Currently Approved Fillers in the US and Beyond

Michael H. Gold, M.D.

Clinical Appointments

- Assistant Clinical Professor
  - Dept. of Medicine, Division of Dermatology, Nashville, TN USA
  - Vanderbilt University School of Medicine
  - Vanderbilt University School of Nursing

- Meharry Medical College
  - Adjunct Assistant Professor, School of Medicine, Nashville, TN USA

- Visiting Professor of Dermatology
  - Huashan Hospital, Fudan University (Shanghai Medical University), Shanghai, China (12/06).
  - The First Hospital of China Medical University, Shenyang, China (11/08)
  - Guangdong Provincial People’s Hospital, Guangzhou, China (7/13)

- Visiting Professor of Plastic Surgery
  - First People’s Hospital of Foshan, University … Foshan, China (07/12)

The Aesthetic Market Today

- Patients want:
  - Quick recovery
  - Minimally invasive procedures
  - Maximal rejuvenation

- Lifting surgery being replaced by:
  - Volume replacement (fillers)
  - Facial muscle relaxation (neuromodulators)
  - Energy based systems with minimal downtime

Facial Characteristics Associated With Female Beauty

- Large, smooth forehead
- Well-proportioned nose
- Round and big eyes, set wide apart, prominent eyelashes
- Jaw with heart-shaped taper
- Lips with plump vermilion border
Facial Characteristics Associated With Male Beauty

- Overhanging brow
- Deep-set eyes
- Well-proportioned nose
- Wide mouth
- Large, squared lower face and jaw, muscular masticator muscles

What Makes People Look Old?


Regaining Youthful Contours

Tear trough depressions: “Dark Circles”

Regaining Youthful Contours

Nasolabial folds: “The Parentheses”


Melomental depressions: “Marionette lines”


HA Fillers - 2013

- Natural polysaccharide polymer that retains water
  - Non-allergenic
  - Soft natural look and feel
- Revisable
  - Dissolves over 6-12 months
  - Can be instantly dissolved with hyaluronidase
- Provides matrix on which collagen and elastic fibers may develop

Hyaluronic Acid
The science and art of hyaluronic acid dermal filler use in esthetic applications

Michael Gold, MD

Summary

The number of dermal fillers has expanded dramatically. Clinicians are faced with a rapidly growing number of products, each with different technical considerations, and use selection now becomes based on the patient's clinical presentation. Dermal fillers are among the most popular of minimally invasive procedures, with the greatest number of patients seeking rejuvenation. This article addresses the complications associated with dermal fillers, as well as the treatment of these complications. It summarizes the current safety data and also highlights the strategies for prevention of complications, and describes management options when complications do occur.

Restylane & Restylane-L

- Bacterial HA; no allergy testing required
- Restylane: FDA approval in 2003
- Restylane-L (includes 0.3% Lidocaine): FDA approval in 2010
- HA concentration: 20 mg/mL
- Particle size: ~260 μm
- Site of placement: mid dermis
- Uses: shallow to moderate wrinkles and folds, lips

Perlane & Perlane-L

- Bacterial HA; no allergy testing required
- Perlane: FDA approval in 2007
- Similar to Restylane, but with higher viscosity (larger particle size)
- Perlane-L (includes 0.3% Lidocaine): FDA approval in 2010
- HA concentration: 20 mg/mL
- Particle size: ~1000 μm
- Site of placement: deep dermis
- Uses: deep folds, facial contours, lips
Restylane®

Treatment areas

- Face, neck, decolletage and back of hands

Not Available in the US
HA Gel for Lips – Effectiveness and Safety

- **Juvéderm Ultra & Juvéderm Ultra XC**
  - Bacterial HAs; no allergy testing required
  - Juvederm ULTRA: FDA approval in 2006
  - Juvederm ULTRA XC (includes 0.3% Lidocaine): FDA approval in 2010
  - HA concentration: 24 mg/mL
  - Particle size: homogeneous gel
  - Site of placement: mid dermis
  - Uses: shallow to moderate wrinkles and folds, lips

