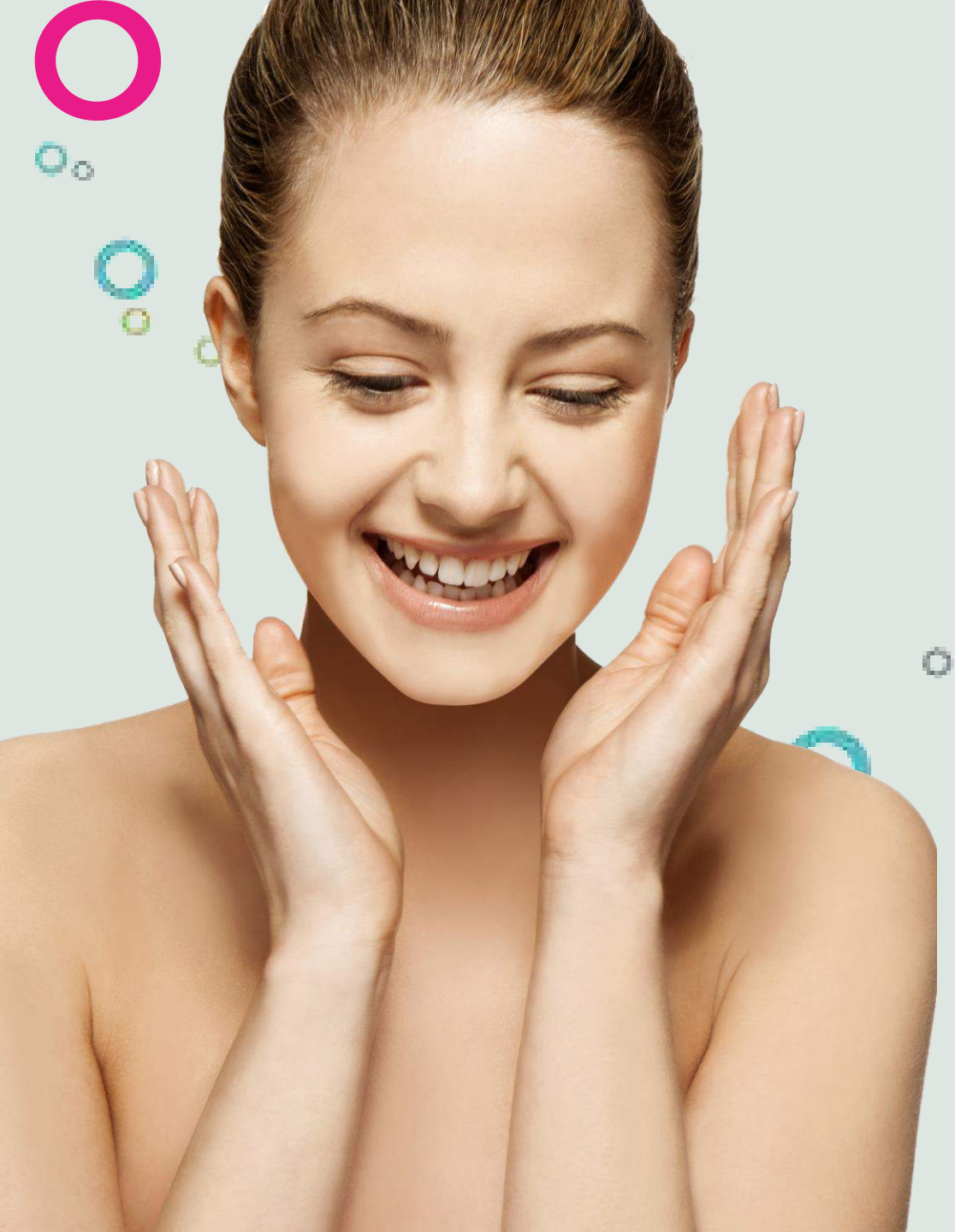

Novoxel®

Forward in Motion

Not for Public Use

Wrinkles

Before on left, After 2 years on right, Courtesy Cheltenham Facials and Therapies, England. No treatment other than Tixel. Settings 14-700 for x 4 treatments, 2 passes over eye & mouth. 5th treatment 10-900, 2 passes on face, 3 passes over lip.

5 TIXEL Sessions

Upper and under eyelid

Before

After

2 Tixel treatments 12/600

Dr. Xavier Martens, Belgium

NoVoxel®

PO Wrinkles

Before

After

3 Tixel treatments

Dr. Harryono Judodihardjo, UK

Under eye Wrinkles

Before

After

ST I-III 12/600 double pass, 10/500 on ST IV
3-5 treatments

Dr. Ofir Artzi Israel

Eye Lids / Brow Symmetry

Before

After

50 years old / photo taken after 3 treatments with 5/1000

Dr. Li Lin Liu, Taiwan

NOVOXEL

A customer treated herself 2 times on upper eyelids in combination with Fusion products

Fusion „F-Lift&Face“ was applied directly after treatment.
At home use „F-ACE“.
Treatment area:
Upper eye lids
2 passes, setting 8/400.
Forehead (above the eyebrow to the hairline) 2 or 3 rows, 2 passes, same setting.

