



Legend ProTM

Dare to imagine

Empowered by
TriPollar[®] RF and VoluDerm[™] Technology
Publication Compendium

Energy to Healthcare

Lumenis is a global leader in the field of minimally-invasive clinical solutions for the Surgical, Ophthalmology and Aesthetic markets, and is a world-renowned expert in developing and commercializing innovative energy-based technologies, including Laser, Intense Pulsed Light (IPL) and Radio-Frequency (RF).

For years, Lumenis' ground-breaking products have redefined medical treatments and have set numerous technological and clinical gold-standards. Lumenis has successfully created solutions for previously untreatable conditions, as well as designed advanced technologies that have revolutionized existing treatment methods in each and every one of the verticals we operate in.

Our drive for innovation stems from an uncompromising commitment to improving the health and well-being of our patients; addressing new and growing needs of aging populations; and in offering medical professionals cutting-edge solutions that fit seamlessly into the health-economics environment of the 21st century.

Legend Pro is intended solely for use by trained physicians and may pertain some risks such as edema or erythema. Refer to the operator manual for a complete list of intended use, contraindications and risks.

www.lumenis.com/Aesthetic

Table of Contents

| | |
|------------------------------|----|
| Testimonials | 4 |
| Bibliography | 6 |
| Peer Reviewed Papers | |
| TriPollar® RF | 6 |
| Voluderm™ (Microneedling RF) | 11 |
| TriFractional™ RF | 13 |
| White Papers | |
| TriPollar® RF | 14 |
| Voluderm™ (Microneedling RF) | 18 |
| TriFractional™ RF | 19 |

Testimonials

"The TriPollar® RF and the VoluDerm™ allows me to customize the treatments for my patients and get optimal results", Says Dr. Tretti Clementoni from Milan, Italy. "My patients are happy going through almost painless treatment, and treatment time is shorten without the need for numbing. The unique technologies allow treating multiple indications and get exceptional results".

Matteo Tretti Clementoni, MD – Laserplast Sagl, Milan, Italy

"TriPollar® RF is a great non-surgical treatment for rejuvenating the skin. We are very excited to offer TriPollar® to our patients. TriPollar® will be a great adjunct to people who already live a healthy lifestyle, who desire a more youthful appearance".

Carlos Ayala M.D. FACS - Ayala ENT & Plastic Surgery

"For years my patients have been asking me to find a low impact alternative to smooth their faces. After researching and testing dozens of devices, I have finally found one that I believe lives up to its promises. I am excited to add the TriPollar® to the list of services we provide at Central Ohio Plastic Surgery Inc. The treatment is generally considered to be an enjoyable experience - comparable to a warm massage".

Jason B. Lichten, MD, FACS - Central Ohio Plastic Surgery Inc



“TriPollar® treatments have a truly attractive profile for non-surgical anti-aging. I have used nearly every other non-invasive technology available, and when it comes to patient satisfaction, TriPollar® is superior. My patients are experiencing remarkable results from the very first treatment with absolutely no pain.”

Dr. Ronald L. Moy, Beverly Hills, California

“The TriPollar® technology generates energy and ultimately remodels collagen for skin rejuvenation. The use of TriPollar® allows for heat to be disseminated through the skin with minimal pain and discomfort. Less pain means more comfort for our patients, and combined with the clinical efficacies which have been demonstrated, makes the Legend one of those go-to machines for skin rejuvenation. With the Legend system, I can totally achieve the results my patients and I desire. The facial dermal volumizing and wrinkle reduction results are exceptional. The skin becomes more supple and elastic and my patients look and feel years younger. Most importantly, the results are natural-looking which is what my patients want.”

Michael H. Gold, M.D., Nashville, Tennessee, USA

“I absolutely recommend TriPollar® as an effective anti-aging solution. Not only does it have a strong safety profile, but I can assure my patients a pleasant and pain-free experience. I’m excited our practice was one of the first in the United States to offer this truly innovative technology.”

