Clinicals:Report on Stretch mark reduction treatment through Dermoelectroporation

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Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of Placentex® for stretch marks reduction treatment through Dermoelectroporation®.

Study Design

- Heavy stretch marks patient were treated
- 1 patients to follow-up in 20 days.
- Placentex® *(Mastelli Farmaceutici, Italy).*
- Ultrapeel® Transderm® Meso System
- Severe stretch marks were treated
- Session number depending on the single patient's condition
- Study conclusion on 90% or more resolution of the affected sites

Fig.1- Before

Materials and Methods

Materials

• Placentex® *(Mastelli Farmaceutici, Italy).*

•Ultrapeel® Transderm Meso® system from Mattioli
Engineering

Methods

•Transdermal delivery of the Placentex® through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion
b)Transdermal delivery of the Placentex® through Ultrapeel® Transderm Meso® system.

•Application of proper SPF at the end.

Fig.2- Local hyperemia post microdermabrasion

Fig.3- scarring – 7 days after

Fig.4 - Result at 15 – 20 days (zoomed)

Results & Conclusions

•1patient was treated with the following results:
1 patient cleared in 1 session.

• The subject was very happy about results

• Transdermal delivery **is possible and safe with no contraindications reported.**

• The patient showed a good level of improvement and she was so happy with results.

Clinicals: Report on Inner Arm excess skin relaxation treatment through Dermoelectroporation

Dr. A.Gessati*,

*Aesthetic medicine Doctor, Milan, Italy.

Preliminary Study

Dermoelectroporation, well known and established method for transdermal substances delivery without the use of needles, allows to get to important results for skin imperfection conditions, such as the inner arm areas relaxation (with the formation of bands of tissue in excess), which are often solved only through surgical methods.
The correction of excessively relaxed skin, related to the loss of elastic features and support, requires biorevitalizing substances transdermal delivery(REVITALASE) commonly injected through a syringe, due to Ultrapeel Transderm Meso system device endorsing Dermoelectroporation technology.
We developed an operating protocol Synergyzing the effect of biostimulanting substances driven through the skin with LED device(OMNILUX REVIVE 633 nm) able to to affect the cellular response.

Study Design

- 5 patients were treated to follow-up every week.
- Revitalase from Mattioli engineering -Italy)
- Ultrapeel® Transderm® Meso System
- Weekly Session (depending on the single patient's condition) for a total of 5 to 8 sessions.
- 20mins application each session (AVG).
- Treated areas : Hips, legs and abdomen.

Materials and Methods

Materials

- Revitalase (*Mattioli engineering*)
- Ultrapeel® Transderm® Meso System(*Mattioli engineering*)

Methods

- *Pre-Sterilised corundum crystals Microdermabrasion up to reach a strong hyperemia .*
- *Transdermal delivery of REVITALASE – (*
- *Hyaluronic acid enriched by Tissue growth factors)*
- *Red LED Photo-biomodulation 633+/-6 nm.*
- *1 session per week for a total of 5-8 sessions* depending on the single patient.

Before

After

Results

Significant decreasing of the patient's cellulite sections and areas.

Result Assessment : Good according to single patient's satisfaction grade.

Conclusions

The present study proved the transdermal delivery of Revitalase through Ultrapeel® Transderm® Meso System is safe, possible and effective.
The administer therapy is :
- Easy to perform.
It doesn't show up any problem either during or after the administration and It is well tolerated This methodology:
- non invasive.
- Pain Free.
- No side effect reported.

Clinicals:Report on Actinic Keratosis reduction treatment through Dermoelectroporation

Dr. Gabriela Vasilescu, M.D.
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Through **Dermoelectroporation®**, the one and most innovative method for transdermal delivery of water based active ingredients into the body without needles, very important results have been acheived when fighting skin imperfections, elder and actinic keratosis normally cancelled using surgery.

All our experiences in treating Actinic keratosis thru **Dermoelectroporation®** have been carried out thru the ose of a microdermabrader (till medium Hyperemia) and Transdermal delivery of skin rigeneration ingredients (Placentex® Mastelli), amino acids, Hyaluronic acid normally injected by syringes, driven through **Transderm®** endorsing **Dermoeletcroporation®.** Technology.

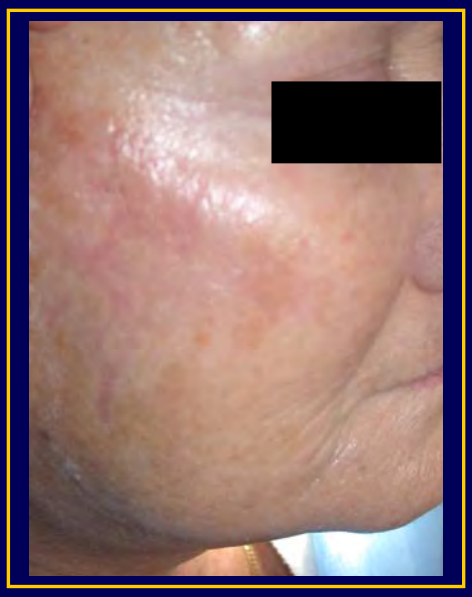
Actinic Keratosis Protocol

- Presterilised cystals Microdermabrasion on thr targeted area untill a medium Hyperemia is reached.

- Transdermal delivery of 1 vial of Placentex® not diluted, 2 cc of aminoacids, 2 cc Hyaluronic Acid.

- 808 nm diode Laser for Photo Thermal lysis

- 1 session every 15 daysifor a total of 4 sessions.



