



DEP
dermo electro poration ES PLUS

THANKS
谢谢聆听



Dermo Electro Poration

超导小光

FDA唯一认证可替代水光注射的无创给药系统



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DEP ES PLUS SYSTEM
超导水光系统介绍

FDA唯一认证可替代水光注射的无创给药系统





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01.

MATTIOLI公司及DEP超导水光系统介绍

02.

DEP应用范围及国际临床论证

03.

DEP疗效临床案例对比



01

MATTIOLI 公司及DEP系统介绍

意大利著名医疗激光公司原装进口



Mattioli Engineering创立于1991年的意大利佛罗伦萨，是一家著名的皮肤激光公司，凭借创始人四十余年的行业经验，开发了第一个微晶磨皮换肤系统 Ultrapeel，并在1996年通过FDA批准，及CE、ISO9001、ISO13485医疗器械认证，产品符合GMP标准规则。拥有众多专利，其中DEP技术更是在2003年通过FDA批准，作为可替代注射的治疗技术，为透皮给药提供了更加高效的手段。

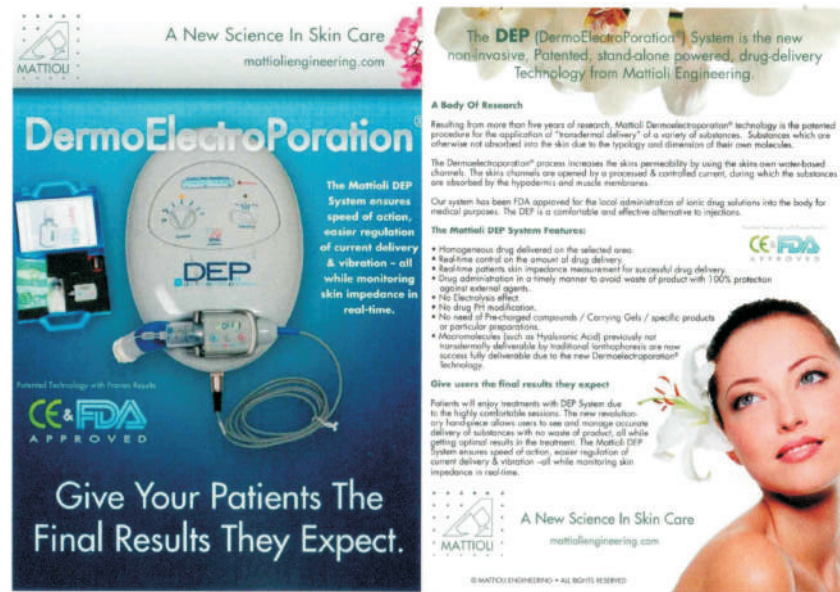
产品远销全球众多国家及地区，在美国、英国等地拥有独立的子公司。



什么是DEP System (超导水光) ?

DEP (Dermoelectroporation®) “超导水光”无创透皮给药系统，是MATTIOLI Engineering公司出品的全新代非侵入性的无针经皮注射仪器。

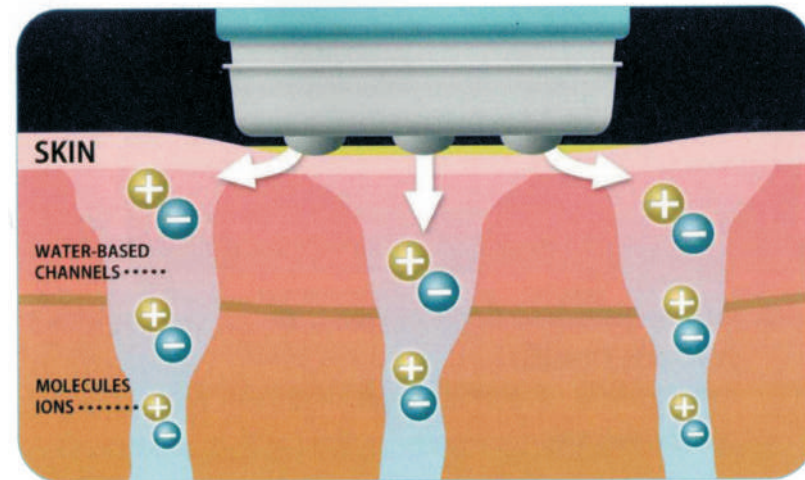
其通过流经细胞外基质的电流脉冲，利用电流传递与振动的方式，让长链糖胺聚糖自身定向产生水孔蛋白（水通道蛋白，细胞膜上蛋白质形成的“孔道”），并允许离子化物质穿过皮肤表皮层传递吸收至真皮层及肌膜，比传统的离子导入疗法更快，穿透层次更深，可有效替代有创注射方式，避免疼痛、炎症期的结痂、敏感、脱屑、瘙痒及色沉问题和风险，无停工期。



