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FEATURE ARTICLE

Is it Really 'Bye-Bye' to Resurfacing Lasers?

We talk to Dr. Harryono Judodihardjo about Thermo-Mechanical Ablation (TMA) and Tixel®

IS IT REALLY 'BYE-BYE' TO RESURFACING LASERS?

Consulting Room Editor, Lorna Jackson talks to Dr. Harryono Judodihardjo about Thermo-Mechanical Ablation (TMA) technology and Tixel®.

If I told you that I had a new device which meant that you could put your current resurfacing laser(s) in the bin, I'm sure you would politely tell me to '*pull the other one*', but that is exactly what one UK Dermatologist has done! (Well, okay, he sold his laser, but you get my point!)

Introducing Tixel®...and its number one fan, Dermatologist, Dr. Harryono Judodihardjo.

Tixel, based on an Israeli invention and engineering, is made by a German company called Novoxel GmbH, and is a novel device used for fractional skin rejuvenation which is based on the principles of Thermo-Mechanical Ablation (TMA) technology.

It can be used for the same cosmetic treatment applications that devices such as ablative and fractionated CO2 or Er:YAG lasers, radiofrequency or high-intensity focused ultrasound (HIFU) are most commonly employed. This means that it can be used to improve fine lines and wrinkles, skin discoloration, sun damaged skin, skin tone and texture, as well as reduce age or pigmented spots, and acne scarring.

"Turning electricity directly to heat - it sounds like putting a hot iron onto your skin - which is a crazy... But, if you think about it properly, what's the problem?"

It has an ablative mode to create deep or shallow micro-channels of controlled damage to the skin to stimulate collagen production and aid rejuvenation, as well as a non-ablative mode which heats within the upper dermis of the skin, whilst protecting the outer layer, to create permeable channels which can be used to assist in the transfer of topical serums and agents into the skin. It can therefore operate in three modes – ablative, non-ablative and open channel.

"*I found it in September 2016 at the EADV in Vienna. As usual, I was just walking around all the exhibitors' stands, and then, just by the corner, on a small little stand, there was this machine that I've never seen before. So, I said to the man, 'what's this?'. He explained that it was TMA and told me more about it. I was impressed, it really made sense to me. So, I decided to just buy it there and then! It was crazy, really*"; said Dr. Judodihardjo in an interview at FACE 2017.

After only a month of use, Harryono was so amazed by the results that he called Novoxel and told them that

they must bring this device to the UK marketplace. Initially without a UK distributor, Tixel is now available through Anthony Zacharek at Aztec Services Ltd following a UK launch in February 2017. Dr. Judodihardjo now finds himself on the Scientific Advisory Board for Novoxel.

So, why is this technology so exciting?

You're going to 'iron' my face?!

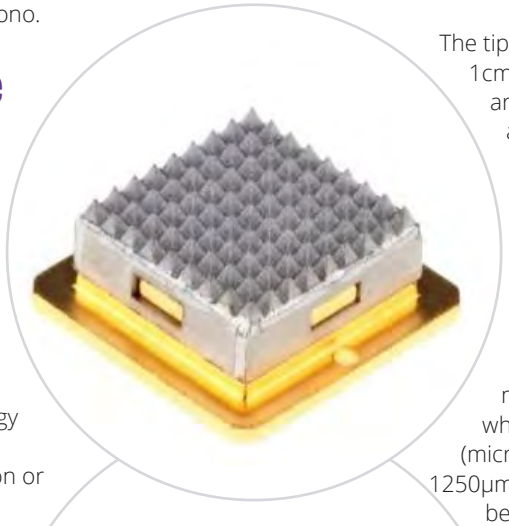
Harryono told me that he does a lot of resurfacing and skin tightening treatments for his patients and as we all know, the gold standard for this is still the use of CO2 (fractionated or unfractionated) lasers. But, he admits that carbon dioxide lasers come with problems – they're painful, thus require topical anaesthetics, even local anaesthetics and sedatives in some cases; the down time is difficult for the patient, and lengthy, sometimes five to seven days; they carry risks related to eye damage, scarring; and create nasty plumes during delivery. From a practical perspective, CO2 lasers are often very large devices and take up quite a chunk of a small treatment room; they require annual service contracts and registration with the likes of the Care Quality Commission (CQC) in England and the Health Inspectorate Wales (HIW). They can be very expensive to run, as well as purchase, and are quite complex devices to operate.