Sabrina Kristmann Germany

NoVoxel

Acne Scars

Before

After

Combination of TIXEL & Q-Switch 3tx

Dr. L. Akerman, Israel

Melasma

Before

After

Glabellar region & nasolabial area
4 treatments, 6 months after 1st
6/400 and depigmentation solution by Mesoestetic.

Dr. Susan Khouw,
Germany

Rosacea

Before **After**

With Topical Botox

Dr. Ophir Artzi, Israel

Neck

Before

After

2cc of Skin boosters & 2 TIXEL Tx

Dr. Lehavit Akerman, Israel

Neck

Before

After 1 month

Combination of Restylane+Ultraformer+ Tixel

Dr. Lehavit Akerman, Israel

Neck

Before

After 1 month

Combination of Restylane+Ultraformer+ Tixel

Dr. Lehavit Akerman, Israel

Decolte

Before

After

2cc of Skinboosters & 2 TIXEL Tx

Dr. Lehavit Akerman, Israel

Stretch Marks

Before

After

Courtesy ekskins.com, Taiwan

Combination Treatment - Full Facial over Four Years

Before

After

Before

After

14 Tixel Treatments at high settings over the period
Occasional fillers and Botox

Dr. Xavier Martens, Euroclinix, Belgium

Novoxel

Dr. Kateryn Perez Willis, Lima Peru

NOVOXEL®

Dr. Kateryn Perez Willis, Lima Peru

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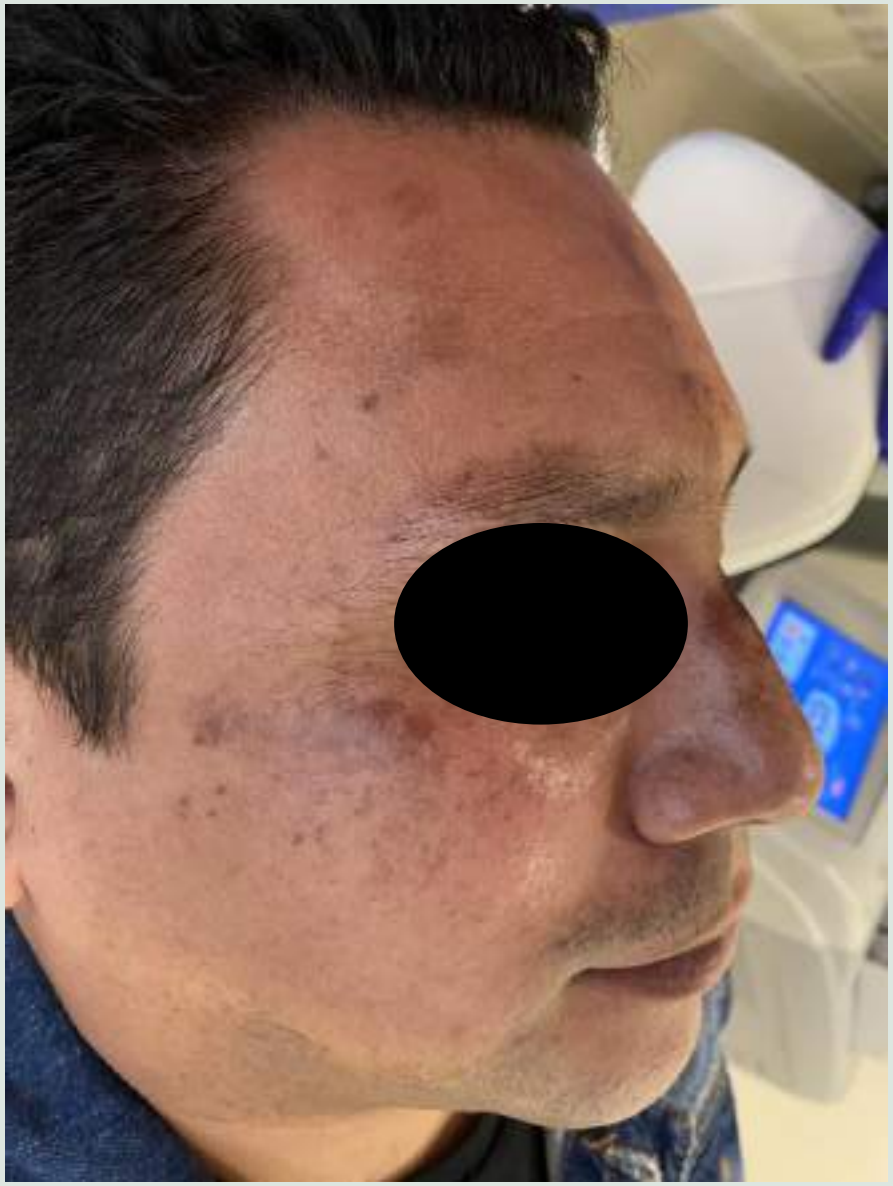
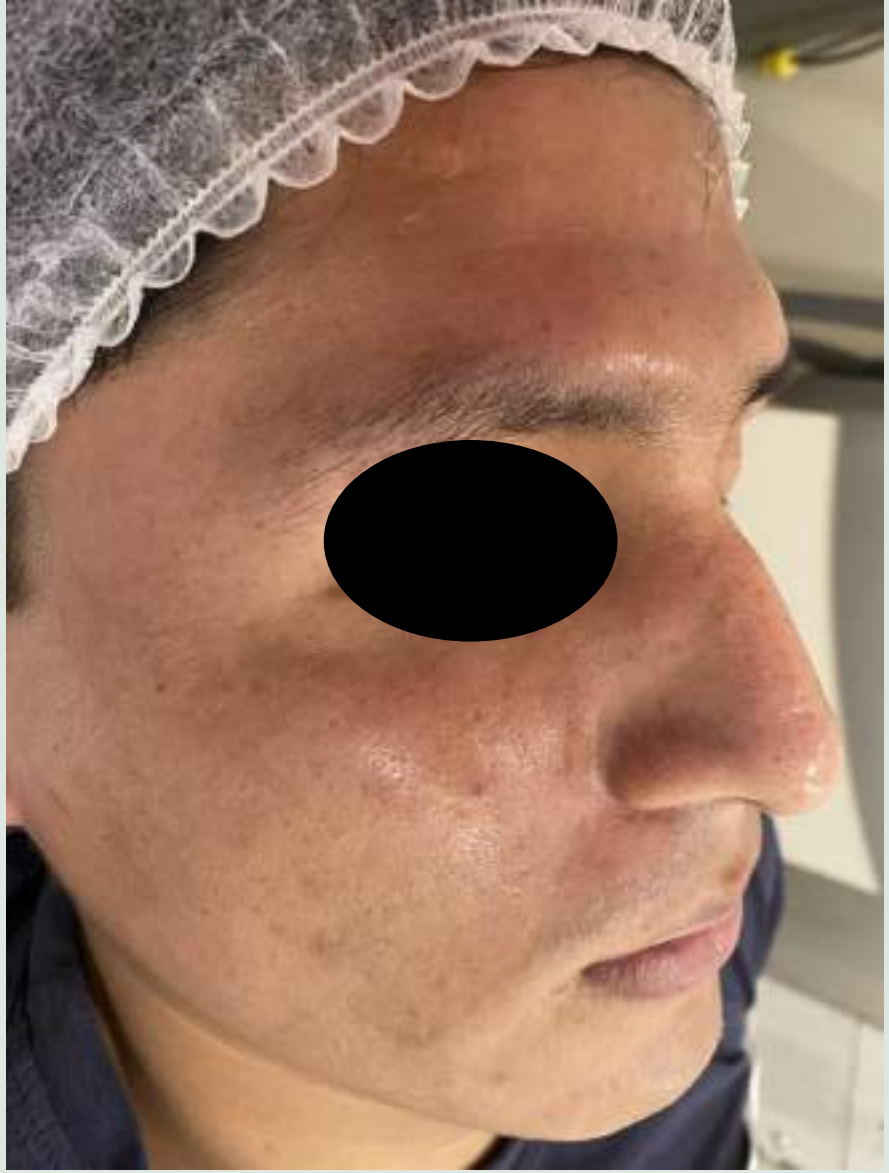


