain/discomfort
  - Visit 2: 5 instances (9.4%) of subject reported pain/discomfort
  - Visit 3: 4 instances (7.8%) of subject reported pain/discomfort
- 7 instances of pain/discomfort associated with subjects completion of the study

Conclusions

- The results of this pilot trial indicate that administration of loteprednol etabonate 0.5% gel BID for 2 days prior to surgery and BID for 4 weeks after surgery was effective for the control of pain and inflammation associated with cataract surgery

- The loteprednol etabonate 0.5% gel formulation was well-tolerated by subjects in this clinical investigation