



Beyond a needle free injector

Mechanism of Action & Clinical Versatility of SYNERJET PRO™



WHY NEEDLE-FREE DELIVERY NOW?

The clinical gap a new transdermal delivery platform has to close

01 NEED FOR A NEW DELIVERY PLATFORM

Burden of pain and bruising

Operator dependence

Difficulty achieving uniform delivery

Fatigue from repeated treatments

Demand for expansion into skin quality and scar treatment

02 Needle-free means strategy, not just replacement

The device is chosen for what it does to the tissue, not simply because it removes the needle.

03 Transdermal drug delivery + skin remodeling (regeneration)

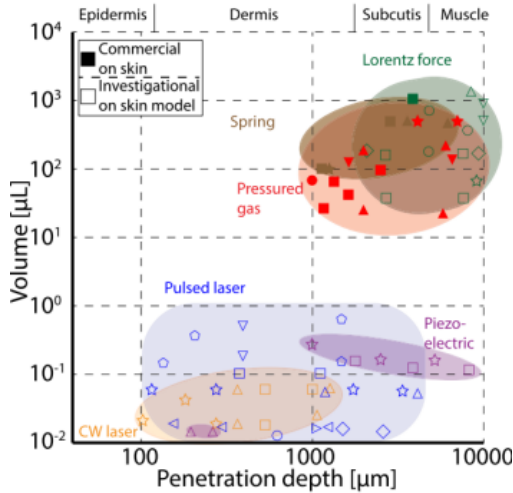
Delivery and device-driven tissue stimulation are pursued in the same session — the second is not a side effect of the first.

A needle-free platform is judged by delivery uniformity, depth control and the regenerative response it triggers.

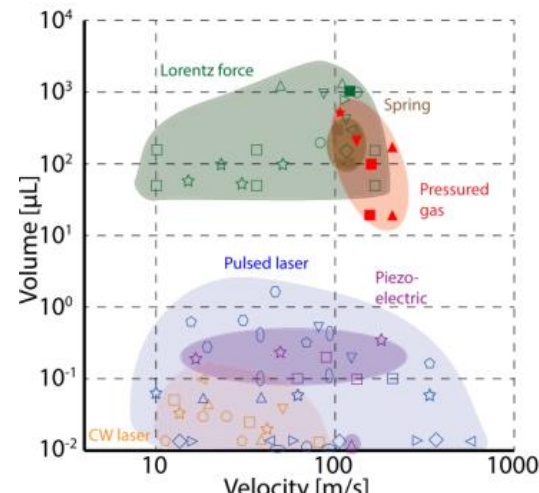
NEEDLE-FREE INJECTORS

Overview of needle-free injection technologies and their characteristics

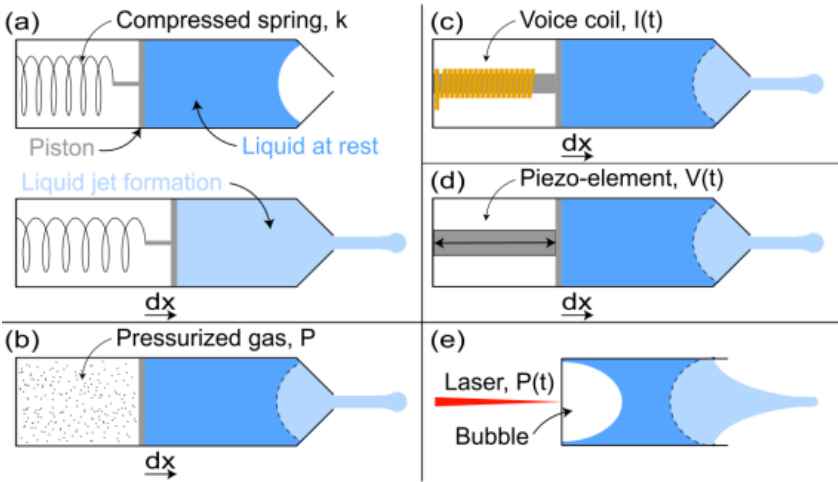
Energy source	Technique	Typical jet volume	Typical velocity	Typical depth	Dynamic jet control	Commercially available
Mechanical	Spring	100–1000 μL	100 m/s	2–10 mm	No	Yes
Mechanical	Compressed gas	100–1000 μL	100–300 m/s	2–10 mm	Limited	Yes
Electromechanical	Piezo-electrical	1–400 nL	50–150 m/s	0.3–5 mm	Yes	No
Electromechanical	Lorentz force	20–1000 μL	50–200 m/s	1–20 mm	Yes	No
Optical	Pulsed laser	1–1000 nL	100–300 m/s	0.1–5 mm	Yes	Yes
Optical	CW laser	1–100 nL	20–100 m/s	0.1–1 mm	Yes	No



Volume spans five orders of magnitude – nanolitre optical jets to millilitre mechanical jets – mapped against epidermis, dermis, subcutis and muscle.



Almost every technique clusters in the 50–300 m/s band that defines skin penetration.

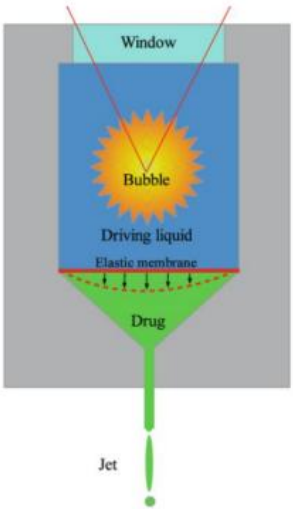


(a) compressed spring · (b) pressurized gas · (c) voice coil · (d) piezo-element · (e) laser-generated bubble. Only electromechanical and optical sources let the jet be shaped during the shot.

Jet volume and jet velocity – not the energy source itself – determine how deep and how uniformly a drug is placed.

NEEDLE-FREE INJECTORS

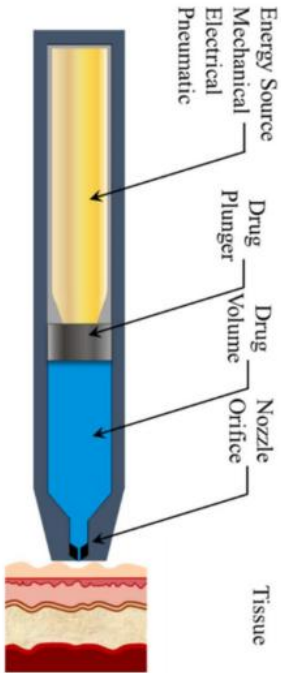
Laser-driven versus electromagnetic jet generation



Laser-induced cavitation bubble drives the drug through an elastic membrane

	Laser energy	Electromagnetic energy
Jet generation	Cavitation bubble	Piston compression
Heat generation	Present	None
Jet type	Very fine jet	Relatively strong cylindrical jet
Penetration depth	Superficial dermis	Can reach deeper dermis
Volume	Nano-dose	Micro-dose
Pressure control	Laser pulse	Mechanical pressure

The energy source decides the trade-off: a laser jet is finer but shallower and carries heat; an electromagnetic jet is stronger, thermally neutral and reaches deeper.



Electromagnetic injector — plunger, nozzle orifice and target tissue

Synerjet Pro uses electromagnetic jet generation — no thermal component, micro-dose volumes, and controllable depth into the deeper dermis.