Dr. Kateryn Perez Willis, Lima Peru

NoVoxel®

Dr. Kateryn Perez Willis, Lima Peru



Dr. Kateryn Perez Willis, Lima Peru

Dr. Kateryn Perez Willis, Lima Peru

NoVoxel®

Dr. Kateryn Perez Willis, Lima Peru

Leading physicians speak about Tixel

Tapan Patel, MD. UK

“One of the best devices I’ve ever bought. Fantastic results, especially with periorbital rejuvenation, scarring and general skin sun damage. Delighted with my purchase.”

Lehavit Ackerman, MD. Dermatologist, Israel

Tixel is in it's own niche of treatments -it's less aggressive then ablative laser but more effective then a non-ablative laser. I really like to use Tixel in combination with other modalities to treat areas where we can’t be aggressive, like the neck. I have 3 Tixel devices and offer it to any patient that I meet

Vernon Ching, MD. Plastic Surgeon, South Africa

Tixel is quickly becoming the number one procedure for our patients. They love Tixel because it’s a minimally invasive procedure , there is no pain and minimal downtime and it’s also affordable to patients. We love it, because it works.

Dr. Xavier Martens | Euroclinix Hasselt/Belgium:

“I am extremely intrigued by this new technology. I believe that this disruptive technology will replace other fractional systems over time, thanks to its cost-effectiveness ratio, its excellent results and multifunctional employability. The ultimate game changer.”