Results & Conclusions

•1patient was treated with the following results:
1 patient cleared in 1 session.

• The subject was very happy about results

• Transdermal delivery **is possible and safe with no contraindications reported.**

• The patient showed a good level of improvement and she was so happy with results.

Treatment of DMLS with transdermal therapy through Dermoelectroporation®

Prof. A. Massirone, President A.M.E (Agorà Medicina estetica), A.M.I.Est. (Associazioni Medici ad Indirizzo Estetico) -. Milano
D.ssa C. De Iulio, Degree S.M.I.E.M. "Esperto e consulente in Medicina ad Indirizzo Estetico", Omeopata - Milano

Background:

Dermatomyoliposclerosis or DMLS is a degenerative process of the subcutaneous fat tissue which becomes a connective structure alteration. A lynphatic venous insufficiency of thighs causes a stasis of subcutaneous connective micro bloodstream and a consequent intercellular edema. This brings to hypertrophy and hyperplasia of the collagene that usually encircles adipose cells, to blood vessels narrowing, alteration of metabolic exchanges, tissue suffering and toxic catabolitics stagnation. The consequence of this process is a fibrosis first, and then a fibroscelrosys with micro and macronodules. Although the element of heredity in DMLS, there are particular conditions that favour its formation, such as: postural alterations, endocrine dysfunctions, smoking, weight, progesterone therapy, incorrect alimentation. The therapy for DMLS is diversified, and one of the proven efficiency steps is mesotherapy with lipolitic, vasodilatator substances.

Project of this study:

We treated 11 patients (female), age between 25 and 53 years, suffering of DMLS of II, III and IV level .

Goal:

Administer to the patient the drug therapy usually used with mesotherapy for DMLS with a non invasive method of transdermal drug delivery, ***Dermoelctroporation®*** (patented by Mattioli

A new method for Medical transdermal Delivery of drugs:

Dermoelectroporation® is a method, approved by the American **FDA**, that allows the transdermal delivery of drugs through a previous microdermabrasion, that lowers the skin impedance, and a pulsed Ionthophoresis, with waveforms similar to electroporation, but with a lower and controlled intensity, for the local administration of ionic drug solutions

The medical unit that utilizes this method is ***Ultrapeel® Transderm® Ionto System (Mattioli Engineering),*** composed by:

one disposable handpiece for microdermoabrasion with sterilized corundum crystals

one dispenser (PLD) that supplies the drug solutions with a variable speed (we used 0,5 ml/min).

Method and duration of the study:

1. Definition of the clinical background:

After having done the pathologic and physiologic anamnesis (legs heaviness, cold feet, cramps during night or day, varicose veins,...), we made an objective examination: skin imperfections, alteration of skin colour (dyscromies and hyperpigmentation), cutis paleness (hypotermic areas), small varicose veins, teleangectasies, stretch marks, etc. Superficial and deep palpation in order to evaluate temperature changes, cutaneous elasticity reduction, increase of flabby skin, presence of micronodules. With termography we evaluated the extension and the gravity of the damage to the cutaneous and hypodermic micro bloodstream, according to the variation of cutaneous temperature. In this way we could understand the level of DMLS.

2. Therapeutic protocol:

During 8 consecutive weeks we treated 8 patients, once per week, with sessions of mesotherapy on one side, and of Dermoelectroporation® on the other side, using the same drug solutions.
The used drug solutions are composed by:
1 ml Aminofillina + 2 ml Lymdiaral + 2 ml Veno-N.
3 further patients were treated once per week with Dermoelectroporation® on both sides, but delivering the drug Solutions only on one side, while on the other just a simple water solution.

3. Indications for the patient :

We recommended to the patients not to do any massage, to pay attention to hyperlipidic food and not to perform sport for 24 hours after the session.

Shopkeeper, 34 years old

Esthetician, 53 years old

Hairdresser, 44 years old

Architect, 28 years old

Results & Conclusions

In those 8 patients treated with the same drug solutions we can state that the delivery of active principles takes place in the same way with Dermoelectroporation® and mesotherapy, while there was no effect where the water solution was used.
The therapy with Ultrapeel®Transderm®Ionto System revealed as a therapy of easy application and there wasn't particular problems during and after the treatment. Patients did not refer of particular bothers. The method revealed non invasive, painless and without consequences.

Clinicals:Report on Abnormal Fat deposition treatments through Dermoelectroporation

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Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of a fat reducion cocktail on abdomen, lateral thigh, medial thigh & back through Dermoelectroporation®.

Study Design

- Toning, not obesity grade treated
- Treatments should be administered every 2 weeks. Average number of treatments 3-4.
- L-Carnitine/Phosphatidylcholine cocktail was delivered
- Ultrapeel® Transderm® Meso System
- Session number depending on the single patient's condition
- Study conclusion on 90% or more resolution of the affected sites

Materials and Methods

Materials

1.L-Carnitine - plays an important role in fat metabolism; shuttles long chain fatty acids across the mitochondrial membrane, once inside stimulates beta oxidation
2.Phosphatidylcholine - penetrates the adipose cell, acts as a fat emulsifier by altering the stored lipids making them water soluble

4.Ultrapeel® Transderm Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) When targeting adipose tissue:
Transdermal delivery of the cocktail through Ultrapeel® Transderm Meso® system. In this way:
Delivered every 1-2 weeks until desired result is achieved .Prepare solution using (2) 10 cc syringes. Use one syringe per respective side. Per 10 cc syringe:
4 cc L-carnitine 500 mg/mL
6 cc Phosphatidylcholine 100 mg/mL.

