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Contents

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Aesthetic Medicine is a multidisciplinary Journal with the aim of informing readers about the most important developments in the field of Aesthetic Medicine.

Submission of manuscripts

All articles in their final version - completed with name, surname, affiliation, address, phone number and e-mail address of the author (s) - must be sent in word format to the Editorial Committee at the following e-mail address: aemj@aestheticmedicinejournal.org. Manuscripts must be written in English, and authors are urged to aim for clarity, brevity, and accuracy of information and language. All manuscripts must include a structured abstract. Authors whose first language is not English should have their manuscripts checked for grammar and stylistic accuracy by a native English speaker.

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The title page should include:
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· The authors must disclose any commercial interest that they may have in the subject of study and the source of any financial or material support

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The length of the abstract should be no more than 250 words and should include the following headings: Background, Aim, Methods, Results, Conclusions

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Up to six keywords should be listed and separated by a comma (please, verify keywords on MeSH).

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The manuscript should be organised in the following sections:
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· Results
· Discussion and Conclusions
· Acknowledgments
· Conflict of interest
· Reference list
· Legends (max 10)

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· Use tab stops or other commands for indents, not the space bar
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The authors declare that they have no conflict of interest.
If potential conflicts of interest do exist, the authors should provide details (see below) for each affected author in a note in a separate DISCLOSURE section of the manuscript document text, before the list of references.

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References

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Journal article - online* *if there is no DOI, provide the URL for the specific article	Coppinger T, Jeanes YM, Hardwick J, Reeves S. Body mass, frequency of eating and breakfast consumption in 9-13- year-olds. *J Hum Nutr Diet.* 2012; 25(1): 43-49. **doi: 10.1111/j.1365-277X.2011.01184.x**
Journal article - online from a library database* *there is no specific way to cite articles found in library databases according to the AMA so double check with your professor	Calhoun D, Trimarco T, Meek R, Locasto D. Distinguishing diabetes: Differentiate between type 1 & type 2 DM. *JEMS* **[serial online].** November 2011; 36(11):32-48. **Available from: CINAHL Plus with Full Text, Ipswich, MA. Accessed February 2, 2012.**
Newspaper article - in print* *if the city name is not part of the newspaper name, it may be added to the official name for clarity * if an article jumps from one page to a later page write the page numbers like D1, D5	Wolf W. State's mail-order drug plan launched. *Minneapolis Star Tribune.* May 14, 2004:1B.
Newspaper article - online	Pollack A. FDA approves new cystic fibrosis drug. *New York Times.* January 31, 2012. http://www.nytimes.com/2012/02/01/business/fda-approves-cystic-fibrosis-drug.html?ref=health Accessed February 1, 2012.
Websites	Outbreak notice: Cholera in Haiti. Centers for Disease Control and Prevention Web site. https://www.cdc.gov Published October 22, 2010. Updated January 9, 2012. Accessed February 1, 2012.
Entire book - in print	Modlin J, Jenkins P. *Decision Analysis in Planning for a Polio Outbreak in the United States.* San Francisco, CA: Pediatric Academic Societies; 2004.
Book chapter - in print	Solensky R. Drug allergy: desensitization and treatment of reactions to antibiotics and aspirin. In: Lockey P, ed. *Allergens and Allergen Immunotherapy.* 3rd ed. New York, NY: Marcel Dekker; 2004:585-606.

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AMA Manual of Style: A Guide for Authors and Editors. 10th ed. Oxford: Oxford UP.

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Example Article

1. Zoellner J, Krzeski E, Harden S, Cook E, Allen K, Estabrooks PA. Qualitative application of the theory of planned behavior to understand beverage consumption behaviors among adults. J Acad Nutr Diet. 2012;112(11):1774-1784. doi: 10.1016/j.jand.2012.06.368.

In-Text Citation Example

LARGE INCREASES IN AMERICANS' CONSUMPTION OF sugar-sweetened beverages (SSB) have been a topic of concern. Between 1977 and 2002, the intake of "caloric" beverages doubled in the United States, with most recent data showing that children and adults in the United States consume about 172 and 175 kcal daily, respectively, from SSB,[1] it is estimated that SSB account for about 10% of total energy intake in adults[2,3]. High intake of SSB has....

References Section Example

References

1. Duffey KJ. Popkin BM. Shifts in patterns and consumptions of beverages between 1965 and 2002. *Obesity.* 2007:15(11):2739-2747.
2. Nielsen SJ. Popkin BM. Changes in beverage intake between 1977 and 2001. *Am J Prev Med.* 2004;27(3):205-210.
3. Drewnowski A. Bellisle F. Liquid calories, sugar, and body weight. *Am J Clin Nutr.* 2007;85(3):651-661.

Use commas to separate multiple citation numbers in text, like you see between references 2 and 3. Unpublished works and personal communications should be cited in the text (and not on the reference list).1 Superscript numbers are placed outside periods and commas, and inside colons and semicolons. When citing the same source more than once, give the number of the original reference, then include the page number (in parentheses) where the information was found. See pages 41-44 of the AMA Manual of Style for more information.

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Citing AMA guide website http://libguides.stkate.edu/c.php?g=101857&p. Updated April 2011. Accessed October 24, 2012.

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Editorial

In modern years, aesthetics has become quite important in every aspect of everyday life: following the hundreds of journals, magazines, blogs and websites pointing their attention towards this interesting and fascinating topic, the request for aesthetic medicine has increased manifolds.

Aesthetic Medicine is a new field of medicine, in which different specialists share the aim of constructing and reconstructing the physical equilibrium of the individual. Treatment of physical aesthetic alterations and unaesthetic sequel of illnesses or injuries, together with the prevention of aging, are perhaps two of the most iconic areas of intervention for Aesthetic Medicine.

However, in order to prevent frailty in the elderly, a program of education is similarly important.

Furthermore, the line between health and beauty is extremely thin: psychosomatic disorders resulting from low self-esteem due to aesthetic reasons are frequent and can- not be ignored by a clinician.

It is therefore clear that there is no figure in the field of medicine which is not involved in Aesthetic Medicine: endocrinologists, gynecologists, angiologists, psychologists and psychiatrists, plastic surgeons, dermatologists, dieticians, physiotherapists, orthopedists, physical education instructors, massophysiotherapists, podologists, and rehabilitation therapists are just some of the specialists who are sooner or later going to have to answer their patients' needs for aesthetic interventions.

The involvement of all these specialists fits the description of health as defined by the WHO: "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" for which, undeniably, a team of different physicians is required.

The number of patients requiring medical consultation for esthetic reasons is rapidly increasing: in order to be able to provide adequate feedback, medical and paramedical specialists should be trained and, more importantly, should be taught how to work together. Existing Societies of Aesthetic Medicine from different countries share the aim of creating such teams and provide constant updates to the literature: the creation of an international network of specialists from all around the world under the flag of Aesthetic Medicine represents a challenge, but at the same time it is the proof of the widespread interest in this topic.

The first issue of this Journal represents the results of the efforts of the many national Societies and of the Union Internationale de Medecine Esthetique, now together as one; it is our hope that in years to come this Journal might improve our knowledge in this field, and provide adequate scientific advancement in the field of Aesthetic Medicine.

Francesco Romanelli
MD Editor-in-chief
Associate Professor at "Sapienza" University of Rome

Editors' notes

Aesthetic Medicine, the booming medical activity

Aesthetic Medicine was born in France 40 years ago.
The French Society of Aesthetic Medicine was the first of its kind in the world, followed by Italy, Belgium and Spain. Starts were rather difficult as aesthetic procedures in those early years were only surgical.
At that time aesthetic doctors and cosmetic dermatologists had very few real medical procedures to offer to their patients for treating aesthetic problems on face and body.
At the beginning of the '80s, viable medical procedures started to emerge in Europe for aesthetic and cosmetic purposes. Mostly, at that time, they were imported from the United States: those included collagen injections for wrinkles (Zyderm by Dr. Stegman), and chemical peels (phenol by Dr. Baker, TCA by Dr. Oba- gi). But, subsequently, European research on Aesthetic Medicine gained momentum. Hyaluronic acid appeared on the market, as it was discovered that it could be used as a dermal filler for wrinkles. During the '90s, the use of lasers offered aesthetic doctors and cosmetic dermatologists new possibilities.
The "beam revolution" started with CO2 laser for facial resurfacing.
Today, CO2 resurfacing is not used as much anymore, because of the long and difficult postop. CO2 laser was replaced with the gentler Nd-YAG and Erbium lasers and more recently with non invasive photonic devices for facial rejuvenation, including IPL, US and radiofrequency. These new technologies allow today's aesthetic doctors and cosmetic dermatologists to offer their patients procedures with low risk of post- op complications. Then, Botulinum Toxin has "invaded" both sides of the Atlantic Ocean.
Today, Botox injections are the most popular treatment for facial expressive wrinkles.
Botox injections are now so common everywhere that many cosmetic surgeons have given up their bistouries for syringes. Last but not least, development in Aesthetic Medicine is shown by mesotherapy and adipolipolysis.
About lipolysis, new data and recent publications have explained that radiofrequency, ultrasounds and cryolyse could have positive action to dissolve fat and to improve some unaesthetic disorders like cellulite.
These non invasive procedures intend to replace the surgical liposculpture with success.
Nowadays, Aesthetic Medicine has the necessary tools to address all major disorders within the aesthetic field. After 40 years, Aesthetic Medicine is now active in 30 countries in the world (France, Italy, Spain, Belgium, Morocco, Poland, Russia, Switzerland, Kazakhstan, Algeria, Argentina, Uruguay, Venezuela, Colombia, Chile, Mexico, U.S.A, Canada, Ecuador, China, South Africa, Turkey, Ukraine, Georgia and recently Croatia, Portugal, India, Guatemala, Peru and Bolivia). All 30 national Societies are members of the Union Internationale de Médecine Esthétique (U.I.M.E.). Aesthetic Medicine is taught in 7 countries (France, Italy, Spain, Argentina, Mexico, Venezuela, Kazakhstan) in universities that deliver UIME's diplomas after 3 to 4 years of studies.