Dry Eye Treatment with Tixel*

Localized thermo-mechanical effect on upper and lower eye lids Triggers a cascade of healing effects

- Relieves dry eye symptoms
- Safe for eyes and skin
- Quick
- Effective and economical
- No disposables
- Does not touch the eyes
- 2 – 3 treatments
- Long lasting (1 year) effect

**In clinical evaluation*

Dry Eye Treatment with Tixel*

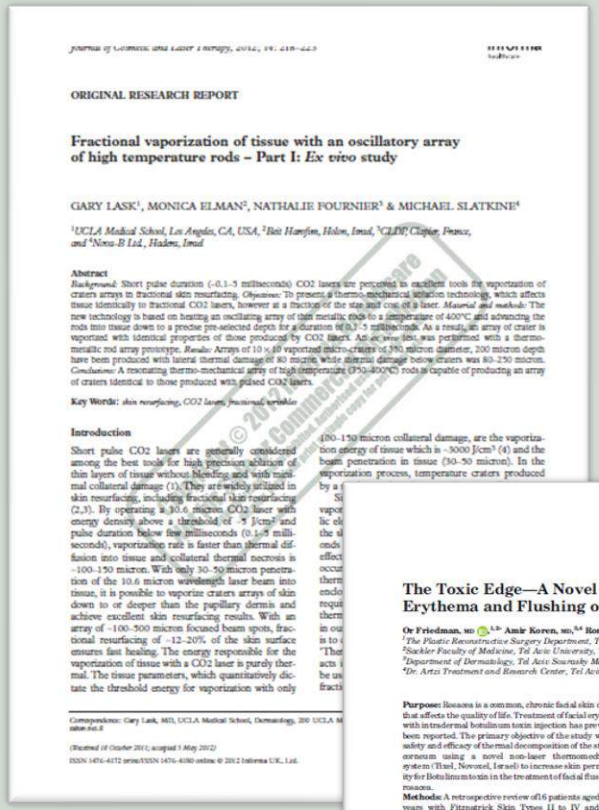
"I am amazed and absolutely delighted with the results of my first treatment of Tixel. My eyes feel much less dry, my vision is much sharper and my eyes seem more open."

*In clinical evaluation

NoVoxel®

SCIENTIFIC EVIDENCE

Peer Reviewed Publications



ORIGINAL RESEARCH REPORT

Fractional vaporization of tissue with an oscillatory array of high temperature rods – Part I: *Ex vivo* study

GARY LASK[1], MONICA ELMAN[2], NATHALIE FOURNIER[3] & MICHAEL SLATKINE[4]

[1]*UCLA Medical School, Los Angeles, CA, USA,* [2]*Bais Hamifim, Holon, Israel,* [3]*CLIP, Clapier, France, and* [4]*Nova-B Ltd., Hadera, Israel*

Abstract

Background: Short pulse duration (~0.1–5 milliseconds) CO_2 lasers are perceived as excellent tools for vaporization of craters arrays in fractional skin resurfacing. *Objectives:* To present a thermo-mechanical ablation technology, which affects tissue identically to fractional CO_2 lasers, however at a fraction of the size and cost of a laser. *Material and methods:* The new technology is based on heating an oscillating array of thin metallic rods to a temperature of 400°C and advancing the rods into tissue down to a precise pre-selected depth for a duration of 0.1–5 milliseconds. As a result, an array of crater is vaporized with identical properties of those produced by CO_2 lasers. An *ex vivo* test was performed with a thermo-metallic rod array prototype. *Results:* Arrays of 10 × 10 vaporized micro-craters of 350 micron diameter, 200 micron depth have been produced with lateral thermal damage of 80 micron, while thermal damage below craters was 80–250 micron. *Conclusions:* A resonating thermo-mechanical array of high temperature (350–400°C) rods is capable of producing an array of craters identical to those produced with pulsed CO_2 lasers.

Key Words: *skin resurfacing, CO_2 lasers, fractional, wrinkles*

Introduction

Short pulse CO_2 lasers are generally considered among the best tools for high precision ablation of thin layers of tissue without bleeding and with minimal collateral damage (1). They are widely utilized in skin resurfacing, including fractional skin resurfacing (2,3). By operating a 30.6 micron CO_2 laser with energy density above a threshold of ~5 J/cm² and pulse duration below few milliseconds (0.1–5 milliseconds), vaporization rate is faster than thermal diffusion into tissue and collateral thermal necrosis is ~100–150 micron. With only 30–50 micron penetration of the 10.6 micron wavelength laser beam into tissue, it is possible to vaporize craters arrays of skin down to or deeper than the papillary dermis and achieve excellent skin resurfacing results. With an array of ~100–500 micron focused beam spots, fractional resurfacing of ~12–20% of the skin surface ensures fast healing. The energy responsible for the vaporization of tissue with a CO_2 laser is purely thermal. The tissue parameters, which quantitatively dictate the threshold energy for vaporization with only 100–150 micron collateral damage, are the vaporization energy of tissue which is ~3000 J/cm³ (4) and the beam penetration in tissue (30–50 micron). In the vaporization process, temperature craters produced by a

JOURNAL OF COSMETIC AND LASER THERAPY

Taylor & Francis

CASE REPORT

Fractional treatment of aging skin with Tixel, a clinical and histological evaluation

Monica Elman[1], Nathalie Fournier[2], Gilbert Barnéon[3], Eric F. Bernstein[4], and Gary Lask[5]