Taking things back to basics, he explained that it was about time that we improved on the gold standard. Taking all the energy devices that we have at our disposal in the aesthetic discipline - be it lasers, radiofrequency or ultrasound – there is always a conduction from electricity (the plug in the wall) to something else (the modality), and ultimately to heat, which is what we use to treat. So, why don't we just forget about the 'middle-man', so to speak, and just go direct to the 'heat' or thermal energy that we all seek.

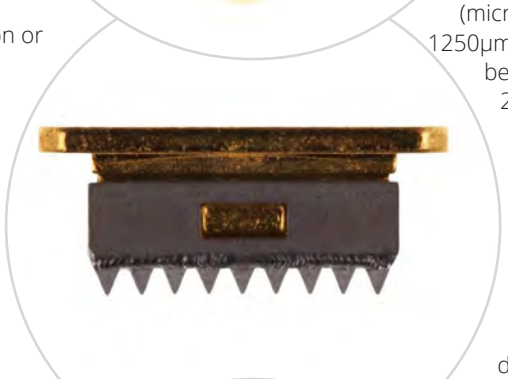
"*Turning electricity directly to heat – it sounds like putting a hot iron onto your skin - which is a crazy thing to think about. But, if you think about it properly, what's the problem? Why can't you do that? We can't just use an iron of course - using that hot metal to touch the skin - because we don't have sufficient control over it; but if we can control the temperature as it touches the skin, the way and pattern, or fractionation, in which it touches the skin and the mechanical action, pressure and duration of that touch, then we have Tixel*"; said Harryono.

The device

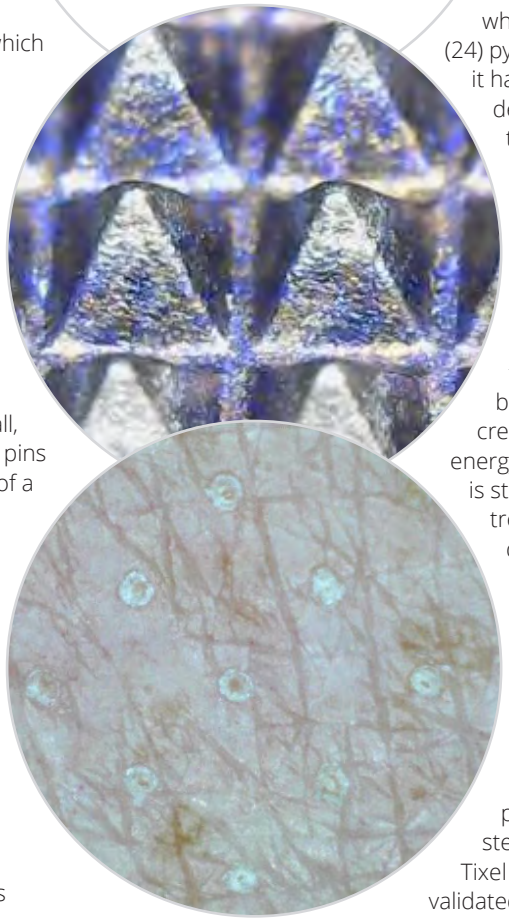
Tixel, which is a table-top sized device weighing in at around 7kg, is powered by a non-laser (non-radiation), non-radiowave energy technology called Thermo-Mechanical Action or TMA.



It requires no consumables or ongoing costs, but a head replacement is required after approximately 100,000 applications at which time the the handpiece is exchanged.



