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Tixel i®: Advancing Management of Evaporative Dry Eye with Thermo-Mechanical Action®

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Abstract

Evaporative Dry Eye Disease (DED), primarily driven by Meibomian Gland Dysfunction (MGD), affects over 30 million individuals in the United States. *Tixel i* ®, a recently FDA-cleared, non-invasive device, applies localized heat and pressure to the external eyelid surface using Thermo-Mechanical Action® (TMA®). This commentary reviews findings pivotal studies, regulatory submissions, and real-world clinical experience demonstrating *Tixel i*'s safety, tolerability, and sustained improvements in TBUT, MGS, and OSDI. Real-world results in both routine and treatment-resistant patients further support its versatility. With a short treatment duration, minimal discomfort, and durable clinical outcomes, *Tixel i* offers an efficient, first-line option for managing DED associated with MGD.

Keywords: Dry Eye; Meibomian Gland Dysfunction; Tixel I; Thermo-Mechanical Action; Tear Break-Up Time; Non-Pharmacologic Therapy; Thermal Pulsation Alternative; OSDI; MGS

Abbreviations: DED: Dry Eye Disease; MGD: Meibomian Gland Dysfunction; TMA: Thermo-Mechanical Action; TBUT: Tear Break-Up Time; MGS: Meibomian Gland Score; OSDI: Ocular Surface Disease Index; FDA: Food and Drug Administration

Introduction

Dry Eye Disease (DED) is a multifactorial condition that can significantly reduce quality of life and visual function. Meibomian Gland Dysfunction (MGD) accounts for up to 86% of evaporative DED cases [1]. Traditional therapies such as warm compresses or anti-inflammatory eye drops provide limited and inconsistent relief. *Tixel i* introduces a novel approach using fractional thermo-mechanical heat applied to the eyelid, promoting lipid secretion and meibomian gland function [2-5].

Device Overview

Tixel i (FDA 510(k) K240512), cleared in 2024 [6], delivers fractional pulses of controlled heat through a titanium-coated tip applied to the external eyelid. Treatment is non-invasive, incision-free, and typically takes under 2 minutes for both eyes. The standard protocol includes three treatments spaced two weeks apart. Topical anesthetic may be used based on clinical discretion but is not mandatory. Manual gland expression is not required.

Clinical Performance

Multiple studies support the effectiveness of Tixel i, with a pivotal randomized trial and its 6-month observational extension serving as the primary evidence base for its safety, durability, and efficacy in the treatment of Meibomian Gland Dysfunction (MGD):

- Tear Break-Up Time (TBUT): Improved from a baseline of 4.0 ± 1.5 to 9.2 ± 4.0 seconds, reaching the normal physiological range and sustained through 3 to 6 months ($P < 0.001$) [2,3].
- Meibomian Gland Score (MGS): Increased by over 17 points, with results that are comparable or superior to thermal pulsation systems [2,3].
- Ocular Surface Disease Index (OSDI): Reduced by more than 21 points, surpassing the threshold for clinically meaningful change [2,3].

- Visual Acuity and Intraocular Pressure (IOP): No adverse changes observed [2,3].

These findings were confirmed across both the pivotal U.S.-based, randomized, masked multicenter trial and the long-term extension study [2,3]. Additional smaller-scale studies, such as those by Safir et al. and Shah et al., have reported similar improvements in TBUT, gland function, and patient-reported outcomes [4,5]. In the pivotal trial, *Tixel i* met its primary endpoint by demonstrating non-inferiority to LipiFlow®. Additionally, statistically significant improvements in TBUT, MGS, and OSDI were observed, with no device-related adverse events. These findings, sustained in the long-term extension study, support *Tixel i* as a high-efficacy, non-pharmacologic treatment option for evaporative dry eye [2,3].

Figure 1: Tixel i device and titanium handpiece applied to the external upper eyelid. The treatment delivers fractional heat using Thermo-Mechanical Action® (TMA®) in under 2 minutes for both eyes.