•Application of proper follow up at the end.

Fig.1- Before

Fig.2- Results after 3 treatments scheduled every 2 weeks for **POST-LIPOSUCTION CORRECTION FOR ABNORMAL FAT DEPOSITION**

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery is possible and safe with no contraindications reported.

Clinicals: Report on Type A Botulinum Toxin delivery for Hyperhidrosis treatment through Dermoelectroporation

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*Unit of Plastic Surgery; IRCCS, Galeazzi Hospital, Milan, Italy. ** Department of Anatomy, Histology and Forensic Medicine, University of Florence, Italy.
§ Department of Experimental Pathology and Oncology, University of Florence, Italy.

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of Botulinum Toxine (*Vistabex ®– Allergan Pharmaceuticals*) for Hyperhidrosis reduction treatment through Dermoelectroporation®.

Study Design

- Heavy stretch marks patient were treated
- 6 female patients to follow-up in 14-20 days.
- Type A botulinum topine (*Vistabex ®– Allergan Pharmaceuticals).*
- Ultrapeel® Transderm® Meso System
- Test of minor for aqpplication control
- Session number depending on the single patient's condition

Materials and Methods

The treatment session has been divided in 3 parts:

- Preliminary execution of Minor test (Fig.) for a quantitative evaluation of patient's sweating.
- Preliminary microdermoabrasion of the selected skin area to decrease patient's skin impedance(Fig.).
- Application of the type A botulinum toxin (**Vistabex® , Allergan Pharmaceuticals**), 50 units per side (under arm) , 2cc saline solution diluted, driven in 10 (ten) minutes by Ultrapeel® Transderm® Meso System, that is indicated for the transdermal administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections (*FDA approval)*. The control have been carried out after two weeks from the session performing a Minor test pos-treatment.

Results

Significant decreasing of the patient's under arm sweating (fig.) by control on Minor test.

Result Assessment : Good according to grade 3 from quartile evaluation scale (Between 51% and 75%)

Side effect : a light post treatment skin erythema

Complications: none.

Fig.1 preliminary Microdermabrasion

Fig.2 Test of Minor
Before application of Type A Botulinum toxin

Fig.3 Test of Minor After application of Type A Botulinum toxin showing that no sweating is present anymore (dry part)

Fig.4 Test of Minor on a not treated axilla.
showing that some sweating is present.

Conclusions

The present study proved the transdermal delivery of type A botulinum toxin (Vistabex® , Allergan Pharmaceuticals) by Ultrapeel® Transderm® Meso System has the main advantage of the complete absence of any pain and trauma associated to the high number of injections normally done in a mesotherapy setting together with the safety and easy use of the device.

Finally it showed the possibility of delivery of a big molecule like botulinum toxin through the skin , opening the future applications with other high molecular substances in dermatology .

Clinicals: Report on Phosphatidylcoline delivery for Cellulite treatment through Dermoelectroporation

M.Cavallini*,

*Unit of Plastic Surgery; IRCCS, Galeazzi Hospital, Milan, Italy.

Preliminary Study

To evaluate the safety, tolerability
and effectiveness of transdermal
delivery of Phosphatitidylcoline for cellulite reduction
treatment
through Dermoelectroporation®.

Study Design

- Heavy cellulite patients were treated
- 6 female patients to follow-up every week.
- Phosphatidylcoline (Intrafosfaderm from Keratrade-Italy)
- Ultrapeel® Transderm® Meso System
- Weekly Session (depending on the single patient's condition) for a total of 8 to 10 sessions.
- 20mins application each session.
- Treated areas : Hips, legs and abdomen.

Materials and Methods

- Preliminary microdermoabrasion of the selected skin area to decrease patient's skin impedance
- Mix the powder bag content with 1 vial of sterile solution (5cc) completely.
- Join this mix to the Nanoemulsion till complete mixing.
- Apply this compound to the part under treatment, distributing it uniformly and then delivering it transdermally with Ultrapeel® Transderm® Meso System
- After 4,5 days from the 1st session a linphodrenatic massage might be recommended

Results

Significant decreasing of the patient's cellulite sections and areas.

Result Assessment : Good according to single patient's satisfaction grade.

Conclusions

The present study proved the transdermal delivery Phosphatitidylcoline for cellulite reduction treatment by Ultrapeel® Transderm® Meso System is safe, possible and effective.
It has the main advantage of the complete absence of any pain and trauma associated to the high number of injections normally done in a mesotherapy setting together with the safety and easy use of the device.

Finally it showed the possibility of delivery of a big molecule like Phosphatidylcoline cocktail through the skin , opening the future applications with other high molecular substances in any application field.






Before

After

Clinicals:Report on Cellulite reduction treatments through Dermoelectroporation

Dr. Suneil Jain, N.M.D.
Scottsdale Natural Medicine and Healing Clinic, LLC, 8390 E. Via de Ventura Blvd. Suite F-111 Scottsdale, AZ 85258

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of a cellulite reduction cocktail on Thighs, Abdomen, Gluteus & Knees through Dermoelectroporation®.

