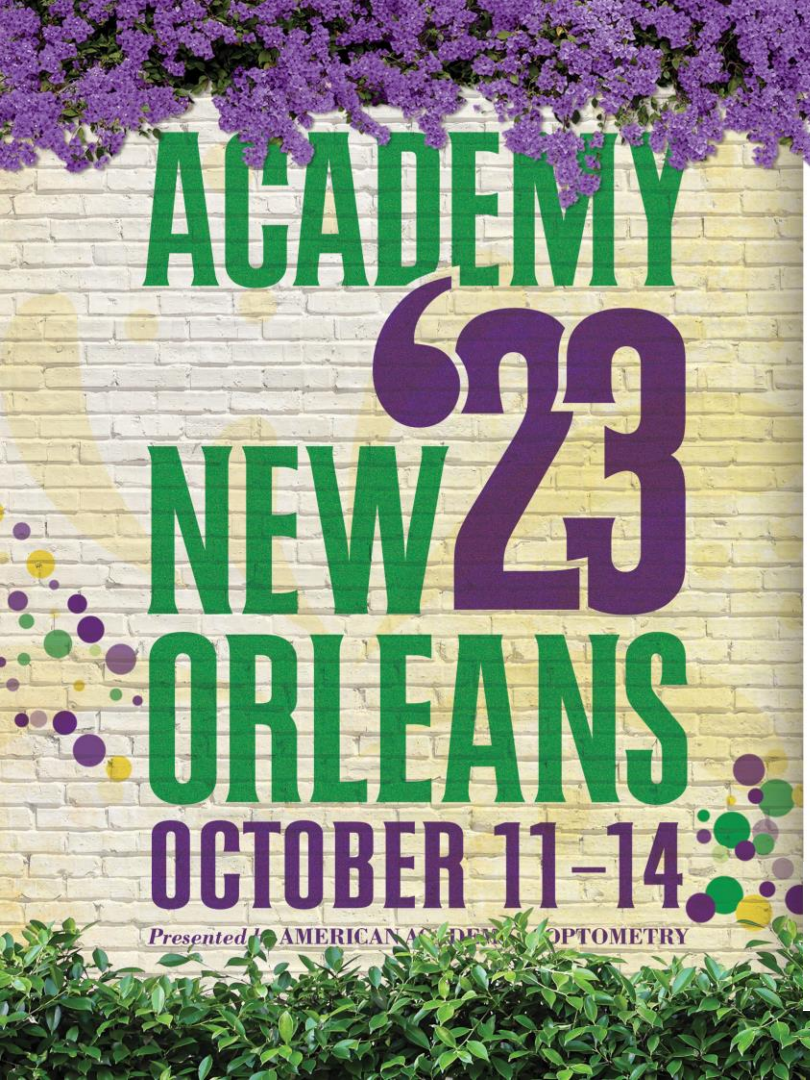

TearCare® Compared to Restasis for Dry Eye Disease

The SAHARA RCT

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Full Title: Aqueous Retention and Meibum Outflow Restoration (ARMOR™) Procedure Compared to Cyclosporine Ophthalmic Emulsion 0.05% (Restasis®) Eyedrops to Treat the Signs and Symptoms of Dry Eye Disease: A Randomized, Controlled Trial.

Disclosure statement:

- Dr. Bloomenstein: consultant for and honoraria (speaker) from Allergan and Sight Sciences; Clinical Investigator in the SAHARA study

- Dr. Chester: grant support, consulting, and speaking for Sight Sciences; Clinical Investigator in the SAHARA study

- Dr. Saenz: consultant and speaker for Sight Sciences and Allergan; Clinical Investigator in the SAHARA study

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Objectives and Background

- Dry Eye Disease (DED) may be the most common ocular affliction globally
- Meibomian gland dysfunction (MGD) may be the leading cause[1]

- Treatment approaches include lid hygiene, medications (e.g. liftegrast, cyclosporine), or procedural based options such as TearCare

- TearCare (Sight Sciences) is a next generation office-based thermal therapeutic eyelid technology cleared by the US Food and Drug Administration for the treatment of evaporative DED due to MGD.