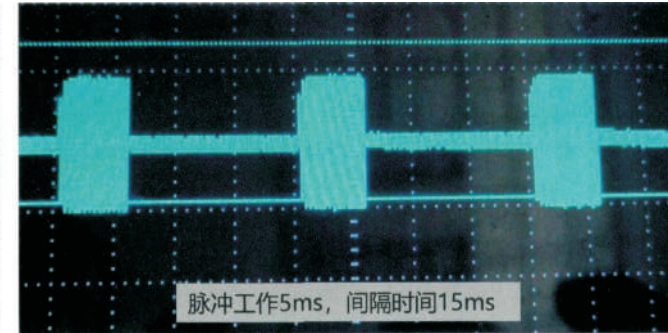
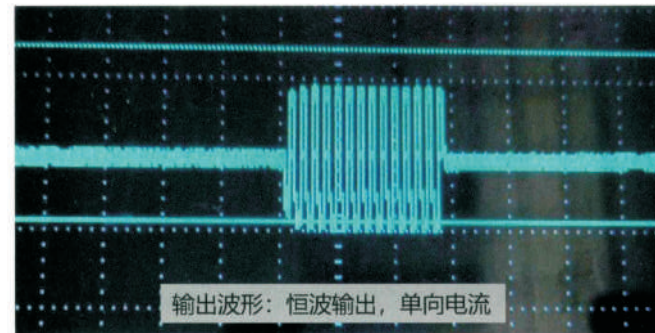
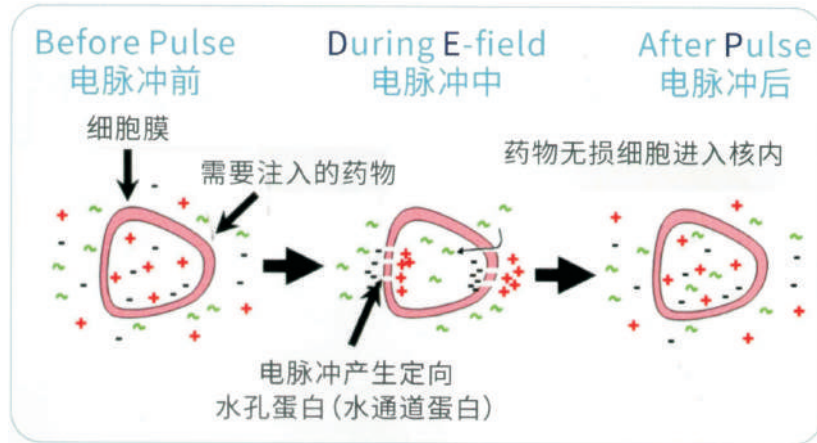
DEP技术原理特点

DEP无创电脉冲超导透皮技术是一种微生物学技术，其将可控的强烈的电场规律性施加到细胞外基质（ECM， Extra Cellular Matrix，主要有不同类型的糖蛋白、蛋白聚糖、透明质酸、胶原及蛋白、矿物质等）上，利用电子脉冲传递和振动，打开“水孔通道”。

这种水孔通道可增加细胞膜的穿透性，允许将药物、营养成分及DNA等微分子、大分子注入细胞内，且不改变液体药物的PH值和离子溶液的电解效果，彻底解决了传统的电离子导入技术无法突破无损细胞膜穿透细胞壁的瓶颈，更好的实现无创透皮给药。



- ① 精准定位均匀施药，无需任何补偿贴剂、凝胶及介质等化合物;
- ② 电脉冲强度、施药剂量实时可控，透皮穿透深度可直达真皮层及肌膜，疗效更卓越;
- ③ 实时反馈皮肤阻抗，确保施药成功;
- ④ 100%贴合皮肤施药，避免产品浪费，安全不受外部介质影响;
- ⑤ 电脉冲打开细胞膜的水孔蛋白（水通道），微分子、大分子均能通过;
- ⑥ 不产生电解作用，不改变药物的PH值，不造成药物的功效损失。



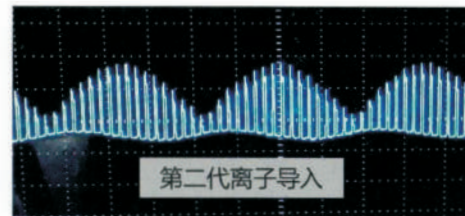
技术优势:

1. 互感单向电流耦合输出，交流变为直流输出;
2. 恒波输出，国际金标准药物导入频率2.5Khz, 每秒打孔625次（1/4脉冲工作时间）；
3. 串脉冲工作方式，脉冲精准工作5ms, 间隔停留15ms, 有较长的散热时间，避免了热积累，杜绝了灼伤现象，提升了客户体验感，安全有效；
4. 子脉冲峰值功率最高到40V, 电流最大值5mA, 深度可以达到真皮深层，打孔孔径在20-30μm，大分子药物均可进入真皮深层，安全无痛无创效果显著。