- **Juvéderm Ultra Plus & Juvéderm Ultra Plus XC**
  - Bacterial HAs; no allergy testing required
  - Similar to Juvéderm Ultra: Juvéderm Ultra Plus XC includes 0.3% Lidocaine
  - HA concentration: 24 mg/mL
  - Particle size: homogeneous gel
  - Site of placement: deep dermis
  - Uses: deep and folds, facial contours, lips
XC = Lidocaine incorporated into syringe

Many more Juvederm products available in Europe

- EU Juvederm® ULTRA 2 = US Juvederm® ULTRA/ULTRA XC
- EU Juvederm® ULTRA 3 = US Juvederm® ULTRA Plus/ULTRA Plus XC
- EU Juvederm® ULTRA 4 = US Juvederm® 30/Forma (FDA approved but not marketed in the US)
- EU Juvederm® SMILE = no US equivalent
- EU Juvederm® Hydrate = no US equivalent

Juvederm with Lidocaine – US Data – FDA Pivotal Trial
J Cosm Derm 2009;8:205-210

Photos courtesy of Michael H. Gold, M.D.
The Laser & Rejuvenation Center of Gold Skin Care Center, Nashville, TN
Juvederm + Mannitol as an antioxidant for skin hydration
The European Aesthetic Guide, Autumn 2010

For volume correction
FDA Approved October 2013

Photos courtesy of Allergan

Photos courtesy of Allergan
Juvederm Ultra – Restylane Sub-Q

Juvederm® UltraPlus
Clinical Example

Immediately post treatment

Photos courtesy of Michael H. Gold, M.D.
The Laser & Rejuvenation Center of Gold Skin Care Center, Nashville, TN

Allergan
Juvederm Ultra Smile

Before
After

Photos courtesy of Allergan
Reduced Pain with Use of Proprietary Hyaluronic Acid with Lidocaine for Correction of Nasolabial Folds: A Patient-Blinded, Prospective, Randomized Controlled Trial

Gloria D. Collin, MD,1,2* Jesse M. Comstock, MD,1 Shane N. Nguyen, PA-C,1,2 Carlos P. Necheles,1,2 Cindy L. PHELPS, MS,1,2 ANDREW HUANG, MD,1,2,3 LIU Jiefan, MD,1,2

**BACKGROUND** Pain during and after injection of dermal gel filters is a common complaint of patients undergoing soft-tissue augmentation. Reduction of pain during injection can reduce patient comfort and improve the overall patient experience.

We evaluated the incidence of pain at the injection site during and after the injection of Prevelle Silk with lidocaine for treatment of nasolabial folds.

**METHODS** & **RESULTS** Three hundred patients, 194 female and 106 male, were randomized into 4 groups—each treated with Prevelle Silk with lidocaine at a dosage of 25% and 50% (Group 1) or 75% (Group 2) lidocaine. The pain scores were recorded at 0, 1, 2, 5, 10, 15, 30, 45, and 60 minutes after injection. Patients were asked to report for an evaluation after 2 weeks and to complete a post-treatment questionnaire during the follow-up period.

**RESULTS** There was significantly less pain associated with the use of Prevelle Silk with lidocaine than with the use of Prevelle Silk without lidocaine. The incidence of pain during injection was significantly lower in patients treated with Prevelle Silk with lidocaine compared to those treated with Prevelle Silk without lidocaine. Pain scores were lower at all time points after injection, and there were no differences in outcomes after 2 weeks.