The thermal energy is emitted by a square tip which is attached to the device and carries a matrix of 81 small, pyramid-shaped pins (9 x 9) made up of a copper and gold heat reservoir covered by a thin titanium shell, which is heated by a small ceramic electric heater.
The choice of materials in itself is interesting – the ceramic heater is pushed tightly to the copper base, which is a great conductor but can crumble in the heat, so a gold outer is added, which will not oxidise, but gold sticks to the skin, so this is where the titanium shell comes in to complete the structure.

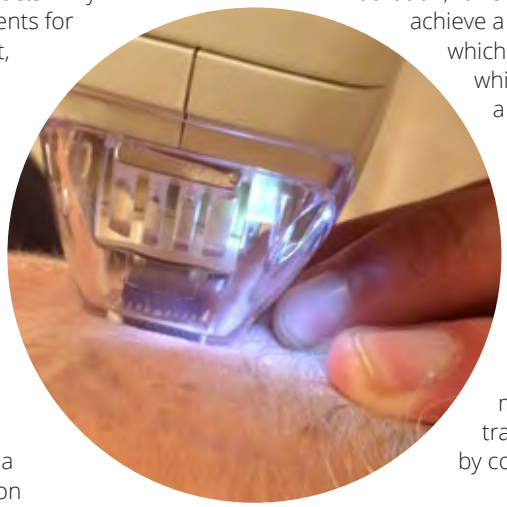


The tip has an area of 1cm2 and the pins are heated up to a temperature of 400ºC, which is comparable to the heat generated by a CO2 laser. The pins can make micro-channels, or micro-pores, which are 170µm (microns) wide, 1250µm apart, and between 50 and 200µm deep, creating discrete and uniform treatment zones.

A second, smaller, same density tip size which has 6 x 4 (24) pyramid pins on it has also been developed for treating harder-to-reach areas, such as the peri-oribital region.

The titanium shell on the tip is biocompatible, creates an efficient energy transfer, is sterile during treatment, durable, non-stick and easy to clean (with a toothbrush) to remove and/or prevent drying of soil or contaminants, plus it is ever-sterile during use. Tixel tip sterility was validated in accordance

with ISO 20857:2010 (Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices).



During treatment, the device tip is applied to the surface of the skin multiple times, via a piston-like action from the handpiece. The pins advance towards the skin by a simple continuous back and forth linear motion at a precisely controlled speed and distance. The pin apexes push the skin and the thermal energy which is stored within them is transferred through the apex of each pyramid in motion. This is done very quickly, during the brief contact with the skin which lasts only a few milliseconds (ms), and can be adjusted to between 5ms and 18ms; (5, 6, 8, 10, 12, 14, 16, and 18ms are possible, depending on what is being treated). The tip distance ("protrusion") can be set to push the skin between 100µm and 1000µm, at intervals of 100µm. An 8ms pulse duration, for example, can achieve a thermal effect which is 100µm deep, while 14ms creates a 200µm deep effect. The pins are not sharp, they do not protrude the skin physically. The technique is therefore a non-invasive method of heat transfer to tissue by contact.

In all, the device has three settings which the practitioner can manipulate: the first (exposure time) determines how long you want the tip to touch the skin (in milliseconds); the second is the protrusion, i.e., how much of the tip comes out from the distance gauge (in microns); and finally, whether it is a single pass or double pass, i.e. touch once or touch twice.

Published trials have shown that after approximately three passes of a carbon dioxide laser, the surface of the skin will reach between 360ºC and 400ºC. The Tixel pins, which are heated to a constant 400ºC, do evaporate the water and tissue from the top layers of skin, instantly, in the same way that fractional CO2 and erbium laser beams do, but without the need for the presence of the water chromophore within the skin to cause the reaction, and without an 'explosive' ablation and tissue coagulation. The reaction, or creation of the tiny micro-channel damage is caused by skin contact with the pins alone, and causes no carbonisation or 'explosion', with modulated coagulation; excess heat is removed by air cooling of the handpiece utilizing a small suction fan within the device.