What is the future of Aesthetic Medicine?

In the last few decades, patients' desires to look and feel younger, have fueled Aesthetic Medicine and Cosmetic Dermatology: many different procedures have been developed to satisfy the demands.
As life-span have increased, patients today are not only asking about aesthetic procedures, they are also asking for a way to stay in good physical conditions in the last decades of their lives. As a direct result, Anti-Aging Medicine, which covers skin aging and general aging, has recently emerged and expanded very quickly. Anti-Aging Medicine can offer senior patients better nutrition, dietary supplementation with vitamins, minerals, antioxidants, and eventually hormone replacement therapy, but only when needed.
Today, and in the near future, both Aesthetic Medicine and Anti-Aging Medicine will offer to our patients, who now live longer, better wellness with aesthetic treatments for skin aging and anti-aging treatments for general aging. Aesthetic Medicine is booming, but all medical practitioners should be correctly trained, so its future will be bright.

Jean-Jacques Legrand
Former General Secretary and Honorary President of UIME
President of the French Society of Aesthetic Medicine

Aesthetic Medicine: a bioethic act

When in 1977 the Italian Society of Aesthetic Medicine published the first issue of the magazine “La Medicina Estetica” Carlo Alberto Bartoletti, the Founder, wrote an editorial in which traced the pathway of the discipline and of the Scientific Society, still valid and projected into the future.
Today from that Editorial Board arise an International Journal, which wants to be indexed, in order to give to the doctors practicing Aestehetic Medicine all around the world a solid basis of shared knowledge.
In the late ‘60s, what was called in Italy Aesthetic Medicine, moved its first steps thanks to “remise en forme and anti aging projects” imported from the experience the “Institutul de geriatrie Bucuresti”, directed by Dr. Ana Aslan.
For this reason,there is the bioethical imperative that the Discipline should be first prevention, then return to physiology and finally correction.
The worldwide diffusion and the efforts of Industries born on the wave of the phenomenon have often led to choose the fastest route to achieve and maintain the physical aspect in the myth of beauty at all costs, without considering that aesthetic is not synonymous of beauty, but it is a balance between body and mind, and the role of the doctor is to take care of the Person globally and not only focusing on the correction of “a badly accepted blemish”.
Faithful to the teaching of my Master had almost 50 years ago, this new journal will have the task of elevating the human resources, aligning and validating methodologies, but above all affirming the humanitas of the medical art in its purest sense to pursue the good and the graceful for the person who relies on it.

Fulvio Tomaselli, MD
Honorary President of the Italian Society of Aesthetic Medicine

Aesthetic Medicine needs science. All over the world

All Aesthetic Doctors know that science is the basis for safety. Safety is the most important issue in our discipline.
Unfortunately, Aesthetic Medicine is more often surrounded by marketing than by science, despite the hard work done by Scientific Societies all over the World. More, too often doctors working in this field are dealing with sellers that promote products with insufficient scientific studies.
However, they sell it anyway. I think that doctors must learn that the first thing to ask about a medical device is the scientific background regarding that product: patients treated, follow up period, adverse events and, most of all, publications.
With this new International Journal completely dedicated to Aesthetic Medicine, proposed by the Italian Society of Aesthetic Medicine, endorsed by UIME and shared by all the National Societies of Aesthetic Medicine belonging to UIME, World Aesthetic Medicine wants to stimulate scientific production in this discipline to increase safety and quality in aesthetic medical procedures.
Another important goal of the Journal is to catalyze the proposal of new protocols and guidelines in Aesthetic Medicine, with the consensus of the entire Aesthetic Medicine Scientific Community.
What this Journal should achieve in the near future is to improve the number and quality of scientific production in Aesthetic Medicine, in order to allow this discipline to grow in the field of evidence based medicine, not only in the rationale field.
I hope this can be the start of a new era for Aesthetic Medicine, with the commitment of all Scientific Societies all over the world.

Emanuele Bartoletti, MD
Managing Editor
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General Secretary of UIME

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Original Article

The effects of shock waves treatment on localized abdominal fat and its reflection upon anthropometric and biochemical parameters

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Abstract

Introduction: localized fat consists of fatty cells hypertrophy that can either be subcutaneous or visceral. Shock wave therapy is one of the resources used in aesthetic treatments, consisting in the conversion of electrical energy into mechanical energy, used to decrease localized fat and improve cellulitis appearance.
Objective: to evaluate the efficiency of the therapy in decreasing measures in the abdominal area as well as its influence on lipid and hepatic metabolism.
Method: eleven volunteers were selected according to inclusion and exclusion criteria; after the signing of an ICF, anthropometrical, biochemical, bio-impedance data was collected, as well as photographic records before and after 10 shock wave sessions.
Results: after the treatment, a comparison was made between the parameters in question, from which it was possible to observe a decrease in anthropometric measures, an increase in serum levels of total triglycerides, lipids and cholesterol, as well as the passage from non-reagent to reagent of C-reactive protein in some of the volunteers.
Conclusion: the increase in VLDL and HDL lipoprotein indices and changes in hepatic markers suggest that the triglycerids are metabolized by the liver and transported by blood circulation without compromising the organ.

Keywords

Shock waves, lipid metabolism, localized fat, body shape, biochemistry, aesthetic health

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Introduction

Over the last few years, the search for aesthetic treatments aiming at improving image and self-esteem has increased. Among the complaints presented in aesthetic clinics, localized abdominal fat is recurring in the daily routine of these centers, especially from the feminine public, who has greater difficulty in decreasing it. In fact, women present a higher number of adipocytes compared to men, due to gestation and because the lipogenesis process is better favored in comparison to lipolysis, a phenomenon caused by a greater concentration of lipolysis inhibiting receptors in relation to lipolytics[1].

In order to treat this aesthetic illness, new technologies are being developed every year. One of the technologies that has been increasingly used in the field of aesthetics is shock waves, which consist of the conversion of electric energy into mechanical energy which is generated by electromagnetism, electro-hydraulic methods, pneumatic methods, or through piezoelectric effect[2]. Such energy is capable of significantly altering a specific area without modifying the structures that surround it[3], and it can be used to decrease localized fat and improve the appearance of the gynoid lipodystrophy (GLD) acting upon the adipocytes and leading to collagen remodeling[4]. The most important mechanical effects of the shock waves are reflexes with pressure and tension forces on the thresholds of different impedances, the generation of cavitation and the formation of micro-jets that cause erosion and micro-perforations in vases and membranes[5,6].

Shock waves induce membrane hyperpolarization, the formation of free radicals and generate oxygen radicals that should perform a fundamental role in the translation of the mechanical energy of the shock waves into a biological effect that, when applied to the skin, promotes the formation of micro-bubbles in the fluids, whose flow is made difficult by the obstacle created by the interface areas. This phenomenon prevents the micro-bubbles from collapsing in a symmetric manner, generating cavitations[2,6].

The lipid profile is comprised of triglycerides, HDL, LDL, total cholesterol, non HDL, VLDL and total lipids. Based on these biochemical exams, it is possible to verify whether the patient in question presents dyslipidemias or not. These changes may be due to the high concentration of circulating fatty acids generated in the liver of patients with excessive body fat[7]. The aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are markers of liver lesions and, because lipid metabolism is performed in the liver, the change of its profile may be related to pathologies in this organ and, consequently, interfere with hepatic markers. Therefore, lesions may occur in this organ when there is an increase in body fat[8]. Finally, C reactive protein (CRP) is a marker present in acute inflammatory processes, whether the latter are or not related to infectious frameworks. Increased body fat also elevates the serum levels of CRP, because adipocytes release pro-inflammatory markers, the adipokines[9].

Taking into account the metabolic changes due to the action of adipokines secreted by adipocytes, such as their effect on hepatic functions, this study aimed at evaluating not only the efficiency of shock wave therapy on decreasing measures in the abdominal area, but also the influence of the action mechanism of the technique on both lipidic and hepatic metabolism.