CADAVERIC TEST

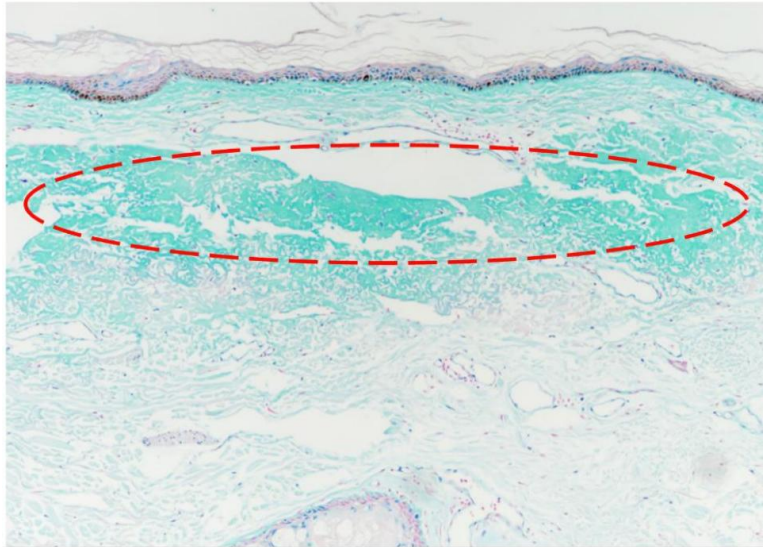
Histological verification of two distinct delivery patterns

HIRONIC

NANO-SPIKE EFFECT

Target: papillary dermis

Skin rejuvenation, scalp scars, striae · distant shot < 20 mm · from 120 V

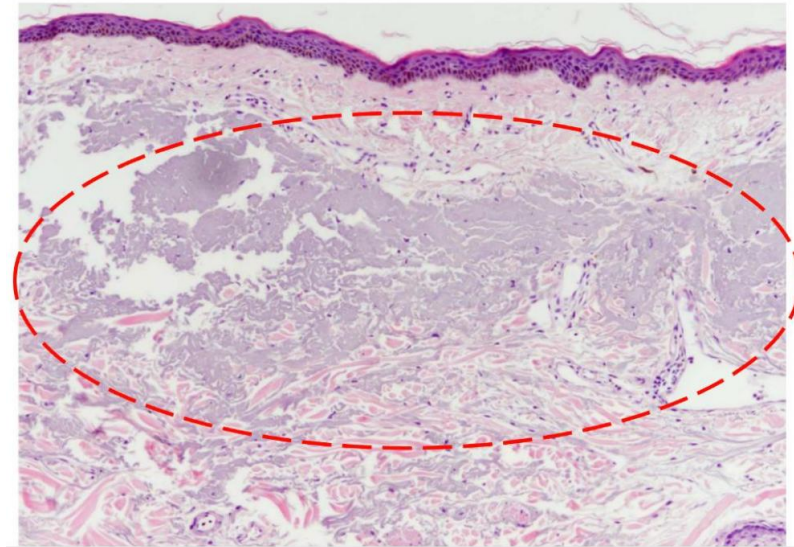


Face — 15 mm distant shot (multi-pass), diluted PDLLA, Alcian blue stain ×100

MICRO-BOMB EFFECT

Target: reticular dermis

Scars, striae, scalp · contact shot · from 100 V · tougher scar tissue needs higher voltage and volume



Face — 5 mm contact shot, diluted PDLLA, H&E stain ×100

Uniform distribution of poly-(lactic acid) particles in the upper and mid dermis — epidermis and blood vessels undisturbed.

WHY COMBINE PHYSICAL ENHANCEMENT METHODS?

In vitro permeation of a hydrophilic macromolecule (FD-4, MW 4.4 kDa) across porcine skin

STUDY

Porcine skin, Franz diffusion cells, 24 h. FD-4 was delivered after pretreatment with microneedles, electroporation and sonophoresis – alone, in every pair, and all three together.

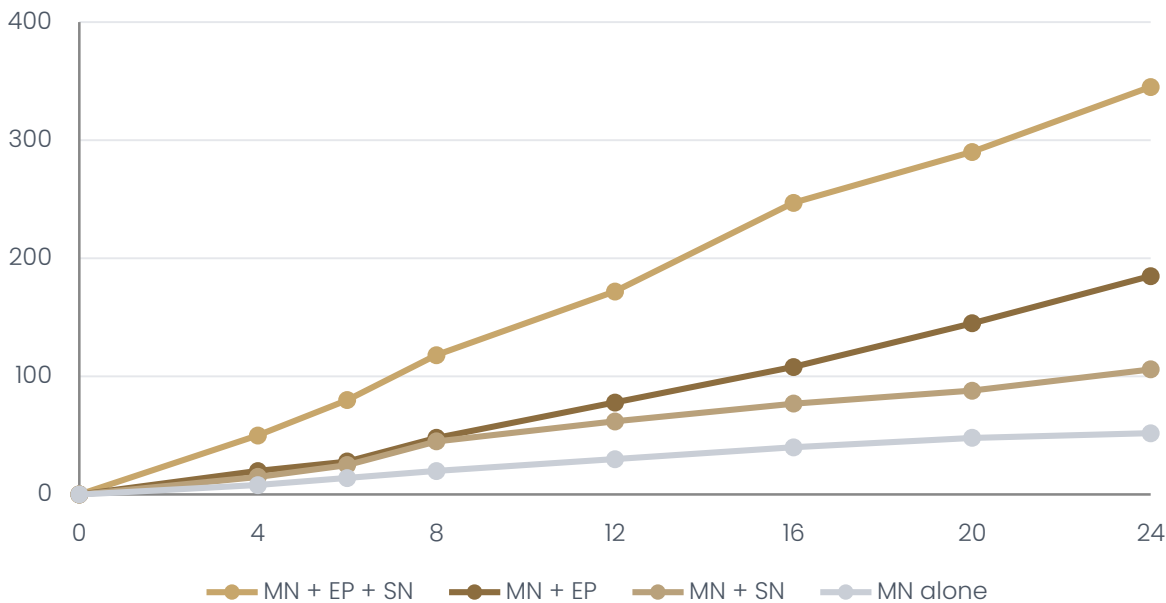
OPTIMISED SETTINGS

MN 10 N · EP 300 V (99 × 1 ms) · SN 20 kHz, 6.1 W/cm²

PERMEATION RATE · TABLE 3

Enhancement method	Flux (µg/cm ² /h)	R ²
MN	2.36 ± 0.55	0.995
EP	0.216 ± 0.085	0.975
SN	0.169 ± 0.040	0.967
MN + EP	7.58 ± 2.22	0.996
MN + SN	3.55 ± 1.12	0.996
EP + SN	0.485 ± 0.140	0.993
MN + EP + SN	16.58 ± 2.35	0.996

CUMULATIVE AMOUNT PERMEATED · µG/CM² VS TIME (H)



EP, SN, EP + SN and untreated skin stayed close to baseline (under ~15 µg/cm² at 24 h) and are omitted here for legibility. Curve values read from the published figure.

Highlighted rows: the one-, two- and three-mechanism progression.

Delivery rises stepwise as mechanisms are added — 2.36 → 7.58 → 16.58 µg/cm²/h — with no structural damage on histology.

SYNERJET

Three technologies combined in a single treatment platform

HIRONIC



01

Micro-jetting

Ultra-fast delivery at up to 580 m/s.
Minimized pain through a fine 180 μ m jet diameter.



02

Electroporation

Temporarily opens cell membranes with microcurrent stimulation, maximizing absorption through gentle electrical impulses.



03

Cold Plasma

Converts oxygen in the air into ions to enhance sterilization and skin absorption.

Barrier preparation, mechanical delivery and electrical uptake are applied in sequence within one pass.

1. PLASMA

How cold plasma prepares the stratum corneum for delivery



Plasma is a partially ionized gas containing high-energy ions, electrons and radicals, including reactive oxygen species and ozone (O_3).

Plasma reacts with the lipid components of the stratum corneum — such as ceramides and cholesterol — inducing oxidation and partial degradation.

1 LIPID LOOSENING

Loosening of the intercellular lipids between corneocytes.

2 SURFACE CHARGE

A change in surface charge makes the skin temporarily more hydrophilic.

3 ELECTRICAL IMPEDANCE

Reduced electrical resistance of the epidermis, with a measurable decrease in impedance.

The hydrophobic lipid layer of the skin barrier is temporarily loosened, creating an environment in which even hydrophilic drugs penetrate more easily.