Jason N. Pozner, M.D. F.A.C.S, Boca Raton, Florida, USA

“I am pleased to be the first practice to work with TriPollar® technology in the USA. We performed 136 treatments in our FDA study, without any side effects. Patients reported a pleasant and pain-free experience and were satisfied with the results. I observed a significant reduction in wrinkles, and, overall, I am impressed by the immediate and long-term results achieved with the TriPollar® technology and its strong safety profile.”

Steven Shapiro, M.D., Palm Beach Gardens, Florida, USA

Bibliography

TriPollar® RF

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|---|---------------------------------|---|---------------------------------|------|-----------------------|
| 1 | Improving Upper Arm Skin Laxity* Using Tripollar® Radiofrequency Device | Yasmeen Kabir MD, Ronald Moy MD | TriPollar®, radio frequency, circumference reduction, skin tightening | Journal of Drugs in Dermatology | 2015 | Peer reviewed article |

Abstract

Non-ablative treatments for excess subcutaneous fat have been increasingly integrated into dermatologic practice. The objective of this study was to determine the safety and efficacy of a TriPollar® radio frequency device on tightening skin and reducing the circumference of the upper arms.

Main article conclusion

TriPollar radio frequency devices offer a safe and effective non-invasive technology with beneficial effects on the circumferential reduction and overall appearance of the posterior and anterior upper arms.

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|---|--|--|--|--|------|-----------------------|
| 2 | Evaluation of Safety and Efficacy of the TriPollar® Technology for Treatment of Wrinkles | Shapiro S. MD, Eros Y. MD, Abrahami. MD, Leviav A. MD | TriPollar®, radio frequency, wrinkle reduction, skin tightening, collagen remodeling | Journal of Cosmetics, Dermatological Sciences and Applications | 2012 | Peer reviewed article |
|---|--|--|--|--|------|-----------------------|

Abstract

Patient demand for non-surgical, non-invasive and no-downtime wrinkle reduction treatment procedures has grown. This study was performed in order to evaluate the safety and efficacy of the TriPollar® radiofrequency (RF) technology and intended for wrinkle reduction treatment. To evaluate treatment, efficacy, pre- and post-treatment photos were assessed using a blinded evaluation by two uninvolved physicians. Results: No unexpected adverse side effects were detected or reports. All subjects participating in the study reported no pain or mild pain during the treatments. The photographic analysis of pre- and post-treatment by the two blinded physicians revealed improvement. All patients were satisfied from treatment results to a different extent.

Main article conclusion

The results of this study clearly indicate that the TriPollar® system offers a non-invasive, effective, safe and virtually painless wrinkle and rhytides reduction treatment.

* Some indications mentioned in the paper might not be cleared by FDA

TriPollar® RF

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|--|-----------|--|---------------------------------------|------|-----------------------|
| 3 | Use of a TriPollar® radio-frequency device for the treatment of acne vulgaris* | Yu, H. MD | Acne vulgaris, radio frequency, Apollo, Tripollar® | Journal of Cosmetic and Laser Therapy | 2011 | Peer reviewed article |

Abstract

Acne vulgaris is a common disease affecting mainly teenagers and young adults. Current treatment modalities include local or systematic medications, which often require long intake. Light and radio frequency (RF) devices have recently been used to treat acne in selected patients. Objective: To evaluate the safety and efficacy of TriPollar® RF technology for non-invasive treatment of acne vulgaris lesions. Results: An average reduction of 42% in active acne lesions was found after six TriPollar® sessions, which was sustained at the 4-week follow-up visit. The average improvement rated by patients at the 4-week follow-up visit was 2.5, indicating good to very good satisfaction. No significant adverse events were recorded during the study and follow-up period.

Main article conclusion

TriPollar® RF treatment offers a painless, quick and convenient treatment method to decrease active acne lesions, improve patients' skin appearance, reduce anxiety related to acne and its treatment, and avoid the development of acne scars. The findings confirm the safety and efficacy of the TriPollar® RF for the treatment of acne vulgaris.