传统的离子经皮给药导入设备是利用同电性相斥的原理，通过电位差将离子或带电荷的化学药物输送到体内的治疗方法。



连续输出方式，电压值在几V，需要长时间敷在治疗区域，没有温度传感器，容易灼伤皮肤



改进为直流脉冲电压，余弦波输出，减少了热累积，但是灼伤的风险依然存在，同时必须是导入离子性、带电荷的化学药物且导入深度比较表浅

DEP超导水光优势：通过电脉冲“打孔”，对药物是否带电荷极性没有要求，通过“打孔”可以将大分子药物带入真皮深层。

常见的另一-经皮给药类别，高压喷射：220米/秒的速度。6.5帕的压力，浅表层清洁补水，药物无法达到真皮层



DEP超导水光优势：穿透深度可直达真皮深层。

	技术原理	穿透深度	使用产品	效果	间隔周期	是否需表麻	是否有恢复期
超导水光	瞬时高压脉冲，经皮电离子水孔蛋白技术	真皮层	化妆品、化妆品	即时效果明显，单次效果维持10~15天，可多次治疗达到最佳效果	10~15天	无需表麻，无创	无
德玛莎	采用负压技术，微针进入皮肤	真皮层	必须械字号	即时红肿无效果呈现，一般3~7天显效，效果维持10~15天	1个月	必须表麻，有创	有

DEP超导水光优势: 非侵入、无创、无恢复期; 可使用的产品更多样化; 可多频次叠加治疗达到更佳效果。



	技术原理	穿透深度	可导入药物成分	吸收效果
高压喷射	高压氧喷	浅表层	小分子量	差
超声波	低频超声波	浅表层	水溶性	一般
离子导入	直流电流	真皮浅层	离子性、带电荷的成分	不错
电子注射（水光）	负压，微针穿刺	真皮层	仪器为医疗器械，需使用械字号产品	很好
超导水光	瞬时的高压脉冲	真皮层	水溶性、脂溶性 带电离子类或中性分子类 小分子、蛋白质、多肽等，大分子类	很好

02

DEP的应用范围及疗效国际论证

FDA唯一认证可替代注射的无创水光



ISO9001认证

13485认证



CE认证

ISTITUTO DI RICERCHE E COLLAUDI
M. MASINI S.r.l.

Organismo Notificato n° 0008 - Notified Body n° 0008

CERTIFICATO CE DI APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITÀ DELLA PRODUZIONE
PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/005-2002 Rev.11

secondo allegato V della direttiva 93/42/CEE sui Dispositivi Medici
in accordance with annex V of the directive 93/42/EEC on medical devices

L'istituto dichiara di avere effettuato l'esame del Sistema di Garanzia della Qualità della Produzione della Società più avanti menzionata, secondo i requisiti della legislazione nazionale e della direttiva 93/42/CEE, e di aver constatato che il Sistema di Garanzia della Qualità della Produzione della Società più avanti menzionata è conforme ai requisiti essenziali della legislazione europea.

The institute declares that an examination of the under mentioned firm production quality system has been carried out following the requirements of the national legislation in which the entrepreneur is subject, transposing annex V of the Directive 93/42/EEC on medical devices. The institute certifies that the production quality system, conforms with the minimum provisions of the aforementioned legislation.

PRATICA: 017/01/DM-CE deliv. 06/06/2001
Practice

FABBRICANTE: MATTIOLI ENGINEERING ITALIA S.p.A.
Manufacturer

36010 Montebelluna (TV) - Italia
36010 Montebelluna (TV) - Italy

DEPOSITIVO: Dermabrasori, apparecchi per fonoforesi, apparecchi IPL.
Devices

MODELLI: vedi allegato 1
Models

CLASSIFICAZIONE: vedi allegato 1
Classification

PRIMA EMISSIONE: 13/03/2002
First issue

PRESENTAZIONE: 12/03/2014
Present issue

VALIDAZIONE: VALDO FINO AL 12/03/2017
Valid until

Documenti di riferimento: Adempimenti allegati
➤ Rapporto di verifica ispettiva / inspection audit report n. 4 datato il 04/03/2014

Esponente certificato da società n. 1 allegato composto da n. 1 foglio / This certificate has been issued by company n. 1 page

Il Responsabile SORPO - The Head of PCSSS Service
Prof. Ing. Giuseppe Lodi

Il Direttore Tecnico - The Technical Manager
Ing. Roberto Tassi

highsigning: 1 sheet / 1 part of the certificate of annex 1

ISTITUTO DI RICERCHE E COLLAUDI
M. MASINI S.r.l.

