

## ORIGINAL CONTRIBUTIONS

# Retrospective study on the safety and tolerability of clinical treatments with a novel Thermomechanical Ablation device on 150 patients

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## Abstract

**Introduction:** There are currently not many publications on the safety of thermomechanical ablation (TMA) devices, and those that are published only have small numbers of subjects. This treatment is gaining popularity in Europe and Asia, and thus there is a need to look at the safety of this treatment.

**Objective:** The purpose of this retrospective study was to evaluate the safety of the clinical use of the novel TMA system (Tixel, Novoxel, Israel) for facial rejuvenation and treatment of acne scars.

**Methods:** We did a retrospective review of our first 150 patients who were treated with the TMA device.

**Results:** One hundred and fifty consecutive patients aged 20 years to 82 years with Fitzpatrick skin types I to V treated with the TMA device were included in this study. The total number of treatment sessions was 327 (average 2.18 treatment per patient). The total number of pulses delivered to these patients was 1 48 856 (average 455 pulses per session). The indications for the treatment were photodamaged skin (n=145) and acne scarring (n=5). All patients were able to use makeup immediately after the treatment at lower settings, thus needing no real recovery time. Patients treated at higher settings were able to use makeup after 2 days. There were four reported complications: post-inflammatory hyperpigmentation (n=2), impetigo (n=1), and dermatitis (n=1).

**Conclusions:** Using the TMA device in the treatment of photodamage and acne scarring is safe in skin types I to V and has a low incidence of temporary side effects with no permanent side effects.

## KEYWORDS

safety, tixel, thermo-mechanical ablation, TMA, photodamage, fractional skin ablation

## 1 | INTRODUCTION

Aging of the skin incorporates textural changes, wrinkles, and pigmentation. Treatment options for skin photoaging are plentiful and include chemical peels and energy-based devices such as ablative

and non-ablative fractional laser devices and radiofrequency-based devices.<sup>1-4</sup> The fact that there are so many treatments suggest that none are perfect and there is a continuing development of new treatments that can improve the effectiveness and/ or safety of existing treatments.

Currently the most effective treatments for skin photoaging are the more invasive ones such as deep chemical peels and full-field ablative lasers.<sup>5,6</sup> While these treatments are highly effective, they are painful, have severe potential side effects such as scarring and permanent hypopigmentation, and require a long recovery time of about 10 to 14 days.<sup>5-7</sup> The post-treatment erythema that follows can take several months before going back to normal skin colour thus making these treatments unsuitable for men or women who are not used to wearing makeup.

The introduction of fractional laser technology has reduced the treatment discomfort, incidence of severe side effects, and recovery time of ablative lasers. However, the treatment is still uncomfortable, requiring nerve blocks and a recovery time of about 7 to 10 days.<sup>8</sup> Fractional lasers are also bulky and expensive and require expensive regular maintenance. Thus, a new device is needed to further improve on the fractional ablative lasers.

### 1.1 | The Thermomechanical Action (TMA) Device

The Tixel (Novoxel, Israel) is a non-laser, non-RF thermomechanical system which directly transfers thermal energy to the skin by conduction. The system is small and weighs about 6 kg (Figure 1).

The system combines thermal energy with motion to increase heat transfer efficacy. The system consists of a handpiece with a treatment tip assembled from a copper base with gold coating capped by a thin layer of implant-grade titanium shell that is heated to between 385°C and 400°C (Figure 2). When the trigger on the handpiece is squeezed, the tip moves towards the skin to achieve good thermal contact between the heated tip and the tissue to be treated. After the contact, the treatment tip then retracted quickly to its nested home position.

The amount of thermal energy delivered to the skin is determined by the treatment duration of the contact time between the tip and the skin, defined by the system as pulse duration. This ranges from 5 milliseconds (mS) to 18 mS. The second system parameter

is the protrusion. This is defined as the distance in which the tip is moved beyond the transparent outer surface of handpiece distance gauge, that is, how much the tip 'presses' on the skin for pulse duration. A higher protrusion provides better contact between the tip and the tissue and ranges from 100 µm to 1000 µm. The treatment tip has a geometrical design which creates fractional damage on the skin that histologically appears very similar to ablative CO<sub>2</sub> lasers but with no charring.<sup>9</sup> This is because at 400°C the temperature is not hot enough to cause the skin to ignite as it would with carbon dioxide laser which operates at a temperature of over 700°C. The treatment tip is blunt causing no mechanical perforation therefore no bleeding occurs during the treatment. The Tixel machine offers two different handpieces, the standard handpiece with 1 cm<sup>2</sup> tip and the peri-orbital handpiece with 0.3 cm<sup>2</sup> tip, which enables accurate treatment of the periorbital tissues.

This retrospective study aimed to assess the safety and tolerability of this novel non-laser, direct-conduction resurfacing system for the treatment of patients with photodamage and acne scars.