Material and Methods

In order to proceed with the survey, the project was submitted to the Research Ethics Committee at Universidade Positivo, the institution in which it was undertaken. After the approval under the report number 2,658,312, a public notice was published for volunteers in social media and a selection was performed after an analysis, in which 11 volunteers complying with inclusion and exclusion criteria were selected. The following criteria were applied: women between 30 and 50 years of age with a Body Mass Index (BMI) equal or above 30Kg/m^2 and waist-hip ratio equal or above 0.80cm. During the selection, the following exclusion criteria were applied: individuals presenting hypertension and/or non-controlled diabetes; referred dislipidemies; liver, heart and/or kidney diseases; neoplasms; epilepsy; pregnant women; nursing women; individuals whose skin in the abdominal area was not whole; individuals who underwent surgeries in the area less than a year ago; individuals with copper IUD or metallic prosthesis in the area; smokers; individuals taking medicines: antihyperlipemic drugs, drugs controlled by legislation, phyto-therapeutic or nutricosmetics substances accelerating metabolism or weight loss, and individuals under treatment with restrictive diets. These criteria were aimed at the maximum decrease of any external interference in the research. The volunteers signed an Informed Consent allowing the use of anthropometric and biochemical data and photographic records and declared to be aware of the study's goals, indications, possible complications, the technique to be used, and number of sessions.

Blood collection (after an eight-hour fasting), the nutritional evaluation (comprised of bioimpedance), anthropometric measures (circumference and weight) and photographic records (front and profile) were carried out in two phases: at the beginning and at the end of the sessions, with the aim of verifying the changes in composition before and after the treatment, At the end of the treatment, the volunteer was asked to fill out a satisfaction survey.

Circumference measurement was done 5 centimeters above the umbilical scar (supra abdominal), right over it (waist), 5 centimeters below the scar (infra abdominal) and of the highest portion of the glutes (hip).

The equipment used in the research was Hygiapulse® provided by KLD Biosistemas®, which is registered at the Agência Nacional de Vigilância Sanitária (ANVISA – National Hygiene Vigilance Agency) – register number 10245230022 –, with a 25mm radial transmitter and set for localized fat, a 100 mJ intensity, a 15 Hz frequency and an emission of 3000 discharges per area (10 X 15 cm). In order to perform the applications, the abdomen

was divided into six quadrants, four in the central portion and two on the sides of the abdomen. Neutral carbopol gel was used as a conducting agent. In order to guarantee the reproducibility of the application technique, the manipulation of the gauntlet was standardized: it was moved vertically, horizontally and diagonally during the emission of the shock waves, in a consecutive manner until the end of the 3,000 pulses.

Results

During the treatment, one of the volunteers gave up treatment for personal reasons. After the end of the treatment of the 10 volunteers, a comparison was performed of the anthropometric measures and the biochemical parameters of each one. In relation to circumference, it was observed that 9 patients presented an average decrease of 3.9 cm in the supra abdominal area, 7 volunteers decreased an average 4.14 cm on their waists, 8 models lost 4.06 cm on their infra abdominal portion, and 9 patients presented an average decrease of 5.1 cm on the circumference of their hips. Volunteers 3, 4, 5, 6 and 8 showed decreased measures in the four areas, and it is important to emphasize the fact that patient 8, who did physical activities three times a week, presented the greatest decrease in measurements in the treatment area. Model 7, who does not do any physical activities and has visceral fat, did not present any decrease in abdominal circumference (*Table 1*).
The parameters gauged by bioimpedance were the following: BMI, lean mass, percentage of body fat and weight (*Table 2*). Of the 10 volunteers, 4 practice some type of physical activity (walking, body building) between one and three times a week and all have a normal diet. Despite these features in common, patient 8 presented a decrease in BMI and weight, model 9 only in BMI, volunteer 2 only in percentage of fat, and patient 1 presented an increase in all of the parameters analyzed by the bioimpedance equipment. The decrease in body fat percentage took place only in four patients, and only two presented decreased weight. The only model who did not present changes in her BMI and weight, and presented gains in her lean mass and loss of body fat was patient 2, who, 31 years old, was the youngest of the group being studied.
From the results obtained in the biochemical analyses (*Table 3*), it can be observed that all the patients presented increased triglycerides and VLDL, some presented a decrease in serum levels of AST (7 volunteers) and ALT (6 volunteers), 8 patients presented increased HDL and 7 presented decreased LDL. There was also an increase in serum levels of total cholesterol in 5 models and total lipids in 9, and CRP was detected as non-reagent on all of them before the treatment, turning into reagent in 6 volunteers after 10 sessions.
In the satisfaction survey based on the Likert scale that was filled by the volunteers, the following topics were verified: skin texture related to tissue flaccidity, decrease in localized fat, definition of body contour, bowel motility, diuresis, changes in menstrual flow and cramps, post-application discomfort, sensibility in the local of application, and positive and negative aspects in relation to the services provided.
In the skin texture item, 71.42% reported significant improvement in local tissue flaccidity, 14.28% did not notice any differences, and 14.28% reported worsening conditions. In relation to decreased localized fat, 42.85% noticed decreases, the same percentage did not notice any differences, and 14.28% reported that it did not decrease. 57.14% of the participants reported an improvement in the definition of body contour, 28.57% did not notice any differences, and 14.28% reported worsening. None of the models presented any changes in bowel motility, presented any post-application discomfort or had any sensitization that might be provoked by the conducing gel. Regarding diuresis, 57.14% did not present any changes and 42.85% noticed an increase in urination frequency. 71.42% did not present any changes in their menstrual cycle nor menstrual cramps different from those they normally have, 14.28% presented some changes in their cycles and dysmenorrhea, and 14.28%

Patient	Supra abdominal before	Supra abdominal after	Waist before	Waist after	Infra abdominal before	Infra abdominal after	Hip before	Hip after
1	87 cm	85 cm	95.6 cm	96 cm	101.5 cm	100 cm	107 cm	99 cm
2	78.2 cm	73 cm	79 cm	81 cm	84 cm	79 cm	84 cm	82 cm
3	88 cm	84 cm	95 cm	89 cm	97 cm	94 cm	107 cm	97 cm
4	100 c m	99 cm	105 cm	103 cm	106 cm	104 cm	107 cm	104 cm
5	80 cm	78 cm	93 cm	88 cm	96 cm	90 cm	103 cm	94 cm
6	97.5 cm	93 cm	100 cm	96 cm	102 cm	101 cm	106 cm	101 cm
7	89 cm	90 cm	96 cm	97 cm	98 cm	99 cm	102 cm	98 cm
8	102 cm	95 cm	108 cm	100 cm	112 cm	104 cm	106 cm	104 cm
9	109 cm	103 cm	118 cm	115 cm	123 cm	123 cm	125 cm	122 cm
10	96.5 cm	94 cm	100 cm	99 cm	107 cm	101 cm	103 cm	104 cm

***Table1** - Circumference comparison before and after 10 sessions.*

use some type of contraceptive method so that they do not menstruate. All of the volunteers classified the services during the period of the treatment as excellent. *Figures 1* and *2* show the result obtained as well as the improvement in skin texture.

Discussion

In this study, the increase in lean mass presented by bioimpedance cannot be directly related to the practice of physical activities, because of the five volunteers that presented muscle gains, only one declared doing some physical activities.

The results pointing to weight and body fat gains, regardless of practicing physical activities or not may be related to the fact that energy spent by the volunteers is lower than the calories obtained through food, which is the most common mechanism of weight gain. The 31-54 age range was adopted because after the age of 25 there is a significant progressive decrease in metabolism[10].

The increase in VLDL and HDL lipoproteins indexes and the changes in AST and ALT hepatic markers remained within the normal parameters and suggest that, during the employment of the technique, triglycerides are metabolized by the liver and transported by blood circulation, but without compromising the organ in healthy individuals and producing mainly higher-density lipoproteins, which are more difficult to be found in higher levels in patients presenting cardiovascular diseases. It is believed that VLDL, even though they are not the main lipoproteins associated to pathologies, were higher because they are the second lipoproteins that are produced by hepatocytes to transport triglycerides, chylomicrons being the first[11].

The elevation in total lipids concentrations in all of the patients, in addition to the increase in total cholesterol in 5 of them, is also justified by the circulating triglycerides released by adipocytes[12].

The fact that the C-Reactive Protein went from non-reagent to reagent in 60% of the volunteers suggests that the extra-corporal therapy by shock waves provokes an inflammatory process in the adipose tissue through its mechanical action, as it is expected that every aesthetic procedure causes a controlled inflammatory reaction. The results of the four patients who did not present this difference may be justified by the use of anti-inflammatory medication near the day or on the very day that blood was collected; by an anti-inflammatory diet, which is comprised of food that is able to inhibit or block the action of inflammatory agents; and by a greater resistance of the body to inflammatory processes.

The physiological effect of mechanical and thermal stress by the shock waves equipment entails tissue damages to the adipocytes which triggers off an inflammatory response and the release of important cytokines[13].

In 2011, Ferraro et al.[14] conducted a study with 50 patients associating shock wave extra- body therapy after the application of cryolipolysis. In the study, the techniques were applied for the treatment of abdominal localized fat in 14 patients, five females and nine males. The average decrease in abdominal circumference at the end of the treatment was of 6.86 cm, showing that when one associates shock waves to cryolipolysis there is an improvement in the results, especially in males, due to the body composition and metabolism that facilitates both lipolysis and apoptosis.