[1]Elman Laser Clinic, Rishon Le-Zion, Israel; [2]CLOP, Clapiers, France; [3]Centre Pathology, Montpellier, France; [4]Main Line Center for Laser Surgery, Ardmore, PA, USA; [5]UCLA Medical School, Los Angeles, CA, USA

ABSTRACT

Objective: This study presents clinical results of Tixel, a new fractional skin resurfacing system based on thermo-mechanical ablation technology. Tixel employs a hot (400°C) metallic tip consisting of 81 pyramids. Treatment is performed by rapidly advancing the tip to the skin for a preset tip–skin contact duration. Thermal energy transfer to the skin creates micro-craters by evaporation. **Methods:** Treatment results with tip types, D and S, with high and low thermal conductivity, were evaluated. Twenty-six subjects received three facial treatments, with 4–5 week intervals between treatments, without analgesia or cooling. In addition, histopathologies of Tixel and CO_2 laser were performed. **Results:** Crater properties are related to contact duration and to thermal conductivity. The D tip created char-free ablative craters 100–320 µm wide with a thermal zone 100–170 µm deep. The S tip created non-ablative coagulation preserving the epidermis. Skin complexion improvement was achieved in all subjects; average treatment pain of 3.1/10, downtime of 0–1 days, and erythema clearance of 3.5 days. Subject's satisfaction was 75% and wrinkle attenuation was achieved in 75% of the cases. There was no incidence of bleeding, scarring, or post-inflammatory hyperpigmentation. **Conclusions:** Tixel may be used safely for ablative and non-ablative resurfacing with low pain, low downtime, and quick healing.

ARTICLE HISTORY
Received 9 December 2014
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KEYWORDS
Ablation; fractional; resurfacing; skin rejuvenation; thermal model

Introduction

Fractional laser resurfacing technologies are widely used in dermatology. Short-pulse CO_2 lasers are generally considered to be among the best modalities for high-precision ablation of thin tissue layers without bleeding and with minimal collateral damage (1). They are widely utilized in skin fractional skin resurfacing (2,3) for improved skin texture and fine wrinkles.

clinical and histopathology data using the Tixel device. A comparison to fractional CO_2 laser histology is also provided.

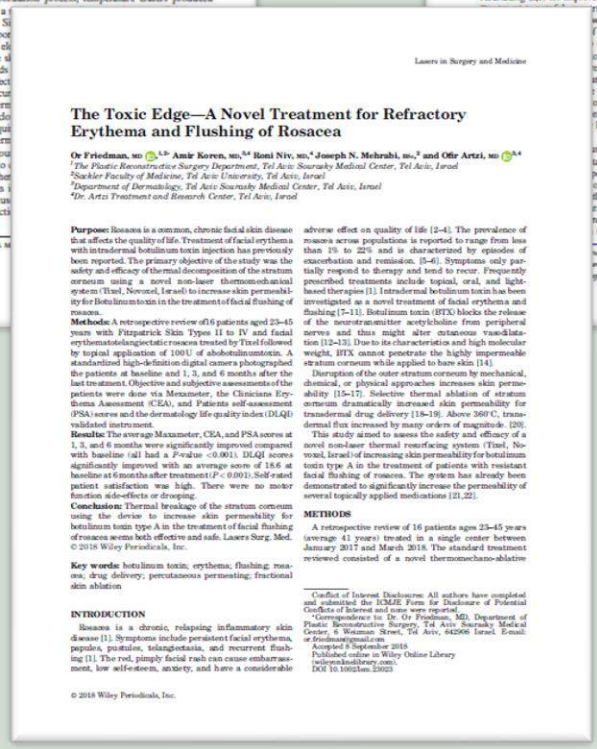
Materials and methods

The Tixel

The Tixel (Novoxel, Germany) is a thermo-mechanical s
for fractional ablation. It applies a tip, made of metallic,
plated biocompatible materials (Figure 1A). The tip is fi
at the distal section of the TixeTs handpiece which is equ
with a linear motor (Figure 1B). The tip's active surface
sists of an array of 81 (9 × 9) pyramids evenly spaced w

(A) The Tixel (B) The Handpiece

Figure 1. (A) D and S types of Tixel pyramidal tip array. (B) Tixel handpiece.



Lasers in Surgery and Medicine

The Toxic Edge—A Novel Treatment for Refractory Erythema and Flushing of Rosacea

Or Friedman, MD[1,2] **Amir Koren, MD**[3,4] **Roni Niv, MD**[3,4] **Joseph N. Mehrabi, BSc**[3] **and Ofir Artzi, MD**[3,4]

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[4]*Dr. Artzi Treatment and Research Center, Tel Aviv, Israel*

Purpose: Rosacea is a common, chronic facial skin disease that affects the quality of life. Treatment of facial erythema with intradermal botulinum toxin injection has previously been reported. The primary objective of the study was the safety and efficacy of thermal decomposition of the stratum corneum using a novel non-laser thermomechanical system (Tixel, Novoxel, Israel) to increase skin permeability for Botulinum toxin in the treatment of facial flushing of rosacea.

