A Clinical Trial:

Comparing the Effects of Pre Surgical Versus Post Surgical Treatment with Voltaren Ophthalmic Solution for the Control of Inflammation in Postoperative Cataract Patients

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In 1996, the FDA approved Voltaren Ophthalmic Solution (diclofenac sodium .1%), a topical nonsteroidal anti-inflammatory medication, for the treatment of postoperative inflammation in patients who had undergone cataract extraction. The availability of Voltaren Ophthalmic provided the first alternative to steroid medications for the reduction of ocular inflammation.

The approved dosage protocol for post cataract extraction is one drop of Voltaren Ophthalmic to the surgical eye four times a day for two weeks after surgery. Recently, Ciba Vision Ophthalmics, the manufacturer of Voltaren, has claimed that better control of inflammation is achieved by initiating treatment with the drug prior to surgery.

With the approval and cooperation of Ciba Vision Ophthalmics, I developed an on-site clinical trial which compared postoperative inflammation in patients treated with Voltaren four times a day for three days before surgery, versus patients who began treatment 24 hours after cataract surgery, per current FDA protocol. By direct comparison of the two groups, I determined if there was a clinically significant difference found in the post surgical inflammatory levels.

Background

To understand why postoperative inflammation should be reduced by using Voltaren Ophthalmic Solution (Voltaren), before versus after cataract surgery, several concepts must be understood. The following review of the arachidonic acid cycle, the inflammatory response facilitated by prostaglandins, and the mechanism of action of nonsteroidal anti-inflammatory medications, is intended to make the reasoning behind this study clear.

The initiating event in the development of inflammation after cataract surgery is the actual tissue injury suffered during surgery. Tissue damage causes the activation of the enzyme phospholipase A2, which breaks down cell membranes and causes the release of arachidonic acid. Free arachidonic acid is quickly converted to endoperoxide, which is then acted upon by cyclooxygenase or lipoxygenase.

Cyclooxgenase produces prostaglandins and thromboxanes from endoperoxide via the cyclooxygenase pathway. Prostaglandins (PGs) are biologically active lipids that have potent inflammatory actions throughout the body. Ocular reactions mediated by these agents vary depending on the specific type of prostaglandin and include disruption of the blood-brain barrier, vasodilation, chemosis, increased capillary permeability and pupillary miosis.[1] Thromboxanes produced by the cyclooxygenase pathway are potent platelet aggregators and vasoconstrictive agents. The specific ocular effects of thromboxanes are unknown but are currently being investigated.[2]

Lipoxygenase acts on endoperoxide to form leukotrienes via the lipoxygenase pathway of the arachidonic acid cycle. Current research suggests some intraocular inflammation is attributable to leukotrienes, including leukocyte infiltration to the anterior chamber and miosis generated without cholinergic stimulation [1]

All nonsteroidal anti-inflammatory medications influence the cyclooxygenase pathway to reduce or prevent the production of prostaglandins. Voltaren prevents the biosynthesis of new prostaglandins and thromboxanes by shifting the intermediates of the arachidonic acid pathway into the lipoxygenase pathway.[3]

In contrast, topical steroids block the entire arachidonic acid cycle by preventing the release of arachidonic acid from plasma membranes. While the efficacy of steroids for ocular inflammatory control is unquestionable, there are serious side effects which can occur with long term steroid use including reduced corneal healing time, reactivation of latent herpes infections, increased ocular pressure and cataract formation.[4]

In addition to inflammatory control, Voltaren offers many unique benefits to patients who have undergone cataract surgery, which are not offered by other medications. Most importantly, Voltaren has a higher safety profile than topical steroids. Transient stinging upon instillation is the only reported adverse reaction, while contraindications include known allergies to ingredients of the medication and concurrent soft contact lens wear.