1. PLASMA

Pico-laser-induced plasma versus NO gas / air plasma devices



Category	Pico-laser-induced plasma	NO gas / air plasma device
Energy source	Ultra-short pulse laser	High voltage, RF, DBD and other electric fields
Site of generation	Laser focus, around pigment particles, localized within or on the tissue	Around the gas flow or electrode, near the skin surface
Time scale	ns- μ s response following a ps pulse	ms-sec sustained or repetitive discharge
Plasma character	Instantaneous, high density, high temperature, capable of strong shock	Cold / non-thermal equilibrium, chemistry-driven
Main biological action	Photomechanical disruption, LIOB, shock wave, cavitation, pigment fragmentation	ROS/RNS, antimicrobial action, inflammation control, wound healing, permeability change
Thermal / mechanical intensity	Very high locally	Designed to remain low
Uniformity	Focus-dependent, spot and fluence dependent	Relatively wide and even surface treatment

Synerjet Pro uses the cold, non-thermal branch — chosen for permeability change rather than photomechanical disruption.

2. NEEDLE-FREE INJECTION

Velocity and pressure thresholds for skin penetration

100–200 m/s

SKIN PENETRATION THRESHOLD

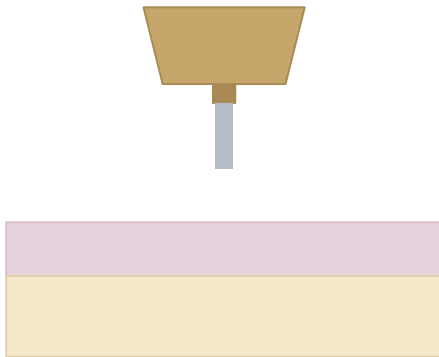
Below this velocity the jet spreads on the surface instead of entering the skin.

10–30 MPa

WORKING PRESSURE WINDOW

In this range the jet penetrates the skin and reaches the dermis to the subcutaneous layer.

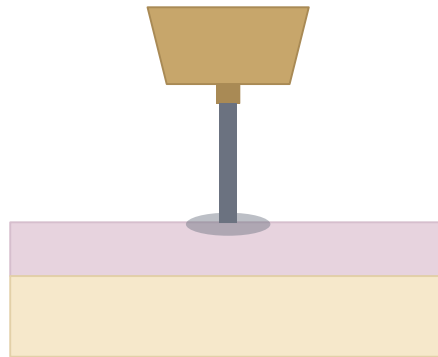
STAGE (a)



Jet formation

Liquid accelerates through the nozzle orifice and a coherent jet forms.

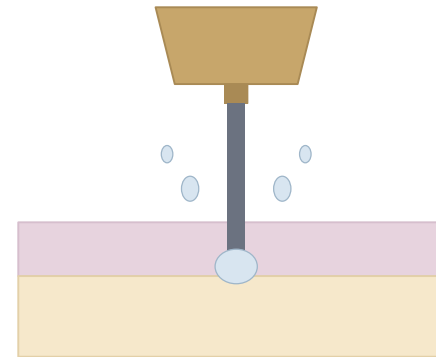
STAGE (b)



Impact

The jet strikes the stratum corneum and pressure builds at the contact point.

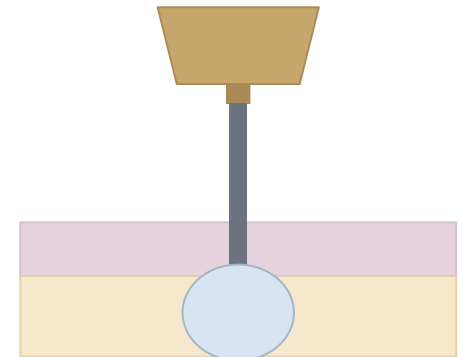
STAGE (c)



Hole formation

The barrier is breached and a narrow channel opens into the skin.

STAGE (d)



Dispersion

The remaining volume disperses as a bulb within the dermis and subcutis.

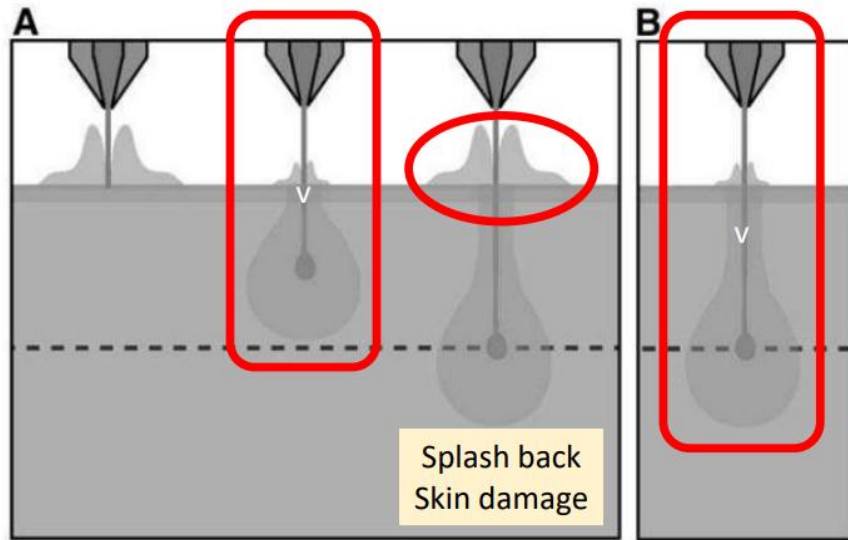
Redrawn after Figure 3, "Mechanism of a liquid injection". Skin layers shown schematically: dermis above, subcutis below.

Above this pressure range the risk of bleeding and hematoma formation increases sharply.

JET VELOCITY & PENETRATION DEPTH

The delivery window between shallow penetration and splash-back

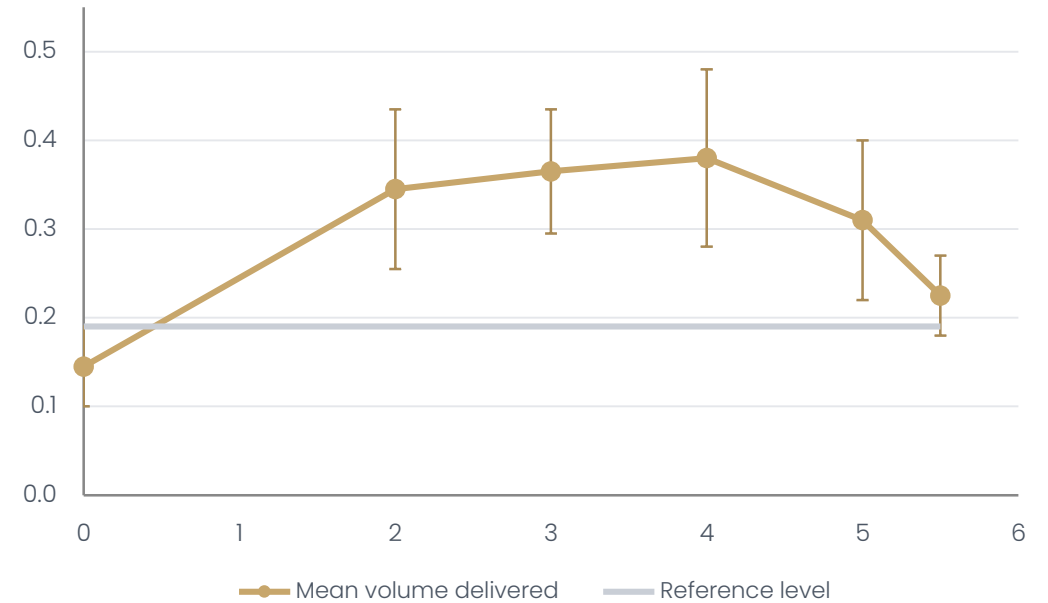
JET-TISSUE INTERACTION · THREE REGIMES



- Shallow penetration** — jet deposits on the surface, delivered volume stays low
- Best delivery** — jet penetrates fully, the bulb forms inside the tissue
- Splash-back & damage** — excess energy drives fluid back out, traumatizing tissue

Panels A and B from Stachowiak et al.; red marks are the author's emphasis on the two cases discussed.