- Restasis is the leading prescription medication used to treat DED

The aim of this study was to compare the effectiveness of Restasis twice-daily versus next generation TearCare technology (2 procedures, baseline and month 5) at 6 months after initiation of treatment on improvement of signs and symptoms of DED.

[1]Nichols KK, et al. Invest Ophthalmol Vis Sci. 2011;52(4):1922-1929.

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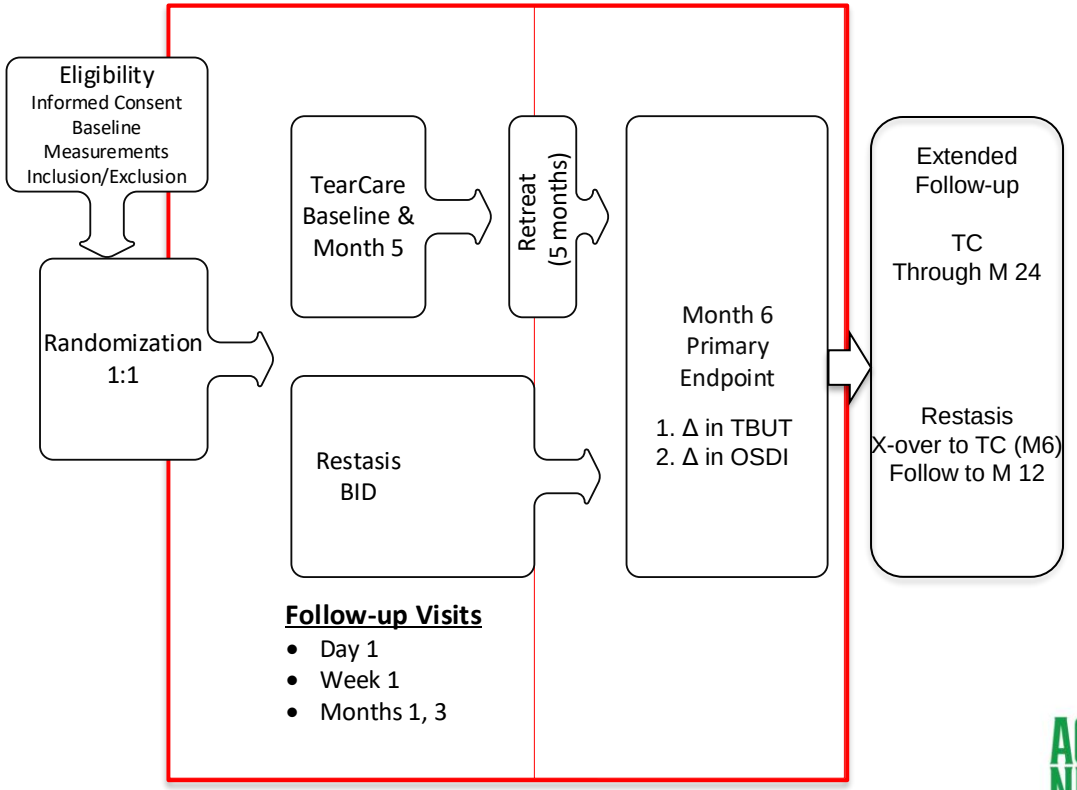
Study Design

SAHARA – Study Schematic



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Baseline demographic and baseline ocular characteristics

	All subjects	TearCare	Restasis	Significance (p)
Subject-level parameters	N=341	N=168	N=173	
Age (yr), mean (SD)	56.2 (14.0)	55.5 (14.9)	56.8 (13.1)	0.4057
Gender, n (%)				
Female	244 (71.6)			0.3120
Male	97 (28.4)		.0)	
Race, n (%)				
White	302 (88.6)		87.3)	0.4979
Black/African American	18 (5.3)		6.9)	
Asian	16 (4.7)		.0)	
Other/Mixed	5 (1.5)		(1.7)	
OSDI, mean (SD)	50.04 (14.74)	50.13 (14.64)	49.96 (14.87)	0.9164
EDS, mean (SD)	64.50 (19.08)	64.67 (18.87)	64.33 (19.33)	0.8706
SANDE score, mean (SD)	66.54 (18.01)	66.12 (17.38)	66.95 (18.65)	0.6705
Eye-level parameters, mean* (SD)				
TBUT (sec)	4.38 (1.21)	4.39 (1.25)	4.37 (1.18)	0.8636
MGSS	7.16 (3.12)	7.20 (3.06)	7.12 (3.19)	0.8255
No. meibomian glands yielding any liquid (MGYLS) (n)	1.14 (1.45)	1.12 (1.48)	1.16 (1.43)	0.7708
No. meibomian glands yielding clear liquid (MGYCS) (n)	0.08 (0.38)	0.08 (0.38)	0.09 (0.38)	0.8560
Corneal staining score	2.76 (2.59)	2.63 (2.46)	2.89 (2.72)	0.3874
Conjunctival staining score	3.52 (3.47)	3.29 (3.51)	3.38 (3.44)	0.8102
Schirmer (mm)	9.39 (3.02)	9.49 (2.90)	9.30 (3.13)	0.5837