Finally, patients with bleeding tendencies should use Voltaren or other NSAIDs with caution.[5]

Secondly, Voltaren has been proven to decrease the incidence and severity of cystoid macular edema (CME) after cataract surgery. CME is a swelling of the macular region that causes a decrease in visual acuity. It is a late stage complication of cataract surgery, with the highest incidence at six to eight weeks status post surgery. There are many hypotheses as to the cause of the macular swelling, however nothing has been proven conclusively at this time.[6]

Thirdly, Voltaren is effective in preventing intrasurgical miosis, which can be a serious surgical complication. It is not well understood what causes the miosis, but prostaglandins are one of several suspected mediators of the response. Voltaren has been proven as effective for the prevention of intrasurgical miosis as some of the early topical NSAIDs, such as flurbiprofen, which are currently used.[6]

Fourth, Voltaren prevents the post surgical pain caused by ocular tissue injury. The tissue damage caused from surgery stimulates the production of prostaglandins, that decrease the threshold of pain fibers causing increased nerve excitability. By preventing the production of prostaglandin, Voltaren maintains the normal threshold of pain neurons and prevents increased firing. This mechanism of action differs from analgesic medications that act directly on the brain to decrease the perception, but not the production of pain.[6]

Finally, intraocular pressure is benefited in two ways by using Voltaren. First, there is no intrinsic risk of increased IOP associated with Voltaren, as there is with topical steroids. Secondly, new research indicates that contrary to the expected rise in IOP that is commonly found after cataract extraction, an actual reduction of IOP may occur beginning six hours after surgery and continuing for one week. It is not suggested that Voltaren has a direct IOP lowering effect, simply that it prevents a pressure spike from occurring after cataract surgery.[7]

Considering the proven benefits of Voltaren Ophthalmic, why is it not the drug of choice for post cataract patients? Because, despite repeated clinical trials to the contrary, some ophthalmologists believe that a nonsteroidal anti-inflammatory can not control inflammation as well as a topical steroid medication.

To encourage more surgeons to include Voltaren in the treatment of their cataract patients, Ciba Vision Ophthalmic claims that improved inflammatory control can be gained by changing the recommended dose of the medication. Instead of initiating treatment 24 hours after surgery, per FDA guidelines, Ciba Vision Ophthamics suggests starting QID treatment three days before surgery.

The new treatment seems logical given that Voltaren can halt the production of prostaglandin via the cyclooxygenase pathway, but it cannot inactivate any prostaglandin that was already produced. By starting treatment before any tissue injury occurs, all of the activated prostaglandin will have been metabolized, leaving no mediators of the cyclooxygenase cycle to cause an inflammatory reaction.

By comparing the inflammatory levels in patients who started treatment three days before surgery to patients who stared treatment 24 hours after surgery, I will determine if a clinically significant advantage is achieved from either dosage regiment

Method

In a masked, randomized study, the one day and two week postoperative examinations of 107 patients who underwent phacoemulsive, extra capsular cataract extraction with foldable, silicone, posterior chamber IOL insertion through a small (2.7-3.5 mm), sutureless, corneal incision were observed. Approximately half of the sample (N=51) received instructions to begin applying one drop of Voltaren to the surgical eye four times a day for three days immediately preceding surgery. The rest of the sample (N= 56) began instilling equal dosage of Voltaren to the surgical eye, 24 hours after surgery. Ocuflox (.3% ofloxacin) was used in combination with Voltaren to provide antibiotic protection and both medications were continued for two weeks following surgery.

Without providing exhaustive statistical data, it was determined by Ciba Vision Ophthalmics that our sample size was large enough to demonstrate a difference in results of the primary variable, to an accuracy of 84%. Their calculations suggested that a total sample size of 80, with 40 patients in each group, would be adequate to demonstrate a statistical difference in inflammatory control between the two sample groups. We were well within this range, having an experimental group with 51 patients, and a control group of 56 patients.

The following twelve observations were recorded at the one day and two week post-op visits: visual acuity (uncorrected and pinhole), intraocular pressure, conjunctival injection, ciliary flush, anterior chamber cell, anterior chamber flare, corneal edema, capsule clarity (including haze or lens precipitates), incision closure, IOL position and patient comfort.

All slit lamp observations were completed by the ophthalmologist who performed the surgical procedures. Precautions were taken to ensure that observation bias did not contaminate the data, including a well-defined observation technique using specific illumination levels, magnification settings, and a detailed grading scale for each category. The observer did not know which sample group a patient belonged to, and the medical record was not marked to indicate which drug protocol a patient was following. At the first and second postoperative visit, patients were questioned by ophthalmic technicians about drug compliance before the ophthalmologist entered the examination room.

