FC12-02: The Use of a Jet-Phoresis Transderm Delivery System for Delivery of Actives

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Conflict of Interest

- Dr. Gold is a Visiting Professor of Dermatology, Huashan Hospital, Fudan University (Shanghai Medical University), Shanghai, China (12/06), and The First Hospital of China Medical University, Shenyang, China (11/08)
- Dr. Gold is a consultant, speaker and has performed research for TavTech
- Dr. Gold is also a consultant, performs research and speaks on behalf of numerous pharmaceutical and medical device companies

Barophoresis in Skin Rejuvenation

What Patients Want in 2011 When it Comes to Treating the Skin & Making One Look Better

- Improvement in their skin
- Subtle not dramatic changes
- Gradual improvement
- Minimal downtime
- No pain
- No risks

Jet Peel's key features

- 1. The painlessness of its mechanical peeling procedures
- 2. Its ability to perfuse sanative supplements transcutaneous without needles
- 3. The performance controlled deep 3 dimension painless peeling, by using mild acids
- 4. The treatments of local lesions aging and sun damage spots, pigmentations, wrinkles
- 5. Assistance in new scars development and old scars diminution
- 6. Acne and post acne scars treatment
- 7. Enhancing lasers, lights and RF technologies
- 8. Absence of hyperemia and skin shedding, viral and septic complications

Jet Peel's new features

- 1. The use of the Jet Peel for drug delivery
 - A. That implies many different agents can be infused with the device
 - B. Topical anti-aging products
 - C. Perhaps toxins and other medicines
 - D. Lidocaine for pain control without needles



Multi-Function Skin Rejuvenation System

- Lymphatic drainage
- 3DVC Multi-dimensional exfoliation
- Deep cleansing
- Oxygen and CO2 therapy
- Transcutaneous supplementation



An innovative, personalized, treatment program, based on advanced technologies

 Simultaneously introduces active nutrients, oxygen, and physiological stream into the skin, using pressure and air

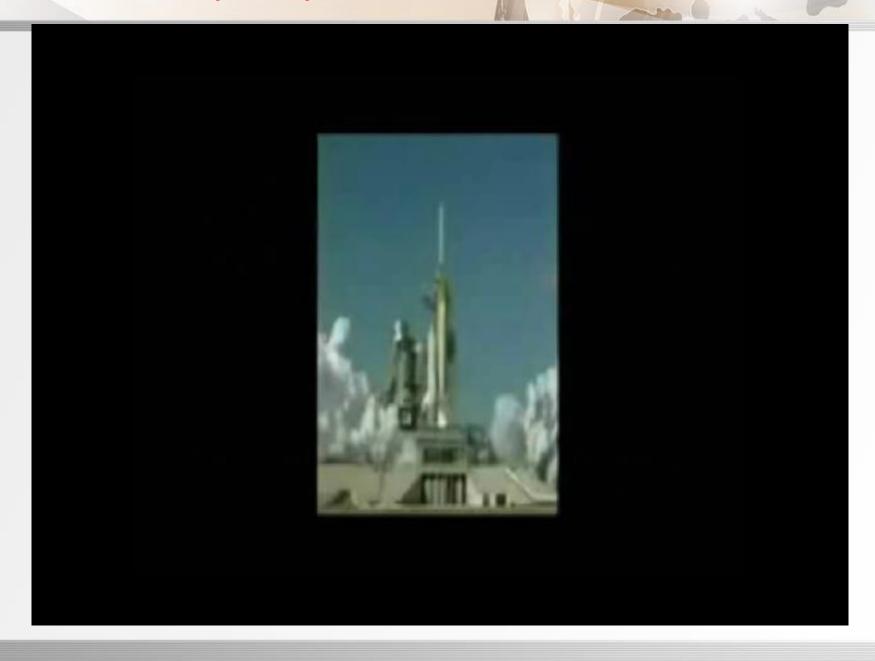
JetPeel - Basic principles

- Pressurized gas is used to accelerate a liquid agent (saline).
- Water droplets accelerated to supersonic velocities (200 m/s)
- The mixture of liquid and gas is emitted through a special nozzle unit.
- The high velocity jet exfoliates the superficial layers of the skin
- * Patented

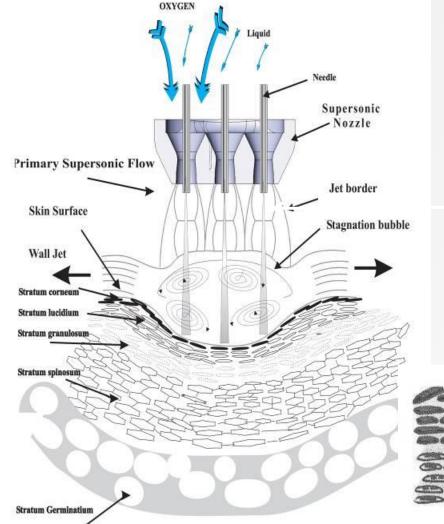
Supersonic Jet Technology

- Supersonic two-phase jet directed onto the skin with specialized handpieces and nozzles.
- Jet Spray consists of micro droplets of saline or supplements and gas (air, oxygen or CO2).
- High velocity spray induces skin rejuvenation through exfoliation and supplementation.