The heat transfer is the same in all tissue components, meaning that Tixel can mimic the action of all laser wavelengths, with a single absorption, as it requires no specific chromophore.

The developers claim this means that the process is less painful and safer, with reduced downtime and faster healing, as there is no risk from burns or charring of tissue, as associated with lasers.

Patients find treatment much more tolerable than with lasers, but application of a topical local anaesthetic is recommended to achieve as near as possible to a pain-free experience, particularly in more sensitive areas, such as when treating crow's feet and

eyelids.

As well as stimulating neo-collagenesis, the resultant micro-pores are more efficacious for transdermal delivery as the high temperature decomposes the stratum corneum, leaves void spaces in the epidermis, and causes a spongy dermis, all of which creates an effective uptake of hydrophilic substances. Carbonisation and increased coagulation if using lasers reduces the efficacy of any transdermal delivery.

Calculations of the actual energy delivered to the skin using Tixel versus manufacturer's data for a Palomar XD 1540nm erbium laser and an Alma Pixel CO2 laser, showed that at a pulse duration of 14ms, the Tixel produced only 0.035 J/cm2, whilst the erbium laser produced 7J/cm2, and the carbon dioxide laser reached 28 J/cm2. This shows that there is much increased potential for aggressive 'damage' and 'explosive' targeting when using lasers.

What is happening?

Reviewing some histological images, Dr. Judodihardjo explained further;

"It's a very simple device, really. For example, if you use a very short contact time, such as 6 milliseconds, and a depth protrusion of only 300 microns, then you only damage the stratum corneum. This means that you create a channel in the epidermis. There's a little bit of the beginnings of denaturation of the dermis, but not much. So, at this setting, we have created a channel and we can push drugs, serums, topicals, PRP etc. into it.

It denatures the top, and studies have shown that it (the channels) actually remain open for at least six hours. This is much better than when using dermarolllers, where studies have shown that if you put a needle in, it opens it, but when you pull the needle out, it shuts."

"Treating for 8 milliseconds, it's very much the same, more denaturation of the stratum corneum, more denaturation of the epidermis. But basically, it's still intact, non-ablated and open channel."

"At 10 milliseconds, this is sublative treatment. The epidermis is starting to be damaged, but it's still there, and you can see the dermis starting to be coagulated."

"But if you go to 12 milliseconds at 800 microns, then the epidermis is obliterated. It's really desiccated, and this whole area is coagulated now. This is equivalent to a CO2 ablative treatment."

Summarising, Harryono stated that treatment with Tixel is essentially in three modes;

"...you have an open channel mode, to allow drugs, vitamin C, hyaluronic acid etc. to go through into the skin. This is a mode that an aesthetician can use. The second is the sublative mode, which is mainly useful for darker skin types because we don't want to create hyperpigmentation. But with Caucasian skin, where we want to be really tighten everything up, then we can use the full ablative mode."

Personal experience

When comparing the Tixel to his previous experience using a DEKA CO2 DOT fractional laser, Dr. Judodihardjo noted that his patients felt much less pain, both during and after treatment, and that their recovery time was much quicker, reducing from seven days to one or two. The Tixel produced similar results to his carbon dioxide laser, and superior results to those achieved with his Lutronic Infini fractional RF micro-needling device – both of which were subsequently put up for sale!