Protocol for Data Collection

Visual Acuity:

Obtained by trained ophthalmic technicians, measured first without correction then through a pinhole aperture, using Snellen charts or finger counting as needed.

Intraocular Pressure:

Measured by trained ophthalmic technicians using Goldmann applanation or Tonopen as needed.

Slit Lamp Observations:

All observations made with the following settings on Zeiss slit lamps.

1) Highest Illumination
2) Slit aperture at .3-.5 mm
3) 16X magnification
4) Dim room illumination

Classification of Inflammation

Anterior Chamber Cell:

0=Absent
1=1 to 5 cells
2=6 to 15 cells
3= 16 to 30 cells
4= > 30 cells

Anterior Chamber Flare:

0= Absent
1= Trace
2= Mild Intensity
3= Moderate Intensity
4= Strong Intensity

Conjunctival injection, ciliary flush, corneal edema, and capsular clarity were all graded on a 0-4 scale, with 0 indicating no response and 4 indicating severe response, as determined by the observer. The corneal incision was either secure or not (0 or 1), and the IOL was either in or out of position (0 or 1).

Results

Of the 51 original patients in the experimental group (designated Group A), 49 completed the study, and of the original 56 patients in the control group (designated Group B), 54 completed the study. Reasons for withdrawal include: one patient lost to follow-up, one patient that discontinued medications prematurely, and two patients that had complications during surgery which required surgical procedures outside the specific parameters of the study. The following data was obtained from the one-day and two-week postoperative visits of the study participants, for a total of 206 examinations.

Visual Acuity

Uncorrected Visual Acuity One Day Post-Op				
	Group A		Group B	
20/20	0	0	2	4%
20/25	0	0	0	0
20/30	2	4%	2	4%
20/40	5	10%	7	13%
20/50	6	12%	7	13%
20/60	4	8%	3	6%
20/70	3	6%	3	6%
20/80	4	8%	5	9%
20/100	2	4%	2	4%
20/200	10	20%	10	18%
20/300	5	10%	2	4%
20/400	3	6%	4	7%
CF	5	10%	7	13%

Pinhole Visual Acuity One Day Post-Op				
	Group A		Group B	
20/20	1	2%	2	4%
20/25	3	6%	7	3%
20/30	7	14%	4	7%
20/40	8	16%	11	20%
20/50	7	14%	12	22%
20/60	4	8%	2	4%
20/70	4	8%	3	6%
20/80	4	8%	4	7%
20/100	3	6%	2	4%
20/200	3	6%	3	6%
20/300	0	0	0	0
20/400	2	4%	1	2%
CF	3	6%	3	6%

Uncorrected Visual Acuity Two Weeks Post-Op				
	Group A		Group B	
20/25	1	2%	6	11%
20/25	4	8%	9	17%
20/30	3	6%	8	15%
20/40	12	25%	8	15%
20/50	9	18%	5	9%
20/60	4	8%	2	4%
20/70	3	6%	2	4%
20/80	1	2%	2	4%
20/100	2	4%	1	2%
20/200	5	10%	9	17%
20/300	3	6%	1	2%
20/400	1	2%	1	2%
CF	0	0	0	0

Pinhole Visual Acuity Two Weeks Post-Op				
	Group A		Group B	
20/20	10	20%	20	37%
20/25	13	27%	12	22%
20/30	11	22%	9	17%
20/40	10	20%	3	6%
20/50	1	2%	4	7%
20/60	0	0	1	2%
20/70	1	2%	0	0
20/80	0	0	1	2%
20/100	0	0	0	0
20/200	2	4%	3	6%
20/300	0	0	0	0
20/400	1	2%	1	2%
CF	0	0	0	0

* Percentages may not equal 100 due to the rounding of results.

Comparing pinhole visual acuity results at the first postoperative exam, 39% of patients in Group A and 44% of patients in Group B had acuity of 20/40 or better, while 16% of Group A and 13% of Group B had 20/200 or worse. At the second visit, 90% of Group A and 82% of Group B had 20/40 or better, while 6% of Group A and 7% of Group B still had 20/200 or worse distance acuity.