VOLUME DELIVERED TO SKIN (μL) VS TIME AT HIGH SPEED (ms)



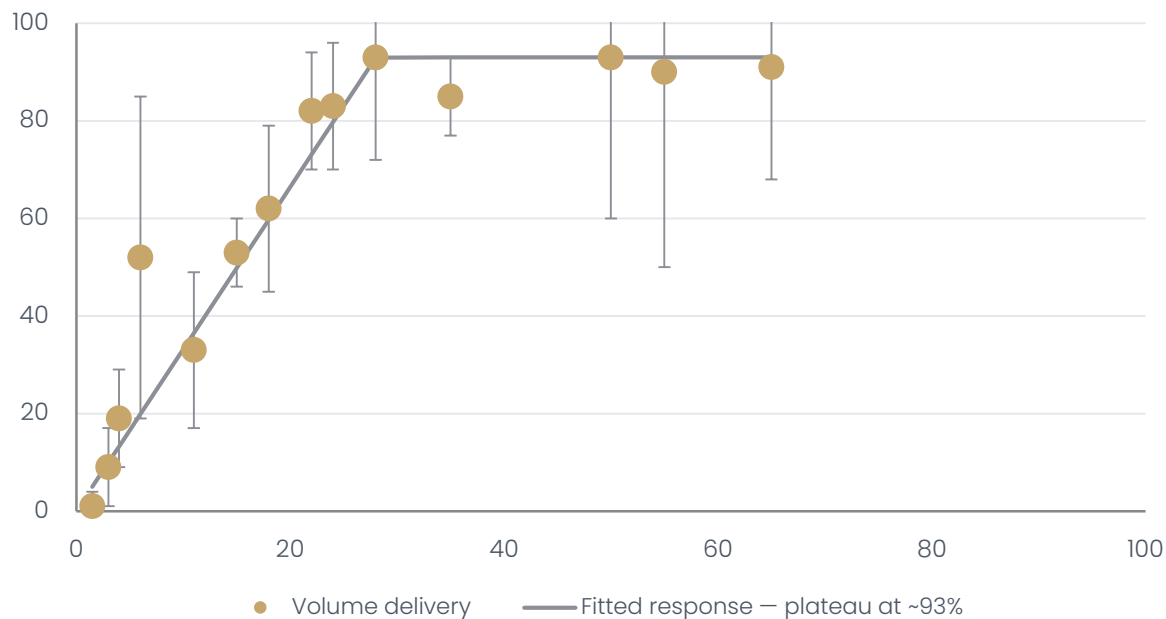
Error bars are the reported spread across replicates. The reference level ($\sim 0.19 \mu\text{L}$) is the delivery obtained without sustained high speed — points below it gain nothing from the shot.

Delivered volume peaks in a narrow window — too little speed leaves the dose on the surface, too much drives it back out.

JET POWER & VOLUME DELIVERY

Dependence of jet penetration into human skin on power at the nozzle exit

VOLUME DELIVERY (%) VS POWER AT NOZZLE EXIT (W)



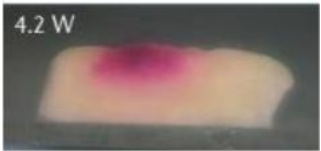
Error bars are the spread reported in the source figure and are wide at several powers — the individual points are far less separated than the trend suggests. Values read from the published graph.

DISPERSION PATTERN IN THE SKIN · BY JET POWER



1.5 W

Extremely shallow — penetration of only a few tens of μm .



4.2 W

A small, compact deposit forms just beneath the surface.



9.3 W

Hemispherical dispersion pattern spreading from the entry point.



37.1 W

Full spherical dispersion pattern deeper within the tissue.

Panel b reproduced from the source figure. Depth and profile also depend on ejection volume and stand-off distance, held constant in this experiment.

The share of the ejected 80 μL that enters the skin rises with power and plateaus at approximately 30 W.

SHOT VOLUME & PENETRATION

How the volume of a single shot changes depth, diffusion and safety



Category	Outcome	Clinical implication
Shot volume 2–3 μL	Consistent penetration depth; uniform distribution within the epidermis	Improved safety and more precise control of the treatment area
Shot volume $\geq$ 8–10 μL	Slightly increased penetration depth; increased tissue diffusion and bleeding	Greater risk of PIH, vascular injury and pain
At the same jet velocity	Increased injection volume $\rightarrow$ longer pressure duration $\rightarrow$ greater cumulative tissue stress	Greater potential for bruising caused by needle-free injection

Fractionated delivery using multiple low-volume pulses, rather than a single large-volume injection, provides a safer and more uniform treatment outcome.

Volume is a safety parameter before it is an efficacy parameter.

FREQUENCY

Shot interval, plunger recovery and the resulting skin response



Frequency	Shot interval	Plunger recovery	Pressure stability	Skin response	Clinical applicability
1–5 Hz	200–1000 ms	Complete	Stable	Very safe, less pain	Very stable — suitable for facial procedures
10–15 Hz	66–100 ms	Nearly complete	Slightly reduced	Mild erythema, uniform penetration	Practical
20–30 Hz	33–50 ms	Partial	Reduced amplitude	Increased edema and bruising	Limited use
≥ 40–50 Hz	20–25 ms	Incomplete	Unstable	Risk of bleeding and traumatic injury	Not recommended

Solenoid-based needle-free injectors show optimal stability at 5–15 Hz. Above this range, incomplete plunger recovery and the risks of cutaneous microinjury and drug reflux (splash-back) increase markedly.

Frequency is chosen for plunger recovery, not for treatment speed.

3. ELECTROPORATION

Reversible nanopore formation in the lipid barrier

01 Electrical tension

Short high-voltage pulses (μs – ms) applied to the skin generate electrical tension across the phospholipid bilayer of the cell membrane.

02 Nanopore formation

Transient nanopores open, allowing the drug to cross both the cell membrane and the lipid barrier of the stratum corneum.

03 Reversible closure

The pores close again within μs – ms , so the entire effect is reversible and the barrier is restored.

ENHANCEMENT OF TRANSDERMAL PERMEATION BY ELECTROPORATION

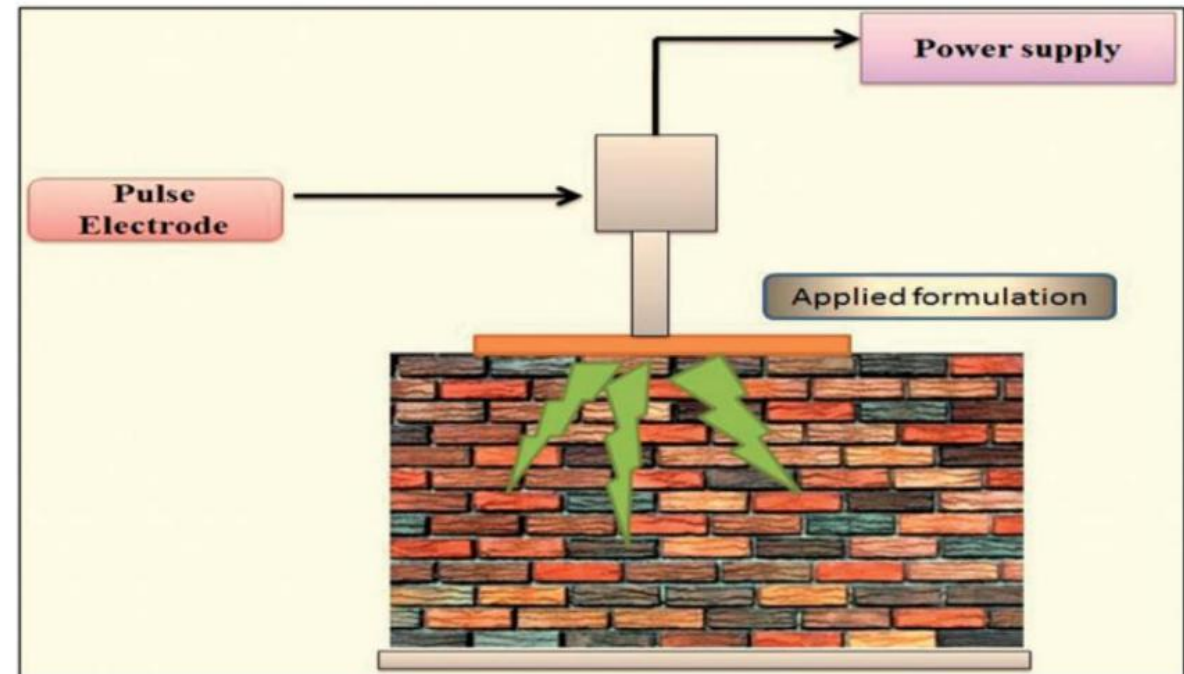
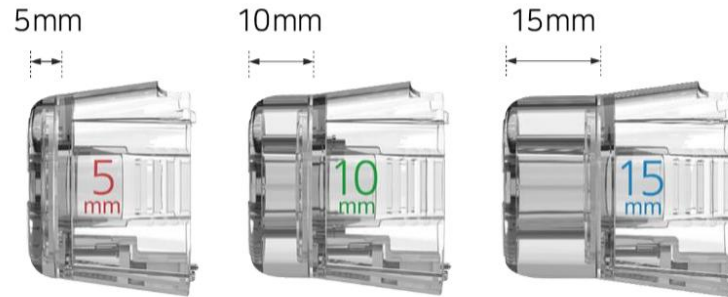


Figure 8 — Enhancement of transdermal permeation by the electroporation technique. The stratum corneum is shown as a brick-and-mortar barrier; the pulse drives the applied formulation through it.