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|---|---|-----------------|---|---------------------------------|------|-----------------------|
| 4 | Clinical Experience with a TriPollar® Radiofrequency system for Facial and Body Aesthetic treatments* | Levenberg A. MD | Collagen, fat, radio frequency, skin tightening, TriPollar® | European Journal of Dermatology | 2010 | Peer reviewed article |
|---|---|-----------------|---|---------------------------------|------|-----------------------|

Abstract

Non-invasive aesthetic treatments aiming at circumference reduction and facial wrinkle improvement are becoming increasingly popular. TriPollar® treatments for the purpose of body contouring and skin tightening procedures have recently gained interest. The purpose of the study was to evaluate the safety and efficacy of the Apollo device for noninvasive treatment of localized excess fat and facial tightening.

Main article conclusion

An improvement of perioral and periorbital wrinkles was achieved and analyzed. No significant changes were found in any of the liver function and lipid profile indicators. Findings confirm safety and efficacy of the new treatment modality for localized fat reduction and for body and face contouring.

* Some indications mentioned in the paper might not be cleared by FDA

TriPolar® RF

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|---|-----------------------------------|--|--|------|-----------------------|
| 5 | Ex vivo human skin evaluation of localized fat reduction and anti-aging effect by TriPolar® radiofrequency treatments.* | Boisnic S. MD, Branchet M. PhD | Collagen, fat, ex vivo, radio frequency, TriPolar® | Journal of Cosmetics and Laser Therapy | 2010 | Peer reviewed article |

Abstract

A wide variety of radio frequency (RF) treatments for localized fat and cellulite reduction as well as anti-aging are available nowadays, but only a few have shown the biological mechanism responsible for the clinical results. The objective of the study was to determine the biological mechanism of the TriPolar® RF device for localized fat and cellulite reduction as well as the collagen remodeling effect.

Main article conclusion

The detected alteration in the hypodermal layer is manifested by fat and cellulite reduction accompanied by structural and biochemical improvement of dermal collagen, which result in overall skin tightening.

| | | | | | | |
|---|----------------------------|-----------------------|---------------------------------------|--|------|-----------------------------|
| 6 | TriPolar® radio frequency* | Manuskiatti, W. MD | Cellulite, TriPolar®, Radio frequency | Cellulite: Pathophysiology and Treatment. Second edition | 2010 | Review article in text book |
|---|----------------------------|-----------------------|---------------------------------------|--|------|-----------------------------|

Abstract

Developed in 2006, TriPolar® RF is the third generation RF technology employing a multiple-electrode configuration (Figs. 22.1–22.2). TriPolar® technology is based on the use of three or more electrodes to deliver focused RF current into the skin, thus generating heat through resistance in both the dermal and subcutaneous layers. The depth of heat penetration is approximately the average distance between the three electrodes. One acts as a positive pole while the other two act as negative poles. The current flowing through the common, positive pole is twice that which flows through each of the negative poles. To avoid overheating of this common pole and of the tissue in contact with this pole, a sequence of electrical modulation is applied so that each electrode, in turn, acts as the common pole. Due to its design, no active cooling of the electrodes or the skin is required.

Main article conclusion

The TriPolar® RF device is a multi-polar RF system which can safely and effectively be used for skin tightening and circumference reduction, particularly on the body and facial areas, as well as for the treatment of cellulite, reduction of localized fat and improvement of striae appearance. Application of this treatment modality is simple, non-invasive and safe on all skin types. Qualitative as well as quantitative assessments have been documented and the outcome from previous research studies has shown that the improvements are maintained as a long-term effect.

* Some indications mentioned in the paper might not be cleared by FDA

TriPollar® RF

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|--|----------------------------|---|--|------|--------------------------|
| 7 | Clinical and Histopathological results following TriPollar® radio frequency skin treatments* | Kaplan H. MD, Gat A. MD | Collagen, fat, radio frequency, TriPollar® | Journal of Cosmetic and Laser Therapy | 2009 | Peer reviewed article |

Abstract

Skin laxity, wrinkles and cellulite are common aesthetic problems associated with the aging process. These symptoms are due to the weakening and thinning of dermal connective tissue and the enlargement of hypodermal fat cells. The aim of this study was to evaluate the safety and efficacy of the TriPollar® RF technology in reducing fat and collagen regeneration.