Organismo Notificato n° 0008 - Notified Body n° 0008

ALLEGATO N. 1 AL CERTIFICATO CE DI APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITÀ DELLA PRODUZIONE
ANNEX No. 1 TO THE PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/005-2002 Rev. 11

secondo allegato V della direttiva 93/42/CEE sui Dispositivi Medici
in accordance with annex V of the directive 93/42/EEC on medical devices

PRIMA EMISSIONE: 13/03/2002
First issue

PRESENTAZIONE: 12/03/2014
Present issue

VALIDAZIONE: VALDO FINO AL 12/03/2017
Valid until

Il presente allegato è da considerarsi riferito ai seguenti prodotti:
This annex refers to the following devices:

TIPO PRODOTTO	NUMERO DI CODICE MODELLO	CLASSE
Type of device	Model number	Class
Dermabrasore	CRYSTAL-GLASS TRAPEZIO	IIa
Dermabrasore con fonoforesi	CRYSTAL-GLASS TRAPEZIO PLUS	IIa
Apparecchio per fonoforesi	TRANSDERM RINNO SPLIT (TRANSDERM SPLIT)	IIa
Apparecchio per fonoforesi	DEP SYSTEM	IIa
Apparecchio per fonoforesi	TRANSDERM MISO DIGITAL (TRANSDERM DIGITAL)	IIa
Apparecchio IPL	PULSE TWO PLUS	IIb
Apparecchio IPL	PULSE THREE PLUS	IIb

highsigning: 1 sheet / 1 part of the certificate of annex 1

FDA认证

ISTITUTO DI RICERCHE E COLLAUDI
M. MASINI S.r.l.

Organismo Notificato n° 0008 - Notified Body n° 0008

CERTIFICATO CE DI APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITÀ DELLA PRODUZIONE
PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/005-2002 Rev.11

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DEP超导水光是唯一被FDA认可的替代注射的产品



DEP超导水光主要临床适用范围

- 面部年轻化 (补水, 美白, 修复, 抗衰, 平纹, 痤疮、敏感等问题皮肤)
 - ✓ 水光注射透皮给药
 - ✓ 美塑治疗
 - ✓ PRP注射等
- 头皮抗衰、护理、生发及养护
- 预激光、水光, 整形手术前后等治疗 (利多卡因的应用-表麻)
- 多汗症治疗
- 妊娠纹、橘皮组织治疗
- 减少脂肪堆积
- 促进血液循环, 疼痛管理
- 对肩周炎、颈椎病、风湿性关节炎等疾病
- 运动药物等

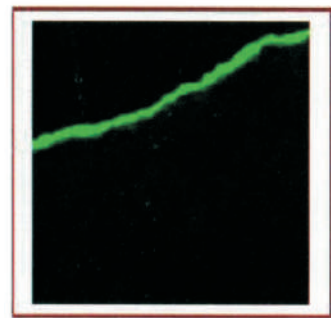
- ✓ 胶原蛋白
- ✓ 透明质酸
- ✓ 利多卡因
- ✓ 左旋肉碱
- ✓ 维生素
- ✓ 氨基酸
- ✓ 肝素
- ✓ 弹性蛋白
- ✓ 水光产品
- ✓ 谷胱甘肽

- ✓ 激素替代
- ✓ Phosphatidylcholine
- ✓ 氨茶碱
- ✓ 透明质酸酶
- ✓ MTE-4
- ✓ 离子皮肤组织Th长凝胶
- ✓ 类固醇
- ✓ A型肉毒杆菌毒素
- ✓ Th生长因子

- ✓ GrowthFactors
- ✓ Lymidiral
- ✓ Veno-M
- ✓ Placentex
- ✓ Diclofenac
- ✓ PRP

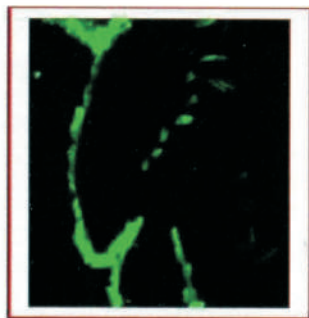
还有很多其他的“鸡尾酒”...





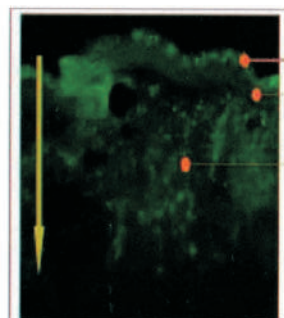
未经治疗的大鼠皮肤

皮肤表面均匀地被荧光层覆盖，而真皮层无荧光显示。150X



进过DEP系统结合透明质酸治疗的大鼠皮肤

皮肤表面均匀覆盖着荧光层，从真皮的最外层到最内层可以观察到很多荧光透明质酸。150X



荧光显微镜显示真皮及皮下有分子量在800K 道尔顿的透明质酸

表皮层

真皮层

皮下组织

佛罗伦萨大学解剖、组织学和法医学“经皮治疗”学部对经皮给药和生物活性分子的形态学、定性和定量分析。Dr.P.Beccatelli, Dr.S.Pacini



一些初步研究评估了DEP结合透皮透明质酸(HA)的安全性、耐受性和有效性。

研究方案:

在10 名健康女性受试者中，每眼有同样对称皱纹的成为研究目标。

效果评估参数:

-摄影-组织学-皮肤科医生盲评-受试者问卷调查

结果最小且短暂的副作用一红斑(10)、轻度擦伤(6)、紫癜(1)

所有受试者耐受性评估良好-平均耐受性分数=2.2*

1 =无不适，•2 =轻度不适，3 =中度不适，•4 =重度不适

受试者问卷调查-平均改善分数= 3.2****

1 =无改善，2 =轻度改善，3 =中度改善，4 =显著改善



before

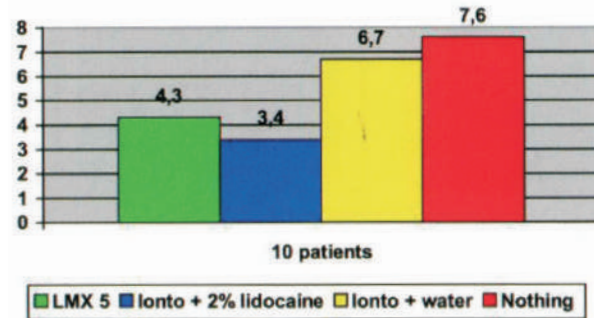


after

Transderm®lonto 是一种动力药物传输系统，用于医疗目的的离子药物溶液的局部给药，可作为注射的替代。

FDA声明，在美国使用的第一个应用 与传统的离子电泳设备相同，即局部麻醉使用2%盐酸利多卡因- 1:100.000 肾上腺素。

试验证明，Transderm lonto 系统已成功用于给病人提供2%盐酸利多卡因 —— 1:100.000 肾上腺素，其结果如下：



DEP结合利多卡因与传统的局部麻醉膏还有其他方式相比，结果很有意义。”研究结果清楚地表明，经皮lonto可以有效地允许利多卡因在设定条件下可渗透到皮肤中，并且可以作为一种麻醉治疗来减轻皮肤美容过程中引起的疼痛和不适。这些结果为今后优化疼痛管理和降低治疗不适感提供了不同参数的研究依据。”

Dermoelectroporation® (DEP) System

DEP超导水光无创给药系统技术结合肉毒素

改善额头皱纹

Botulinum toxin has therapeutic and aesthetic actions. I began to use a non-invasive method for use this method for the correction of forehead wrinkles with botulinum toxin type A, and later for the improvement of acetylcholine at the neuromuscular junction. System from Mattioli Engineering Italia, palm and axillary hyperhidrosis.

Moreover, its secondary action is the inhibition of sweat glands, offering a new aspect in the treatment of palms and the axillary similar to those of electroporation, but with dermabrasion with sterile aluminium oxide region. a lower and controlled intensity. corundum crystals to lower the skin impedance. Then with the use of two handpieces Effects of Dermoelectroporation stimulation of 1.5 cm and 5 cm diameter, we delivered the opening of water based channels the botulinum toxin Vistabex, using a special precision liquid dispenser. This dispenser releases the drug at 0.5 ml per second to handpieces with different shapes and sizes, in order to have a slow and homogeneous diffusion and distribution given at a controlled and low intensity.....

Maurizio Cavallini, M.D.
医学博士，整形外科医生，意大利米兰



DEP新型无创经皮给药系统技术的发展

新型无创经皮给药系统——完美取代传统注射

- ☒ 唯一获得美国FDA认证的无创经皮给药系统
- ☒ 完美取代传统注射与美塑疗法
- ☒ 创新的经皮DEP超导水光
- ☒ 允许多剂量多种类的药物精准传输
- ☒ 临床应用范围广泛



新型经皮给药系统改善面部皱纹 HA透明质酸

结论:

通过DEP System导入HA透明质酸是安全并且有效的

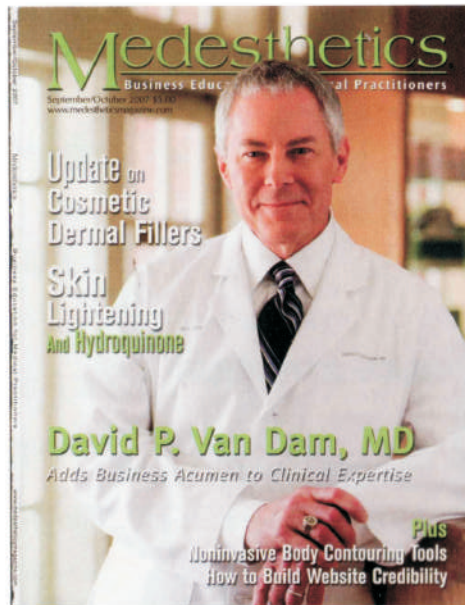
这一技术也可能会提高其他生物制剂和药物的效率，如麻醉药、抗感染药和光敏剂



Mattioli Develops New Approach to Facial hydration Reduction

无创经皮给药系统在面部补水嫩肤的应用

DAVID P.VAN DAM, MD
Italy

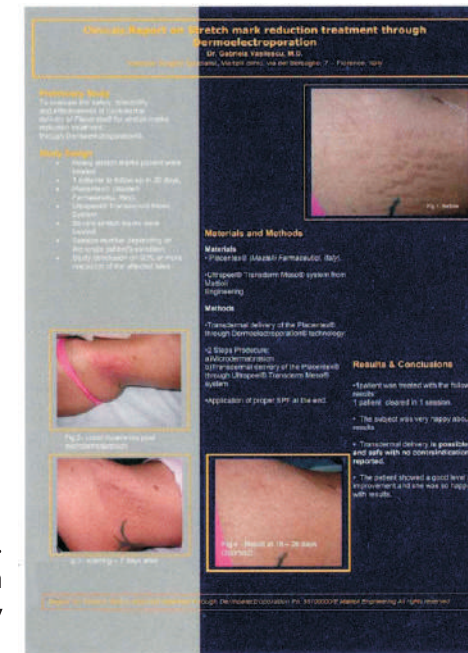


Mattioli Develops New Approach to Orange peel degeneration Reduction

DEP超导水光无创经皮肤给药系统治疗产后橘皮样变及妊娠纹的明显改善

结论：
DEP无创经皮肤给药系统治疗产后橘皮样变及妊娠纹有明显改善

Dr.Gabriela Vasilescu,M.D.
Vascular Surgery Specialist,Martelli clinic,via del Bersaglio,7 - Florence,Italy



Mattioli Develops New Approach to Cellulite Reduction

DEP system 新型经皮给药系统改善橘皮组织、减少脂肪堆积

结论:

通过DEP System 结合左旋肉碱有助于脂肪分解，减少脂肪堆积，改善橘皮组织

Maurizio Cavallini, M.D.
医学博士，整形外科医生，意大利米兰

Mattioli Develops New Approach to Cellulite Reduction

Dr. Maurizio Cavallini, M.D., a plastic surgeon from Milan, Italy, "This process managed to open 'special passages' in the passing of different molecules through the cell wall."

Ultrasound Transderm favors the transdermal absorption of many molecules. "Thanks to electrical impulses given at the same time they allow the passage of hydrophilic substances (electrical passage) and lipophilic substances (electrical passage)." This phenomenon has been verified by recent clinical studies confirming the passing of both micromolecules and macromolecules like lidocaine, collagen, the precursors of collagen and elastin, and rhinocortolides for different areas and clinical applications.

"To take maximum advantage of a substance already known in the field of cellulite treatments: L-carnitine," Dr. Cavallini said. "This substance was identified in 1969 as a natural component of cells, where it plays an important role in the utilization of the lipidic substratum." Carnitine is synthesized by amino acids such as lysine and methionine.

"To understand the role of L-carnitine in the metabolism against cellulite, it is important to remember that this substance is the only means where by fat acids can pass through the mitochondrial membrane with beta-oxidation as their final target," Dr. Cavallini said. "L-carnitine is the only way that the process of lipolysis transforms the triglyceride in glycerol and fat acids, which must move from the cytoplasm to the mitochondria, in order to be destroyed."

Dr. Cavallini has adopted a usage of L-carnitine via Dermoelectroporation. He often combines treatment with mesotherapy (lipolytic drugs). "Mesotherapy is a widely used procedure to treat cellulite. It consists of an intradermal penetration of medications capable of melting fat away through microinjections." In 12 women, Dr. Cavallini applied two to four grams of L-carnitine through a programmable dispenser. Dermoelectroporation was administered on the tracheanthic areas and on the internal part of the thighs.

"At the beginning, the application of L-carnitine was immediately followed by mesotherapy with retinone," Dr. Cavallini said. "But now, a high dose of L-carnitine has been necessary to favor the demolition of fat acids. This is why I currently apply Dermoelectroporation with carnitine before mesotherapy. After 12 applications, the results have been satisfactory, with reductions both in the volume and in the aesthetic appearance of the treated areas."

Dr. Cavallini stressed that cellulite must be considered a complex metabolic disorder affecting the fat tissue. "When cellulite is combined with other complications, the situation can become gradually worse."