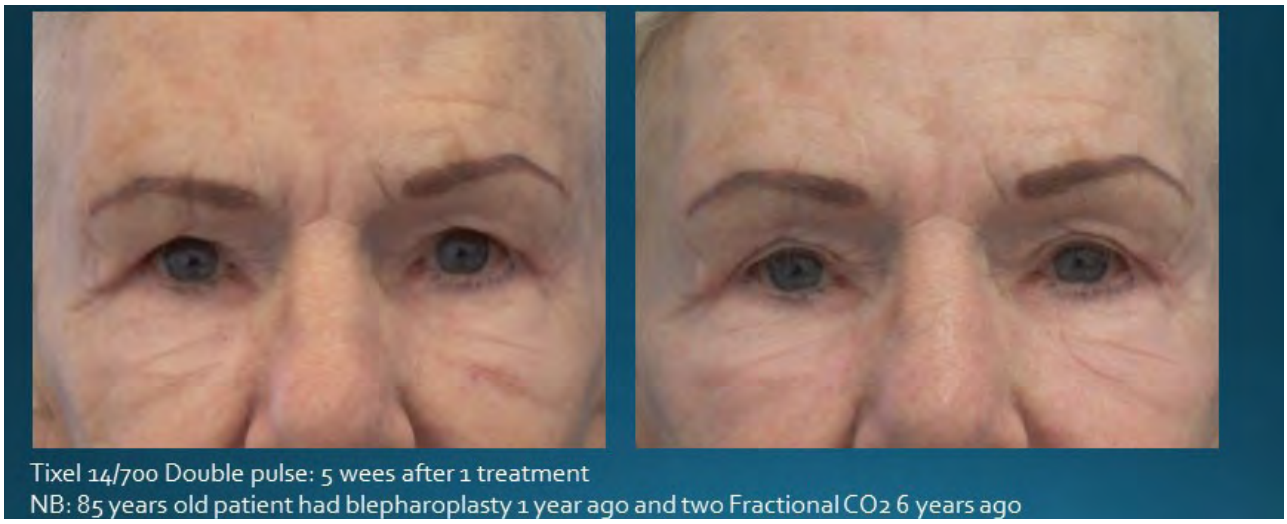
"The nice thing I've found with Tixel is that patients are motivated to come back. Whereas with CO2, which I haven't used in practice since early April 2017, it's very hard to get them to have a second treatment. The pain and recovery time from the CO2 is a de-motivator. With Tixel, it's amazing because patients are calling me to say: 'when can I have my next one?'!"; he quipped.

As well as treating a variety of patients for skin resurfacing and acne scarring, Harryono has also treated much older patients with the Tixel device. This case of an 85-year-old female clearly demonstrates the efficacious results achievable, even in a face with significant skin laxity.

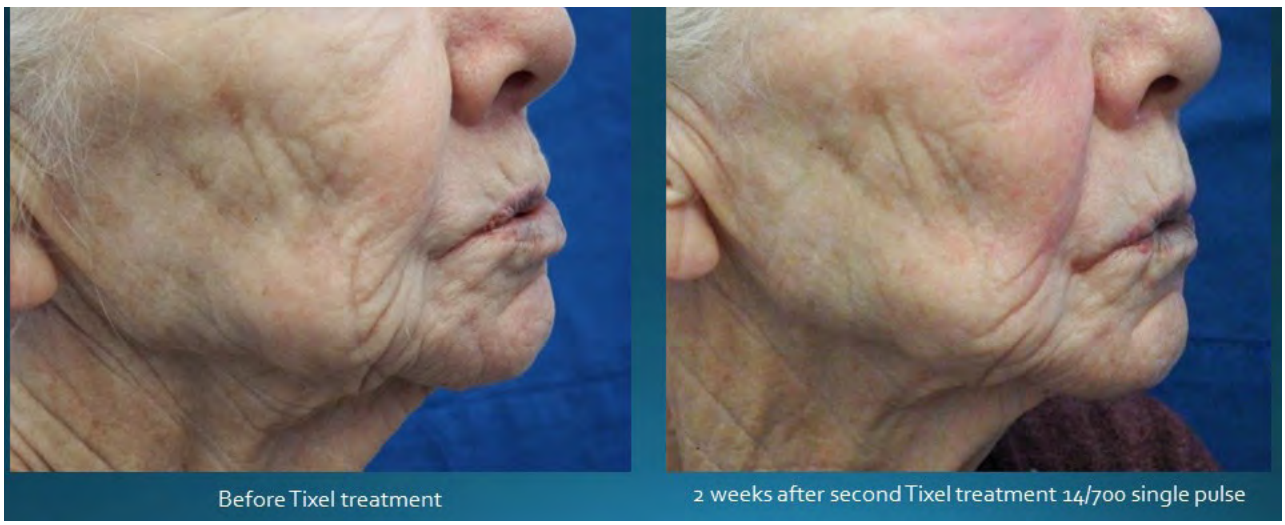
"You're achieving two things here"; he highlighted. "You're achieving the rejuvenation that you would expect from a laser, but you're also achieving a lot of tightening. Lasers are often marketed as offering tightening, but that's really a side effect of their main purpose, but with Tixel you get incredible tightening."