Methods: A retrospective review of16 patients aged 23–45 years with Fitzpatrick Skin Types II to IV and facial erythematotelangiectatic rosacea treated by Tixel followed by topical application of 100U of abobotulinumtoxin. A standardized high-definition digital camera photographed the patients at baseline and 1, 3, and 6 months after the last treatment. Objective and subjective assessments of the patients were done via Mexameter, the Clinicians Erythema Assessment (CEA), and Patients self-assessment (PSA) scores and the dermatology life quality index (DLQI) validated instrument.

Results: The average Mexameter, CEA, and PSA scores at 1, 3, and 6 months were significantly improved compared with baseline (all had a *P*-value <0.001). DLQI scores significantly improved with an average score of 18.6 at baseline at 6 months after treatment ($P < 0.001$). Self-rated patient satisfaction was high. There were no motor function side-effects or drooping.

Conclusion: Thermal breakage of the stratum corneum using the device to increase skin permeability for botulinum toxin type A in the treatment of facial flushing of rosacea seems both effective and safe. Lasers Surg. Med. © 2018 Wiley Periodicals, Inc.

Key words: botulinum toxin; erythema; flushing; rosacea; drug delivery; percutaneous permeating; fractional skin ablation

INTRODUCTION

Rosacea is a chronic, relapsing inflammatory skin disease [1]. Symptoms include persistent facial erythema, papules, pustules, telangiectasia, and recurrent flushing [1]. The red, pimply facial rash can cause embarrassment, low self-esteem, anxiety, and have a considerable adverse effect on quality of life [2–4]. The prevalence of rosacea across populations is reported to range from less than 1% to 22% and is characterized by episodes of exacerbation and remission. [5–6]. Symptoms only partially respond to therapy and tend to recur. Frequently prescribed treatments include topical, oral, and light-based therapies [1]. Intradermal botulinum toxin has been investigated as a novel treatment of facial erythema and flushing [7–11]. Botulinum toxin (BTX) blocks the release of the neurotransmitter acetylcholine from peripheral nerves and thus might alter cutaneous vasodilatation [12–13]. Due to its characteristics and high molecular weight, BTX cannot penetrate the highly impermeable stratum corneum while applied to bare skin [14].

Disruption of the outer stratum corneum by mechanical, chemical, or physical approaches increases skin permeability [15–17]. Selective thermal ablation of stratum corneum dramatically increased skin permeability for transdermal drug delivery [18–19]. Above 360°C, transdermal flux increased by many orders of magnitude. [20].

This study aimed to assess the safety and efficacy of a novel non-laser thermal resurfacing system (Tixl, Novoxel, Israel) of increasing skin permeability for botulinum toxin type A in the treatment of patients with resistant facial flushing of rosacea. The system has already been demonstrated to significantly increase the permeability of several topically applied medications [21,22].

METHODS

A retrospective review of 16 patients ages 23–45 years (average 41 years) treated in a single center between January 2017 and March 2018. The standard treatment reviewed consisted of a novel thermomechano-ablative

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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ORIGINAL RESEARCH

The Scar Bane, Without the Pain: A New Approach in the Treatment of Elevated Scars: Thermomechanical Delivery of Topical Triamcinolone Acetonide and 5-Fluorouracil

Ofir Artzi · Amir Koren · Roni Niv · Joseph N. Mehrabi · Or Friedman

Received: March 9, 2019

ABSTRACT

Introduction: Keloids are challenging to treat due to their inadequate response to treatment and high recurrence rate. Intralesional triamcinolone acetonide (TAC) injection with or without 5-fluorouracil (5FU) is considered the first-line treatment for keloids. Three significant disadvantages of intralesional injections are the pain associated with the procedure, the uneven topography, and epidermal atrophy. Fractionated ablative carbon dioxide (CO_2) laser-assisted drug delivery (LADD) of the topical solution can help facilitate transdermal drug delivery and shows promise in scar remodeling. This study examined the use of a thermomechanical device (Tixel, Novoxel) to facilitate the transdermal delivery of TAC and 5-FU in the treatment of keloid scars.

Methods: Seven patients each received eight topical thermal ablations, with one ablation performed every 2–3 weeks. TAC and 5FU were applied after each ablation. Outcomes were evaluated using the Vancouver Scar Scale (VSS), and pain was assessed using the Visual Analog Scale (VAS).

Results: Mean keloid VSS reduced from 8.6 ± 1.2 to 5 ± 2.7 after the eight treatments. Mean treatment pain VAS score was 2.4 ± 0.7. Patients rated their satisfaction level as moderate-high. No severe adverse reactions were noted.

Conclusion: Thermomechanical drug delivery of TAC and 5-FU is safe and effective. This is a promising option for the treatment of keloid scars, particularly in the pediatric population.

Keywords: Keloid; Fluorouracil; Fractional skin ablation; Percutaneous permeating; Resurfacing Scar; Tixel; Transdermal drug delivery; Triamcinolone

Enhanced Digital Features To view enhanced digital features for this article go to https://doi.org/10.6084/m9.figshare.7987415.