No Baseline differences between groups

*average of OD and OS

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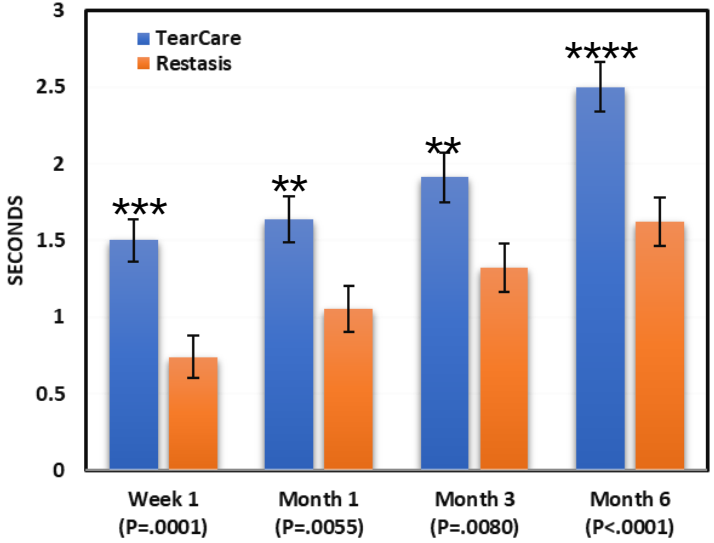
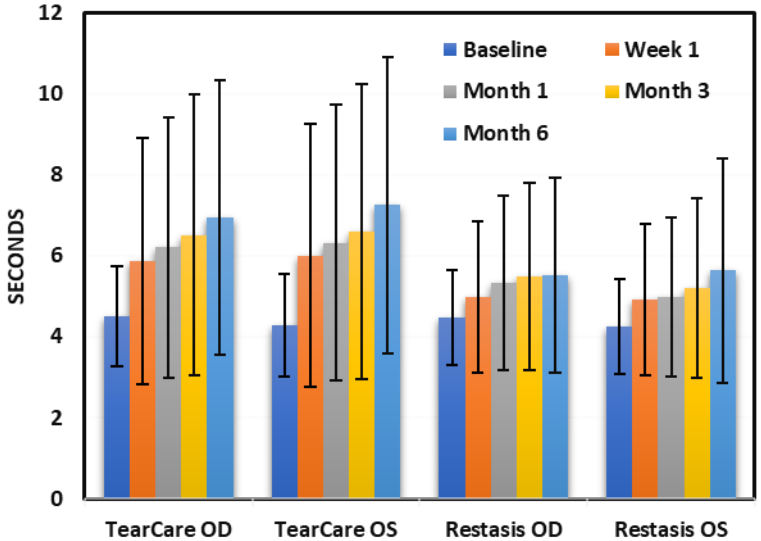
SAHARA – 1st Primary Effectiveness Endpoint - TBUT

Endpoint - TBUT Change from Baseline

TearCare <u>superior</u> to Restasis in TBUT change from baseline at 6 months (P<.0001)



TBUT - Actual



Means, ± 1 SD

All time points, both groups p<.0001 vs. baseline

Analysis: Linear mixed effects with adjustment for baseline, site, and random subject effect. LS means, ± 1 SE