In his 2017 study, Diogo et al.[15] analyzed the lipid profile of six male individuals before and after they were submitted to an ultra-cavitation procedure that, like the shock wave equipment, also promotes lipolysis and cellular apoptosis. In the study, it was found that the serum levels of triglycerides and VLDL increased both in the active group, that practiced some type of physical activity, and in the sedentary group, so that in the first this increase doubled in comparison with the second group, having found out that lipolysis is more effective

Patient	IMC before	IMC after	% lean body mass before	% lean body mass after	% body fat before	% body fat after	Weight before	Weight after
1	29.6 Kg/m^2	30 Kg/m^2	25.7 Kg	25.4 Kg	36.4%	42.4%	71.20 Kg	72.9 Kg
2	19.4 Kg/m^2	19.4 Kg/m^2	14.3 Kg	22.9 Kg	35.3%	28.4%	42.60 Kg	42.60 Kg
3	32.6 Kg/m^2	33.2 Kg/m^2	22.2 Kg	22.5 Kg	44%	48.7%	72.1 Kg	73.7 Kg
4	32.6 Kg/m^2	31.7 Kg/m^2	25.8 Kg	22.7 Kg	43%	47.4%	80.7 Kg	81.6 Kg
5	27.3 Kg/m^2	28.8 Kg/m^2	24 Kg	34.2 Kg	36.1%	29%	67.55 Kg	69.9 Kg
6	27.4 Kg/m^2	27.2 Kg/m^2	21.2 Kg	28.1 Kg	44.5%	33%	70.5 Kg	69.7 Kg
7	29.1 Kg/m^2	29.6 Kg/m^2	22.6 Kg	32.8 Kg	37.3%	32.5%	64.75 Kg	66.5 Kg
8	35.8 Kg/m^2	35.7 Kg/m^2	24.5 Kg	23.6 Kg	44.5%	47.6%	80.9 Kg	80.3 Kg
9	37.3 Kg/m^2	37.2 Kg/m^2	29.4 Kg	22.2 Kg	46.5%	50.4%	97.4 Kg	97.5 Kg
10	27.6 Kg/m^2	28 Kg/m^2	30.2 Kg	27.4 Kg	33%	38.1%	80 Kg	81.9 Kg