The pores close within μs – ms — the barrier is opened for the duration of the pulse, not permanently breached.

EP TIP

Three stand-off distances for control of depth and spread



5 mm

Contact-range delivery

The shortest stand-off concentrates energy and reaches the deepest — used for scars and striae with contact shots.

10 mm

Standard working distance

The balanced setting used in the comparative clinical study; combines depth with a controlled spread.

15 mm

Widest, most superficial

The broadest and shallowest spread — the basis of the shallow-penetration rejuvenation protocol.

Stand-off distance is the primary depth control before power or volume are touched.

STUDY DESIGN

Plasma → needle-free injection + electroporation, split-face comparison

Plasma → needle-free injection + electroporation, split-face comparison



TEST GROUP · RIGHT SIDE

GOURI cosmetic mixed with normal saline at 1:2, 1.5 cc applied to the right side of the face.

1) PLASMA – 2 PASSES

Mode	Power	ON time	Repetition
Continuous	2	0.5 sec	0.5 sec

2) SPRAY WITH SJ 10 MM EP TIP, UPTAKE BY ELECTROPORATION

Distance	Power	Hz	Volume	EP level
10 mm (EP tip)	150	10	2.0	2

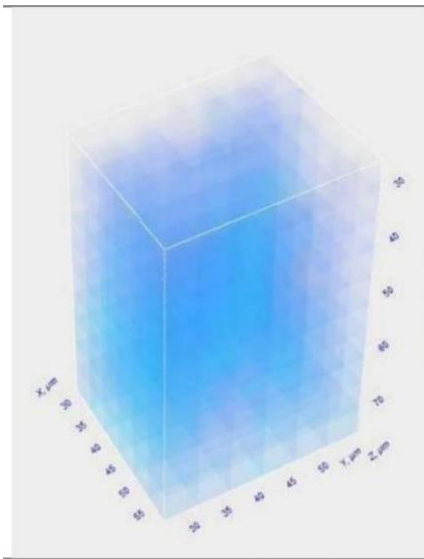
CONTROL GROUP • LEFT SIDE

Same mixture. Sprayed with SJ at a 10 mm stand-off, then absorbed by rubbing with a gloved hand.

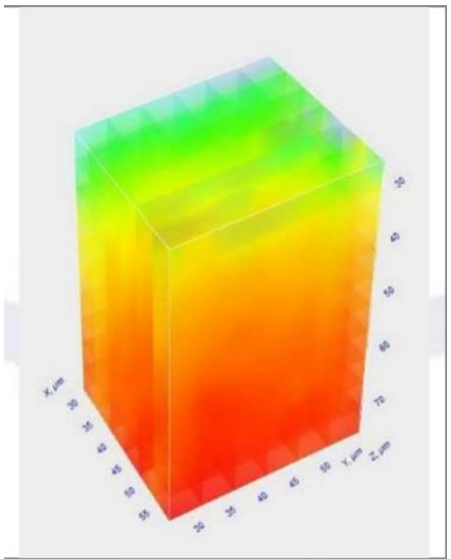
Distance	Power	Hz	Volume	EP level
10 mm (no EP tip)	150	10	2.0	X

3D Raman spectroscopy · skin absorption

Before use



After a single use



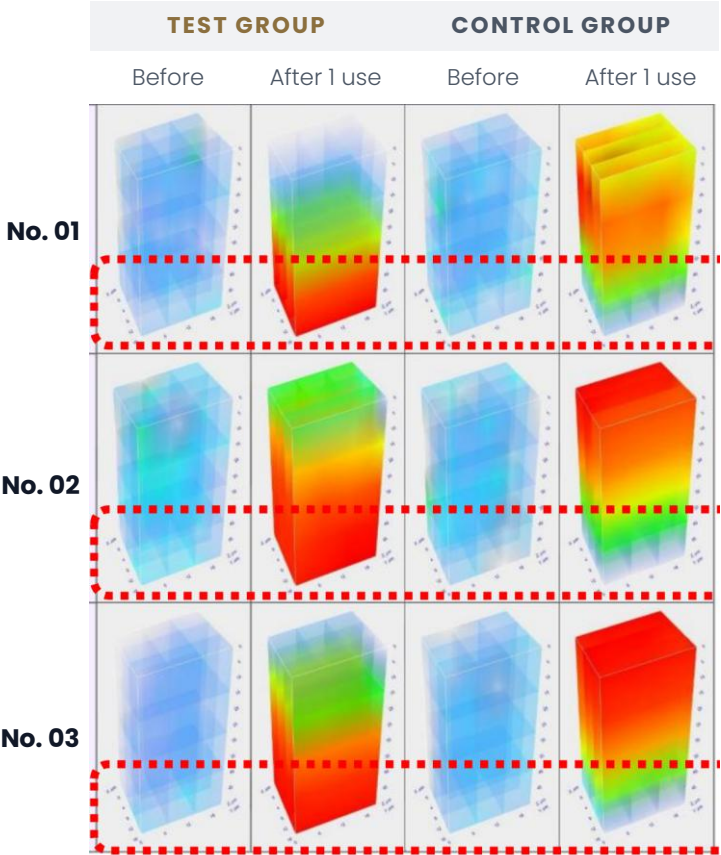
Warmer colour indicates higher absorbed concentration through the measured depth of the skin volume.

Plasma pre-treatment followed by jet delivery with electroporation produced a visibly deeper absorption profile after one session.