210 European Aesthetic Buyers Guide, Autumn 2009 www.mattioli.com

Mattioli Develops New Approach to Hyperhidrosis

DEP无创经皮肤给药系统治疗腋下多汗症

结论:

无创经皮肤给药系统治疗腋下多汗症有明显效果

Maurizio Cavallini, M.D.
医学博士，整形外科医生，意大利米兰

PULSED CURRENT IONTOPHORESIS OF TYPE A BOTULINUM TOXIN FOR TREATMENT OF FOCAL HYPERHIDROSIS

M. Cavallini, S. Paoletti, M. Gualtiero, M. Ruggieri

Unit of Plastic Surgery (M.C.), General Hospital, Milan, Italy; *Department of Anatomy, Histology and Forensic Medicine, University of Florence, Italy; †Department of Experimental Pathology and Oncology, University of Florence, Italy

Introduction

Focal hyperhidrosis is a common disorder with chronic relapse. There are several therapeutic approaches, all of which are invasive, reflexive, and/or have long-term effects. Among them, the application of botulinum toxin (Botox) is the most effective. However, Botox is a neurotoxin and its use is limited by the risk of systemic complications. The aim of this study is to evaluate the efficacy of pulsed current iontophoresis (PC-IT) in the treatment of focal hyperhidrosis.

Materials and Methods

To evaluate the efficacy of pulsed current iontophoresis (PC-IT) in the treatment of focal hyperhidrosis, a series of 10 patients with focal hyperhidrosis of the axillae were treated with PC-IT. The treatment was performed on the axillae using a programmable dispenser.

Results

The results showed that PC-IT was effective in the treatment of focal hyperhidrosis. The patients reported a significant reduction in the amount of sweat produced after the treatment.

Conclusions

The present study has demonstrated that PC-IT is an effective and safe method for the treatment of focal hyperhidrosis. The results suggest that PC-IT may be a useful alternative to Botox in the treatment of focal hyperhidrosis.

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Report on Inner Arm excess skin relaxation treatment through Dermoelectroporation

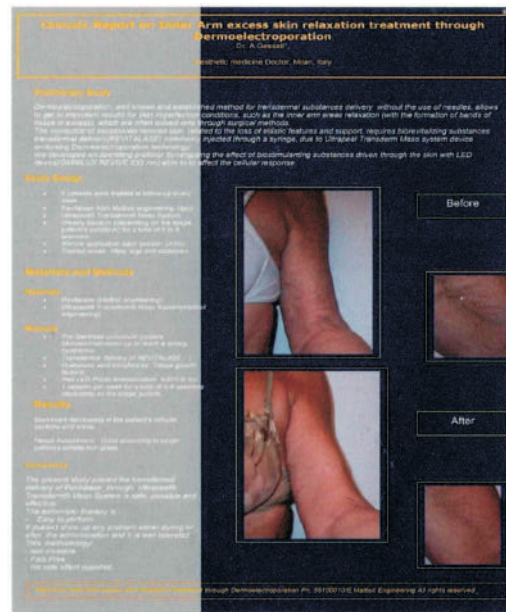
DEP无创经皮肤给药系统技术治疗上臂内侧松弛及过多脂肪的明显改善

结论:

通过DEP System 可以明显改善上臂松弛, 减少脂肪堆积, 改善橘皮组织

Dr. A.Gessati*

*Aesthetic medicine Doctor, Milan, Italy



Transdermal delivery of Hyaluronic acid -Journal of DermatologicalScience

(2006) 44, 169—171 Transdermal delivery of Hyaluronic acid, S. Pacini, T. Punzi, M. Gulisano Dep. of Anatomy, Histology and forensic medicine, University of Florence-Italy - M. Ruggiero, Dept. of Experimental pathology and oncology, University of Florence, Italy

Transdermal delivery of Clostridium Botulinum Toxin Type A by pulsed current Iontophoresis

S. Pacini, T. Punzi, M. Gulisano Dep. of Anatomy, Histology and forensic medicine, University of Florence -Italy - M. Ruggiero, Dept. of Experimental pathology and oncology, University of Florence - Italy American Academy of dermatology, 65th Annual meeting, 2007, Washington D.C. Category: Dermatopharmacology/

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fasc. 3

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Transdermal delivery of hyaluronic acid by pulsed current iontophoresis

M. Ruggiero, S. Pacini, M. Gulisano, American Academy of dermatology, 64th Annual meeting, 2006, S. Francisco CA,

Poster n. P1125 Category: Dermatopharmacology/Cosmeceuticals

Cellulite. Pathophysiology and treatment.

M.P. Goldman, P.A. Bacci, G. Libaschoff, D. Hessel, F. Angelini, Cap. 18 The role of Dermoelectroporation. P. A. Bacci