Main article conclusion

The TriPollar is a safe and effective non-invasive technology leading to skin tightening and body shaping. Histology results indicate changes at the dermal and fat layers following TriPollar® treatments resulting in increased collagen regeneration and stimulated fat metabolism.

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|---|---|----------------------|--|--|------|--------------------------|
| 8 | Treatment of striae distensae with a TriPollar® radiofrequency device: A pilot study* | Manuskiatti W. MD | Collagen remodeling, radiofrequency device, striae, volumetric heating | Journal of Dermatological Treatment | 2009 | Peer reviewed article |
|---|---|----------------------|--|--|------|--------------------------|

Abstract

Striae distensae are a frequent skin condition for which treatment remains a challenge. Objectives: To determine the efficacy and safety of a TriPollar® radiofrequency (RF) device for the treatment of striae in skin phototypes IV–V.

Main article conclusion

TriPollar® RF appears to be a promising alternative for the treatment of striae distensae.

* Some indications mentioned in the paper might not be cleared by FDA

TriPollar® RF

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|--|--------------------|--|--|------|-----------------------|
| 9 | Circumference reduction and cellulite treatment with a TriPollar® radiofrequency device: A pilot study.* | Manuskiatti, W. MD | Cellulite, circumference reduction, localized fat, radio frequency | Journal of the European Academy of Dermatology and Venereology | 2009 | Peer reviewed article |

Abstract

A wide variety of treatments for circumference reduction and cellulite are available, but most procedures offer sub optimal clinical effect and/or delayed therapeutic outcome. The objective of this study was to determine the safety and efficacy of the TriPollar® radio frequency device for cellulite treatment and circumference reduction.

Main article conclusion

TriPollar radio frequency provided beneficial effects on the reduction of abdomen and thigh circumference and cellulite appearance.

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|----|--|----------------|--|-------------------------------|------|-----------------------|
| 10 | An Ex-Vivo study of the Regen™ TriPollar® RF device using an experimental human skin model.* | Boisnic, S. MD | Cellulite, TriPollar®, radio frequency, collagenesis | Les Nouvelles Dermatologiques | 2008 | Peer reviewed article |
|----|--|----------------|--|-------------------------------|------|-----------------------|

Abstract

The aim of this ex vivo study was to test the anti-cellulite and skin tightening effects of a TriPollar® radio frequency technology (Regen™) on ex-vivo human skin samples harvested from abdominoplasty surgery and maintained in survival conditions.

Main article conclusion

The effects of TriPollar® radio frequency showed a significant increase of glycerol released by the skin, indicating lipolysis. Additional findings included vasoconstriction of the capillaries and improvement of collagen fibers which leads to tightening of the skin.

* Some indications mentioned in the paper might not be cleared by FDA

Voluderm™ (Microneedling RF)

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|--|--------------------------------|--|---|------|-----------------------|
| 1 | Treating the neck with Hybrid Energy Technology* | Ancona D. MD, Valerio P. MD | Micro-needle radio frequency, skin laxity, wrinkles, Hybrid Energy, wound healing response | Prime International Journal of Aesthetic and Anti-ageing medicine | 2016 | Peer reviewed article |

Abstract

The article discusses the results of a comparison study between two non-surgical technologies (Hybrid Energy, Pollogen) to treat the ageing neck, including wrinkles, skin texture and skin laxity.

Main article conclusion

Fractional microneedle radio frequency technology has shown to be safe and effective in the treatment of skin wrinkles and neck skin laxity, as indicated by patient satisfaction, minimal pain, and short downtime.