Pointing to the images of her neck, he explained how you can see the depth of the results achievable with Tixel after two treatments, the appearance of a volumising effect, caused by new collagen stimulation and not by adding any filler products.

Dr. Judodihardjo has, to date, only encountered one complication from almost a year of active use of the Tixel device. This resulted in hyperpigmentation on an Asian patient following a high, ablative setting. A colleague, also pioneering the device has reported one additional complication where the patient contracted impetigo after treatment, but was later found to have contaminated the skin post-treatment by not following aftercare advice with regards to touching the area. The shallow depth of penetration of Tixel means that inducing scarring is relatively impossible. Patients can expect some erythema and swelling post-treatment, but there should be no crusting, flaking, bruising, blistering, nor bleeding.



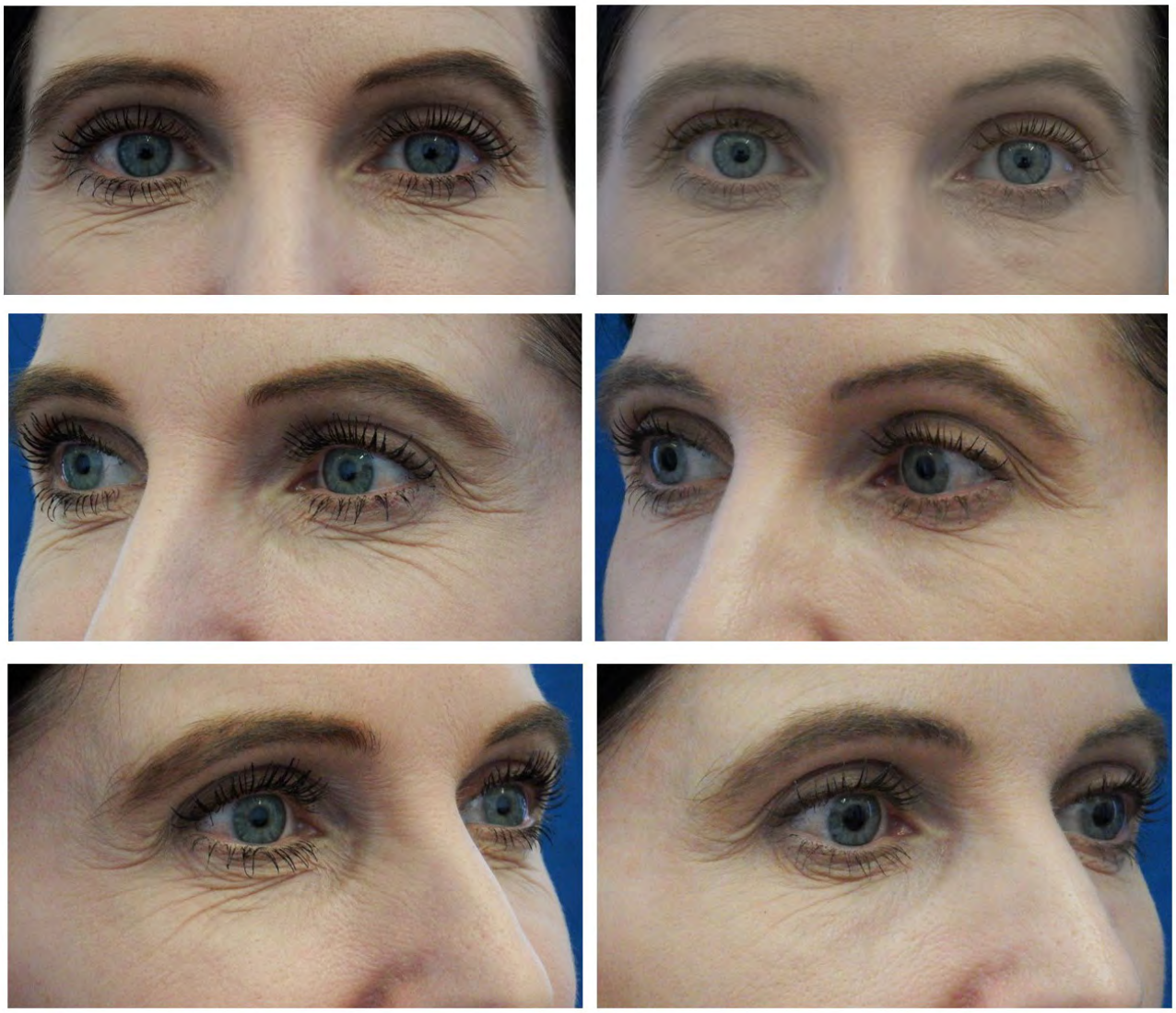
Tixel 14/700 Double pulse: 5 wees after 1 treatment
NB: 85 years old patient had blepharoplasty 1 year ago and two Fractional CO_2 6 years ago