Study Design

-Grades 1-2, some 3 were treated
-Treatments should be administered every 2 weeks. Average number of treatments 5-8.
-Hyaluronidase /L-Carnitine/Phosphatidylcholine cocktail was delivered
-Ultrapeel® Transderm® Meso System

Materials and Methods

Materials

1.L-Carnitine - plays an important role in fat metabolism; shuttles long chain fatty acids across the mitochondrial membrane, once inside stimulates beta oxidation
2.Phosphatidylcholine - penetrates the adipose cell, acts as a fat emulsifier by altering the stored lipids making them water soluble
3.Hyaluronidase - naturally occurring enzyme that helps break up connective tissue bonds that create dimpling effect
4.Ultrapeel® Transderm Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) When targeting adipose tissue:
Transdermal delivery of the cocktail through Ultrapeel® Transderm Meso® system. In this way: Delivered every 1-2 weeks until desired result is achieved . Prepare solution using (2) 10 cc syringes. Use one syringe per respective side. Areas are referred to as abdomen, thighs, etc.
Per 10 cc syringe:
4 cc Hyaluronidase 300 units/mL
4 cc L-carnitine 500 mg/mL
2 cc Phosphatidylcholine 100 mg/mL
.
•Application of proper follow up at the end.

Results & Conclusions

•Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

Fig.1- Before

Fig.2- Results after 3 treatments scheduled every 2 weeks

Fig.1- Before

Fig.2- Results after 4 treatments scheduled every 2 weeks

Clinicals:Report on Steroids transdermal Delivery through Dermoelectroporation

Prof. G.A. Farber

Board Certified, Professor of Dermatology, Medical e Surgical Institute Inc., Kenner LA - Medical Director

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal corticosteroid preparation delivery using Dermelectroporation®.

Study Design

- 24 patients were treated
- Corticosteroid cream
- Ultrapeel® Transderm® Ionto System
- Various large areas were treated (20% of the body)
- Psoriasis Plaque type and Lichen Planus Plaque type were treated
- Session number depending on the single patient's condition

Materials and Methods

Materials

•Clobetasol by Galderma pharmaceuticals

•Ultrapeel® + Transdrm Ionto® system from Mattioi Engineering

Methods

•Application of the corticosteroid locally applied and transdermal delivery with Tansderm® Ionto System

Results

•12 out of 24 were treated with the following results:
1 patient cleared in 2 sessions
1 patient cleared in 3 sessions
1 patients cleared within 6 sessions.
1 patient cleared within 7 sessions
6 patients cleared in 1 session.
1 Patient dropped down the treatment after 1 session

- All subjects were happy about results

CASE STUDY:

Adult black female elbows- Transderm to top half of plaque right elbow and lower half of plaque left elbow; 1 month treatment time.

CASE STUDY:

Latin male 20 years old –

leg rush ; Four (4) bilateral treatments interrupted by the hurricanes

Conclusions

- Study conclusion on 90% or more resolution of the affected sites through Dermoelectroporation®, **safely.**
- Each patient showed a some level of reasonable improvement and they were happy with results.
- Some difficulties have been encountered in longer follow up due to the hurricanes.

Clinicals : Improvement of Facial Rhytids through a Novel Transdermal Drug Delivery System

Jaggy Rao, MD* , MD Division of Dermatology, University of Alberta
Edmonton, Alberta, Canada

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal Hyaluronic Acid (HA) delivery using Dermelectroporation®

Study Design

•10 healthy female subjects
• Symmetrical periorbital rhytids
• Randomization: Only RIGHT or LEFT face treated
• Efficacy Parameters:
- Photography
- Histology
- Blinded dermatologist assessment
- Subject questionnaires

Results

•Minimal and transient side effects
- erythema (10), mild abrasions (6), purpura (1)
• All subjects tolerated the treatments well
- average Tolerability Score = 2.2*
• Subject questionnaires
- average Improvement Score = 3.2**

- 1 = no discomfort,
- 2 = mild discomfort,
- 3 = moderate discomfort,
- 4 = severe discomfort

** 1 = no improvement, 2 = mild improvement, 3 = moderate improvement, and 4 = dramatic improvement

•Average change in Wrinkle Class (1 – 5) *
- Treated Side = - 1.3
- Control Side = - 0.2
• Pre- and 4-week follow-up photos evaluated by four independent blinded physician observers
- Average improvement treated side = 3.3 **
- Average improvement control side = 1.2 **
* As determined by blinded dermatologist reviewer
** 1 = no improvement,
2 = mild improvement,
3 = moderate improvement,
4 = dramatic improvement

Conclusions and Implications

•Through Dermoelectroporation®, transdermal drug delivery of **HA is possible and safe**
• this concept may improve the efficiency of other biological agents and drugs such as **anesthetics, anti-inflammatory**, and **photosensitizes**
• New studies are in progress to further examine the potential scope of this process

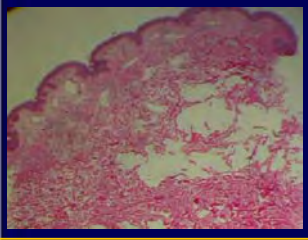
Materials and Methods

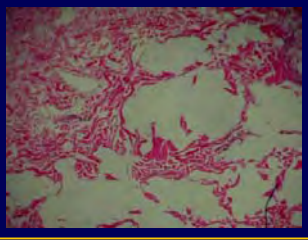
Materials
•Hyaluronic Acid 15 mg/ml, very low viscosity from Apothécure, Inc., Dallas, Texas
•Ultrapeel® + TransDerm Ionto® from Mattioli Engineering, Florence, Italy
Methods
•Side to be treated scrubbed with acetone
• Periorbital region treated with microdermabrasion **(Picture 1)**
• 3.0 milliliters of HA transdermally delivered per Tx approximately 5 – 10 minutes per session **(Picture 2)**
• Two transdermal treatments given, 2 weeks apart
• Mupirocin ointment immediately post-treatment
• 2 mm punch biopsies at 4 weeks post-treatment

Before

After

Histology





Clinicals: Report on Hyaluronic acid cocktail treatments through Dermoelectroporation

Dr. Suneil Jain, N.M.D.
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Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of a Hyaluronic Acid cocktail on Perioribital & Perioral Areas through Dermoelectroporation®.