The results of this study clearly demonstrated that the Hybrid Energy technology was a safer, more satisfactory and tolerable treatment option for the ageing neck, with minimal pain and no downtime.

| | | | | | | |
|---|---|----------------|---|--|------|-----------------------|
| 2 | VoluDerm Micro-Needle Technology for Treating Skin Laxity and Wrinkles-Initial Clinical Experience* | Shapiro, S. MD | VoluDerm, Micro-needle RF technology, skin tightening, volumizing, skin enhancement | Jacobs Journal of Experimental Dermatology | 2015 | Peer reviewed article |
|---|---|----------------|---|--|------|-----------------------|

Abstract

In the past years, fractional radio frequency (RF) systems have been popular skin rejuvenation and anti-aging procedures for the treatment of wrinkles, scars and general facial enhancement associated with minimal down time and low risk. The newest fractional RF technology to come to market is VoluDerm™ (VO). VO delivers energy into the dermis by a matrix of micro-needles that penetrate the skin stimulating a controlled wound effect that promotes a natural fractional healing process for dermal volume enhancement and skin resurfacing. This article evaluated the safety and effectiveness of the novel VO technology for collagen remodeling, skin volume enhancing and wrinkle reduction.

Main article conclusion

The novel VoluDerm micro-needle technology is a safe and effective treatment for wrinkles, skin tightening, volumizing, texture improvement and natural looking skin enhancement in facial and neck areas with negligible side effects, minimal pain, and quick visual healing.

* Some indications mentioned in the paper might not be cleared by FDA

Voluderm™ (Microneedling RF)

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|--|-----------------------------------|---|---------------------------------|------|-----------------------|
| 3 | Ex vivo study of hybrid energy technology using a human skin model.* | Boisnic S. MD, Branchet M. PhD | Hybrid energy, Fractional Radio frequency, Hyaluronic Acid, Collagen, Ex-Vivo Histology | European Journal of Dermatology | 2014 | Peer reviewed article |

Abstract

More aging adults and the social acceptance of aesthetic treatments have increased the demand for minimally invasive aesthetic treatments. Skin resurfacing is very effective at improving aging symptoms, including wrinkles and skin imperfections. Following the negative effects of full skin resurfacing, in addition to a very long downtime, fractional lasers and fractional radiofrequency (RF) technologies were introduced, since gaining popularity. Their efficacy, along with minimal downtime, has enabled an effective and safer treatment. A novel technology based on fractional Hybrid Energy™ (HE), combines RF and an additional electrical energy for enhancing the thermal effect. Objective: This study evaluated the morphological and histological effects of the new HE technology on epidermal and dermal skin layers, using an ex-vivo human skin model.

Main article conclusion

Hybrid Energy technology significantly affected collagen remodeling and an increase in mid to deep dermis GAGs in addition to epidermal mitotic index, resulting in long term structural and biochemical dermal and epidermal improvement.

| | | | | | | |
|---|--|--------------------------------|--|--|------|-----------------------|
| 4 | VoluDerm Microneedle Technology for Skin Treatments – In Vivo Histological Evidence. | Gershonowitz A. DVM, Gat A. MD | Antiaging, fractional, radio frequency, VoluDerm | Journal of Cosmetics and Laser Therapy | 2014 | Peer reviewed article |
|---|--|--------------------------------|--|--|------|-----------------------|

Abstract

The growing demand for skin rejuvenation procedures with minimal down time and low risk has led to the development of fractional radio frequency (RF) systems. The new VoluDerm™ RF micro-needle technology creates minute columns of tissue thermal microablation. Treatment triggers natural fractional healing, resulting in dermal volumizing and skin renewal. This pre-clinical research assessed the safety and efficacy of VoluDerm through histological evaluation of morphological changes in the target tissue.

Main article conclusion

The major impact of VoluDerm is on the dermal layer, thus treatment is associated with less to no downtime, less patient discomfort, and less predisposition to side effects compared with no-needles fractional technologies or other micro-needle technologies in which penetration mechanism is mechanical. With VoluDerm, the visible impact on the epidermal layer is relatively minor and less prominent compared with these technologies, although the desired micro-resurfacing effect is achieved. Due to the RF-assisted smooth penetration of the VoluDerm micro-needles into the skin and to the unique tip electrodes design, treatments result in effective and safe treatment coverage and clinical outcome, thus there is no need for longer needles to achieve the desired clinical effect.