Table 2 *- Comparison of bio-impedance results before and after 10 sessions.*

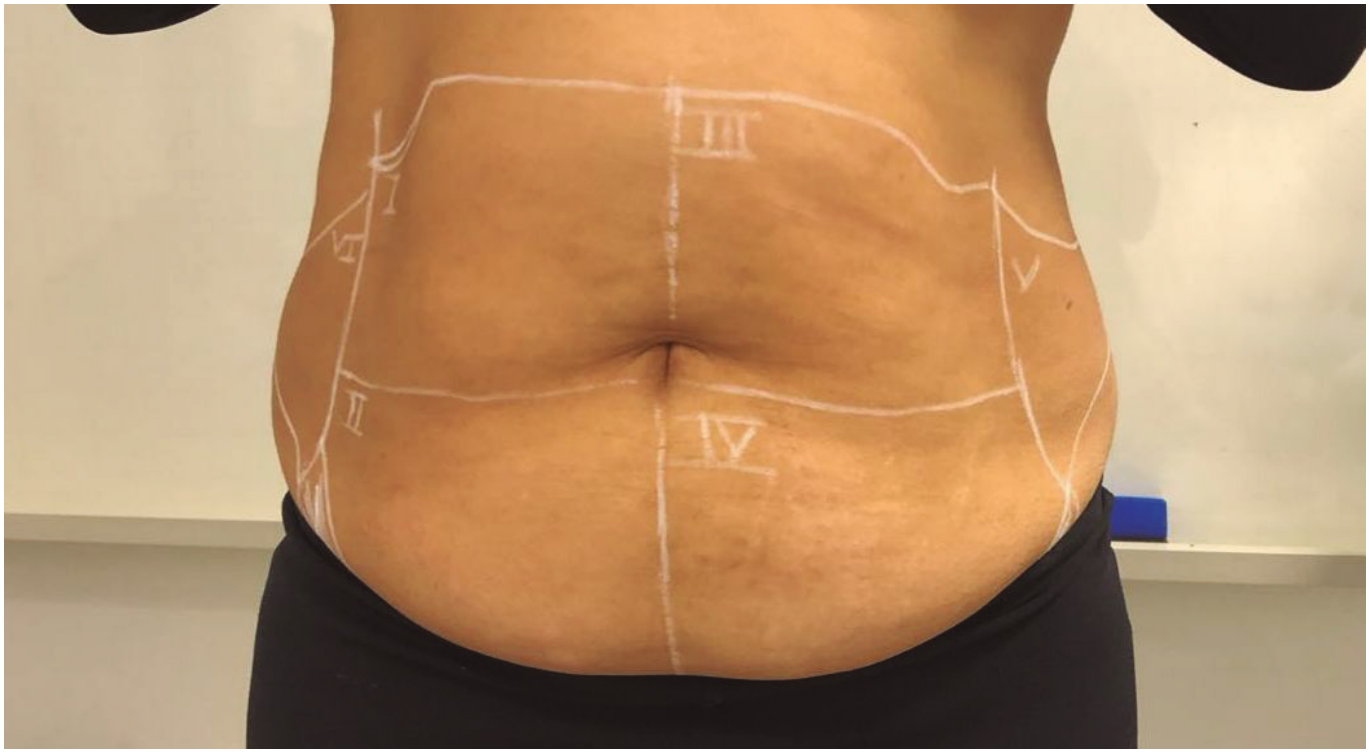

Figure 1 *- Photograph of patient 1 before starting the treatment.*

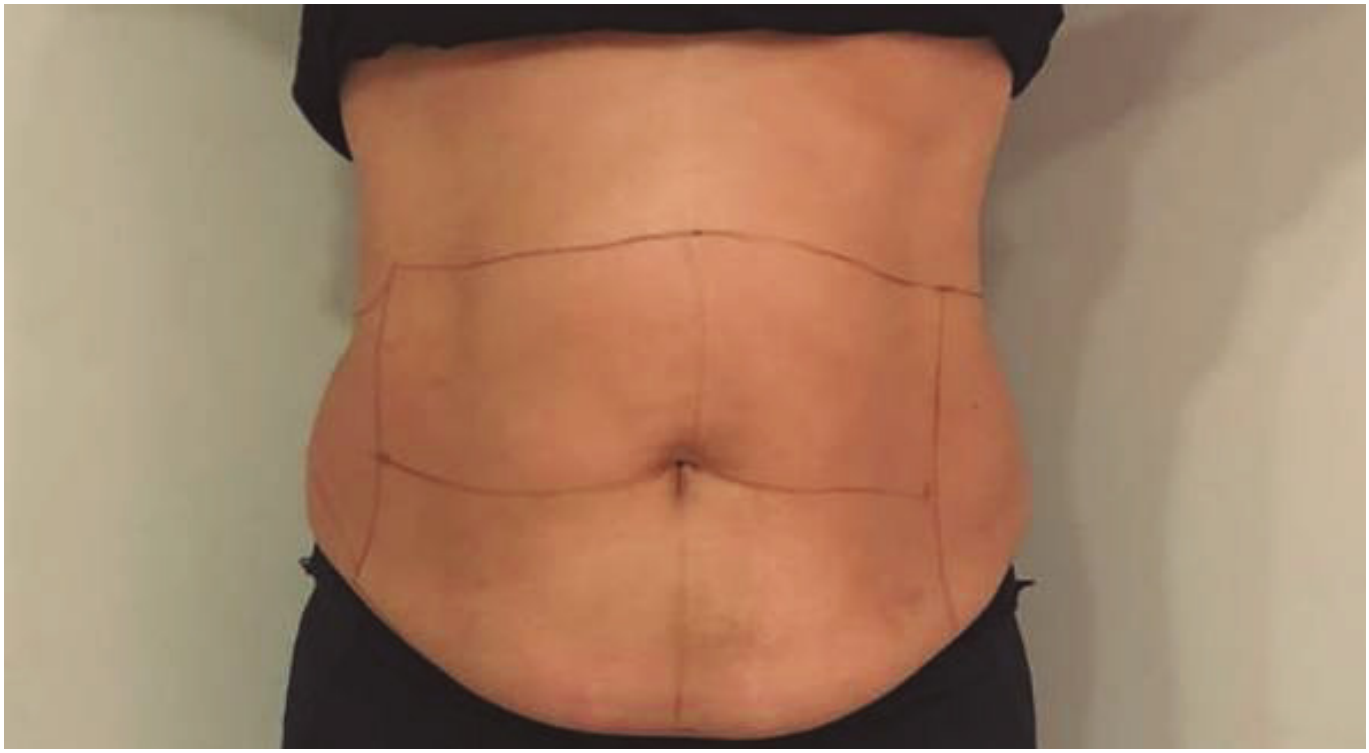

Figure 2 *- Photograph of patient 1 after 10 sessions.*

Patient	1	2	3	4	5	6	7	8	9	10
PCR before Non Reagent (NR) or Reagent (R)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
PCR after Non Reagent (NR) or Pure Reagent (R)	NR	PR	PR	1:4 Reagent	PR	PR	NR	NR	PR	NR
ALT before (U/L)	5.8	15.66	11	7.61	21.71	18.51	5.19	17.13	5.88	10.03
ALT after (U/L)	8.74	8.74	11.07	16.35	8.22	16.09	5.1	15.92	10.9	6.31
AST before (U/L)	10.99	32.78	11	24.13	34.6	17.3	14.01	16.18	8.22	15.62
AST aft er (U/L)	10.55	18.51	8.65	14.96	13.23	14.88	8.91	31.05	10.81	23.79
Triglycerides before (mg/dL)	179.61	162.43	91	204.66	176.16	179.05	180.14	185.72	183.47	174.84
Triglycerides after (mg/dL)	191.73	208.87	183.06	209.45	183.07	206.6	193.8	203.09	205.78	204.79
HDL before (mg/dL)	38.17	46.37	50	40.07	42.62	38.69	40.67	38.74	41.45	39.75
HDL after (mg/dL)	41.44	49.56	38.41	44.13	43.55	42.86	40.65	41.95	45.49	42.08
LDL before (mg/dL)	118.61	97.3	173.8	126.4	107.54	104.34	115.75	135.26	122.83	103.37
LDL after (mg/dL)	115.61	120.52	126.97	119.64	116.54	105.11	108.7	114.68	107.96	98.53
Total cholesterol before (mg/dL)	192.7	176.15	242	207.4	185.39	178.84	192.45	211.15	200.97	178.08
Total cholesterol after (mg/dL)	195.39	211.73	202	205.66	196.7	189.29	188.11	197.25	194 .61	181.56
VLDL before (mg/dL)	35.92	32.49	18.2	40.93	35.23	35.81	36.03	37.14	36.69	34.97
VLDL after (mg/dL)	38.35	41.65	36.61	41.89	36.61	41.32	38.76	40.62	41.16	40,96
Total lipids before (mg/dL)	615.11	560.54	540	673.39	595.14	583.23	615.07	662.91	637 .68	577.3
Total lipids after (mg/dL)	633.32	686.78	639.58	674.25	627.61	634.4	618.92	648.87	645.6	615.12

Reference Values: PCR: non reagent (NR). ALT: 10 to 37 U/L. AST: 10 to 37 U/L.
Triglycerides: Desirable <150mg/ dL; High: 150 to 199 mg/ dL; Elevated: 200 to 499 mg/ dL; Very high: 500 mg/ dL.

HDL: Low <40 mg/dl; Desirable ≥ 60mg/ dL.
LDL: Optimum <100mg; dL; Optimum threshold: 100 to 129 mg/ dL; High threshold: 130 to 159 mg/ dL; High: 160 to 189 mg/ dL; Very high ≥190 mg/ dL
Total Cholesterol: Desirable < 200 mg/ dL; Higher threshold: 200 to 239 mg/ dL; High ≥240 mg/ dL.
VLDL: Normal: 2 to 30 mg/dl; High > 30mg/ dL.
Total lipids: Normal: 400 to 800 mg/dL

Table 3 *- Comparison of biochemical parameters PCR, AST, ALT triglycerides, HDL, LDL, total cholesterol, VLDL and total lipids before and after 10 sessions.*

when there is an association of an aesthetic treatment and physical activity.
The decrease in abdominal circumference confirms the efficacy of the treatment mainly on the outlook of the volunteers.
The significant improvement in tissue flaccidity in the abdomen takes place because of the lesion caused by cavitation generated by the shock waves, which leads to the production of vascular endothelial growth factor (VEGF) and endothelial nitric oxide synthase, inducing the neocollagenesis process, improving the structure and quality of collagen and elastic fibers of the tissue[16]. Because of its ability of tissue decompression and lipolysis through its mechanical and cavitational effects described in the review by Modena et al. 2017[17], the greater definition in body contour and the decrease in localized fat were noticed at a great scale by the models, in addition to being proved through measures and photographs. Increased diuresis and dysmenorrhea reported by the majority of the patients may be due to the vibration provoked by the equipment, which stimulates the contraction of the smooth muscles, both in organs and vessels, increasing kidney overload and may cause accentuated menstrual cramps during the treatment period.

Conclusion

This study showed that, when having an extra-corporeal shock wave therapy, the volunteers presented decreased abdominal located fat as well as improved body contour and skin appearance. Through the analysis of the biochemical parameters obtained, it was observed that shock wave therapy does not appear to cause liver lesions and consequently leads to pathogenic metabolic changes. It is suggested that a future survey is carried out with a greater number of participants, taking into account predisposing genetic factors and feeding habits that might interfere with the investigation, in addition to comparing the efficiency of the technique in patients who practice physical activities and sedentary ones.

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Conflict of interests

There is no conflict of interests in this article.

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Original Article

"REAL LIFE" efficacy evaluation of a new hyaluronic acid gel suitable for deep hydration and fine wrinkles correction

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Abstract

Injectable hyaluronic acid-based (HA) fillers are largely used to improve facial deep wrinkles and volume deficiency. Recently, new objectives are being pursued, such as deep skin hydration, that may improve skin surface roughness and fine wrinkles. Viscoderm® Hydrobooster (IBSA Farmaceutici Italia Srl) is a ready-to-use solution of stabilized, injectable HA characterized by high deformability and low stiffness and viscosity, thus allowing deep dermal hydration and mechanical stretching of superficial wrinkles. One hundred consecutive women with Glogau Wrinkle Scale grade 2-3, requiring deep hydration according to medical advice, have been enrolled by three Italian physicians and administered two injections of the studied product 2 months apart. Patients were assessed at baseline, 2 months after the first injection and 3 months after the second injection. The aesthetic results were judged highly satisfactory by both patients and physicians and the tolerability profile was reassuring.

Keywords

Hyaluronic acid, wrinkle correction, hydrostretching, deep hydration

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Hyaluronic acid and its role as a dermal filler

Hyaluronic acid (HA) is a linear polysaccharide composed of repeating b-1,4-linked D-glucuronic acid (GlcA) and b-1,3-linked N-acetyl-D-glucosamine (GlcNAc) disaccharide units, which is found ubiquitously in the extracellular matrix (ECM) of all vertebrate tissues, although in widely variable concentrations and bound to different partners. It is also named "hyaluronate" referring to its salt form, or "hyaluronan", a term that includes all forms of the molecule[1]. More than 50% of HA in our body is localized in the skin, where it is synthesized by fibroblasts, keratinocytes, and endothelial cells of the dermal microcirculation in many variants of different molecular weight[2]. Under normal circumstances, HA is quite abundant in the dermis, where, due to its viscoelasticity and capacity to retain water, it plays a crucial role in controlling tissue hydration, keeping an appropriate tissue volume to protect skin cells from mechanical damage, and maintaining structural stability[3]. In the epidermis, it carries out a trophometabolic activity, contributing to the preservation of cutaneous homeostasis[2]. HA is a non-immunogenic molecule, a polymer devoid of protein epitopes, and it also has the advantage that, regardless of the problem, it can be easily removed by digestion with hyaluronidase[4].

HA plays important and different roles in the process of tissue repair. Its interactions with specific signaling receptors maintain structural cell integrity and promote recovery from tissue injury[1]. Since aesthetic medicine is nowadays not only aimed at alleviating (skin) diseases but also at improving one's perception of wellness, the repairing properties and the safety characteristics of HA have made it, in the last decades, the most commonly used material for soft tissue augmentation in aesthetic medicine[4]. In fact, the marked reduction in HA content characteristic of the aged skin plays a crucial role in dermal thinning and wrinkles formation[5-7]. Therefore, injected HA-based fillers are largely used to "fill-up" the dermis and improve facial wrinkles[4].

The different HA dermal fillers vary widely in their physical and chemical characteristics and the many variables affect their overall performance. In general, they improve skin turgor and elasticity. In recent years, different techniques have been developed with the aim of improving HA stability, thus slowing its degradation in tissues and allowing manufacturers to control the gel stiffness[4].

Material and Methods

Product characteristics

Interestingly, besides improvement of deep wrinkles and volume deficiency, new objectives are being pursued with HA-based fillers, such as deep skin hydration. Intradermal injections of HA may be used to boost the water content in the extracellular matrix of the dermis, resulting in deep dermal hydration and improvement of skin surface roughness and fine wrinkles[8].

The studied product is a ready-to-use solution of stabilized, injectable HA which has unique rheological properties[9] (*Table 1*), that give the product high deformability and low stiffness and viscosity. For these reasons, the product offers a dual function, called "hydrostretching", consisting of both a process of dermal hydration and tissue bio-restructuring, and a mechanical stretching action on superficial wrinkles. The low stiffness and viscosity and the high plasticity also favor an optimal tissue integration and enable the product to be injected into different layers of the dermis, up to the most superficial ones, making it particularly effective on the most dynamic facial areas (perioral and periocular areas and the forehead)[9].

G' (Pa)	**37 ± 2**
G"(Pa)	**20 ± 2**

Table 1 *- Rheological parameters of the studied product[9].*

The studied product is suitable to improve dry skin, with poor elasticity and/or poor skin texture, and to stretch superficial wrinkles, in particular mimic wrinkles, and to correct acne scars. A recent study on 18 volunteers who had undergone two injections of the studied product 2 months apart and followed up for a further 3 months, demonstrated a significant improvement of wrinkles grade around the eyes and the lip, and wrinkles severity of nasolabial folds already after the first injection. In addition to this there was an improvement of the aging/photoaging grade and surface microrelief after 2 months, following the second injection, and a parallel improvement of instrumental skin profilometry and optical colorimetry[9]. This study also confirmed the good tolerability profile of the product and the duration of its effect.