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Real-World Clinical Experience

Beyond published clinical trials, real-world outcomes with *Tixel i* continue to demonstrate its growing value in routine ophthalmic care. Physicians report rapid adoption driven by high patient satisfaction, ease of integration into practice workflows, and outcomes that align with controlled study findings. At Center for Sight New York, led by Noaman Sanni, MD, *Tixel i* was initially introduced for patients with advanced Meibomian Gland Dysfunction (MGD). Early results demonstrated rapid symptom relief, high patient tolerance, and ease of application. The clinic has had an Ocular Surface Disease program for over 10 years and has employed different modalities to retain meibomian gland function. Based on *Tixel i* outcomes, the practice expanded treatment to a broader group, including patients whose imaging showed evidence of ocular surface disease (OSD) even though there were no overt symptoms - as 50% of OSD patients may not present with any symptoms at all.

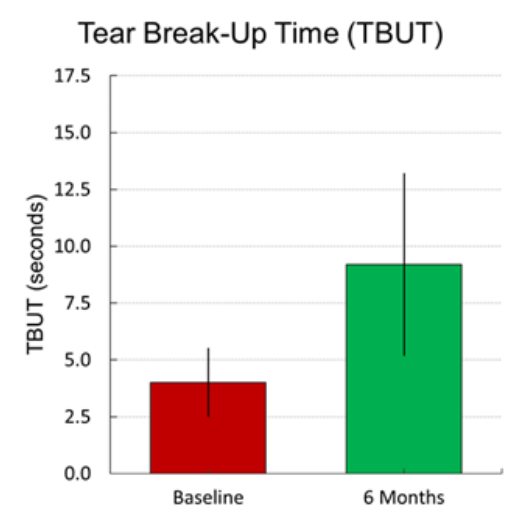

Figure 2: Tear Break-Up Time (TBUT) increased from 4.0 ± 1.5 to 9.2 ± 4.0 seconds following Tixel treatment, demonstrating significantly improved tear film stability (P < 0.001).

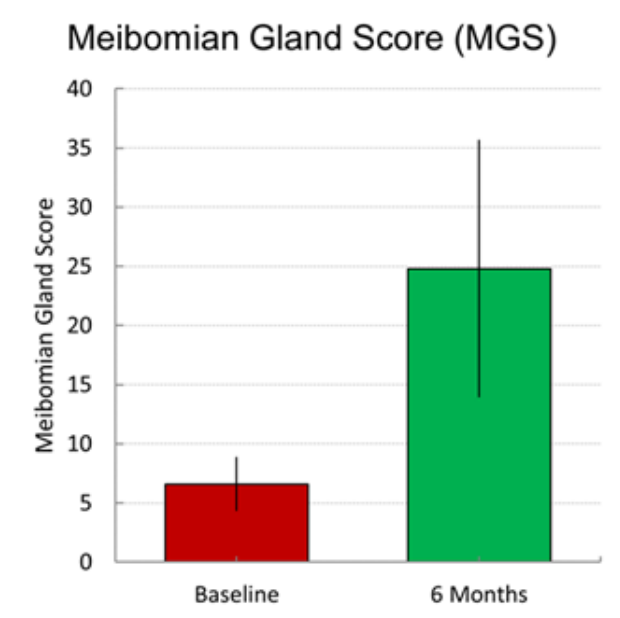

Figure 3: Meibomian Gland Score (MGS) increased from 6.6 ± 2.3 to 24.8 ± 10.9. after Tixel treatment in 6 months after Tixel treatment, indicating markedly improved gland function (P < 0.0001).