* Some indications mentioned in the paper might not be cleared by FDA

TriFractional™ RF

| STUDY | TITLE | AUTHORS | MAIN TOPICS | PUBLICATION | YEAR | TYPE |
|-------|--|-----------------------------------|---|---------------------------------------|------|-----------------------|
| 1 | Evaluation of Safety and Efficacy of the TriFractional™ RF technology for treatment of facial wrinkles.* | Gold M. MD, Adelglass J. MD | Anti-aging, radio frequency, skin resurfacing, TriFractional, wrinkle reduction | Journal of Cosmetic and Laser Therapy | 2013 | Peer reviewed article |

Abstract

Skin resurfacing is an accepted gold standard for the treatment of skin laxity, photo damage, and appearance of visible lines and wrinkles. However, the relatively significant risk and the long downtime associated with whole area resurfacing treatments have led to the introduction of fractional resurfacing lasers and radiofrequency (RF) technologies. This study was performed in order to evaluate the safety and efficacy of the new TriFractional technology using the 3F Applicator (A3F), designed to enable skin resurfacing and treatment of wrinkles using fractional RF energy.

Main article conclusion

The results of this study clearly indicate that the TriFractional technology using the 3F applicator provides a safe, tolerable, and effective treatment of facial wrinkles.

* Some indications mentioned in the paper might not be cleared by FDA

White Papers

TriPollar® RF

| STUDY | TITLE | AUTHORS | YEAR | TYPE |
|-------|--|----------------------|------|-------------|
| 1 | Apollo™ - TriPollar® Non-Surgical Facial Treatment | Alex Levenberg, M.D. | 2009 | White paper |

Abstract

Objective: To evaluate the safety and efficacy of the Apollo™ device for facial treatments.

Methods: Seven female subjects underwent facial treatments once a week using the Apollo™ system. The system is equipped with both a medium and a small applicator specifically designed for facial treatments. Results were objectively recorded and analyzed with a three-dimensional imaging system.

Results: Following the apollo facial treatments, an improvement of perioral and periorbital wrinkles was achieved and analyzed using the Primos imaging system.

Main article conclusion

Findings demonstrated the safety and efficacy of the Apollo™ treatment protocol for facial skin tightening. Treatments resulted in tighter, 'lifted' skin with improvement of fine lines and wrinkles.

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|---|---|----------------------|------|-------------|
| 2 | Circumference Reduction by TriPollar® RF Technology Using the Apollo™ Device* | Alex Levenberg, M.D. | 2008 | White paper |
|---|---|----------------------|------|-------------|

Abstract

Background: Aesthetic procedures aiming at circumference reduction are desired by both women and men worldwide. Non-invasive treatments using IR light, RF, laser or ultrasound are common practice but do not necessarily provide the optimal solution. Apollo™ is the first medical grade non invasive system that uses cutting edge 3rd generation TriPollar® RF technology, for the purpose of circumference reduction.

Objective: The evaluation of the safety and efficacy of the Apollo™ device for non invasive treatment of excess fat manifested by circumference reduction.

Method: 37 healthy female patients in three clinics underwent sessions of TriPollar® treatments using the Apollo™ device. Body treatments were performed at one week intervals between sessions. Results were assessed using photographs and circumferential measurements.

Results: Significant reduction in body circumferences was observed following the treatment period. The average circumference reduction in the main body areas (abdomen, buttocks, thighs) was 3.6 ± 2.4 cm with a maximum reduction of up to 10.5 cm in the abdomen. No adverse events were recorded during the evaluation period.

Main article conclusion

The Apollo™ device powered by TriPollar® technology, is a safe and effective procedure for the treatment of excess fat and circumferential reduction.

* Some indications mentioned in the paper might not be cleared by FDA

TriPollar® RF

| STUDY | TITLE | AUTHORS | YEAR | TYPE |
|-------|---|-------------------|------|-------------|
| 3 | TriPollar® RF Non-Surgical Face Lift & Skin Tightening – Long Term Results* | Omer Buhsem, M.D. | 2008 | White paper |

Abstract

Background: It has been well established that TriPollar® RF treatments depict immediate visible results. The question of long term collagen remodeling and maintaining the clinical results have been addressed in this study by way of thorough analysis.