Patients selection

One hundred women with Glogau Wrinkle Scale grade 2-3, requiring deep hydration according to medical advice, have been consecutively enrolled from March to June 2018 by three Italian physicians within their patients. Patients were asked to maintain their habits (food, physical activity, make-up use, facial cosmetics and cleansing products) and not to expose their face to strong UV irradiation without proper sun protection.

Patients with the following characteristics were excluded: pregnancy; lactation; smoking; alcohol or drug abuse; having received skin treatments for esthetic correction 6 months prior to the study treatment; having already performed permanent dermal fillers; dermatological diseases as well as general diseases (diabetes, endocrine disease, hepatic, renal, cardiac and pulmonary disorders, cancer, neurological diseases); drug allergy; inflammatory and/or immunosuppressive diseases. All the patients signed an Informed Consent allowing the use of photographic record for scientific publications, in which they declared to be aware of the product, treatment choice, alternative treatments and alternative products, possible complications and number of sessions.

Treatment protocol

The studied product was administered with three different techniques:

- a microlinear or microbolus technique (<0.05 ml each) in the areas of the face requiring deep hydration (malar/submalar areas);
- a microbolus technique to stretch the dynamic facial wrinkles (microdroplet injections ≤0.01 ml each along the path of the wrinkle);
- a combined technique to stretch the static facial wrinkles (microlinear retrograde technique ≤0.01 ml each below the path of the wrinkle, followed by microdroplet injections ≤0.01 ml on the same wrinkle).

Two injections were administered to each patients 60 days apart. The most commonly treated areas were the periocular and perioral zones, which are highly dynamic and have thin skin, being quite difficult to treat. In these areas 30G or 33G needles were preferred. Subjects were asked to express their degree of satisfaction about the improvement of facial microroughness, by answering to the question "How satisfied are you with the improvement in you facial microroughness following the treatment?" on a 1 to 10 verbal rating scale (VRS), where 1 means "not at all satisfied" and 10 "completely satisfied". Evaluations were requested twice: 2 months after the first injection (T1) immediately before performing the second injections and then 3 months after the second injection (T2). At the same timepoints, physicians as well were asked to grade their degree of satisfaction with the treatment on 1-10 VRS.

Results

The mean score expressed by patients and physicians at the two study timepoints is reported in *Table 2*. In particular, at the end of the study, the mean scores were 8.5 and 8 respectively. Pictures of some example cases are reported in *figures 1-4*. From a tolerability standpoint, only a few deposits were observed in some patients with particularly thin skin, that remained perceivable for 2 weeks before complete reabsorption. No adverse events related to the product have been reported. Approximatively 20% of the treated patents reported discomfort/unpleasant sensation, which is in line with a previously published study[9].

	T1*	T2**
Patients	6.52	8.54
Physicians	7.00	8.00

Table 2 *- Degree of satisfaction expressed by patients and physicians at the study timepoints.*

*2 months after the 1st product injection;
**5 months after the 1st and 3 months after the 2nd injection Mean score on a 1-10 VRS.

Figure 1 *- Patient CL at baseline (T0, left) and 3 months after the 2nd injection (T5, right).*

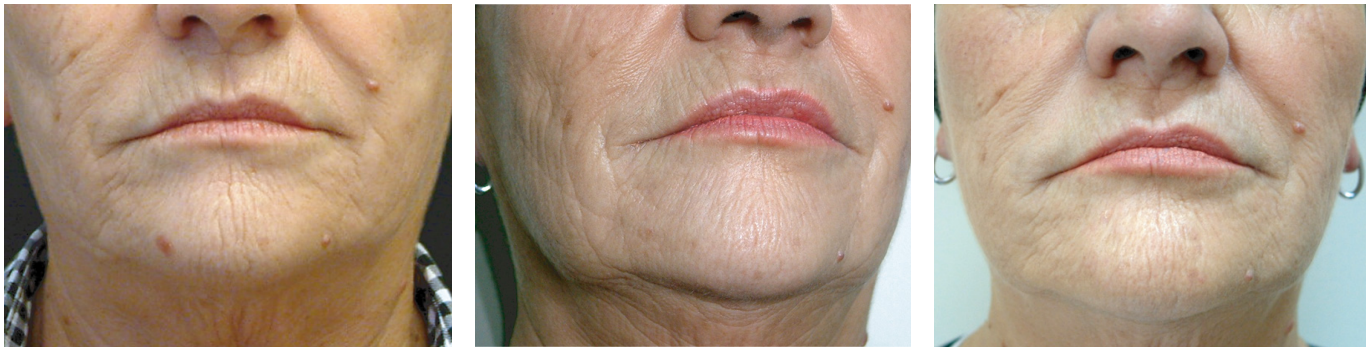

Figure 2 *- Perioral detail of patient AB at T0 (top left), 2 months after the 1st injection (T2, centre), and at T5 (top right).*

Figure 3 *- Periocular detail of patient EP at T0 (top) and T5 (bottom).*

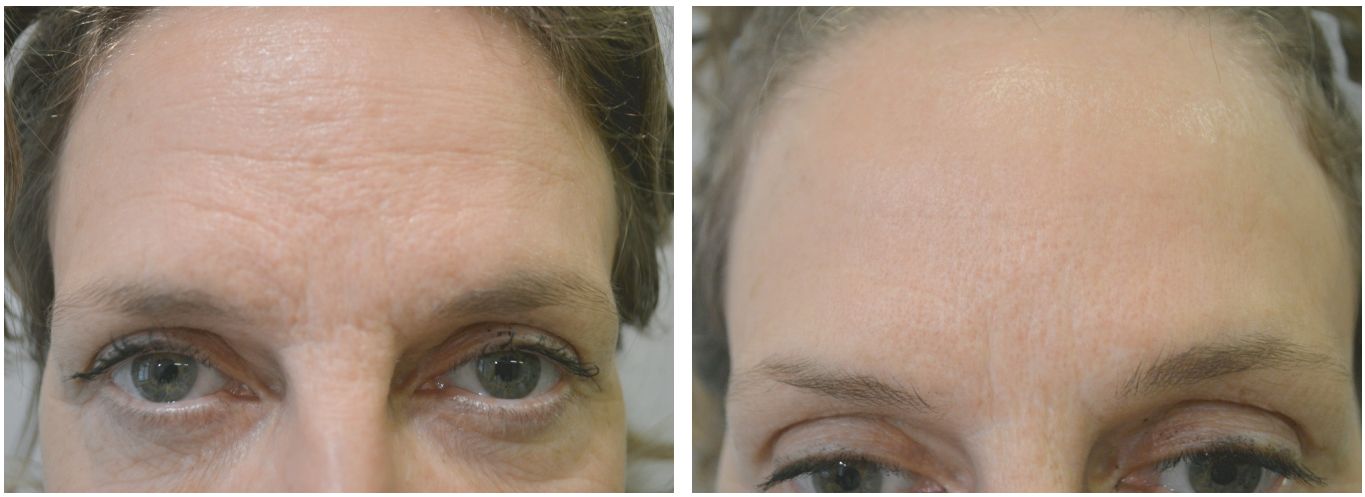

Figure 4 *- Forehead detail of patient FN at T0 (top) and T5 (bottom).*

Conclusions

Viscoderm® Hydrobooster is a stabilized HA injectable preparation, characterized by low viscosity and stiffness and high deformability. Its rheological properties favor tissue integration and allow to inject the product in different layers of the dermis, thus providing a dual function: deep hydration and tissue restructuring on one side, together with a mechanical action aimed at stretching the most superficial wrinkles on the other. Clinical experience has shown a good tolerability and a high degree of satisfaction by both patients and physicians.

Acknowledgment/Conflict of interest

The authors are grateful to Renata Perego for the help in writing the manuscript. Medical writing has been sponsored by IBSA Farmaceutici Italia. The authors report no other conflicts of interest in this work.

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aesthetic medicine

Original Article

The effectiveness of PLLA/PCL aptos thread on skin quality

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Abstract

For many patients, it is important to improve skin quality and to appear younger. Many aesthetic treatment methods are used for this purpose. The objective of this study is to investigate the effectiveness of PLLA on skin quality. Two groups of patients took part in the study. The first group received only PLLA/PCL Aptos threads and the second group received HIFU and PLLA /PCL Aptos thread combined treatment. The treatment covered a 3-month period. The differences before and after the treatment were assessed with the help of photographs and a statistical program. The results were evaluated by both the patient and the doctor. By means of a survey, the evaluations concentrated on skin hydration, color, fine lines, jawline, mouth lines, eye lines, skin elasticity, and thread pain. The survey data revealed improvements for 65% of patients in the PLLA/PCL Aptos thread group and 76% of the patients in the combined treatment group. Specifically, the jawline, mouth lines and skin elasticity results showed a high degee of improvement. The results showed that, PLLA/PCL Aptos thread has a significant effect on skin quality. In addition, the treatment reduces fine lines, increases flexibility and creates a younger and brighter appearance.