Study Design

- fine to medium lines of the face
- Treatments should be administered every 2 weeks for 3 treatments. Thereafter every 6-8 weeks for maintenance.
- L-Carnitine/Phosphatidylcholine cocktail was delivered
- Ultrapeel® Transderm® Meso System
- Session number depending on the single patient's condition
- Study conclusion on 90% or more resolution of the affected sites

Fig.1- Before

Fig.1- After

Materials and Methods

Materials

1.Hyaluronic Acid - plays an important role in tissue hydration, lubrication and cellular function; removes wastes from cells with no direct blood supply; able to hold more water than any other natural substance which results in smoothness, softening and decrease in wrinkles
2.Glutathione - "master antioxidant"; acts to reconstitute Vitamin C and E after they have been oxidized; protects cells from free radical damage; works in conjunction with Super Oxide Dismutase (enzymes that play a major role in the protection of cells from oxidative stress) to help with detoxification
3. MTE-4 – contains 4 multi-trace elements
a. **Copper:** important for conversion of L-tyrosine to melanin aiding in UV protections; needed for conversion of carotene to retinol; needed for CT maturation; provides cross-linking of aldehydes in collagen and elastin tissues; stimulates SOD enzyme b. **Manganese**: activates enzymes in formation of collagen; tones & firms skin
c. **Zinc Sulfate**: required for synthesis of collagen; protects against UV rays; stimulates transport of Vitamin A from liver to skin; stimulates SOD enzyme
d. **Chromium**: can help with acne by improving localized glucose sensitivity

4.Ultrapeel® Transderm Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) When targeting adipose tissue:
Transdermal delivery of the cocktail through Ultrapeel® Transderm Meso® system. In this way. Deliver
every 2 weeks for 3 treatments. Thereafter every 6-8 weeks for maintenance. Prepare solution using a 10 cc syringe. After combining the ingredients transfer half of the solution to another 10 cc syringe. Use 1 syringe per side of the face.

2 cc Sodium Hyaluronate 25 mg/mL
2 cc Glutathione 100 mg/mL
2 cc MTE 4 containing: (1 mg copper, 0.5 mg manganese, 10 mcg chromium, 22 mg zinc sulfate) per mL

•Application of proper follow up at the end.

Results & Conclusions

•Patients were treated with the following results: Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she

Clinicals: Report on smoker's face lines treatment through Dermoelectroporation

Dr. A.Gessati*,

*Aesthetic medicine Doctor, Milan, Italy.

Preliminary Study

Dermoelectroporation, well known and established method for transdermal substances delivery without the use of needles, promote the opening of membrane channels and allows the transdermal delivery of Hyaluronic acide based bio revitalizing and growth factor cocktails.
The LED stimulation provokes , due to a controlled , low intensity, ionizing light radiation, a biological response from the treated tissues.The procedure consists of a skin-compatible proteins transdermal delivery to improve the cellular cleaning and the restoration of microcirculation pathways in order to get a fast improvement on the external skin tissues.

Study Design

- 10 patients were treated on 5 sessions - once per week.
- Follow up after one month
- Revitalase (Mattioli engineering -Italy)
- Ultrapeel® Transderm® Meso System
- 15mins application each session (AVG).
- Treated areas : Per oral area.

Before

Materials and Methods

Materials

- Revitalase (*Mattioli engineering*)
- Ultrapeel® Transderm® Meso System(*Mattioli engineering*)
- L.E.D. Photo Stumulation device

Methods

- *Pre-Sterilised corundum crystals Microdermabrasion up to reach a strong hyperemia.*
- *Transdermal delivery of 3cc Revitalase – (*
- *Hyaluronic acid enriched by Tissue Growth Factors)cocktail*
- *LED Photo-biomodulation 633+/-6 nm.*
- *1 session per week for a total of 5 sessions* depending on the single patient.
- *Follow up after 1 month.*

After

Results

Significant decreasing of the patient's smoker's lines on the selected areas.

Result Assessment : Good according to single patient's satisfaction grade.

Conclusions

The present study proved the transdermal delivery of Revitalase through Ultrapeel® Transderm® Meso System is safe, possible and effective.
The administer therapy is :
- Easy to perform.
It doesn't show up any problem either durino or after the administration
It is well tolerated by the patient
This methodology:
- non invasive.
- Pain Free.
- No side effect reported.

Clinicals: Report on Treating the Crow's feet through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of Oligopeptides serum for crow's feet treatment purposes through Dermoelectroporation®.

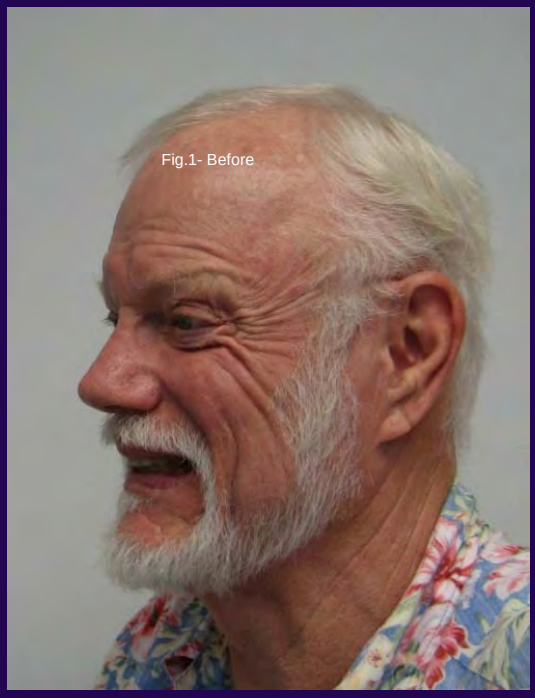

Fig.1- Before

Study Design

- Delivered every week for a total of 4 treatments.
- Oligopeptides (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill desired sresult is achieved.