Conjunctival Injection

Conjunctival Injection One Day Post-Op				
	Group A		Group B	
+0	45	92%	49	91%
+1	4	8%	3	6%
+2	0	0	2	3%
+3	0	0	0	0
+4	0	0	0	0

Conjunctival Injection Two Weeks Post-Op				
	Group A		Group B	
+0	49	100%	53	98%
+1	0	0	1	2%
+2	0	0	0	0
+3	0	0	0	0
+4	0	0	0	0

Conjunctival injection occurred in only a small number of the patients in either group. In Group A, 8% had 1+ conjunctival injection, while Group B had 6% with 1+ and 3% with 2+ results. At the second visit, no patients in group A had residual inflammation, while 2% of patients in the control group still showed a mild (1+) conjunctival injection.

Anterior Chamber Inflammation

Anterior Chamber Cell One Day Post-Op				
	Group A		Group B	
+0	40	82%	52	96%
+1	7	14%	2	4%
+2	2	4%	0	0
+3	0	0	0	0
+4	0	0	0	0

Anterior Chamber Cell Two Weeks Post-Op				
	Group A		Group B	
+0	45	92%	51	94%
+1	2	4%	3	6%
+2	0	0	0	0
+3	0	0	0	0
+4	0	0	0	0

Anterior Chamber Flare One Day Post-Op				
	Group A		Group B	
+0	40	82%	49	90%
+1	7	14%	3	6%
+2	2	4%	2	4%
+3	0	0	0	0
+4	0	0	0	0

Anterior Chamber Flare Two Weeks Post-Op				
	Group A		Group B	
+0	47	96%	51	94%
+1	2	4%	3	6%
+2	0	0	0	0
+3	0	0	0	0
+4	0	0	0	0

In Group A, the one-day findings for anterior chamber cell showed 14% of participants with a grade 1 response (1-5 cells), and 4% with a Grade 2 response (6-15 cells). The one-day findings for Group B had 4% with a Grade 1 response and no patients with Grade 2 or greater response. Two weeks later the amount of inflammation was more comparable between the two groups with 4% of Group A, and 6% of Group B still having Grade 1 inflammation.

Similar results occurred with anterior chamber flare. At the first exam, Group A had 14% of patients with Grade 1 and 4% with Grade 2 flare levels. At the same visit, Group B had 6% of patients with Grade 1 and 4% with Grade 2 flare levels. At the second visit, Group A had 4% of participants with Grade 1 response and Group B had 6% with the same level.

Corneal Edema

Corneal Edema One Day Post-Op				
	Group A		Group B	
Present	15	31%	16	30%
Absent	34	69%	38	70%

Corneal Edema Two Weeks Post-Op				
	Group A		Group B	
Present	1	2%	4	7%
Absent	48	98%	50	93%

Corneal edema was present in equal amounts between the two samples at the one-day visit with 31% of Group A and 31% of Group B having edema present. At the two week visit only 2% of Group A and 7% of Group B had corneal edema.

Intraocular Pressure

Intraocular Pressure One Day Post-Op				
MmHg	Group A		Group B	
<15	10	20%	9	17%
16-25	25	51%	33	61%
26-35	8	15%	9	17%
36+	6	12%	3	6%

Intraocular Pressure Two Weeks Post-Op				
MmHg	Group A		Group B	
<15	21	43%	24	44%
16-25	25	51%	28	52%
26-35	3	6%	2	4%
36+	0	0	0	0

To make useful comparisons of postoperative intraocular pressure, I divided the results into the following subgroups: lower than average pressure (<9 mmHg), normal pressure (10-21 mmHg), slightly to moderately above average pressure (23-30 mmHg), and elevated pressures requiring medication (>30 mmHg).

The only significant difference in findings occurred at the one-day visit, when 12% of Group A and 6% or Group B had high pressures requiring medications. All other results were nearly equal between Group A and B at both visits.

Patient Comfort

Patient comfort was completely subjective and rated on the following scale:

0=not at all uncomfortable
1= mildly uncomfortable
2=moderately uncomfortable
3=extremely uncomfortable

At the first visit Group A had one patient with a high IOP (58 mmHg), who rated discomfort a 2+. At the second visit, four patients ranked their discomfort at 2+, with "pickiness" and foreign body sensation described. Group B had no patients that complained of discomfort at either the one-day or two-week visit.