Keywords

PLLA, Poly-L-Lactic Acid, skin quality, skin hyration, aptos thread lift, skin elasticity, Ulterapy, HIFU

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Introduction

1. Skin structure

The skin is a sense organ that covers the body. It regulates the body temperature, gets pale with sweating, serves as both a thermostat and a protection barrier[1-3]. Its thickness is between 1 mm and 4 mm. It is the largest and heaviest organ of the body, constituting 16% of the total body weight. The thinnest skin is to be found on the eyelids while the thickest on the sole of the foot.

The basic structure of the skin has three different layers:

Epidermis: It is the outermost layer of the skin that acts as a protective layer. The skin renewal takes place in this layer.

Dermis: It is the middle layer which is effective in the durability of the skin. Hair follicles, sweat glands and sebaceous glands are found in this section.

Hypodermis: An inner layer of subcutaneous fat. It provides energy to the skin and is responsible for the insulation function[3-8].

2. Poly-L-Lactic Acid (PLLA)

Poly-L-Lactic Acid (PLLA) based filler was first introduced in Europe in 1999 under the trade name "New Fill" and then in 2004 in the United States market under the trade name Sculptra L for use in HIV-related lipoatrophy cases. Approximately 150,000 patients were treated in the 10-year period after use[9,10]. Several studies have been conducted on PLLA safety, efficacy and persistence[11-13]. PLLA is mostly used in the face but there are sources in the literature that show it can be used in other areas.

PLLA has been used as a suture material and absorbable screw for approximately 40 years in medicine. Its biocompatibility and efficacy have been shown in previous studies. In a study conducted in Brazil in 2008, it was reported that the injection to nasolabial folds still persists after 3 years[14]. PLLA creates a foreign tissue reaction at the site where it is applied, increasing the number of macrophages, mast cells and lymphocytes in that region, decreasing fibroblastic activity and increasing neocollagenesis slowly[15]. New collagen formation appears at 1 month, and until the 9th month, the formation is observed to increase. In the previous studies the PLLA particles showed signs of disappearance in the 6th month and they are eliminated completely in the 9th month[15].

Methodology

The experiment was performed on patients aged between 34 and 61 years old, some of whom had undergone medical aesthetic treatments, while the remaining patients had not. The participants were divided into 2 groups. There were 10 participants in each group.

All the patients signed an Informed Consent allowing the use of photographic record for scientific publications, in which they declared to be aware of the product, treatment choice, alternative treatments and alternative products, possible complications and number of sessions.

Information about the groups is given below:

Group 1: In this group, 10 patients received APTOS brand PLLA/CL. No other medical aesthetic procedures were performed at the same time and no other medical aesthetic procedure was performed for 3 months.

Group 2: In this group, 10 patients were treated with HiFu application and PLLA / CL were applied to the face during the same week. No other medical aesthetic procedure was applied for 3 months.

After the applications, the participants were evaluated with VAS questionnaire from 0 to 10 points. The questions were answered by both the practitioner and the participant before, during and after the application twice, first, 1 month after the application and then 3 months later. The skin color and stains, skin moisture, fine lines, elasticity and sag (especially in the jaw line) were evaluated. A statistical program and photographs were used to evaluate the results.

Statistical analyses were performed using SPSS software (version 25.5). Basic descriptive statistics were assessed to describe the survey results as the means ± standard deviations.

Results

The total VAS score is shown in *Table 1* and *Figure 2*.

In the first group of patients undergoing PLLA/PCL Aptos thread, the total VAS score of the patients was 30.60±6.5 before the treatment and 37.5±6.88 after the treatment. This value was determined as 50.5±4.6 3 months after the treatment. These results indicate a improvement of 65% after a 3 month-treatment according to patient evaluation. The total VAS score was found to be 32.8±6.08 before the treatment and 53.0±5.92 after 3 months of treatment, and the healing rate was 62% according to doctor evaluation.

In the second group with HIFU and PLLA/PCL Aptos thread combined application, the total VAS score was found to be 30.8±11.9 before the treatment, 39.6±11.5 after the treatment, 46.2±9.97 1 month after the treatment and 54.2±8.48 3 months after the treatment. The rate of recovery was 29% after treatment, 50% after 1 month of treatment and 76% after the 3 month-treatment. In this group, the total VAS score was found to be 35.9 ± 9.82 before the treatment and 55.8±7.65 after the treatment and the recovery rate was found to be 55% according to doctor evaluation. *Table 2* shows the skin characteristics according to the patients. In the evaluation of the study, the skin hydration was found to be 5.10 ± 1.79 before the treatment in the first group and 7.20 ± 1.31 the third month after the treatment. In the second group, the mean pre-operative average was 4.5 ± 2.8, and the mean value after treatment was 3.40 ± 2.01. Skin hydration increased by 42% in the first group and 65% in the second group.

Before the treatment the mean skin color was 4.90 ± 2.42 in the first group and 4.8 ± 2.29 in the second group. In the first group, mean skin color was measured as 5.30 ± 2.00, 1 month after the treatment and as 6.01 ± 0.56,

	Before Treatment	During Treatment Pain	After Treatment	After 1 month	After 3 month
Group 1 Patient	30.60±6,5	7.20±2,04	37.5±6,88	42.7±5.86	50.5±4.6
Group 1 Doctor	32.8±6.08	7.7±1.49	38.6±7.38	44.3±5.96	53.0±5.92
Group 2 Patient	30.8±11.9	9.6±0.69	39.6±11.5	46.2±9.97	54.2±8.48
Group 2 Doctor	35.9±9.82	9.7±0.48	41.4±14.93	49.2±8.56	55.8±7.65

Table 1 *- Evaluation of groups according to total VAS score.*

% Change			
	After Treatment Before Treatment	After 1 month Before Treatment	After 3 month Before Treatment
Group 1 Patient	22.55%	39.54%	65.03%
Group 1 Doctor	17.68%	35.06%	61.59%
Group 2 Patient	28.57%	50.00%	75.97%
Group 2 Doctor	15.32%	37.05%	55.43%

Table 1A *- Percent Change in Evaluations.*

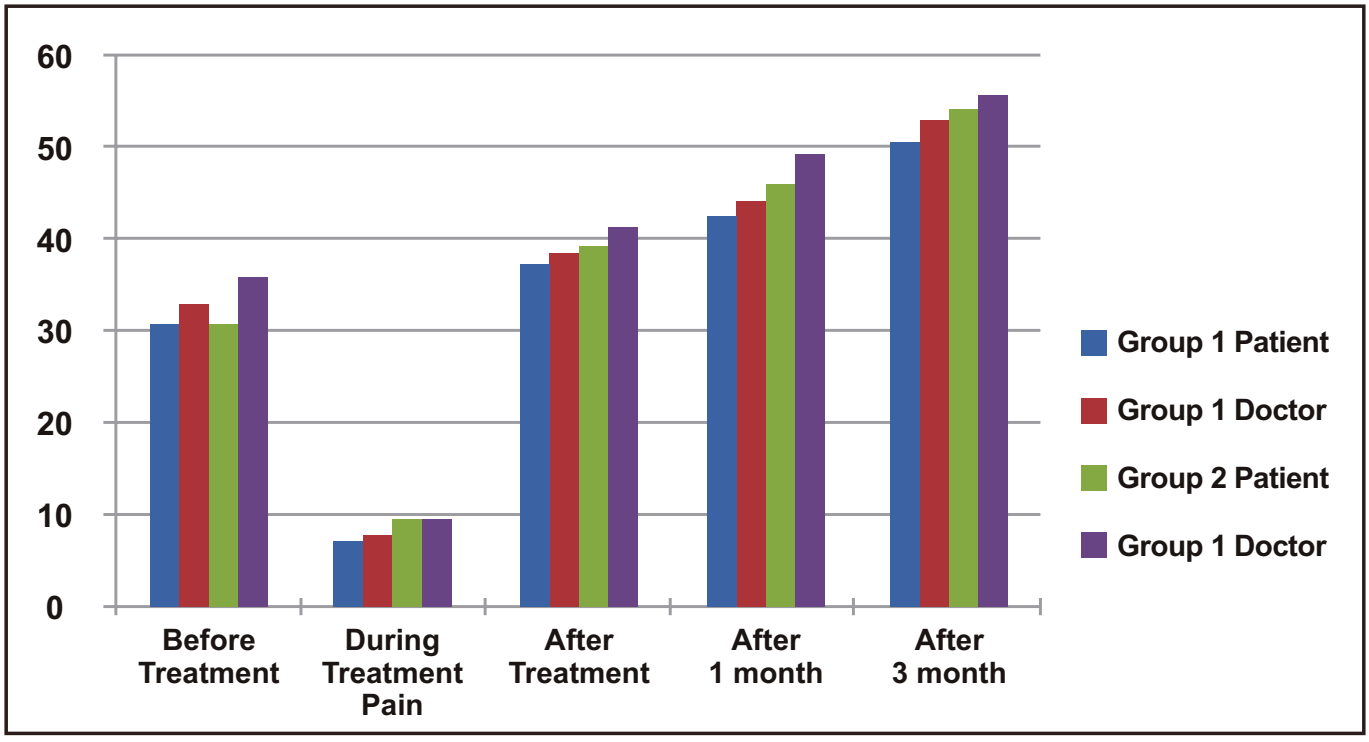

Figure 2 *- Evaluation of groups according to total VAS score.*

	Before Treatment		Durıng Treatment		After Treatment		After 1 month		After 3 months	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Skin hydratation	5.10±1.79	4.5±2.8			5.10±1.79	5.30±2.49	6.20±1.47	6.30±2.26	7.20±1.31	7.40±2.01
Skin color	4.90±2.42	4.8±2.29			4.90±2.42	2.49±2.22	5.30±2.00	6.50±2.41	6.01±0.56	7.20±2.20
Thin lines	6.5±2.71	5.2±3.15			6.50±2.71	5.90±2.72	6.90±2.07	6.70±2.16	7.60±1.50	7.80±1.81
Jaw line	3.30±1.63	3.4±1.57			5.70±1.56	5.70±1.88	6.30±1.41	6.80±2.16	8.0±0.94	8.30±1.15
Mouth lines	3.50±1.50	3.3±1.63			6.10±1.28	5.50±2.06	6.80±1.13	6.50±1.64	7.90±1.19	8.01±0.15
Eye lines	5.50±1.26	5.0±1.94			5.80±1.31	6.0±1.69	6.20±1.13	6.90±1.37	6.90±0.99	7.90±1.19
Skin elasticity	3.30±1.33	4.6±1.83			3.40±1.42	5.60±1.42	5.01±0.05	6.51±0.26	6.90±0.87	7.60±1.26
Pain			7.20±2.04	9.6±0.69						