Before Tixel treatment

2 weeks after second Tixel treatment 14/700 single pulse

49 years old female, Before and 6 weeks after 1 treatment
Tixel setting: 14/700, single pulse to peri-orbital area only



Clinical evidence

Personal and anecdotal experience is of course credible, but does not serve to provide the cast iron clinical evidence that most practitioners seek when evaluating both the safety and efficacy of a device, and the business returns it could bring. Tixel, although relatively new, does come with some published clinical data to validate both the science and the experiences of Dr. Judodihardjo.

Proof of concept came in 2012 in a research report[1] published in the *Journal of Cosmetic and Laser Therapy* by a multi-centre group from Israel, France and the USA, which included Gary Lask, Monica Elman, Nathalie Fournier and Michael Slatkine. The authors examined, what was then a prototype device for thermo-mechanical ablation technology. This 'new' technology was 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. An ex-vivo test produced arrays of 10 x 10 vaporised micro-craters of 350µm in diameter, 200µm in depth, with lateral thermal damage of 80µm and thermal damage below the craters of 80 - 250µm. This early prototype study showed that 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 CO2 lasers.

A case report[2] published in the *Journal of Cosmetic and Laser Therapy* in January 2016 by several of the previous prototype-testing authors, and others, evaluated the clinical results achieved with Tixel on twenty-six subjects. All received three facial treatments, spaced four to five weeks part, without analgesia or cooling. In addition, histopathologies of Tixel and CO2 laser were performed.

Results showed that with ablative setting, char-free craters, typically 100-320µm wide with a thermal zone 100-170µm deep were created. 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. The authors were satisfied that this proved the safety of Tixel for ablative and non-ablative resurfacing.

Another collaborative paper[3] was published in the *International Journal*

of Phamaceutics in September 2016, by Amnon Sintova from an Israeli University Department of Biomedical Engineering and Maja Hofmannb from a German University Department of Dermatology, Venerology and Allergy.

The authors aimed to evaluate the effect of Tixel on the skin permeability of three hydrophilic molecular models: verapamil hydrochloride (a calcium-channel blocking agent used for hypertension), diclofenac sodium (an NSAID), and magnesium ascorbyl phosphate (a stable, water-soluble derivative of Vitamin C). Tixel was applied on the skin for 8ms or 9ms at a protrusion of 400µm. The experiments were carried out partly in-vivo (in humans) using a fluorescent dye and a confocal microscopy, and partly in-vitro using porcine skin and a Franz diffusion cell system.