Materials and Methods

Materials

1. Oligopeptides serum
Reduces Lines & Generates New Collagen
2 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using a 10cc syringe. Use one syringe concentrating on problematic areas like the cheeks and forehead at lateral brow line.
Per 10cc syringe
10cc Oligopeptides

•Application of proper follow up at the end.

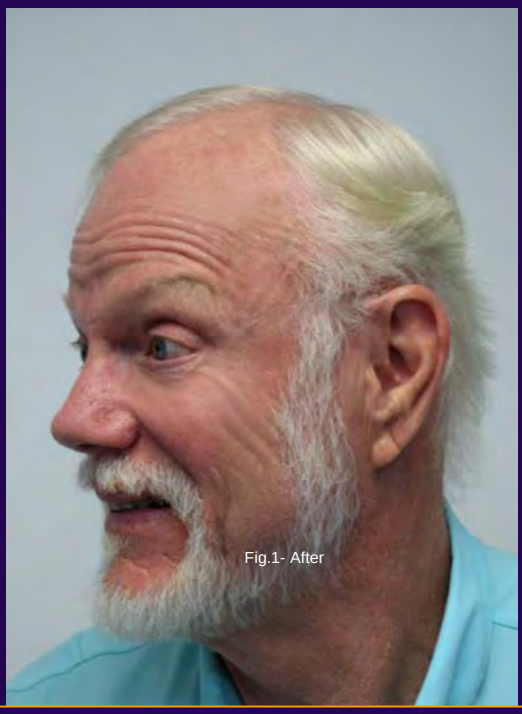

Fig.1- After

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Treating the Crow's feet through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of Oligopeptides serum for crow's feet treatment purposes through Dermoelectroporation®.

Study Design

- Delivered every week for a total of 4 treatments.
- Oligopeptides (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill desired sresult is achieved.

Materials and Methods

Materials

1. Oligopeptides serum
Reduces Lines & Generates New Collagen
2 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using a 10cc syringe. Use one syringe concentrating on problematic areas like the cheeks and forehead at lateral brow line.
Per 10cc syringe
10cc Oligopeptides

•Application of proper follow up at the end.

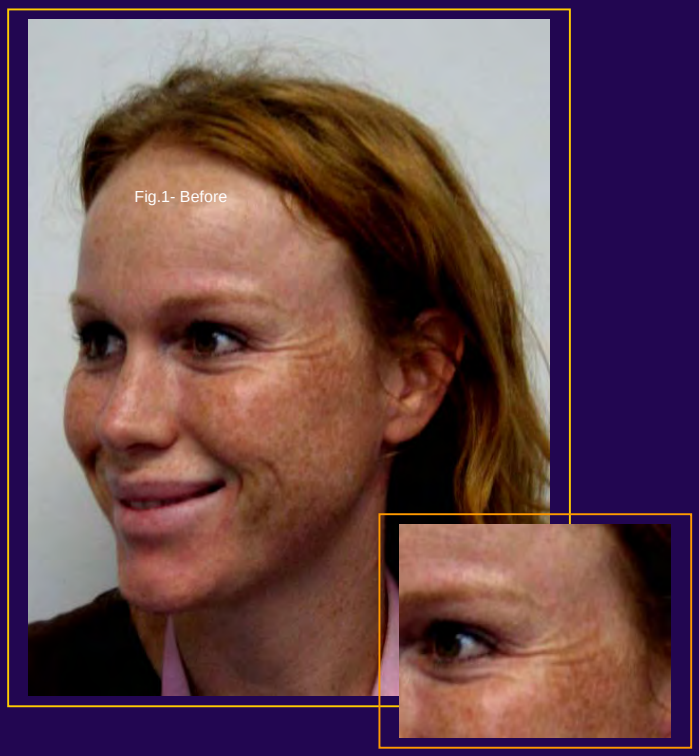

Fig.1- Before

Fig.1- After

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Treating the mimetic muscles through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of Oligopeptides serum for treating mimetic muscles purposes through Dermoelectroporation®.

Study Design

- Delivered every week for a total of 4 treatments.
- Oligopeptides (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill desired sresult is achieved.

Materials and Methods

Materials

1. Oligopeptides serum
Reduces Lines & Generates New Collagen
2 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using a 10cc syringe. Use one syringe concentrating on problematic areas like the cheeks and forehead at lateral brow line.
Per 10cc syringe
10cc Oligopeptides

•Application of proper follow up at the end.