* P<.05; ** P<.01; *** P<.001; **** P<.0001

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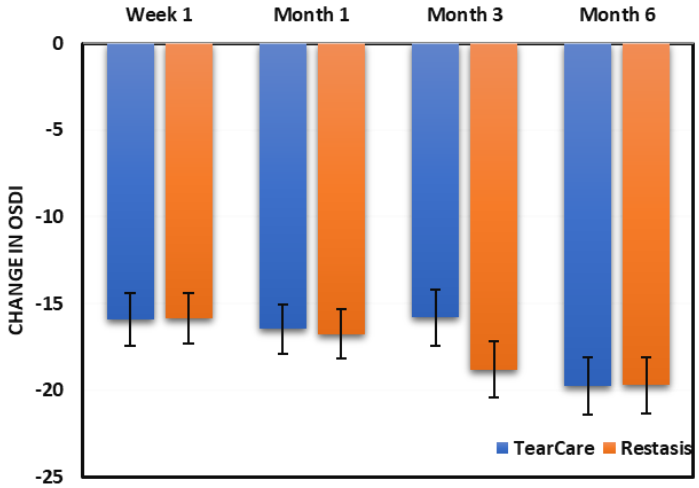
SAHARA – 2nd Primary Effectiveness Endpoint - OSDI

Endpoint - OSDI Change from Baseline

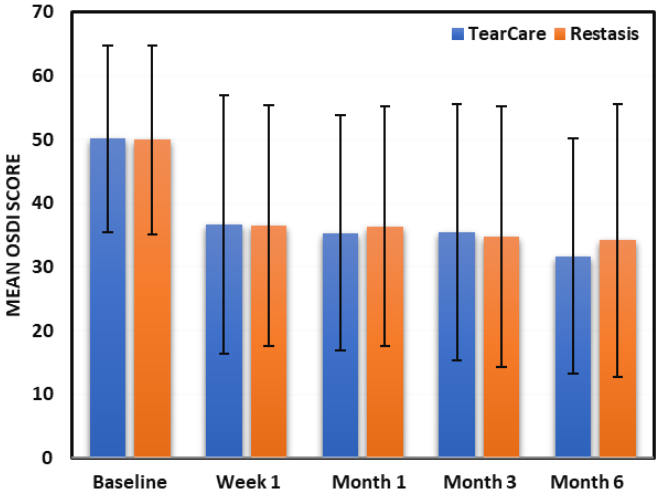
TearCare non-inferior to Restasis in OSDI change from baseline at 6 months (P=.9843)



All time points, both groups p<.0001 vs. baseline

Analysis: ANCOVA model with adjustment for baseline and site.
LS means, ± 1 SE

OSDI - Actual



Means, ± 1 SD

OSDI scale is 0 to 100
Based on the score, the patients' symptoms can be categorized as:
normal (0–12), mild dry eye (13–22), moderate dry eye (23–32), or severe dry eye (33–100)

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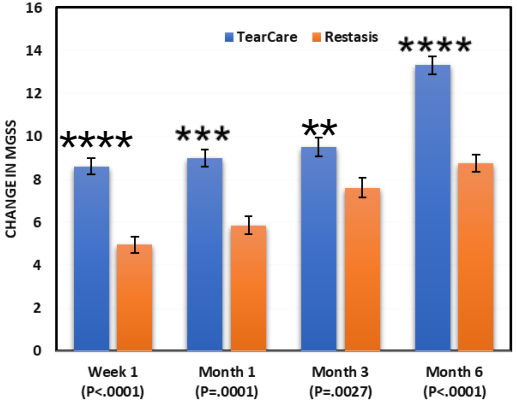
SAHARA – Secondary Endpoints – Signs – Meibomian Gland Outcomes

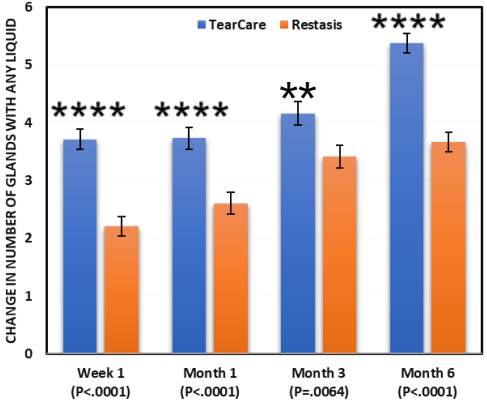
TearCare <u>superior</u> to Restasis in change from BL at M6 for:

- Meibomian gland secretion score (MGSS) (P<0.0001)
- Number of glands yielding any liquid (MGYALS) (P<0.0001)
- Number of glands yielding clear liquid (MGYCLS) (P<.0008)

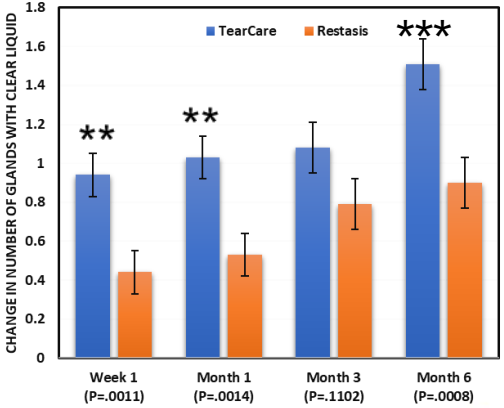
Meibomian Gland Secretion Score



Glands Yielding Any Liquid



Glands Yielding Clear Liquid



Analysis: Linear mixed effects with adjustment for baseline, site, and random subject effect. LS means, ± 1 SE

MGSS, MGYALS - All time points, both groups, P<.0001 vs. baseline

MGYCLS – All time points for TC group P<.0001 vs, baseline; Restasis p<.001 for Wk1, M1, M3 and <.0001 M6

* P<.05; ** P<.01; *** P<.001; **** P<.0001

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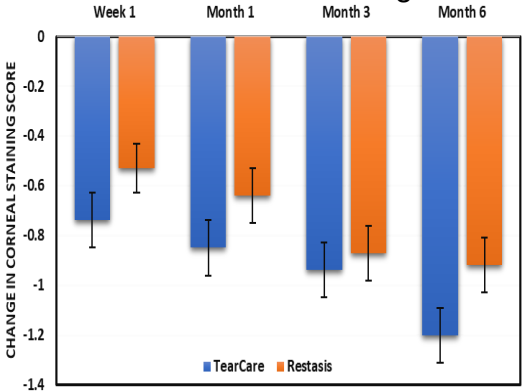
SAHARA – Secondary Endpoints – Signs – Corneal & Conj Staining; Schirmer

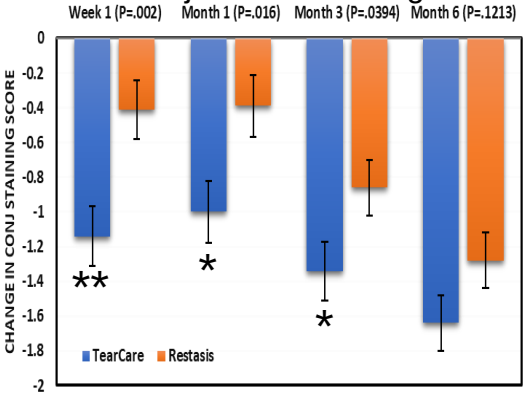
TearCare non-inferior to Restasis (Change from BL at M6):

- Corneal Staining Score (P=.0820)
- Conjunctival Staining Score (P=.1213)
- Schirmer Test Score (P=.7910)

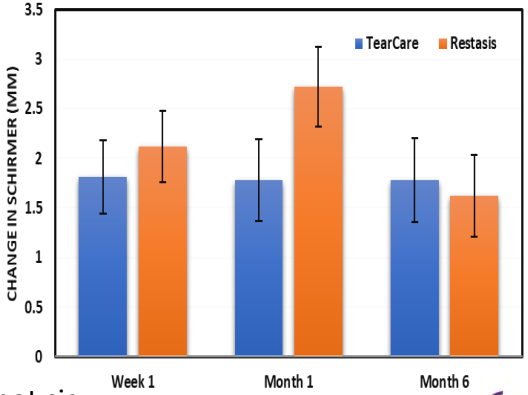
Corneal Staining



Conjunctival Staining



Schirmer Test



- Cornea - TC vs. BL - All time points, P<.0001; Restasis vs. BL, P≤.05 except OS W1 not sig
- Conjunctiva – TC vs. BL – All time points, P≤.01; Restasis vs. BL - M3 (OD), M6 (OU) P<.05; W1 (OU), M1 (OU), M3 (OS) not sig
- Schirmer – All time points for both groups vs. BL - P<.0001 except Restasis M6 (P=.0005 OD / .0006 OS)