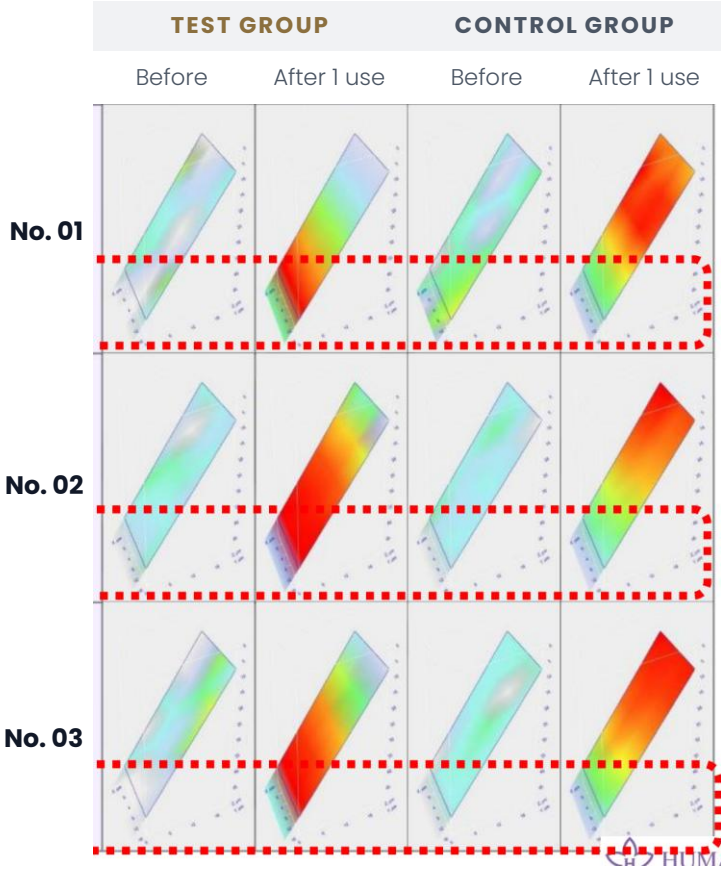
3D RAMAN SPECTROSCOPY

Skin absorption depth — 3D volume and cross-sectional imaging, three subjects

3D absorption volume



Cross-sectional view

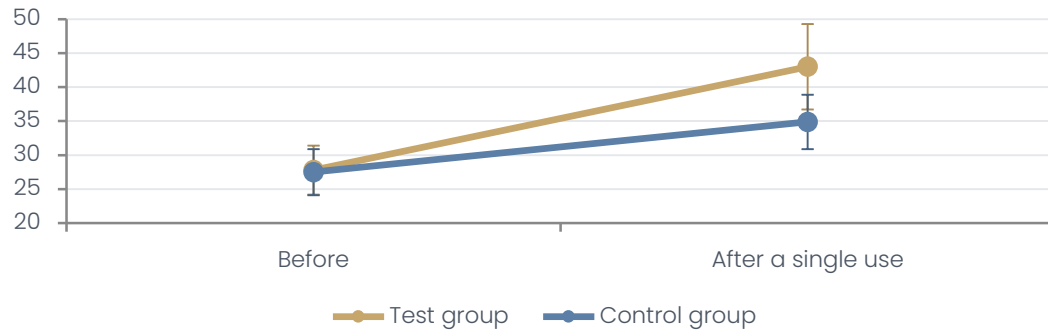


Across all three subjects the test side shows a deeper and more uniform absorption profile than the control side.

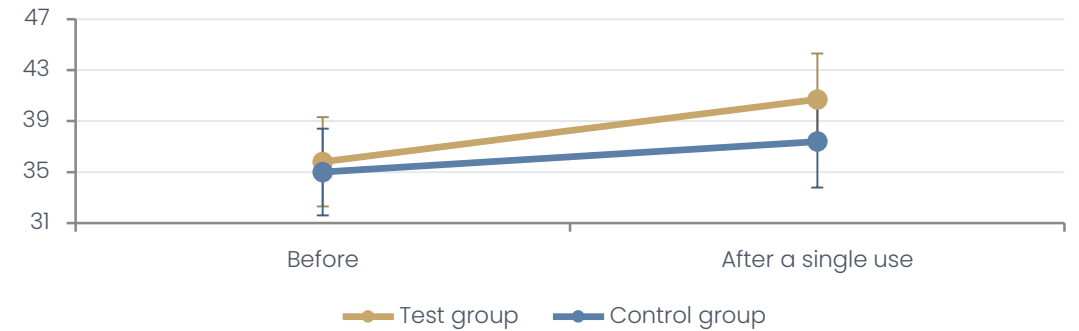
SKIN HYDRATION OUTCOMES

Single-use split-face comparison — test group versus control group

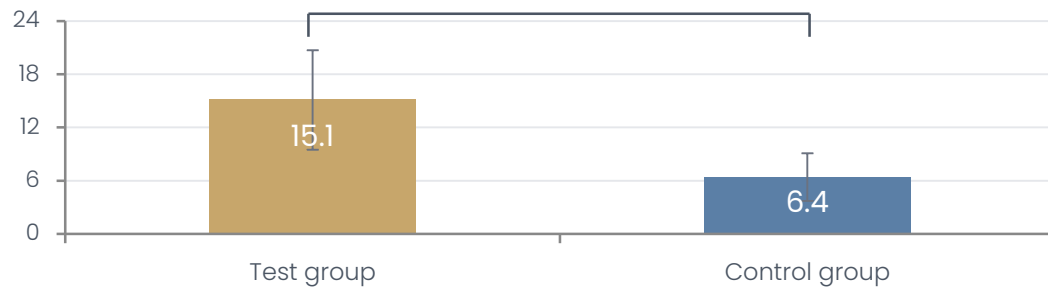
SURFACE SKIN HYDRATION · MEAN PERMITTIVITY (ϵ)



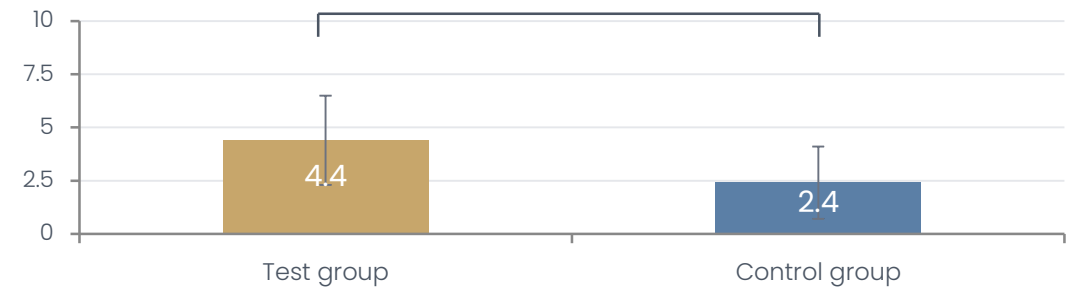
DEEP SKIN HYDRATION · TISSUE DIELECTRIC CONSTANT (TDC)



Δ SURFACE HYDRATION · AFTER MINUS BEFORE
**



Δ DEEP HYDRATION (TDC) · AFTER MINUS BEFORE
**

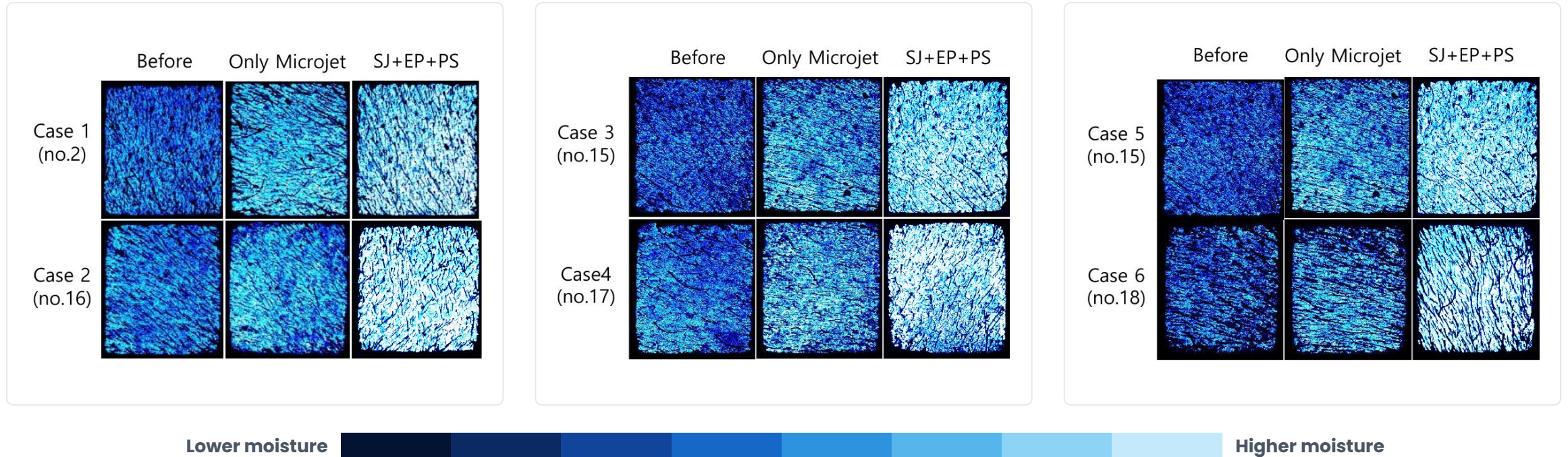


Both groups improved after a single use, but the gain in the test group was roughly twice that of the control on each measure.

* $p < 0.05$ versus initial value. ** $p < 0.05$ between groups. Error bars as reported; values read from the source graphs. Clinical testing: HUMAN Clinical Trial Center.

