

Evaluation of clinical response to treatment with FDA-cleared Avenova (i-Lid Cleanser) in patients with blepharitis in an optometric practice¹.

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Poster: A0074

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Introduction

- Blepharitis: A common eyelid disease with a chronic inflammatory condition, difficult to treat due to patient's non-compliance and lack of proper therapeutic treatment options. Blepharitis is one of the most common eye disease seen by Ophthalmologists and Optometrists, nearly 37% to 47% of patients has evidence of blepharitis¹.
- There is no consensus on treatment or current FDA approved drug products specific for blepharitis. As a results lots of traditional therapies are used to unsuccessfully treat this condition.
- A review of recent clinical trials has summarized the use of topical antibiotics, oral antibiotics and topical corticosteroids to treat blepharitis². However, in chronic disease such as blepharitis long-term use of such treatment options increases the risk of bacterial resistance and steroid related secondary issues.
- Therefore, a mild form of treatment, which is both effective and easy to use with high patient compliance and low side effects is highly desirable.
- Authors explored if Avenova™ can be effective in treating various stages of blepharitis.

Purpose

- The purpose of this study was to evaluate the efficacy, patient's compliance and tolerability of FDA cleared Avenova™ (i-Lid Cleanser, NovaBay Pharmaceuticals Inc., Emeryville, CA.) in patients with mild to moderate blepharitis.

Materials & Methods

- Patients with signs and symptoms of mild to moderate blepharitis were treated with FDA cleared Avenova™ (i-Lid Cleanser).
- A total of 18 patients with mild to moderate blepharitis were treated with Avenova™ twice daily for two weeks according to manufacturer's guidelines.
- Efficacy of treatment was evaluated based on slit lamp biomicroscopic examination and assessment of clinical signs and symptoms. These observations were compared pre-Avenova™ treatment (day 0) and post- Avenova™ treatment at 2 weeks (day 14±1).
- Signs and symptoms: following signs and symptoms were used to diagnose severity of blepharitis and to closely monitor efficacy of the treatment.
 - Eyelid redness; eyelid debris; eyelid swelling; eyelash collarettes; eyelid irritation.
- A scale of 0 to 3 was used to identify the severity and monitor the progression of blepharitis. 0-absent, 1-mild, 2-moderate, 3-severe.
- Patients with a total score of ≤8 were categorized as mild blepharitis group (G1)
- Patients with a total score of >8 and <12 were categorized as moderate blepharitis group (G2), patients with scores higher than 12 were not included in this study.
- Patient compliance, tolerability and ease of use was assessed based on patient's feedback.

Materials & Methods

- Avenova™ contains a novel pure 0.01% hypochlorous acid in a 0.9% saline solution at pH 4 (Neutrox™) (Fig 1)
- Directions for use (package insert): Apply Avenova™ as an eyelid skin cleanser starting 1 week prior to intraocular surgery. Also use Avenova™ to clean lids and lashes to remove debris from lid margin.
 - Remove any make up around your eyes.
 - Apply 2-3 spray of Avenova™ to a 100% sterile cotton round or oval swab.
 - Close your eyes.
 - Using a horizontal (Hz) motion, gently wipe the base of all the upper lid lashes at least three times.
 - With eyes open, look up and wipe the base of the lower lashes with a Hz motion at least three times.
 - Gently clean the entire lower lid from nose to the side of face.
 - With a new cotton swab, repeat on the other eye.
 - Repeat twice daily or as needed/recommended.