Objective: This study aims to determine the long term clinical efficacy and safety of the non-ablative regen™ system, employing TriPollar® RF technology, in the treatment of skin tightening and circumference reduction of facial, neck and abdominal skin.

Method: Subjects enrolled in the study were healthy female patients between the ages of 18-65 with lax and excess fatty facial, neck and abdominal skin were recruited for the study. Using the regen™ system, the subjects (patients) underwent a regimen of 8 TriPollar® RF treatments at weekly intervals. Throughout the study, before and after each treatment, the patient's progress was photographically documented. Treatments continued until a full treatment course was concluded and expectations were met. These results were evaluated during a final clinical assessment 6 months after the last treatment, which included patient self-assessment as well.

Results: Immediate visible results were noticed from the first treatment. The patient's results, observed gradually over the full course of treatment, revealed a significant circumference reduction and observable lifting of sagging skin. Further, these clinical results improved 6 months after last treatment due to collagen remodeling. The patient's self-assessment after the full course of the treatment was "excellent". No adverse side effects during or after any of the treatments. Further, throughout the study none of the patients experienced any need for downtime following any of the treatments.

Main article conclusion

This clinical study concluded a very good overall improvement in skin laxity and circumference reduction with absolutely no downtime for any patients. The TriPollar RF treatments are safe and effective for non-surgical face lifting, skin tightening and circumference reduction on all skin types. Long term results are excellent.

* Some indications mentioned in the paper might not be cleared by FDA

TriPollar® RF

| STUDY | TITLE | AUTHORS | YEAR | TYPE |
|-------|---|-------------------|------|-------------|
| 4 | TriPollar® RF Non-Surgical Face Lift & Skin Tightening – Long Term Results* | Omer Buhsem, M.D. | 2008 | White paper |

Abstract

Background: It has been well established that TriPollar® RF treatments depict immediate visible results. The question of long term collagen remodeling and maintaining the clinical results have been addressed in this study by way of thorough analysis.

Objective: This study aims to determine the long term clinical efficacy and safety of the non-ablative regen™ system, employing TriPollar® RF technology, in the treatment of skin tightening and circumference reduction of facial, neck and abdominal skin.

Method: Subjects enrolled in the study were healthy female patients between the ages of 18-65 with lax and excess fatty facial, neck and abdominal skin were recruited for the study. Using the regen™ system, the subjects (patients) underwent a regimen of 8 TriPollar® RF treatments at weekly intervals. Throughout the study, before and after each treatment, the patient's progress was photographically documented. Treatments continued until a full treatment course was concluded and expectations were met. These results were evaluated during a final clinical assessment 6 months after the last treatment, which included patient self-assessment as well.

Results: Immediate visible results were noticed from the first treatment. The patient's results, observed gradually over the full course of treatment, revealed a significant circumference reduction and observable lifting of sagging skin. Further, these clinical results improved 6 months after last treatment due to collagen remodeling. The patient's self-assessment after the full course of the treatment was "excellent". No adverse side effects during or after any of the treatments. Further, throughout the study none of the patients experienced any need for downtime following any of the treatments.

Main article conclusion

This clinical study concluded a very good overall improvement in skin laxity and circumference reduction with absolutely no downtime for any patients. The TriPollar® RF treatments are safe and effective for skin tightening and circumference reduction on Asian skin types. Further studies are needed to optimize the number and frequency of treatments.

* Some indications mentioned in the paper might not be cleared by FDA

TriPollar® RF

| STUDY | TITLE | AUTHORS | YEAR | TYPE |
|-------|--|------------------|------|-------------|
| 5 | TriPollar® RF Skin Tightening & Circumference Reduction Treatment on Asian Skin* | Sehyun Kim, M.D. | 2007 | White paper |

Abstract

Background: It has been well established that Asian skin types are more sensitive to laser or IPL treatments (light-based treatments) due to a larger concentration of melanin in the skin. A new non-ablative treatment modality based on selective electro-heating, TriPollar® RF Technology, was recently introduced aimed at skin tightening for skin laxity and circumference reduction on facial, neck and arm skin. As this new treatment does not utilize any type of light it is not skin color dependent and is wholly suitable for Asian skin types.