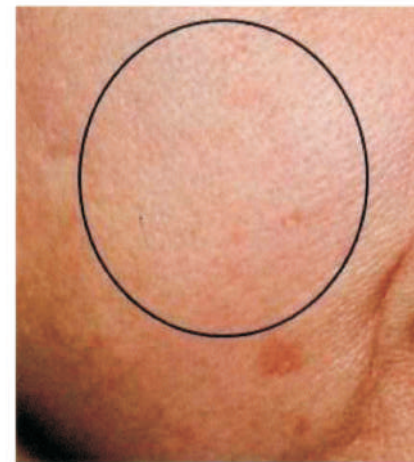
03

DEP系统疗效案例对比

非侵入无创给药，安全可靠疗效确切



Before



After





Before



After



Before



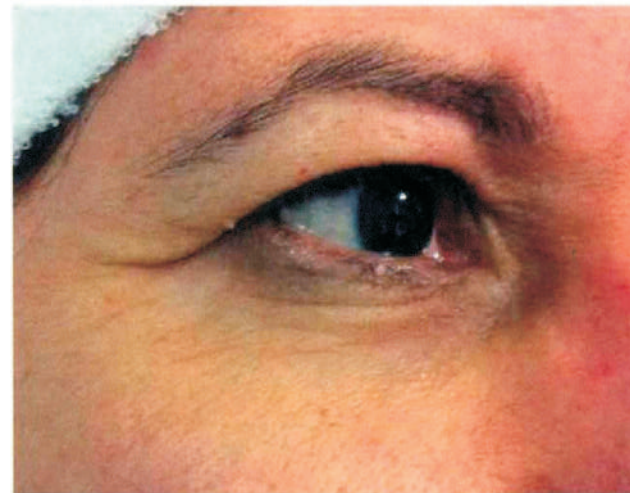
After



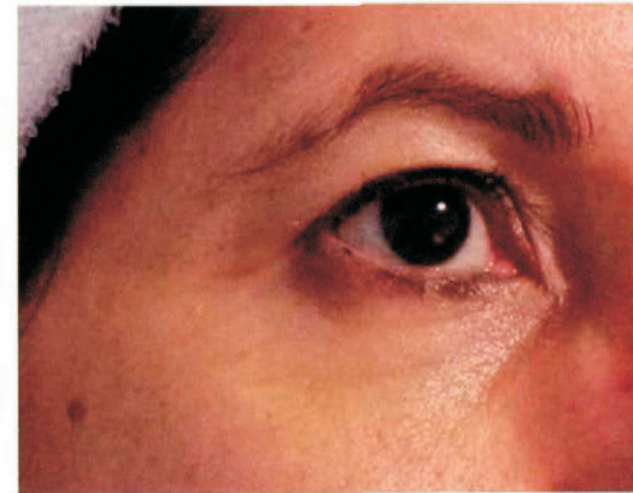
Before



After



Before



After



Before



After



Before



After



Before



After



Before



After



Before



After



Before



After



Before

After



Before

After

6 sessions Dermoelectroporation®

Courtesy of Innovative Concept



Before

6 sessions Dermoelectroporation®

After

Courtesy of Innovative Concept

Post-liposuction correction for abnormal fat deposition



Before

L-carnitine + Phosphatidylcholine + Dermoelectroporation®

After

Courtesy of Dr. suneil Jain -, Scottsdale AZ - USA

Liposuction divets treatment

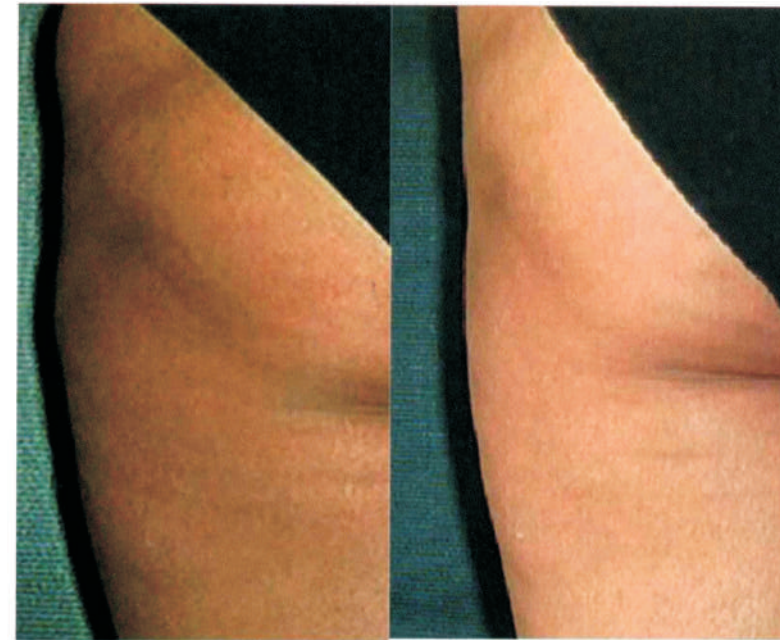


Before

After

HA + Dermoelectroporation®

Courtesy of Dr. Fulton, MD James E Fulton Jr MD PhD Vivant Skin Care, Miami, Florida USA



Before

After



卖点总结
增效
增量



- 电压电流: 输出9V DC, 1A max
- 平均脉冲电流: +/- 1mA, 2mA, 3mA, 4mA, 5mA用户可选, ±20%
- 负载阻抗: 0~15KOhm
- 脉冲频率: 2200Hz
- 持续时间: 10msec.
- 持续频率: 50Hz
- 可透皮药物大小: 800K Da max