MICRO-JET ALONE VS TRIPLE TECHNOLOGY

Difference in surface hydration improvement — micro-jet only versus Synerjet (PS + SJ + EP)



In every case the triple-technology column (SJ + EP + PS) is markedly brighter than the micro-jet-only column, indicating a higher surface moisture level after a single session.

Measurement device: Epsilon EI00 (Biox Systems Ltd., England). Test product: GOURI cosmetic (PCL).

SHALLOW PENETRATION PARAMETERS

Baseline settings for superficial rejuvenation work



TIP

15 mm EP tip

The widest stand-off, giving the broadest and most superficial spread.

POWER

120 – 140

Enough to cross the barrier without driving the jet into the reticular dermis.

VOLUME

1.4 – 1.6

Low shot volume keeps penetration depth consistent and diffusion controlled.

FREQUENCY

10 – 15 Hz

Within the stable band for plunger recovery — uniform penetration, mild erythema.

ELECTROPORATION

EP level 3

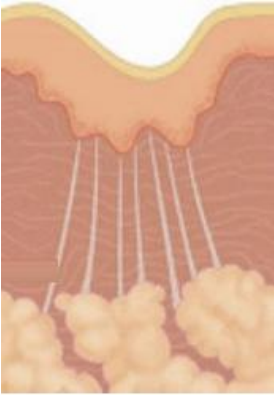
Maximizes uptake of what has already been placed in the superficial layers.

Depth is set by tip distance first, then trimmed with power and volume — never the other way round.

JET SUBCISION

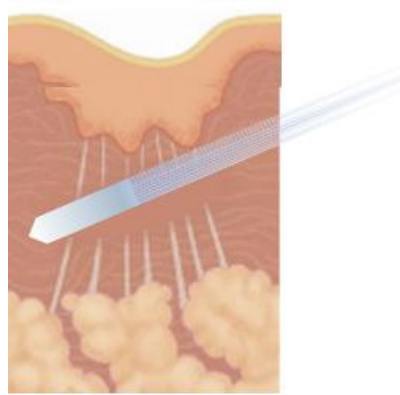
Mechanical release of fibrotic bands combined with agent delivery

In atrophic acne scarring, fibrous bands tether the skin surface to deeper tissue. The jet releases these bands mechanically while simultaneously delivering the therapeutic agent into the released space.



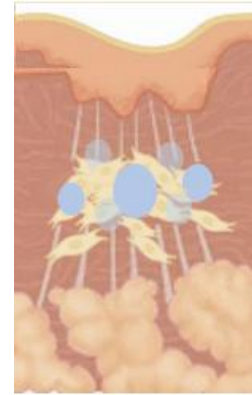
01 Pre-treatment

Fibrotic acne scarring with fibrous scar tissue bands tethering the depressed surface downward.



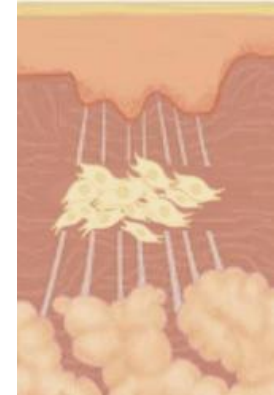
02 Jet subcision

Fibrotic band release, plus therapeutic agent delivery and an immediate volume fill-up effect.



03 Wound healing

An enhanced wound healing response drives enhanced new collagen formation in the released space.



04 Collagen deposition

Collagen deposition consolidates the correction and the scar depression is lifted.

Release, fill and stimulate in a single pass — the mechanical effect of the jet is itself part of the treatment.

Fibrous scar tissue bands are shown as the pale strands running from the depressed surface down into the subcutis.

PNEUMATIC INJECTION FOR ATROPHIC ACNE SCARS

Comparison of normal saline injection with a pneumatic injector versus needle subcision

EFFICACY

One session of needle subcision yields similar scar resolution to three sessions of pneumatic injection with normal saline.

The needle-free route needs more sessions, but each one is far less traumatic.

TOLERABILITY

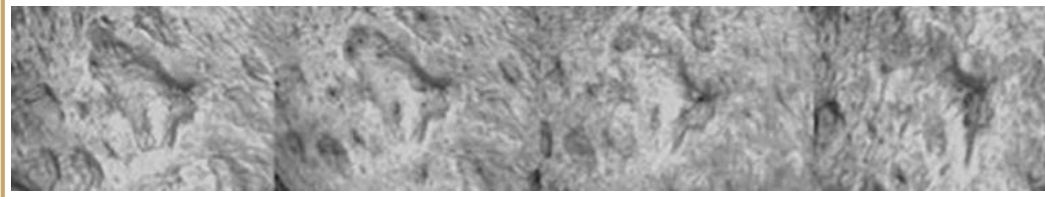
Pneumatic injection with normal saline showed good efficacy, minimal adverse effects and minimal pain on moderate-to-severe scars.

The trade-off is session count against downtime, bruising and patient comfort.

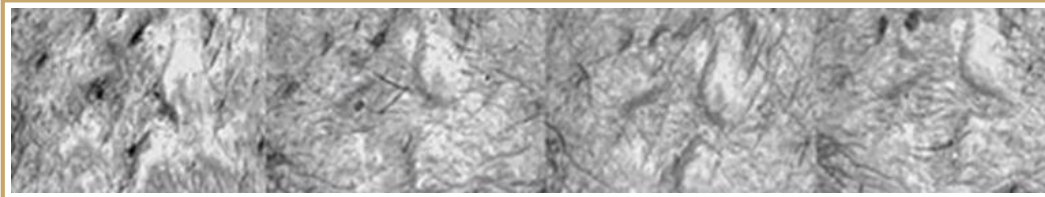
PNEUMATIC INJECTOR · normal saline, 3 sessions

Week 0 Week 4 Week 8 Week 12

Boxcar



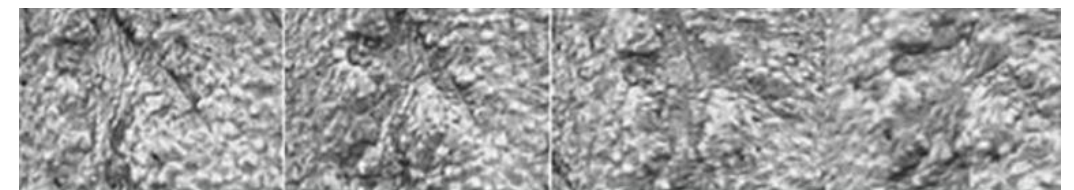
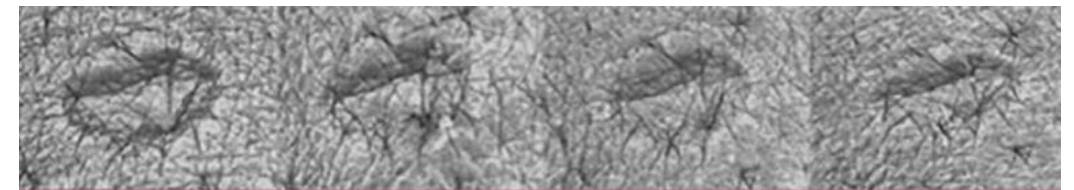
Rolling



Gold outline marks the pneumatic-injector arms — the comparison the lecture draws on.

NEEDLE SUBCISION · 1 session

Week 0 Week 4 Week 8 Week 12



Study design: split-lesion comparison assessed with Visioscan VC 98 imaging at weeks 0, 4, 8 and 12 on boxcar and rolling acne scar types.

Needle-free subcision is a credible alternative where pain, bruising and downtime drive the treatment choice.

Pravangsuk J, Udompataikul M, Cheyasak N, Kamanamool N. — J Clin Aesthet Dermatol. 2021;14(5):50–55. Visioscan images from Figures 1–4.

NEEDLE VERSUS NEEDLE-FREE JET INJECTOR

Polynucleotide filler for skin rejuvenation — split-face comparison

CLINICAL RESULT · BEFORE AND AFTER



(A) · (B) clinical photographs from the study

The source slide carries no before/after labelling for these two frames — confirm against the article before captioning them in the talk.