Conclusions

Only two of the recorded variables, anterior chamber cell and anterior chamber flare are pure indications of inflammation. At the two-week visit, the patients treated with Voltaren prior to surgery showed slightly less anterior cell and flare. The same group also had slightly better pinhole acuity results, less corneal edema and less conjunctival injection at the two week visit then Group B. Why there was an improvement in Group A in the results of these other variables is a mystery, since nothing but inflammatory reactions should have been altered by different dosages of Voltaren.

For instance, corneal edema is not cause by an inflammatory mechanism. Instead, it is the result of damage to the corneal endothelium by instruments, intraocular lens implantation or excessive bending of the cornea during surgery.[8] Since the same surgeon performed all of the cataract procedures using the same skill and technique on each patient, the occurrence of corneal edema should have been nearly equal between groups at the two week visit. Instead, Group B had almost three times more patients with corneal edema.

Without knowing the entering visual acuity of the study participants it is difficult to draw any conclusions from the results. While Group A did have a significantly higher percentage of patients with acuity of 20/40 or better, it is easy to assume that the difference is due to the presurgical administration of Voltaren. However, it would be presumptuous to make that claim without knowing if patients in Group B had poorer presurgical acuity. In the age group requiring cataract extraction there is a high prevalence of factors that would reduce final acuity, such as age related macular degeneration, diabetic retinopathy, and corneal irregularity. Conversely, it is also hasty to say that the higher final acuity in Group A was not attributable to Voltaren. For instance, perhaps there was subclinical CME present in Group B that was prevented in Group A, yielding a better final acuity result.

As expected, there was no significant difference between the IOP levels of the two groups at either visit. However, between the first and second postoperative visits, there was a significant, uniform reduction of the IOP in both groups. This corroborates the pressure lowering effect found in the German study sited early.

By far the most unexpected result of this study was the large discrepancy in the anterior chamber cell and flare levels observed at the one-day postoperative visit. As I explained in the discussion section, the prostaglandin level should have been extremely low in Group A by the time surgical trauma was induced, causing the immediate inflammatory response to be reduced. In Group B, the immediate inflammatory response should have been unaffected, resulting in higher anterior chamber cell and flare levels. Contrary to my prediction, the patients in Group A had four times more cell, and two times more flare present in the anterior chamber than patients in Group B.

What could explain this surprising result? Recall that Voltaren decreases prostaglandin production by shifting the intermediates of the cyclooxygenase pathway into the lipoxygenase pathway. Not only is the production of prostaglandins and thromboxanes reduced, but also the production of leukotrienes is greatly increased.. It seems plausible that the inflammatory spike seen at the one-day post-op visit was due to the build-up of leukotrienes generated by the presurgical instillation of Voltaren. Although the role that leukotrienes play in ocular inflammation has not been clearly identified the following reference suggests that they may have caused the increase in inflammation:

"Leukotrienes and other lipoxygenase products of the arachidonic acid metabolism represent an important group of agents that are intimately involved with many complex manifestations of inflammation and other diverse physiologic actions...Studies show leukotriene B4 (LTB4) promoted leukocyte infiltration...We have yet to scratch the surface of the multiple roles of the different leukotrienes and how they interact with their cousins, the prostaglandins...New experimental lipoxygenase inhibitors appear to be effective in reducing intraocular inflammation."9

In conclusion, two weeks after phacoemulsive extra capsular cataract extraction with foldable, silicone, posterior chamber IOL implantation through a clear corneal suture, the anterior chamber cell and flare levels in patients who started treatment with Voltaren before surgery were lower then in patients who started treatment after surgery. This direct reduction in inflammation validates the hypothesis of this study. Additionally, the percentage of patients with 20/40 or better pinhole visual acuity was higher in this group, and the occurrence and severity of conjunctival injection and corneal edema was lower.

While all of these results are not direct measures of inflammation, a trend can be demonstrated for better surgical outcome when Voltaren Ophthalmic Solution is used three days before surgery. These results may suggest that even if no reduction in inflammation is observed, there may be a faster healing time in patients who use Voltaren before surgery, although more research would be necessary to make a final decision.