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INTRODUCTION

Keloid scars are an uncommon but severe result of impaired wound healing. Keloid scars may develop after acne vulgaris, trauma, surgical incisions, burn injuries, or without an obvious

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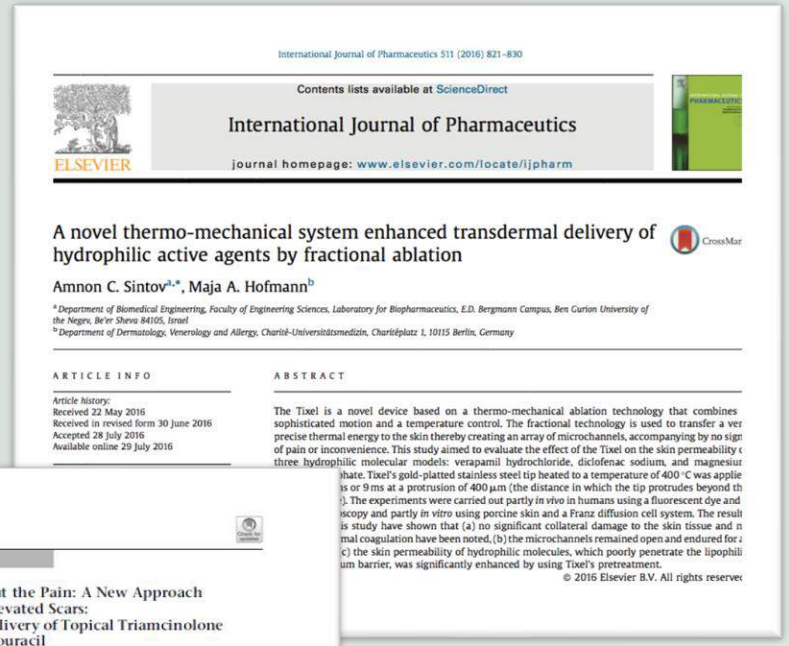

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A novel thermo-mechanical system enhanced transdermal delivery of hydrophilic active agents by fractional ablation

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ABSTRACT

The Tixel is a novel device based on a thermo-mechanical ablation technology that combines sophisticated motion and a temperature control. The fractional technology is used to transfer a ver precise thermal energy to the skin thereby creating an array of microchannels, accompanying by no sign of pain or inconvenience. This study aimed to evaluate the effect of the Tixel on the skin permeability three hydrophilic molecular models: verapamil hydrochloride, diclofenac sodium, and magnesiu hate. Tixel's gold-platted stainless steel tip heated to a temperature of 400 °C was applie s or 9 ms at a protrusion of 400 µm (the distance in which the tip protrudes beyond th). The experiments were carried out partly *in vivo* in humans using a fluorescent dye and scopy and partly *in vitro* using porcine skin and a Franz diffusion cell system. The result is study have shown that (a) no significant collateral damage to the skin tissue and n mal coagulation have been noted, (b) the microchannels remained open and endured for c) the skin permeability of hydrophilic molecules, which poorly penetrate the lipophili um barrier, was significantly enhanced by using Tixel's pretreatment.

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Tixel in scientific publications

Key findings	Publications
Thermomechanical drug delivery of TAC and 5-FU is safe and effective. This is a promising option for the treatment of keloid scars, particularly in the pediatric population.	**The Scar Bane Without the Pain: A New Approach in the Treatment of Elevated Scars: Thermomechanical Delivery of Topical Triamcinolone Acetonide and 5-Fluorouracil** Ofir Artzi, Amir Koren, Roni Niv, Joseph N. Mehrabi, Or Friedman
By using Tixel for drug delivery, we have demonstrated for the first time an increased permeability of hydrophilic active compounds. Fractional ablation of the upper layer of the skin carried out by the Tixel's pretreatment procedure can result in an enhanced transdermal delivery of poorly permeable drugs.	**A Novel Thermo-mechanical System Enhanced Transdermal Delivery of Hydrophilic Active Agents by Fractional Ablation** Amnon C. Sintov, Maja A. Hofmann

Tixel in scientific publications - cont.

Key findings	Publications
Thermal breakage of the stratum corneum using Tixel to increase skin permeability for botulinum toxin type A in the treatment of facial flushing of rosacea seems both effective and safe.	**The Toxic Edge - A Novel Treatment for Refractory Erythema and Flushing of Rosacea.** Or Friedman, MD, Amir Koren, MD, Roni Niv, MD, Joseph N. Mehrabi, BSc and Ofir Artzi, MD
Pretreatment with TMFI (Tixel) at low-energy pulse duration of 6 milliseconds increased the percutaneous permeation of ALA linearly over the first 5 hours from application when the compounded 20% ALA gel was used.	**A New Method for Percutaneous Drug Delivery by Thermo-Mechanical Fractional Injury.** Ronen Shavit, MSc and Christine Dierickx, MD

Tixel in scientific publications - cont.