Fig.1- Before

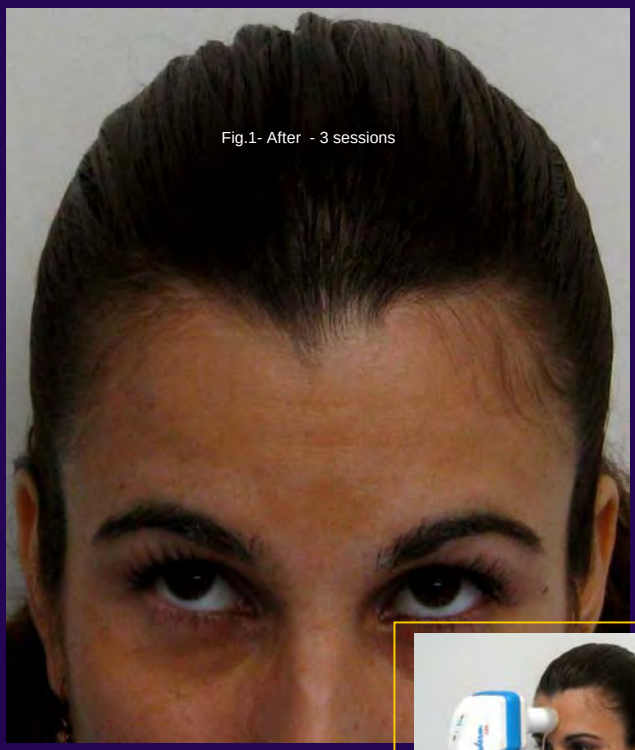

Fig.1- After - 3 sessions

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Treating the mimetic muscles through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of Oligopeptides serum for treating mimetic muscles purposes through Dermoelectroporation®.

Study Design

- Delivered every week for a total of 4 treatments.
- Oligopeptides (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill desired sresult is achieved.

Materials and Methods

Materials

1. Oligopeptides serum
Reduces Lines & Generates New Collagen
2 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using a 10cc syringe. Use one syringe concentrating on problematic areas like the cheeks and forehead at lateral brow line.
Per 10cc syringe
10cc Oligopeptides

•Application of proper follow up at the end.

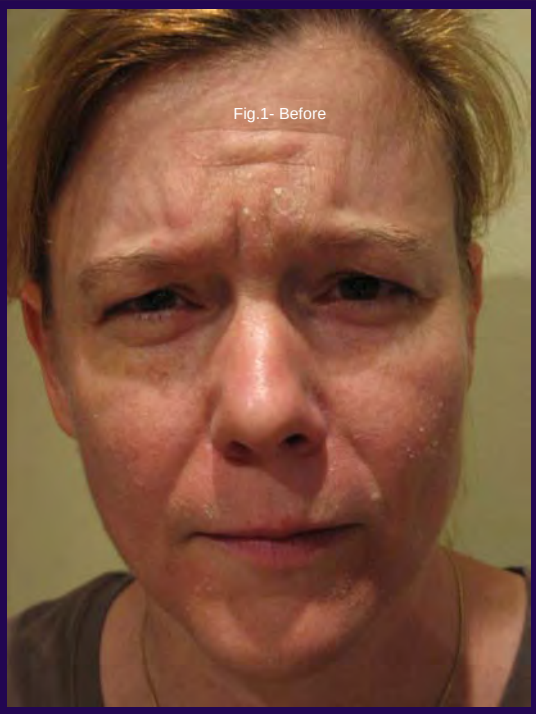

Fig.1- Before

Fig.1- After

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Senile Purpura treatments through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability
and effectiveness of transdermal
delivery of a Arnica & 2% HA serum cocktail for senile purpura purposes
through Dermoelectroporation®.

Study Design

- Delivered every 1 weeks for a total of 4 treatments.
- Arnica –Hyaluronic acid serum 2% (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill desired results is acheived

Materials and Methods

Materials

1 Arnica –Hyaluronic acid serum 2% trests senile purpura

2 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using a 10cc syringe. Use one syringe per area being treated, concentrating on problematic areas.
Per 10cc syringe
5cc Arnica Infusion

•Application of proper follow up at the end.

Fig.1- Before

Fig.1- After - 3 sessions once a day

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Reversing Photodamage through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of a Rejuv serumwith HA and antioxidants cocktail for reversing photodamage purposes through Dermoelectroporation®.

Fig.1- Before

Study Design

- Delivered every week for a total of 8 treatments.
- Rejuv serumwith 1%HA and antioxidants cocktail (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill the desired result is achieved.

Materials and Methods

Materials

1. Rejuv serum
Reduces Lines & Generates New Collagen
2 Hyaluronic acid serum 1%
Fills out the Dermis and Hydrates the Joints
3 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Fig.1- After - 6 sessions

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using a 10cc syringe. Use 5cc's per side of the face, concentrating on problematic areas like the cheeks and forehead at lateral brow line.
Per 10cc syringe
10cc Rejuv serum

•Application of proper follow up at the end.

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Hyaluronic Acid & Oligopeptides cocktail treatments through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of a Hyaluronic Acid & Oligopeptides cocktail for either facial lifting and finelines reduction purposes through Dermoelectroporation®.

Study Design

- Delivered every 1 or 2 weeks for a total of 8 treatments.
- Oligopeptides with Hyaluronic acid gel (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every 12 week

Materials and Methods

Materials

1. Oligopeptides serum 10%
Reduces Lines & Generates New Collagen
2 Hyaluronic acid serum 1%
Fills out the Dermis and Hydrates the Joints
3 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using a 10cc syringe. Use 5cc's per side of the face, concentrating on problematic areas like the cheeks and forehead at lateral brow line.
Per 10cc syringe
5cc Oligopeptides

•Application of proper follow up at the end.

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Fig.1- Before – 6 sessions

Fig.1- Before – 8 sessions

Fig.1- After - 6 sessions

Fig.1- After - 8 sessions

Clinicals: Report Filling Liposuction Divets through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of a Hyaluronic Acid for filling liposuction divets purposes through Dermoelectroporation®.