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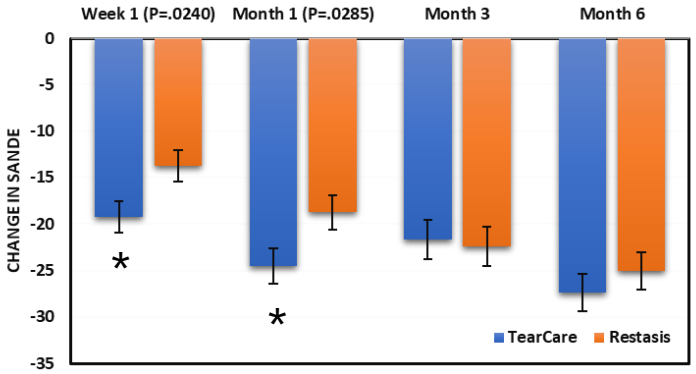
Analysis: Linear mixed effects with adjustment for baseline, site, and random subject effect. LS means, ± 1 SE * P<.05; ** P<.01

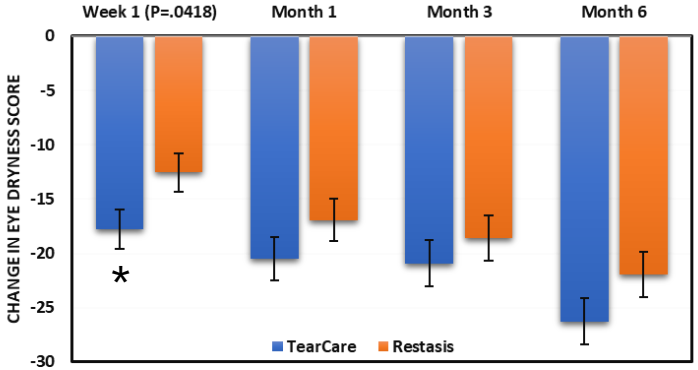
SAHARA – Secondary Endpoints – Symptoms



Symptom Assessment In Dry Eye (SANDE)

TearCare <u>non-inferior</u> to Restasis in SANDE change from baseline at 6 months (P=.4222)

All time points, both groups p<.0001 vs. baseline



Eye Dryness Score

TearCare <u>non-inferior</u> to Restasis in EDS change from baseline at 6 months (P=.1492)

All time points, both groups p<.0001 vs. baseline

* P<.05

Analysis: ANCOVA model with adjustment for baseline and site.
LS means, ± 1 SE

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SAHARA - Safety

Both treatments were generally safe and well tolerated

- 19 adverse events (AE) in each treatment group (11.0%)
  - 2 in the TearCare group and 8 in the Restasis group were graded as possibly related to study treatment
  - All graded as mild (n=9) or moderate (n=1) in severity.
- Ocular AEs occurring in 2 or more eyes were:
  - 2 cases of loss of BCVA>10 letters (both in the Restasis group)
  - 2 cases of medication instillation discomfort (both in the Restasis group)
  - 2 cases of conjunctival hyperemia (one in each group)
- No statistically or clinically significant changes or differences between treatment groups were seen in BCVA or IOP.

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Conclusions

When 2nd generation TearCare technology and procedure was compared to Restasis, TearCare was:

- Statistically superior in TBUT and multiple measures of meibomian gland secretion
- Non-inferior to Restasis in OSDI, corneal and conjunctival staining, SANDE score, EDS, and STS, providing statistically significant and clinically meaningful improvement .

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Conclusions

- Traditional therapy for DED (typically eyedrops) is reliant on patient adherence for effectiveness but patients with DED often do not adhere to their eyedrops at the specified frequency.[2]

- In this study as in many clinical trials[3], subject adherence to drop therapy was very good (not typical of “real-world” behavior) and used an average 5.7 bottles over 6 months.

- TearCare does not rely on patient adherence, thus outcomes reported here should be similar to “real world” use.

2. Uchino M, et al. J Clin Med. 2022;11(2):367.
3. Osterberg L, Blaschke T. N Engl J Med. 2005;353(5):487-497

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