**CONCLUSION** Addition of lidocaine to a gel resulted in significantly less pain associated with the procedure without compromising outcomes.
Belotero Balance
Merz Aesthetics – FDA Approved Nov, 2011

Note – only Basic = Balance in US

Belotero Soft
Correction of fine superficial folds

Belotero Balance (US)
Correction of moderate to deep folds

Belotero Intense
Correction of moderate to deep folds
BELOTERO BALANCE® Dermal Filler*

- BELOTERO BALANCE® Dermal Filler* has a high concentration of hyaluronic acid (HA) and a unique cross-linking technology.
- BELOTERO BALANCE® Dermal Filler was approved in November 2011 by the FDA for injection into the mid-to-deep dermis for correction of moderate-to-severe facial wrinkles and folds, such as nasolabial folds.

*Homogenous gel, 22.5 mg/mL HA manufactured by Anteis S.A.

The BELOTERO BALANCE® Dermal Filler Difference

Stage 5: Second cross-linking step, unique to BELOTERO BALANCE® Dermal Filler, along with the further addition of HA

Adapted from Bezzola A and Micheels P. J Med Esthet Chir Dermatol 2005;125:11-20
Differentiating HA Gels

BELOTERO® BASIC is homogenous and cohesive, allowing for a soft, smooth fill that works by adapting to the wrinkle.

*Homogenous gel, 22.5 mg/mL HA manufactured by Anteis


Subject 1

Subject's left: BELOTERO BALANCE®
Subject's right: Zyplast®


Subject 2

• Subject's left: BELOTERO BALANCE®
• Subject's right: Zyplast®


Merz Belotero – OLEX Study

Improvement in Nondermal Folds with a Hyaluronic Acid Filler Using a Cohesive Polydensified Matrix Technology. Results from an 18-Month Open-Label Extension Trial

BELOTERO BALANCE® OLEX Trial

- Initial injection of BELOTERO BALANCE® Dermal Filler at baseline in the double-blind phase (mean volume)\(^1\):
  - 1.09 mL for subjects receiving one injection
  - 2.0 mL for subjects receiving two injections
- First re-injection at Week 24 (mean volume)\(^2\):
  - 0.71 mL for NLF previously treated with BELOTERO BALANCE® Dermal Filler
  - 1.04 mL for NLF previously treated with ZYPLAST®
- Second re-injection, if needed, at 32, 48, 72 or 96 weeks after initial injection (mean volume)\(^3\):
  - Range from 0.46 mL to 0.69 mL for NLF previously treated with BELOTERO BALANCE® Dermal Filler


Optimal Duration of BELOTERO BALANCE® Dermal Filler

- 80.2% of patients persisted without repeat treatment for at least one 48-week interval (almost 1 year) → either Weeks 24 to 72 or Weeks 48 to 96

Conclusions: Persons of Color Study

- Injection of BELOTERO BALANCE® Dermal Filler showed no evidence of an association with hypopigmentation, hyperpigmentation or scarring
- Adverse events were generally mild to moderate in intensity ≤7 days

In this study, BELOTERO BALANCE® Dermal Filler was safe and well-tolerated for treating NLFs in patients of color with Fitzpatrick skin types IV, V and VI

Data on File, Merz Aesthetics, Inc. 2012.
Belotero
Glabellar Lines

Before After

1cc under eye

Photos courtesy of Michael H. Gold, M.D.
The Laser & Rejuvenation Center of Gold Skin Care Center, Nashville, TN

HA Filler for Correction of Deep Lines and Wrinkles

Before Belotero
7/16/2012

After Belotero
8/1/2012

One Treatment – 2 Weeks

Photos Courtesy of Michael H. Gold, MD
Gold Skin Care Center, The Laser and Rejuvenation Center, Nashville, TN
Sculptra®

- NewFill/Sculptra® – Biotech Industries/Dermik Aesthetics
  - Polylactic acid hydrogel
  - Sculptra® (injectable poly-L-lactic acid) is intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus

Product now owned by Valeant Pharmaceuticals

For Volume, Duration, and Safety in patients with facial fat loss (lipoatrophy)

- Volume
  - Restores fullness of the face, creating a more natural appearance
- Duration
  - Improvements in dermal thickness persisted for up to 2 years
- Safety
  - Clinically proven safe and well tolerated. No skin test required. Biodegradable, biocompatible

Sculptra Aesthetic received FDA clearance in July, 2009

• For the correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles which are treated with the appropriate injection technique in healthy people.