Objective: This study aims to determine the clinical efficacy and safety of the non-ablative regen™ system, employing TriPollar® RF technology, in the treatment of skin tightening and circumference reduction of facial, neck and arm skin in Asian skin types.

Method: 100 Asian adult patients with lax and excess fatty facial, neck and arm skin were recruited for the study. Using the regen™ system, the patients underwent a regimen of one TriPollar® RF treatment at weekly intervals. Throughout the study, before and after each treatment, the patient's progress was photographically documented. Treatment continued until expectations were met. These results were evaluated during a final clinical assessment, which included patient self-assessment as well.

Results: Immediate visible results were noticed from the first treatment. As seen in the photographs below (fig. 7), the patient's results, observed gradually over the full course of treatment, revealed a significant circumference reduction and observable lifting of sagging skin. The patient's self-assessment after the full course of the treatment was "excellent". This patient experienced no adverse side effects during or after any of the treatments. Further, throughout the study none of the patients experienced any need for downtime following the treatments.

Main article conclusion

This clinical study concluded a very good overall improvement in skin laxity and circumference reduction with absolutely no downtime for any patients. The TriPollar® RF treatments are safe and effective for skin tightening and circumference reduction on Asian skin types. Further studies are needed to optimize the number and frequency of treatments.

* Some indications mentioned in the paper might not be cleared by FDA

Voluderm™ (Microneedling RF)

| STUDY | TITLE | AUTHORS | YEAR | TYPE |
|-------|---|--|------|-------------|
| 1 | Surgen™ Hybrid Energy™ - A novel Micro-Needles Technology for Skin Treatment* | Levenberg, A. MD, Salazar C, MD, Branchet M, PhD, Boisnic S., MD | 2012 | White paper |

Abstract

Demand for skin rejuvenation and anti-aging procedures with minimal down time and low risk has led to the development of methods for non-surgical treatment of wrinkles, scars and general facial enhancement. In the past few years, fractional radio frequency (RF) systems have been introduced that enable controlled skin resurfacing. The new Hybrid Energy™ (HE) micro-needle technology delivers hot and electrical energies creating micro-ablation thus promoting natural fractional healing process for dermal refilling and skin renewal. The objective of the current research was to evaluate the safety and effectiveness of the Hybrid Energy™ applicator for collagen remodeling, skin volume refilling and wrinkles reduction.

Main article conclusion

Hybrid Energy™ invisible micro-ablation treatment results in a significant dermal enhancement and skin renewal while minimizing epidermal visible response. Hybrid Energy technology™ delivers results with none to minimal pain and no downtime.

* Some indications mentioned in the paper might not be cleared by FDA

TriFractional™ RF

| STUDY | TITLE | AUTHORS | YEAR | TYPE |
|-------|--|---------------------------------|------|-------------|
| 1 | A Novel Fractional Radiofrequency Technology for Skin Resurfacing and Treatment of Wrinkles – Clinical Histological Results* | Levenberg A, M.D Gat A, M.D. | 2011 | White paper |

Abstract

The need for cosmetic facial enhancement procedures with minimal down time and low risk has led to the development of methods for non-surgical skin rejuvenation. Various ablative lasers were developed, which remove full skin surface in a controlled manner. However, the prolonged recovery and the significant risks prompted the development of fractional lasers which ablate the skin in a fractional manner, leaving untreated area to improve healing process. In the past few years, fractional RF systems have been introduced that enabled control skin resurfacing accompanied with dermal collagen remodeling. The new TriFractional™ technology from Pollogen is designed to enable skin resurfacing and treatment of wrinkles.

Main article conclusion

TriFractional™ is a promising technology for skin resurfacing, treatment of wrinkles and improvement of additional aesthetic indications such as acne scars. The TriLipo™ MED procedure is a unique combination approach for the total facial rejuvenation and contouring.

* Some indications mentioned in the paper might not be cleared by FDA

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