The results showed that there was no significant collateral damage to the skin tissue, and no necrosis or dermal coagulation from the application of Tixel. It also showed that the micro-channels remained open and endured for at least 6 hours. Finally, and more significantly, the skin permeability of hydrophilic molecules, which poorly penetrate the lipophilic stratum corneum barrier was significantly enhanced by pre-treating with Tixel. The penetration of verapamil hydrochloride increased between about 10 and 20 times, and penetration of sodium diclofenac increased about 3 times. While no permeation of magnesium ascorbyl phosphate was noted through untreated skin, a quantitative transdermal penetration (6 hours post-application) was detected after skin had been pre-treated with Tixel.

In concluding, they noted; "*Apart from the safety, an interesting phenomenon has been noted in the human study, which was the endurance of the micro-channels hours after their formation. In addition, the permeability of the hydrophilic marker even increased with time. The mechanism of this phenomenon is not thoroughly clear and remains to be explored. The safety and the skin permeability of hydrophilic active compounds after Tixel's double-pulse (or multi-pulse) pre-treatments of the skin should also be further experimented. In addition, high molecular weight compounds, such as proteins and polysaccharides, are remained to be studied, widening the potential uses of the Tixel.*"

Looking forward...

Looking to the future for the Tixel device, Harryono explained that currently there is only one model available, as we have discussed. However, it is expected that by 2018 there will also be an additional model which is limited to a 12ms pulse duration, creating a stand-alone model suitable for use by aesthetic nurses and advanced trained aestheticians. This safer, lower-powered device would predominantly be for use in transdermal delivery of topical agents, providing clinics with multiple in-house options for using one, or more devices with different specialist staff.

It is noteworthy that the novel Tixel device is ticking quite a few boxes when it comes to deciding if it can replace multi-modality options currently employed in aesthetic practice for skin rejuvenation, skin resurfacing and transdermal delivery of pharmaceutical and cosmeceutical agents. Certainly, the experiences of Dr. Judodihardjo are quite compelling, and his portfolio of patient before and after photographs is definitely worth looking at if you encounter him at forthcoming conferences and meetings; he's more than happy to tell you about it.

Having a device that can convincingly take on the gold standard, is not something that comes along very often. You would be right to be sceptical, of course, but has Harryono really stumbled upon the reason to say farewell to your lasers? Only time, and more study will tell – meanwhile if you're looking for some second-hand aesthetic devices, he's got a few going cheap!

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All before and after photographs are supplied by Dr. Harryono Judodihardjo. These are his own patients - images are not for republication.

Lorna Jackson, BSc.

Lorna has been Editor of Consulting Room since 2003. She is an industry commentator on a number of different areas related to the aesthetic industry. Lorna has been published in Aesthetic Medicine, Cosmetic News, Journal of Aesthetic Nursing, Body Language, PMFA News and Aesthetic Dentistry Today, as well as supplements in The Times and The Independent on Sunday. She has also presented at various industry events, including Smart Ideas, FACE and CCR Expo. Lorna was awarded Journalist of the Year 2014 at the MyFaceMyBody Awards.

Dr Harryono Judodihardjo, MB BCh BAO, MSc, PhD. DCH, DipGum, DDSc.

Harryono is the Medical Director of the multi-award winning Cellite Clinic in Cardiff started by him in 1998, and a partner of the Belgravia Dermatology Limited in London. He was the past Vice President of the British Association of Cosmetic Doctors and was a board director of the British College of Aesthetic Medicine. He is a graduate from the Queen's University of Belfast with a medical degree MB BCH BAO. He further obtained postgraduate qualifications, Master of Science in Dermatology (MSc) and Doctor of Philosophy (PhD), from The University of Wales in Cardiff where he used to work as a clinical lecturer. He is also on the Scientific Advisory Board for Novoxel GmbH.