Photos courtesy of Michael H. Gold, M.D.
Gold Skin Care Center, Nashville, TN


Young Investigators Writing Competition Winners:
Cosmetic Use of Poly-L-Lactic Acid: A Retrospective Study of 130 Patients

Michelle M. Flax, MD, and Thomas E. Westerfield, MD, and Kenneth J. Stolovick, MD, and Michael H. Gold, MD

Background: Poly-L-Lactic Acid (PLLA) is an effective treatment for soft tissue deficiency. Although the Food and Drug Administration has approved PLLA for use in people with deep nasolabial fold lines, the technique for treating nasolabial fold lines is not described. This study compares before and after results of subcutaneous injections of PLLA injection in 130 treatment sessions.

Methods: This is a retrospective, observational study of 130 A-1 negative patients treated with PLLA from 2004 to 2005. Patient satisfaction and incidence of adverse reactions were evaluated.

Results: The mean volume injected was 0.05 mL (range 0.001-1.0 mL). A total of 110 (84%) patients were women. The nasolabial fold was evaluated bilaterally. An average of 3.9 (range 1-10) treatment sessions were performed per patient (range 1-10). A total of 293 (94%) of all the injections were bilateral and 6 (2%) were unilateral. Overall, 56% of the patients were treated on one side, 38% on both sides, and 6% on both sides of the face. The mean age of the study participants was 47 years (range 30-80). Treatment sites were determined based on individual needs and preferences. The most common treatment sites were the nasolabial fold, midcheek, and tear trough. Treatment sites varied from 1 to 15 per patient. Of the patients, 89% (116 patients) reported satisfaction with the result. Of these, 84% (97) were very satisfied. A total of 87% (113) of patients would repeat the procedure.

Conclusion: PLLA is an effective, noninvasive alternative to restoring the signs of aging in patients with nasolabial folds. The random nature and subjective evaluation of the study limits the ability to draw definitive conclusions. Further studies are required to determine the long-term efficacy and safety of PLLA treatment for nasolabial fold correction.
Clinical studies prove that in many patients RADIENSE lasts a year or longer and delivers a natural look that results in very high patient satisfaction.

- Synthetic Calcium Hydroxyapatite (CaHA) microspheres [30%] suspended in a carboxy-methylcellulose resorbable aqueous gel carrier [70%]
- Stimulates the body to produce new collagen
- No skin or allergy testing
- No special handling requirements
- 1.5-cc Volume Advantage
- 0.8-cc Moderate Fill
- 0.3-cc Touch Up

US Regulatory Approvals

- RADIENSE received approval from the FDA December 26, 2006 for facial soft tissue augmentation
  - Treatment of facial wrinkles and folds, such as nasolabial folds, marionette lines, etc.
  - Correction of facial wasting as a result of HIV-associated Lipoatrophy

- RADIENSE mixed with Lidocaine
  - FDA approved for facial aesthetic indication July 16, 2009

Merger of Merz and BioForm = Merz Aesthetics
Radiesse®

For Hollow Cheeks

Before Radiesse
July 16, 2012

After Radiesse
August 1, 2012

1.2cc tear troughs
1cc mid-face
L/R Cheek, jaw line
and oral commissures

Radiesse® Mixed With Lidocaine

Radiesse®

For volumising pre-jowl sulcus

Before Radiesse
July 16, 2012

After Radiesse
August 1, 2012

1.2cc tear troughs
1cc mid-face
L/R Cheek, jaw line
and oral commissures

Photos courtesy of Michael H. Gold, M.D.
The Laser & Rejuvenation Center of Gold Skin Care Center, Nashville, TN.