## 2 | METHODS

Data were extracted from the medical notes of 150 consecutive patients with photoaging and acne scars who were treated on the face and/or neck with the thermomechanical action device (Novoxel, Tixel, Israel) across two centres in the UK. Patients were treated by the authors only. Treatments took place between October 2016 and June 2018.

The pulse duration was set between 5 ms and 14 ms. The tip protrusion was set to between 400 µm to 1000 µm. All parameters were set according to the patient's skin type and treatment objectives.

Before treatment, makeup was removed, and the skin was sterilised with isopropyl alcohol 70% and wiped dry. With the lower treatment settings (under 8 mS contact time), no anaesthesia was needed. With higher settings (8 mS and above contact time), topical anaesthesia (Pliaglis by Galderma, Switzerland) was applied and left for 30 minutes before the treatment. During the treatment, the device treatment tip was applied carefully so that there is not too much overlap of the treated area. Patients were treated with a single pass. Areas with excessive skin laxity or with more severe acne scars were treated with two passes with a few minutes in between the passes to cool and prevent bulk heating of the skin.

Immediately after the treatment, nothing was applied to the skin to let it cool. Patients were advised to apply a moisturising lotion (Cetaphil by Galderma, Switzerland) in the evening of the day of treatment and then twice a day for the next 5 to 10 days. Patients were advised to avoid UV exposure for 3 months after the treatment, using a hat and sunscreen.

Patients were advised to have three to six treatments at 4 to 6 weeks interval, for optimal results. Review was not compulsory, but patients were asked to come back at 4 to 6 weeks after the last treatment for final assessment.



FIGURE 1 Photo of Tixel machine

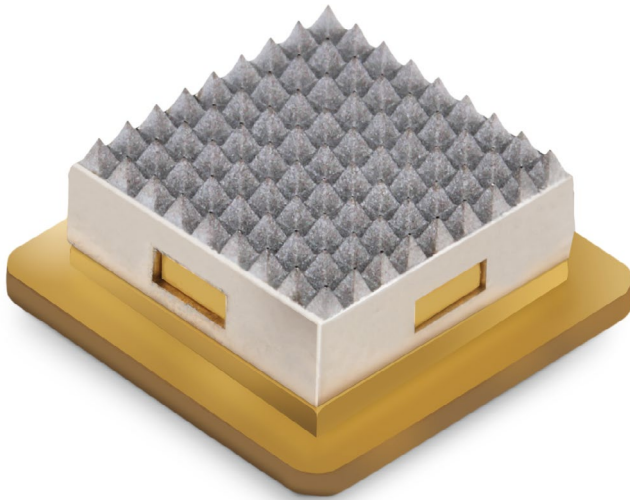


FIGURE 2 Tixel treatment tip

### 3 | RESULTS

The total number of treatments for the 150 patients (male=16 and female=134) in 21 months, when the data were collected, was 327 (Table 1). The areas treated were décolleté (n=1), peri-orbital (n=65), peri-orbital and neck (n=2), peri-orbital and peri-oral (n=2), entire face (n=178), face and neck (n=59), face, neck, and décolleté (n=2), neck (n=5), and peri-oral (n=13). The indications for the treatment were photodamage (n=145) and acne scars (n=5).

The age range of the 150 patients was 20 years to 82 years old with a mean age of 51.75 years, and the gender distribution was 16 male and 134 female patients. The Fitzpatrick skin types distribution are type 1 (n=8), type 2 (n=44), type 3 (n=51), type 4 (n=33), and type 5 (n=14).

The handpieces (HP) were used in the following manner: standard HP only (n=259), peri-orbital HP only (n=65), and combination of both HP (n=3). The pulse duration settings used were as follows: 5 mS (n=81), 6 mS (n=40), 8 mS (n=22), 10 mS (n=28), 12 mS (n=8), and 14 mS (n=148) (Table 2). The protrusion settings used are as follows: 400  $\mu$ m (n=10), 500  $\mu$ m (n=12), 600  $\mu$ m (n=16), 700  $\mu$ m (n=134) and 800  $\mu$ m (n=13), and 1000  $\mu$ m (n=142).

The number of pulses used ranged from seven pulses for treating a few acne scars to 1192 pulses for treating large areas of face, neck,

TABLE 1 Distribution of number of treatments completed by patients

Number of treatments	Number of patients
1	65
2	39
3	27
4	6
> 4	13

TABLE 2 Distribution of contact time in milliseconds (mS) according to patients' Fitzpatrick skin types

	Skin type 1	Skin type 2	Skin type 3	Skin type 4	Skin type 5
5 mS	1	25	17	24	14
6 mS	1	7	13	18	1
8 mS	2	3	9	3	5
10 mS	1	3	9	0	15
12 mS	2	2	4	0	0
14 mS	7	42	59	39	1

and décolletage. The total number of pulses used in the 327 treatments was 1 48 856 pulses (mean 455 pulses per treatment).

Complications noted were post-inflammatory hyperpigmentation (n=2), dermatitis (n=1), and mild impetigo (n=1).