This study raised some interesting questions. Namely, what role do leukotrienes play in the inflammatory response, and would a medication targeted for the reduction of leukotrienes enhance current non steroidal anti-inflammatory medications? Secondly, is there an enhanced healing time caused by pre surgical treatment with Voltaren, which could account for the better two week results in areas that should not be effected by an anti-inflammatory medication (visual acuity, corneal edema, conjunctival injection)?

Obviously, the results of my study would have to be repeated before any definite conclusions can be made. If I performed this study again, I would make several changes in the design to allow for more conclusive results. First, I would want at least two impartial observers, or optimally, a laser flaremeter to measure anterior chamber inflammation objectively. Secondly, I would like results of presurgical potential acuity measurements so that final visual acuity results would have some comparative worth. Lastly, I would like to re-examine all patients at eight to ten weeks post surgery to monitor for the presence of cystoid macular edema and determine if Voltaren decreases the occurrence.

References

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Adjunct Forms
Designed by the Author

Patient Consent for Voltaren Study

After any type of surgery, the body produces an inflammatory response due to disruption of the normal body chemistry in the surgical area. In order to control this natural response, anti-inflammatory medications are used in combination with antibiotics to control inflammation, increase patient comfort and speed the healing process.

At Garrett Eye Center we use a nonsteroidal anti-inflammatory (NSAID) eye drop called Voltaren. At this time we are performing a study to decide which dosage of this medication is best at controlling inflammation. Half of the participants will start taking the drop three days before surgery and the other half will start using the drop the day of surgery. The results of your routine post operative exams will allow us to determine whether there is any benefit to a particular dosing regiment.

Currently, Voltaren is approved for use following immediately after surgery. However, there are no restrictions preventing the use before surgery. Voltaren has been proven to be a very safe drug and no serious side effects have been found. Since the drug is in the same class as aspirin, the only patients who may not want to participate in the study are those who have known bleeding tendencies or those receiving other medications that prolong bleeding time.

This is a masked study, which means Dr. Garrett does not know which dosage you received, in order that his observations at the post-surgical exams are not biased. If you have any questions regarding the medications, please ask one of the surgical nurses or technicians who will speak to Dr. Garrett in a way that does not compromise the masking of the study.

Remember, both methods are very safe. Garrett Eye Center is running this study to find the most effective way to treat our patients. We are receiving no payment nor will we profit from this study in any way.

ARRIVE AT _____ ON _____

PRE OP INSRUCTIONS

NOTHING TO EAT OR DRINK

AFTER:_____

1. OCUFLOX: (tan cap-yellow label). One drop in BOTH eyes the night before surgery and again the morning of your surgery.

2.CYCLOMYDRIL: (red cap). One drop in the eye to be operated on 30 minutes before leaving home; 15 minutes before leaving home; and again as leaving home on the day of surgery.

3.VOLTAREN: (gray cap-gray label). Starting three days before surgery, put one drop in the eye, four times a day.

BRING ALL DROPS AND ALL MEDICATIONS WITH YOU ON THE DAY OF SURGERY!

Group A Presurgical Dosage		Group B Same Day Dosage	
Patient #	Surgical Date	Patient #	Surgical Date

Post -Op Examination Form

Date of Surgery:_____ Patient ID:_____ OD/OS

	Date _____ S/P 1	Date _____ S/P 2
Visual Acuity	sRx	
Manifest Refraction (S/P 2 only)	PH	
Applination Tonometry **(ou)**		
Assessment of Inflammation:		
Conjunctival Injection (0-4) 0=none		
Ciliary Flush (0-4) 0=none		
Anterior Chamber Cells (0-4) 0=none		
Anterior Chamber Flare (0-4) 0=none		
Lens Precipitates (0-4) 0=none		
Corneal Edema 0=absent 1=present		
Incision Closure 0=absent 1=secure		
IOL position 0=in position 1=other		
Posterior Capsule 0=intact 1=other		
Discomfort Evaluation:		
0=not uncomfortable		
1=mildly uncomfortable		
2=moderately uncomfortable		
3=extremely uncomfortable		