RADIESSE Mixed With Lidocaine

FDA approved for facial aesthetic use indication July 16, 2009


Summary of Studies

- RADIESSE demonstrates long term safety
  - As safe as collagen and hyaluronic acid
  - No reports in either study of late forming nodules/granulomas
- RADIESSE demonstrates long term effectiveness
  - A significant proportion of NLFS treated with RADIESSE show long term cosmetic improvement (up to 3 years)
- RADIESSE is a safe and effective material for soft tissue augmentation
- RADIESSE is safe for nasolabial fold treatment in persons of color
Comprised of biocompatible PMMA microspheres suspended in a 'more rapidly' dissolving bovine collagen carrier with 0.3% lidocaine

Created to induce "reactive" long-term collagen deposition

30-50 micron microspheres are too big to be phagocytized (20 microns is the cut off), but small enough to inject through a 26 gauge needle

What is ArteFill®

Artefill - Nasolabial Folds
Suneva Medical

Before Treatment
5 weeks post treatment with 2cc
Photos courtesy of Michael H. Gold, M.D.
The Laser and Rejuvenation Center of Gold Skin Care Center, Nashville, TN

ArteFill® Results: Actual patient

5 Year Prospective Artefill Safety Study

• The largest and longest prospective clinical study to date for dermal fillers in the US and EU

• Objectives
  • Overall assessment of Artefill safety in 1,000 subjects based upon the incidence of:
    • Anticipated & unanticipated adverse events (AEs)
    • Serious adverse events (SAEs)
  • The incidence of granuloma formation
  • Subjects' assessment of satisfaction
  • Interim analysis was completed at 31 months

Before Treatment After 6 Months After 1 Year After 5 Years
Photos Courtesy of © Artes Medical, Inc.
Hyaluronic Acid Fillers

**JDD 11(8): 2012**

**Hyaluronic Acid Fillers on the Horizon: Roundtable Discussion**

Gary Mitchell MD, Philippe Keramidas MD, Marina Sudkem MD

*JDD Phase 2 & 3 Clinical Research Center and University of Alabama at Birmingham, Birmingham, AL*  
*9/15* Patient: Tawad and New Directions, New, Future  
*Cosmetics*; *Converse, CA, Laser Imaging, R. Hedy, MD*

**ABSTRACT**

In this roundtable discussion, the physicochemical properties and internal clinical evaluations of two new ranges of hyaluronic acid fillers are examined. These include the safety and clinical acceptability of these interventions for use in cosmetic and aesthetic applications, and how this research is important for practitioners who are interested in the field of aesthetic medicine.

**Fillers Outside the US- 2013**

- Atlean
- Emervel
- Teosyl
- Glytone
- Zimmer
- Revanesse
- Succeev
- Stylage
- VarioFill
- Eilianse
- Princess
- Aquamid

- Many others being used in Europe and Asia – but many not on the US radar at this point
Lip Augmentation

- **Volume:** 2 ml glass syringe
- **HA concentration:** 26mg/ml
- **Needles:**
  - 1 Needle 25G 26 mm
  - 1 Cannula 22G 50 mm
  - 1 Cannula 25G 40mm (for injections with the AIS)
- **Injection level:** deep dermis, subcutaneously or in the upper periostea
- **Indications:** restore facial volumes (e.g., enhance the cheeks or chin) MODELIS® is also indicated to correct the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus.
A. Initial amortization of the injection
Reduced tissue trauma, as it has time to adapt to the change in volume.

B. Unparalleled injection precision
Throughput is maintained at +/- 2.5% of the target volume, whatever tissue resistance it meets, which limits both trauma and pain.

Significant Pain Reduction
The EMERVEL range provides five dermal fillers adapted to all patient needs.