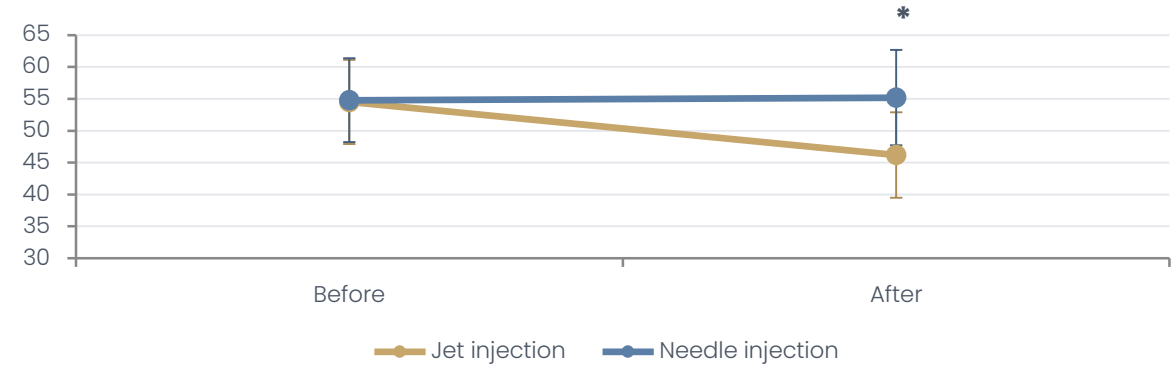
A more pronounced improvement rate was observed on the needle-free injector side compared with the needle injection side, for both pore and wrinkle indices.

* $p < 0.05$ ** $p < 0.01$, jet versus needle side after treatment.

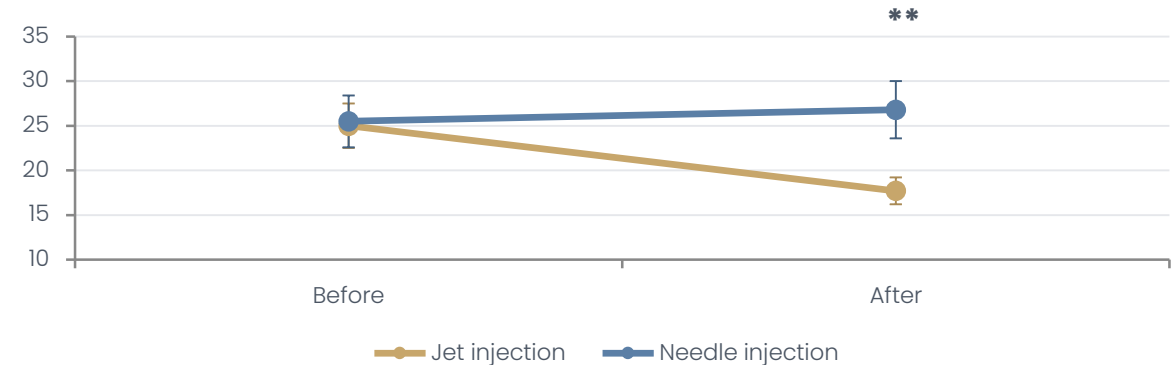
Error bars are wide at baseline — the separation appears after treatment, not before.

Hong J.Y., Lee Y.H., Kim H.-J., Park K.Y. — Therapeutic Performance of Needle Injection Versus Needle-Free Jet Injector System for Polynucleotide Filler in Skin Rejuvenation.

PORE INDEX



WRINKLE INDEX



For polynucleotide skin boosters, the delivery method itself changed the outcome.

POTENTIAL EFFECTS OF SYNERJET ON THE SKIN

Device-driven effects independent of the agent being delivered



Mechanism of action	Expected effects	Remarks
Plasma stimulation	Superficial exfoliation, melanin suppression and antimicrobial effects	Mechanistically similar to plasma skin resurfacing
Solenoid jet pressure stimulation	Mild fibroblast stimulation leading to micro-collagen remodeling	Depends on jet settings, including pressure and shot number; may resemble micro-subcision
Electroporation-mediated electrical stimulation	Repolarization of the cell membrane, resulting in enhanced metabolic activity and ATP production	May improve skin vitality and radiance
Combined stimulation	Epidermal regeneration, enhanced transdermal delivery and increased microcirculation	May provide temporary improvement in elasticity, skin glow and texture

The device contributes effects of its own — which is why it is a platform rather than a syringe substitute.

CLINICAL PROTOCOL

From one of our KOLs. Two settings chosen by what the patient is prioritising.

PRIORITY: PAIN & DOWNTIME

If minimizing pain and downtime is the priority

AGENT

Skin booster — Celexo-cica (exosome), K-booster and similar

Power	110 – 140
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Volume	1.2 – 1.4
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Frequency	12 – 20 Hz
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High frequency with low volume keeps each shot small and the treatment comfortable.

PRIORITY: EFFECTIVENESS

If effectiveness matters more than pain and downtime

AGENT

Scar & skin tightening — PNRN, PN, PDLLA, PCL and similar

Power	170
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Volume	2.0
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Frequency	1 – 3 Hz
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Low frequency with full plunger recovery allows maximum pressure per shot.

The same device, two opposite parameter families — chosen by indication, not by habit.

Settings shared from clinical practice; they are not a manufacturer recommendation and should be adapted to the individual patient.

LEGAL ISSUES OF SKIN BOOSTERS

The Korean regulatory framework that applies to device-assisted application

Statute	Article	Key wording
Cosmetics Act, Art. 2 (Definitions)	Item 1	Articles used by applying, rubbing or spraying onto the human body or by similar methods , having only a mild action on the body
Medical Devices Act, Art. 2 (Definitions)	Item 1	Instruments, machines and apparatus intended to affect the structure or function of the body
Medical Service Act, Art. 27 (Prohibition of unlicensed practice)	—	No person other than a licensed medical practitioner may perform a medical practice
Cosmetic Labelling & Advertising Guideline (2025 revision)	Art. 4	Expressions such as treatment, regeneration, penetration or drug delivery are not permitted as cosmetic efficacy claims

- 1 Application assisted by a device may fall within the phrase **“or by similar methods”** in the Cosmetics Act definition.
- 2 If the purpose of the device is read as **inducing penetration or affecting skin structure**, it may fall under the **Medical Devices Act** or be classified as a **medical practice**.
- 3 It is therefore safest to keep three elements explicit at the stage of protocol design, advertising and wording:

Epidermal application

+

Mild action on the body

+

Cosmetic purpose

Hold all three together and the procedure stays cosmetic; drop any one of them and it can be read as a medical act.

LEGAL ISSUES OF COSMETIC SKIN BOOSTERS

Three questions that decide which regulatory regime applies

INTENDED USE IS DECISIVE

“Simple application (cosmetic)” versus “penetration or therapeutic purpose (medical use)” changes the regulatory category.

If a device is used with the purpose of driving cosmetic ingredients into the epidermis, regulators are unlikely to treat the procedure as a simple cosmetic application.

POSSIBLE RECLASSIFICATION

A medical device combined with a cosmetic may be treated as a combination product.

That can mean safety and efficacy evidence is required for both components, or that the pair is reclassified as a drug or a medical device. The device itself remains subject to medical-device approval and review.

LIABILITY & MEDICAL PRACTICE

If an adverse event occurs, medical response, reporting and legal liability follow.

The exposure arises from the invasiveness of the procedure and the entry of the substance into the body. Performance by a non-medical practitioner may constitute unlicensed medical practice.

Keep the intent, the claim and the operator consistent with one another — that is what the regulator actually examines.

Republic of Korea — regulatory position as summarised for this lecture; not legal advice.

KEY INSIGHTS

Synerjet Pro in one page

SHIRONIC

01

More than a delivery tool

A platform with device-driven effects of its own — plasma, jet pressure and electroporation each act on the tissue.

02

Jet velocity & volume control the outcome

They set penetration depth and delivery efficiency; frequency and stand-off distance keep both stable.

03

Extends from skin quality to scars

Agent selection and technology combination still decide the result more than the device alone.

04

Cosmetic-type and injectable boosters differ

One is device-centered, the other indication-centered — and they sit under different regulatory regimes.



Beyond a needle free injector

Mechanism of Action & Clinical Versatility of SYNERJET PRO™