### 4 | DISCUSSION

Non-surgical aesthetic medical treatment has been gravitating towards less-invasive procedures with less discomfort and downtime with similar outcomes as more-invasive treatments. The demand for deep resurfacing treatment to the entire skin such as phenol peel and full-face CO<sup>2</sup> laser is in decline as more patients are electing for fractional skin resurfacing. Fractional CO<sup>2</sup> laser is debatably the current gold standard for fractional skin resurfacing, but it can be a painful treatment with about 7 days of downtime and potentially severe side effects such as scarring and damage to the eyes.<sup>10</sup>

The thermo-mechanical ablation (TMA) machine is a new treatment modality that promises results that can match that of fractional CO<sup>2</sup> and yet claimed to have less downtime and discomfort during treatment, and it is safe for the eyes.<sup>11</sup> TMA can achieve this because the heat it produces is capped at 400°C, which is below the temperature needed to ignite the skin. This means no charring after TMA treatment so that patient can cover the healing skin with makeup immediately after the treatment with the lower setting or after 48 hours in higher-setting treatments. The authors consider any pulse duration setting that is less than 8 mS as the low setting.

TMA is a device that uses conduction to transfer the energy or heat to the skin. Therefore, for the energy to be transferred most efficiently, the best possible contact between the treatment tip and the skin is needed. Initially, we were using a variable protrusion setting to adjust the amount of energy transferred, as was recommended by the manufacturer. However, after seeing the safety evidence of several hundreds of treatments, we then decided to keep the protrusion setting at the maximum so as to allow best conduction at all times and vary the intensity of the treatments by only adjusting the contact time. Based on our experience, we have now made the TMA treatments simpler by only having one variable, the contact time. The protrusion setting mentioned in this paper, less than 1000  $\mu$ m, was the early parameter that we used when we were learning how to optimise the TMA treatment.

TABLE 3 Treatment details of the complications

Complication	Pulse Duration (mS)	Protrusion Setting ( $\mu\text{M}$ )	Total number of pulses used	Skin type	Treatment area
Post Inflammatory Hyperpigmentation	14	700	407	4	Face
Post Inflammatory Hyperpigmentation	14	1000	917	4	Face and neck
Impetigo	14	700	814	3	Face and neck
Contact Dermatitis	14	700	405	3	Face and neck



FIGURE 3 Erythema and oedema on the face due to contact allergy

This retrospective study specifically looked for the side effects due to the TMA treatment. Out of the 327 treatments in 150 patients, only 4 patients were found to have complications post treatment (Table 3). Two patients, both of whom were of Oriental origin with Fitzpatrick's skin type 4, developed post-inflammatory hyperpigmentation (PIH) about 3 weeks after the treatment. They had the higher pulse duration treatment setting of 14 mS, protrusion of 1000  $\mu\text{M}$  for one patient and 700  $\mu\text{M}$  for the other. The PIH cleared in about 3 months with no medical intervention other than the advice to avoid sun exposure and use sunblock daily. Since these two cases of PIH, the authors started to use pulse duration setting of no more than 10 mS for all patients with Fitzpatrick's skin type above 3, and no further cases of PIH were noted. One patient sent us pictures of herself four days after the treatment showing mild facial swelling and erythematous patches resembling dermatitis (Figure 3). She had treatment settings of 14 mS for pulse duration and 1000  $\mu\text{M}$  protrusion. Upon specific questioning, she confessed that she had used several over the counter "anti-ageing" topicals instead of Cetaphil lotion that she had been advised. The authors suspected that she probably had contact dermatitis due to product ingredients penetrating into the treated skin that has a reduced barrier function. She was asked to immediately wash her face with copious amount of water to remove the topicals on her skin and not to apply anything else on the skin, not even the Cetaphil lotion. The mild facial swelling settled down in about 2 days, and the erythema cleared 7 days later. The last side effects of TMA noted in this study was mild impetigo,

which was reported 2 days after the treatment. Her treatment setting was pulse duration of 14 mS and 700  $\mu\text{M}$  protrusion. Yellow crust was noted on the right lower cheek area which cleared with the usage of Mupirocin twice daily as topical treatment for 5 days.

## 5 | CONCLUSION

This retrospective study showed that the novel TMA treatment is safe and has a very low incidence of side effects that can be mitigated further by reducing the pulse duration setting to 10 mS or less for Fitzpatrick skin types 4 and 5 and by advising the patient to protect the skin well against UV light post treatment. The main concern of energy-based treatment is permanent complications such as scarring or pigmentary changes, and none was seen in this study.

## ETHICS STATEMENT

This study was a retrospective study by looking at the patients notes. No ethical approval was required for such study in the UK. We did not seek ethical approval for this study.

## DISCLOSURE

Dr Harryono Judodihardjo is a member of the Medical Advisory Board of Novoxel (Israel) and is a Medical Director of AZTEC services UK which distributes Novoxel products in the UK and Ireland. Dr Sajjad Rajpar has no financial disclosure to make.

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