**LIDOCAINE (0.3% W/V*) AVAILABLE IN 4 EMERVEL FILLERS**
- EMERVEL Classic**
- EMERVEL Deep**
- EMERVEL Lips
- EMERVEL Volume

**PROVIDES PAIN RELIEF**
- Within 1-5 minutes
- Up to 2 hours following injection

*N.B. Total amount well below maximum authorised amount of 200 mg (Xylocaine® injectable solution, Vidal 2009)*

* w/v: weight to volume ratio

**EMERVEL Optimal Balance Technology**

**OPTIMAL BALANCE**
- Variable crosslinking and calibration depending on target
- Single 20mg/ml HA concentration for an active reservoir of HA

**THE PLUS**
- No addition of inefficient uncrosslinked HA
- Calibration taking into account the needle gauge
- Small diameter of syringe for reduced extrusion strength
- Big inner diameter of needle for decreased injection force
EMERVEL Optimal Balance Technology

The Result of An Advanced Manufacturing Process
Optimal Balance Technology™

BALANCE BETWEEN THREE MAIN PARAMETERS:
Crosslinking
Calibration
Concentration

Figure 2 Standardized photographs of a representative patient from the open-label Group A.

Emervel Deep, Galderma
CHEEK FOLDS

Pre-injection + 3 weeks + 6 months

Classic: 0.6 ml

Teosyal

Teoxane Laboratories, Geneva
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**Teosyal After 1 Treatment Session**

![Image of facial treatment results after 1 session]
Glytone Fillers

Glytone 3: Deep Wrinkle Filler


Assessment of the clinical efficacy of a hyaluronic acid–based deep wrinkle filler using new instrumental methods

Virgine Turlier, Amandine Rouquier, David Black, Christine Aderholdt, Sabine Turliez, Agnès Brunet, Marie-Noëlle Gaudin, Christine Sandmaury, Véronique Fargues, Catherine Coutelier Bousset, Catherine Corbin-Grosbois, Barbara Thibodeau-Coppard, Arnaud Erginay, A. Anne-Marie Schmitt

Centre de Dermatologie Charles Percheron à la Roche-sur/Yon, Cutis, Cutis, Ferney-Voltaire, France, Cutis de Dermatologie à la Roche-sur/Yon, Paris, France and Dermatologie, Paris, France
The Revanesse® Family of Products

The Revanesse® family of products incorporates the latest advancements in cross-linking technology, resulting in a high-quality, safe, long-lasting dermal filler. The Revanesse® family of products offers the highest concentration of stabilized hyaluronic acid (SH) available, in addition to the rejuvenating properties of non-carrageenan HA. This line of products includes:

- Revanesse®
- Revanesse® ULTRA
- Revanesse® LITE
- Redesis
- Redesis ULTRA

Succeev
Hyaluronic Acid

Stylage

Stylage
- Europe has more fillers than US
- US FDA more stringent, therefore companies have to spend many $$ to bring a product into the US
- Then must determine ROI and time frame required before making commitment to US market
- Most companies want US market – not for all

Conclusions – OUS Fillers

Anatomic Location of Hyaluronic Acid Filler Material Injected into Nasolabial Fold: A Histologic Study

Dermatol Surgery 2008; 34: S56-S63

Anatomic Location of Hyaluronic Acid Filler Material Injected into Nasolabial Fold: A Histologic Study

CONCLUSIONS: This preliminary study demonstrates the clinical feasibility of a new injectable treatment for nasolabial folds. The anatomic location of hyaluronic acid filler material injected into nasolabial fold was evaluated using histologic analysis. The results showed that the filler material was predominantly located in the superficial and mid-reticular dermis, with a secondary deposit in the subcutaneous fat layer. The authors suggest that further research is needed to confirm these findings.
Cannulas and Advanced Injection Techniques

- Cannulas are rapidly becoming very popular in 2013 with filler injections
- Making less needle injections
- Making less inflammation
- Making more comfortable injections for patients


**A Randomized Trial to Determine the Influence of Laser Therapy, Monopolar Radiofrequency Treatment, and Intense Pulsed Light Therapy Administered Immediately after Hyaluronic Acid Gel Implantation**

**METHODS:** Participants with atrophy of the buccal fat pad were enrolled. Participants were randomized into three groups: laser treatment, radiofrequency treatment, and control. The primary outcome was volumetric measurement of the buccal fat pad at baseline and at 6 weeks following treatment.