Figure 1. Avenova™ (i-Lid Cleanser) Rx Only

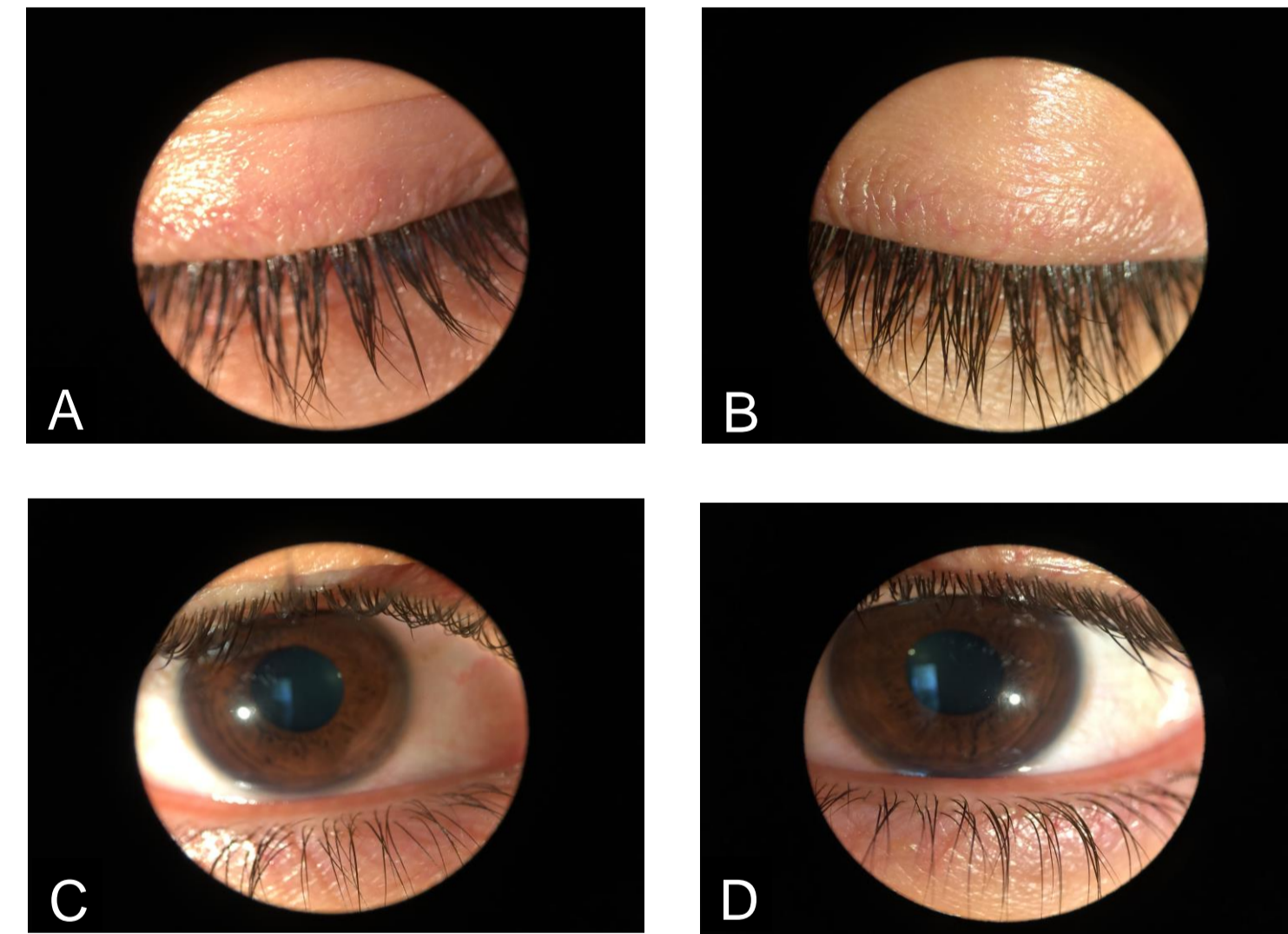


Figure 2. A, B. Mild blepharitis pre-Avenova™ treatment (day 0). C, D. Mild blepharitis post-Avenova™ treatment (day 14±1)