Study Design

- Delivered every 1 weeks for a total of 8 treatments.
- Hyaluronic Acid serum 1% (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill desired results is acheived

Materials and Methods

Materials

1 Hyaluronic acid serum 1%
Fills out the Dermis and Hydrates the Joints

2 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using (2) 10cc syringe. Use one syringe per area being treated, concentrating on problematic areas. Areas are referred to as abdomen, lateral thigh, medial thigh, back, arms, etc.
Per 10cc syringe
5 or 10cc Hyaluronic Acid

•Application of proper follow up at the end.

Fig.1- Before – 8 sessions

Fig.1- After - 8 sessions

Fig.1- After - 8 sessions

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Localized Fat Deposits treatments through Dermoelectroporation

Dr. James Fulton, vivant Skin Care , Miami Florida, USA

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of a cellulitic serum for localized fat deposits reduction purposes through Dermoelectroporation®.

Study Design

- Delivered every 1 weeks for a total of 8 treatments.
- Cellulitic serum 5% (Vivant Skin Care) was delivered
- Ultrapeel® Transderm® Ionto Meso System
- Repeat ideally every week untill desired results is acheived

Materials and Methods

Materials

1 Cellulitic serum 5 Dissolves Localized Fatty deposits

2 Ultrapeel® Transderm Ionto Meso® system from Mattioli Engineering

Methods

•Transdermal delivery of the cocktail through Dermoelectroporation® technology:

•2 Steps Prodecure:
a)Microdermabrasion

b) Transdermal delivery of :
Prepare solution using (2) 10cc syringe. Use one syringe per area being treated, concentrating on problematic areas. Areas are referred to as abdomen, lateral thigh, medial thigh, back, arms, etc.
Per 10cc syringe
10cc Cellulytic Serum

•Application of proper follow up at the end.

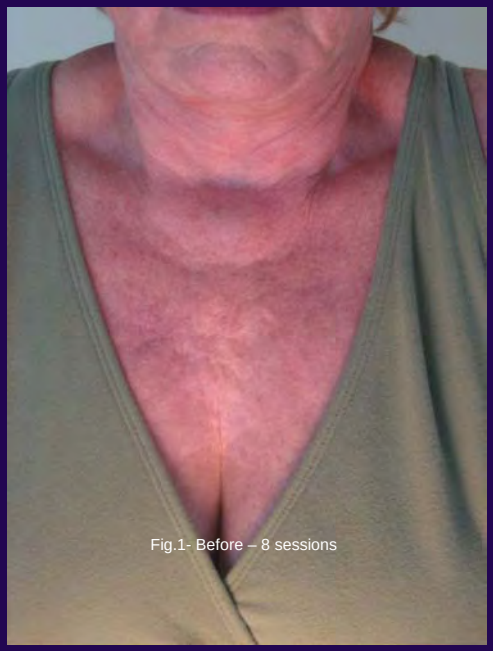

Fig.1- Before – 8 sessions

Fig.1- After - 8 sessions

Results & Conclusions

•Patients were treated with the following results:
Patients drastically reduced inches in weeks.

• Transdermal delivery **is possible and safe with no contraindications reported.**

• all patients showed a good level of improvement and she was so happy with results.

Clinicals: Report on Type A Botulinum Toxine delivery for Face and decolleté rejuvenation treatment through Dermoelectroporation

M.Cavallini, Plastic Surgery Specialist ,Unit of Plastic Surgery; IRCCS, Galeazzi Hospital, Milan, Italy.

Preliminary Study

To evaluate the safety, tolerability and effectiveness of transdermal delivery of Botulinum Toxine (*Vistabex ®– Allergan Pharmaceuticals*) for Skin rejuvenation treatment (mesobotox) through Dermoelectroporation®.

Study Design

- Heavy stretch marks patient were treated
- 6 female patients to follow-up in 4-5 days.
- Type A botulinum topine (*Vistabex ®– Allergan Pharmaceuticals).*
- Ultrapeel® Transderm® Meso System
- PDRN Placentex (Mastelli pharmaceuticals - Polydesoxyribonucleotidis)

Materials and Methods

The treatment session has been divided in 3 parts:

- Preliminary microdermoabrasion of the selected skin area to decrease patient's skin impedance
- Dilution of type A botulinum toxin (Vistabex® , Allergan Pharmaceuticals), 50 units into 1,25 mcl saline solution, then dilute 10-20 units of this cocktail into 3ml PDRN (Mastelli pharmaceuticals)
- for the application.
- Deliver transdemally the cocktail for approx. 20 mins by means of Ultrapeel® Transderm® Meso System, that is indicated for the transdermal administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections (US*FDA approval).* The control have been carried out after a few days with increase of skin's elasticity, hydration and a very significant wrinkles reduction on the treated areas.

Results

Significant decreasing of the patient's wrinkles and fine lines.
Result Assessment : exdellent according to the final skins condition (Hydration-moisturizing-elasticity)
Side effect : non registered.
Complications: none.

Conclusions

The present study proved the transdermal delivery of type A botulinum toxin (Vistabex® , Allergan Pharmaceuticals) by Ultrapeel® Transderm® Meso System has the main advantage of the complete absence of any pain and trauma associated to the high number of injections normally done in a mesotherapy setting together with the safety and easy use of the device.

Finally it showed the possibility of delivery of a big molecule like botulinum toxin through the skin , opening the future applications with other high molecular substances in dermatology .