**RESULTS:** There were no statistically significant differences between the groups in terms of volume change. The laser group showed a significant increase in volume compared to the control group. The radiofrequency group showed a trend towards increased volume, but this was not statistically significant.

**CONCLUSION:** Laser treatment appears to be effective in increasing the volume of the buccal fat pad. Further studies are needed to confirm these findings and to determine the optimal treatment parameters.
**Cannulas**

- Cannulas available in 2013
  - Merz Aesthetics Cannulas
  - Dermasculpt
  - Softfill Needles
  - Q-Med AB pix’L Microncannulas
  - .......

**WHERE TO FILL?**

- Dermal Break Down: WRINKLES
  - permanent wrinkling of Glabella, Lips, Cheeks…
- Folds: Nasolabial fold, marionette lines/sadness lines
- Lips Augmentation
- VOLUME of cheeks
- SCULPTING the face

**FILLING meant VOLUMIZING and SCULPTING**

Filling no long means erasing folds and wrinkles

It means giving volume - It means sculpting the skin, creating stimulation of the fibroblasts anywhere in the skin, therefore regenerating it.

Microcannulas allow to fill in all directions and at all levels of the skin and almost without any bruising and pain.
Cannulas – Merz Aesthetics

• Blunt tip for gentle insertion
• Lateral orifice near the tip for careful control
• Large inner diameter for very low extrusion force

These innovative, ultra-thin-wall cannulas are designed to provide excellent cosmetic results with potentially less bruising, swelling, pain and less down time.

Cannulas
Precise application for a range of indications
• Nasolabial folds
• Marionette lines
• Eyebrows
• Temples
• Back of Hands
• Lips
• Cheeks
• Chin
• Jawline

From stiff 18G canulas... to the new Dermasculpt flexible microcannulas 25G, 27G and 30G
Point of entry / areas

Lips

Tear Troughs and Periocular Depressions

SoftFil Needles

Soft Medical Aesthetics
The China Filler Market

China – Country of Cosmetic Filler Counterfeiting or Genuine Commerce?

A recent hot topic for debate within the aesthetic industry has been the number of counterfeit filler products flooding the European marketplace, and thus the global aesthetic market, in recent years due to a lack of multilevel regulations and the ease with which approval for sale in Europe can be obtained, in comparison to stricter American regulations.

Many of the products that do arise on our shores are from legitimate pharmaceutical companies with many years of experience in the field, although it could be argued that their products often lack credibility due to the small size, and thus the majority however are unproven, or even products, particularly in terms of hyaluronic acid-based fillers, emerging from the growing pharmaceutical industry in China.

We investigated the scale of this trend and looked at some of the ways that companies are seeking to route the back of the successions of major brands to get their counterfeit products in the hands of global clinicians and consumers alike.

Unfortunately, on further investigation we found that they have in fact taken this statement, and many others, directly from their website and their section or questions and answers in relation to the Rynessure® range. They simply changed the brand name to fit the bill.
The China Filler Market

| Fake | Real |

 Fake OTESALY Deep Lines  
 Real TEOSYAL Deep Lines

Conclusions

- We are in the greatest specialty with so many fun and exciting innovations
- You need to embrace this new technology and treat your patients with these great new options
- And most of all, enjoy this specialty and this field

Thank You

Michael H. Gold, M.D.
Gold Skin Care Center
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School of Medicine, School of Nursing
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