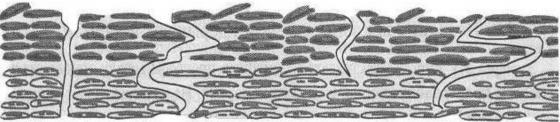
JetPeel - Basic principles - Video



JetPeel - Basic principles



Supersonic jet flow Opens intercellular channels



Skin Rejuvenation

Goal:

Restore youthful function and appearance

How:

- Reduce cellular buildup
- Exercise and strengthen capillary respiration
- Remove metabolic waste from tissues
- Hydrate, oxygenate tissues
- Provide nutritional support and protection
- Energize cell renewal and wound healing process

Where Innovation, Science and Results Meet



The nutritional elements that are used include:

- Hyaluronic acid, which enriches the natural connective tissue
- Vitamin C, which improves the cell's ability to even out pigment

Vitamins E, B, and A, which are important ingredients for the proper functioning of cells

Barophoresis in Skin Rejuvenation - JetPeel

Before

After 3 treatments (2 weeks after last session)



Barophoresis in Skin Rejuvenation

Before

After three treatments





Barophoresis in Skin Rejuvenation - JetPeel



65 year old woman : Crow's feet Before and after one treatment

Study Design – Pain Control Using Barophoresis

- Prospective clinical study to compare lidocaine jetphoresis trans-cutaneous anesthesia to EMLA 5% topical cream
- 20 patients that were scheduled to undergo needling roller for upper lip rhytids enrolled into study
- Each patient served as own control so 40 lips evaluated

Results

- Statistically significant advantage of pain control in the lidocaine jet-phoresis group compared to EMLA group (p<0.005)
- Jet-phoresis lidocaine pain control was better or comparable to EMLA in > 82% of lips
- Further confirmed reversing the sides of the tested lips in the same subjects



- Study supports observation for the jet-phoresis system allowing penetration of the cutaneous barrier and delivering actives into the skin
- Lidocaine in this study worked better with jetphoresis than topical lidocaine in this small prospective study
- Further, larger clinical trials needed to determine optimal strengths of lidocaine which can be used and for other actives to be delivered into the skin

Jet-Phoresis Lasers Surg Med 2010; 22:97



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THE USE OF A JET-PHORESIS TRANSDERMAL DELIVERY SYSTEM FOR PAIN CONTROL Michael Gold, Ram Burvin

Gold Skin Care Center, Tennessee Clinical Research Center, Nashville, TN, Craniofacial Plastic Surgery, Jerusalem, Israel Background: Conventional cutaneous numbing using topical xylocaine formulations is an extremely popular practice prior to medical or cosmetic procedures obliveating the use of sub-dermal needle injections.

Study: This prospective study was undertaken to compare prospectively lidocaine jet-phoresis trans-cutaneous anesthesia

THE USE OF A JET-PHORESIS TRANSDERMAL DELIVERY SYSTEM FOR PAIN CONTROL Michael Gold, Ram Burvin

maximal anesthetic effect. The contra-lateral portion of the lip was treated with lidocaine 3% jet-phoresis for 5 minutes. Pain in the upper lip was elicited with needling roller uniformly applied to the whole of the upper lip. Pain response was measured using standardized pain ruler.

Conclusion: There was statistically significant advantage of pain control in the lidocaine jet-phoresis group compared to the EMLA group (p < 0.005). Jet-phoresis lidocaine pain control was better or comparable to EMLA cream, in more than 82% of lips (In 14 lips better, in 19 lips comparable, and in 7 lips less). This was further confirmed reversing the sides of the tested lips in the same subjects. We noticed marked improvement in anesthetic effect using higher 3% licodaine concentration. This study confirmed that: 1) Jet-phoresis facilitates cutaneous pre-operative anesthesia in a very short 5 min. application, in contrast to common practiced non-invasive time consuming methods, and 2) Jet-phoresis concept is painless, soothing experience, and easily applicable in an out-patient office setting.

Jet Peel – The Future

- 1. Jet Peel Lidocaine infusion $\sqrt{}$
- 2. Jet Peel Botulinum Toxin for hyperhidrosis

TavTech Research Project – 2010 Tennessee Clinical Research Center, Nashville, TN

- The Safety and Efficacy Evaluation of the JetPeel Device in Transdermal Delivery of Glycolic Acid as a Skin Conditioning Agent
 - IRB Study
 - One treatment; 16 patients enrolled
 - Follow-up evaluations at 7 days and 4 weeks
 - Physician and patient assessments
 - Results strong for safety and efficacy

TavTech Research Project – 2010 Tennessee Clinical Research Center, Nashville, TN

- Results:
 - Skin Radiance: 87.5% improvement in 1 week;
 93.8% improvement at 4 weeks
 - Skin Smoothness: 100% improvement at 1 week
 - Pore Appearance: 81.3% improvement at 1 week
 - Evenness: 81.3% improvement at 1 week
 - Overall Appearance: 87.5% improvement at 1 week; 100% improvement at 4 weeks

TavTech Research Project – 2010 05 RCW – One month post treatment



Photos courtesy of Michael H. Gold, M.D. Tennessee Clinical Research Center, Nashville, TN

TavTech Research Project – 2010 05 RCW – One month post treatment



Photos courtesy of Michael H. Gold, M.D. Tennessee Clinical Research Center, Nashville, TN

TavTech Research Project – 2010 05 RCW – One month post treatment



Photos courtesy of Michael H. Gold, M.D. Tennessee Clinical Research Center, Nashville, TN

Thank you

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