Key findings	Publications
Tixel may be used safely for ablative and non-ablative resurfacing with low pain, low downtime, and quick healing. Subject's satisfaction was 75% and wrinkle attenuation was achieved in 75% of the cases. There was no incidence of bleeding, scarring, or post-inflammatory hyperpigmentation.	**Fractional Treatment of Aging Skin with Tixel, a Clinical and Histological Evaluation**. Monica Elman, Nathalie Fournier, Gilbert Barnıon, Eric F. Bernstein and Gary Lask.
Wound healing after thermomechanical skin ablation is much faster compared with other fractionated ablation methods. Treatment intervals of 2–4 weeks could be recommended.	**Wound Healing Process After Thermomechanical Skin Ablation** Georgios Kokolakis, Leonie von Grawert, Martina Ulrich, Juergen Lademann, Torsten Zuberbier, and Maja A. Hofmann

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Tixel in scientific publications - cont.

Key findings	Publications
Tixel treatment followed by topical application of Botulinum Toxin can be considered in the treatment of Hailey-Hailey disease. This approach is less invasive, less painful and yet effective as well as safe.	**An Enhanced Transcutenous Delivery of Botulinum Toxin for the Treatment of Hailey-Hailey Disease.** Bar Ilan E, Koren A. Shehadeh W., Mashiah J., Sprecher E., Artzi O.
The use of drug delivery system combined with topical rapamycin has no adverse effects, improves the results of PDL treatment for port wine stains, and can reduce the total number of required PDL sessions.	**Treatment of Port Wine Stain with Tixel Induced Rapamycin Delivery Followed by Pulse Dye Laser Application.** Ofir Artzi, Jos N. Mehrabi, Lee Heyman, Or Friedman, Jacob Mashiah.

ASLMS 2020 Abstracts (to be published)

Key findings	Publications
The thermo-mechanical fractional ablative device is safe and effective for the treatment of peri-orbital lines and laxity in Asian.	**A Prospective Study of the Safety and Efficacy of a Thermo-Mechanical Fractional Ablative Device for Periorbital Rejuvenation in Asians.** Kwankamol Woottisheattapaiboon, M.D., Woraphong Manuskiatti, M.D., Nudpanuda Tevechodperathum, M.D.
TMFI (Tixel) exposure before incubation with 20% ALA gel- and cream- vehicles significantly enhanced skin surface PpIX fluorescence intensities, in addition the cream vehicle increased PpIX fluorescence intensities in epidermis, but not in dermis. Formulation characteristics and TMFI pretreatment exert influence on ALA skin distribution.	**Thermo-mechanical fractional injury enhances skin surface- and epidermis- Protoporphyrin IX fluorescence: Comparison of 5-aminolevulinic acid in cream and gel vehicles.** Camilla Foged; Merete Haedersdal; Liora Bik; Christine Dierickx, Peter Alshede Phillipsen; Katrine Togsverd-Bo.

ASCRS 2020 Abstract (to be published)

Key findings	Publications
Tixel treatment significantly improves clinical signs and symptoms of dry eye and it is a proven technology for dry eye treatment. Patients impression of Tixel was subjectively better than testing revealed and quite impressive compared to IPL treatments.	A Prospective Study Assessing the Impact of Tixel, a Novel Treatment on Dry Eye Symptoms and Signs. Sunil Shah, Debarun Dutta, Ludger Hanneken, Marisa Martins, Toni Qualey, Mukesh Taneja, Shehzad Naroo

Accepted Manuscripts

Key findings	Publications
TMA used immediately prior to ALA application may enhance the effectiveness of PDT in the treatment of acne with minimal side effects, reduced downtime, and fewer sessions. The exact mechanism of TMA assisted PDT is still to be understood.	**Thermo-mechanical ablation assisted photodynamic therapy for the treatment of acne vulgaris. A retrospective chart review of 30 patients.** Y. Hilerowicz, O. Friedman, E. Zur, R. Ziv, A. Koren, F. Salameh, Joseph N. Mehrabi, O. Artzi

Case Reports

Key findings	Publications
Anti-aging and rejuvenation users know about the difficulties of treating the neck and décolleté. This alternative treatment method shows an impressive response of the areas to be treated. As a side effect, it was also shown that the skin cells in the area of the vitiligo sites are activated. This should be discussed through further case reports in medicine and aesthetics and supported by studies, so that thermomechanical infiltration could possibly be used more frequently.	**The neck doesn't lie - Tixel® the safe and low-risk treatment option for the treatment of wrinkles in the neck area: Case Report** Dr. med. Arna Shab[1], Dr. med. Catharina Shab[1] [1]Private practice for dermatology and aesthetic medicine, Frankfurt am Main

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Case Reports

Key findings	Publications
Neurotoxins and dermal ?llers are the foundations of all aesthetic medical practice. However, to be able to truly reverse the effect of photodamage and skin ageing, skin resurfacing treatment is often needed. Tixel is a new skin resurfacing device that has largely taken over from deep chemical peels and fractional CO2 laser in my practice. So far, I have been very impressed with the device; the results are pleasing to the patients and the side effects appear to be minimal.	**Treating Severe Photo ageing** **Dr. Harryono Judodihardjo**

NoVoxel®

Thank You!

PN 1665 Rev. 001