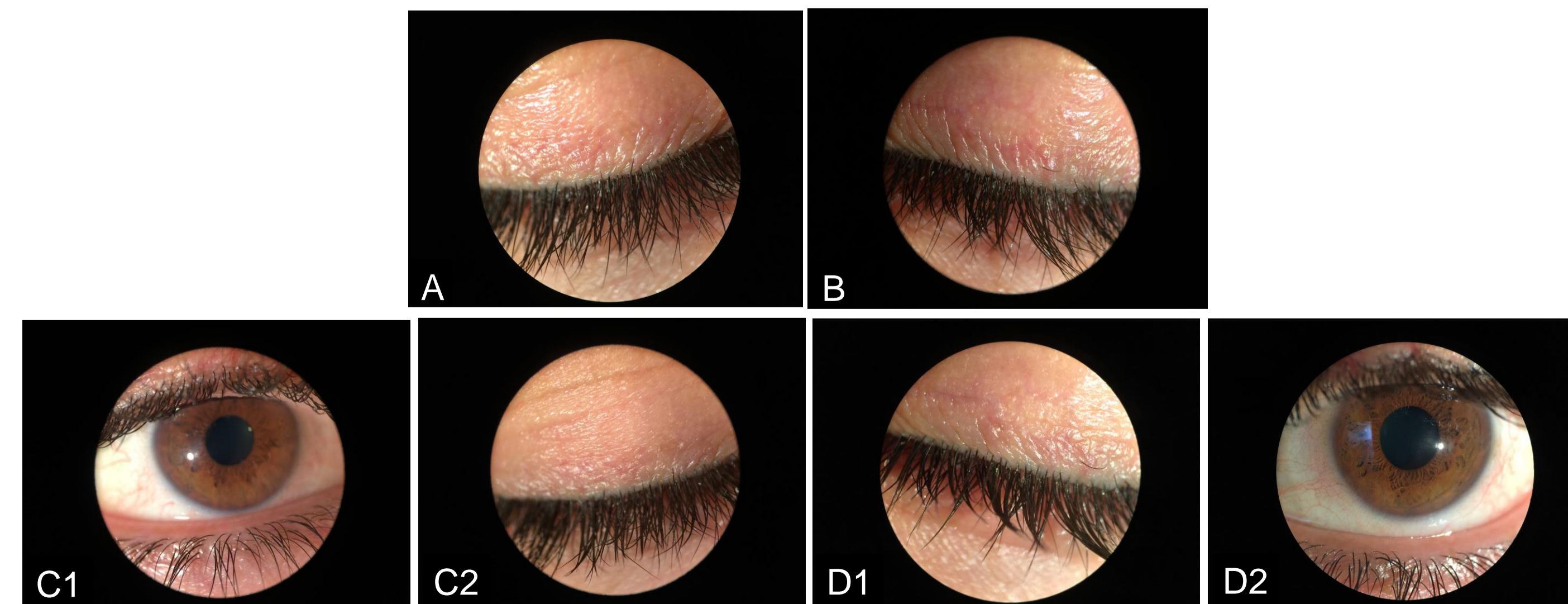


Figure 3. A, B. Moderate blepharitis pre-Avenova™ treatment (day 0) C1,C2, D1,D2. Moderate blepharitis post-Avenova™ treatment (day 14±1).

Results

- Score improvement:** 100% of patients with mild blepharitis (n=10) improved score by at least one point in all categories. However, in group with moderate blepharitis (n=8) there was inconsistent score improvements from one point to no point in some categories.
- Signs:** Avenova™ treatment showed significant improvement in signs of blepharitis in mild blepharitis group and comparatively less improvement in moderate blepharitis group in two weeks.
- Symptoms:** Avenova™ treatment showed improvement and resolution of symptoms of blepharitis in both mild and moderate blepharitis group.
- Compliance:** Patient with mild blepharitis reported high compliance rate of over 95%; moderate blepharitis compliance rate was comparatively lower at about 80%.
- Ease of use:** both groups (mild and moderate blepharitis) reported 100% ease of use, post-application comfort and relief of symptoms with the use of Avenova™.

Group 1: Mild Blepharitis

Symptoms/ Patient ID	Eyelid Redness		Eyelid Debris		Eyelid Swelling		Eyelash Collarettes		Eyelid Irritation		Total Score (Max 15)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
G1001	1	0	1	0	0	0	1	0	1	0	4	0
G1002	1	0	2	0	1	0	2	1	2	0	8	1
G1003	0	0	1	0	0	0	1	0	1	0	3	0
G1004	1	0	1	0	1	0	2	1	1	0	6	1
G1005	1	0	2	0	0	0	2	0	2	1	7	1
G1006	1	0	2	1	0	0	2	1	1	0	6	2
G1007	1	0	1	0	1	0	1	0	1	0	4	0
G1008	1	0	1	0	1	0	2	0	1	0	6	0
G1009	2	0	1	0	1	0	2	1	2	0	8	1
G1010	2	1	1	0	0	0	2	0	2	1	7	2

Group 2: Moderate Blepharitis

Symptoms/ Patient ID	Eyelid Redness		Eyelid Debris		Eyelid Swelling		Eyelash Collarettes		Eyelid Irritation		Total Score (Max 15)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
G2001	2	1	2	1	1	0	2	1	2	1	9	4
G2002	2	1	3	3	1	1	2	2	2	1	10	8
G2003	2	1	2	2	2	1	3	2	2	1	11	7
G2004	2	1	3	2	2	1	3	2	2	2	12	8
G2005	2	2	2	1	2	2	3	2	2	2	11	9
G2006	2	1	3	2	1	1	2	1	1	1	9	6
G2007	2	1	3	2	1	1	3	2	2	1	11	7
G2008	2	2	3	2	2	1	3	2	2	2	12	9

Conclusions

- Authors believe results are very encouraging in group of patients with mild blepharitis.
- Avenova™ treatment showed significant improvement in sign and symptoms of mild blepharitis.
- However, patients with moderate blepharitis needed long-term treatment (4-5 weeks) to achieve similar effect.
- Patient compliance was high (>95%) in mild blepharitis group, however in moderate blepharitis group patient compliance was comparatively lower (80%) and may in part explain the need for extended treatment or combination therapy.
- Studies are underway to increase study subjects in each group, especially in group with moderate blepharitis to determine the efficacy and duration of treatment to effectively treat moderate blepharitis.
- Severe blepharitis group will also be included in the study for comparison.

Disclosures

- G. Sharma: Optometrist, Family Eye Care Optometry; Assistant Professor, College of Optometry, Western University of Health Sciences.
- M. Sharma: Assistant Professor, College of Optometry, Western University of Health Sciences.
- Authors would like to thank NovaBay Pharmaceuticals Inc. for generously providing samples of Avenova™ for this study.

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