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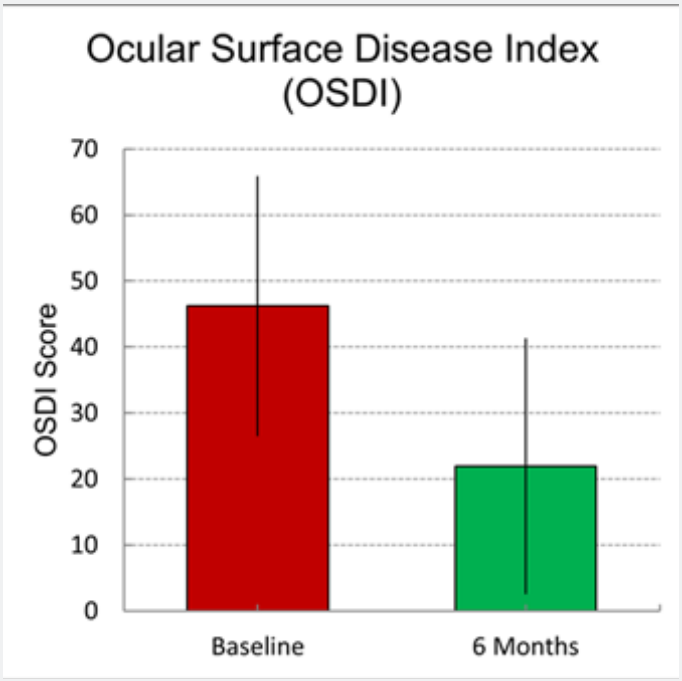

Figure 4: Ocular Surface Disease Index (OSDI) decreased from 46.2 ± 19.7 to 21.9 ± 19.4, six months after Tixel therapy, representing substantial relief in patient-reported dry eye symptoms (P = 0.0004).

Dr. Sanni notes that manual gland expression after *Tixel i* treatment may be performed to observe immediate results. Patients routinely report lighter eyelids, increased moisture, and enhanced end-of-day comfort following treatment. Patients may repeat *Tixel i* treatments to preserve meibomian gland function for the duration of their lives. Practice administrator Brian Case, who personally suffers from evaporative dry eye, underwent a single *Tixel i* treatment and no longer requires eye drops. Following these early successes, Center for Sight New York formally acquired the device, and within three months, the practice was treating up to 50 patients daily with higher satisfaction than seen with prior therapies.

Debra Koloms, MD, further endorsed the real-world impact of *Tixel i* stating: "I have dry eye, and after two Tixel treatments, I no longer need punctal plugs or drops. I've personally treated over 50 patients in the past six weeks. In 40 years of practice, this is the most impressive treatment I've ever seen for Meibomian Gland Dysfunction. Most of my treatments are not based upon the patient reporting of symptoms, but upon imaging and other diagnostics ".

At West Plano Dry Eye and Aesthetics, clinicians treated a 76-year-old patient with a neuro-ophthalmic disorder that impaired eyelid and eye movement function. The patient had severe dry eye, was unable to tolerate IPL, and found traditional eye drops difficult to manage. *Tixel i* was introduced alongside bandage contact lenses and nightly moisture chambers. The team observed meaningful improvement. *"Tixel i is perfect for him and many of our low vision patients. It's quick, easy, and finally gave us a way forward after hitting so many walls."*

The team also treated a 53-year-old patient with a two-year history of severe dry eye, who was using eye drops 4-6 times daily. Following a treatment plan that included three sessions of *Tixel i* the patient reported noticeable improvement in discomfort and a substantial reduction in the impact of dry eye on daily activities. By the four-week follow-up, her clinical severity had improved from severe to moderate, drop usage had decreased, and objective metrics showed dramatic improvement:

- OSDI: from 93 at baseline to 20
- TBUT: from 0 to 8 seconds in both eyes
- MGSS: from 2 to 40 (OD) and 2 to 39 (OS)

Another patient, age 67, was treated for mild dry eye for over two years and used drops 3-4 times daily. After two *Tixel i* treatments and prior to the four-week follow-up, the patient showed marked improvement in both symptoms and gland function:

- TBUT: improved from 5 to 10 seconds in both eyes
- MGS: increased from 15 to 35-41 in both eyes

These cases highlight *Tixel i* 's versatility across a range of dry eye severity levels and its role in helping manage even the most challenging patient profiles.

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Discussion

Tixel i represents an innovative, efficient alternative to pharmacologic and thermal therapies. Its ability to deliver significant, sustained outcomes with a short treatment time and minimal discomfort makes it a practical first-line option, especially for patients seeking relief without ongoing drug dependency. The device's ease of use and short treatment cycle make it ideal for clinical settings with high patient throughput.

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