Table 2 *- Evaluation of skin characteristics according to patients.*

3 months after the treatment. In the second group, the mean skin color was 6.50 ± 2.41 after 1 month and 7.20 ± 2.20 after 3 months of treatment. An improvement of the skin color was observed by 22% and 50% for the first group and the second group respectively. The presence of fine lines was determined as 6.5 ± 2.71 in the first group and 5.2 ± 3.15 in the second group before the treatment.

At the end of the treatment, there was an improvement of 17% in the first group and 50% in the second group. In the evaluation of the jaw line, the mean value was 3.30 ± 1.63 in the first group and 3.4 ± 1.57 in the second group before the treatment. The evaluation on the third month following the treatment revealed that, the mean of the first group was 8.0 ± 0.94 and the second group was 8.30 ± 1.15.

The flatness and tension of the jaw line increased by 142% in the first group and 144% in the second group. The recovery rate of the lines around the mouth was 112% in the first group and 142% in the second group. The improvement in the lines around the eyes was recorded at 25% in the first group and 58% in the second group.

In the evaluation of skin elasticity, the mean pre-treatment in the first group was 3.30 ± 1.33, 5.01 ± 0.05 1 month after the treatment and 6.90 ± 0.87 3 months after the treatment. In the second group, the mean pre-treatment, 1 month after the treatment and 3 months after the treatment was 4.6 ± 1.83, 6.51 ± 0.26 and 7.60 ± 1.26 respectively.

The increase in skin elasticity was 109% in the first group and 65% in the second group. During the treatment, the pain level was determined as 7.20 ± 2.04 in the first group and 9,6 ± 0,69 in the second group.

Table 3 shows the skin characteristics evaluations by the doctor. The skin hydration was evaulated at 5.10 ± 1.79 before the treatment in the first group and 7.70±0.82 the third month after the treatment. In the second group, the pre-treatment average was 5.1±1.83, and the mean value after 3 months of treatment was 7.80±1.81. Skin hydration increased by 50% in the first group and by 53% in the second group.

The mean skin color was 4.8±2.52 in the first group and 5.50±2.22 in the second group. In the first group, skin color after 1 month was measured as 5.40±2.01, and after 3 months of treatment as 6.40±1.57.

In the second group, the skin color was 7.30±1.88 after 1 month and 7.90±1.72 after 3 months of treatment. An improvement of the skin color was observed at 33 % for the first group and 44 % for the second group.

The presence of fine lines was determined as 6.50±2.79 in the first group and 5.90±2.68 in the second group before the treatment. After the end of the treatment, there was an improvement of 17% in the first group and 36 % in the second group. In the evaluation of the jaw line, the mean value was 3.20±1.93 in the first group and 4.10±1.52 in the second group before the treatment. 3 months after treatment, the mean of the first group was 8.40±0.96 and the second group was 8.20±1.13. The flatness and tension of the jaw line increased by 162% in the first group and by 100% in the second group. The recovery rate of the lines around the mouth was 130% in the first group and 93% in the second group. The lines around the eyes were improved by 33% in the first group and by 32% in the second group.

In the evaluation of skin elasticity, the mean pre-treatment in the first group was 3.10±1.37, 5.20±1.03 after 1 month of treatment and 7.30±1.15 after 3 months of treatment. In the second group, the mean pre-treatment, after 1 month-treatment and after 3 month-treatment was 5.20±1.54, 6.90±1.37 and 8.0±0.81 respectively. The increase in skin elasticity was 135% in the first group and 54 % in the second group. During the treatment, the pain level was determined as 7.70±1.49 in the first group and 9.70±0.48 in the second group.

	Before Treatment		Durıng Treatment		After Treatment		After 1 month		After 3 months	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Skin hydratation	5.10±1.79	5.1±1.83			5.10±1.79	5.90±2.23	6.40±1.26	6.70±1.88	7.70±0.82	7.80±1.81
Skin color	4.8±2.52	5.50±2.22			4.80±2.52	6.30±2.05	5.40±2.01	7.30±1.88	6.40±1.57	7.90±1.72
Thin lines	6.50±2.79	5.90±2.68			6.50±2,79	6.60±2.36	6.90±2.33	7.10±1.79	7.60±1.50	8.01±0.69
Jaw line	3.20±1.93	4.10±1.52			6.40±1.57	6.10±1.72	6.90±1.19	7.01±0.24	8.40±0.96	8.20±1.13
Mouth lines	3.60±1.42	4.20±1.39			6.50±1.08	6.01±0.94	7.10±0.99	6.80±1.47	8.30±1.15	8.10±1.10
Eye lines	5.50±1.26	5.90±1.79			6.01±0.33	6.40±1.77	6.40±1.26	7.40±1.42	7.30±1.33	7.80±1.31
Skin elasticity	3.10±1.37	5.20±1.54			3.30±1.41	6.10±1.79	5.20±1.03	6.90±1.37	7.30±1.15	8.0±0.81
Pain			7.70±1.49	9.70±0.48						

Table 3 *- Evaluation of skin characteristics according to the doctor.*

% Change						
	Patient Evaluation			Doctor Evaluation		
	After Treatment	After 1 Month Treatment	After 3 Months Treatment	After Treatment	After 1 Month Treatment	After 3 Months Treatment
Group 1						
Skin hydration	0%	22%	41%	0%	25%	51%
Skin color	0%	8%	22%	0%	13%	33%
Thin lines	0%	6%	17%	0%	6%	17%
Jaw line	42%	91%	42%	100%	116%	163%
Mouth lines	43%	94%	126%	81%	97%	131%
Eye lines	5%	13%	25%	9%	16%	33%
Skin elasticity	3%	52%	109%	3%	63%	128%
Group 2						
Skin hydration	15%	40%	64%	16%	31%	53%
Skin color	14%	35%	50%	15%	33%	44%
Thin lines	12%	29%	50%	12%	20%	36%
Jaw line	40%	100%	144%	49%	71%	100%
Mouth lines	40%	97%	142%	43%	62%	93%
Eye lines	17%	38%	58%	8%	25%	32%
Skin elasticity	18%	41%	65%	17%	33%	54%

Table 4 *- Percent Change in the Evaluations.*

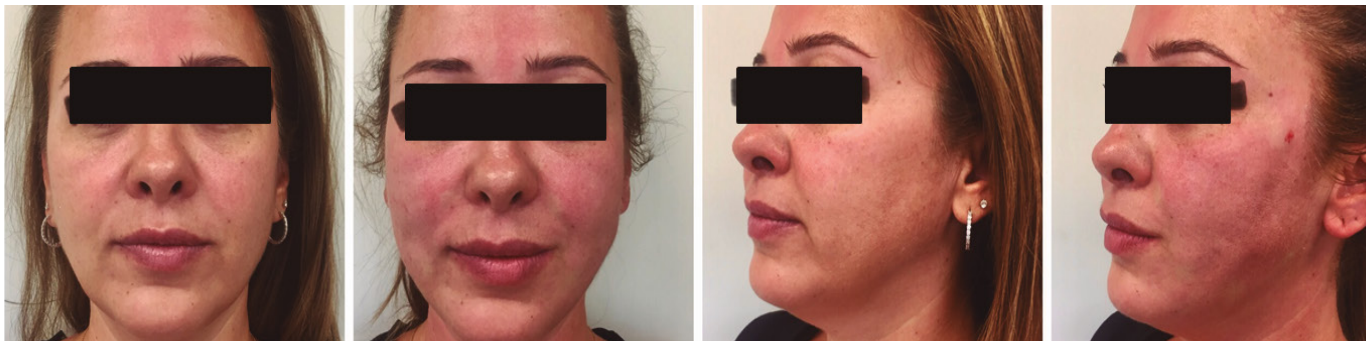

Figure 3 *- Patient view immediately after PLLA/PCL Aptos thread application. a) Pre-treatment b) immediately after the treatment c) Oblique view before the treatment d) Oblique view immediately after the treatment.*

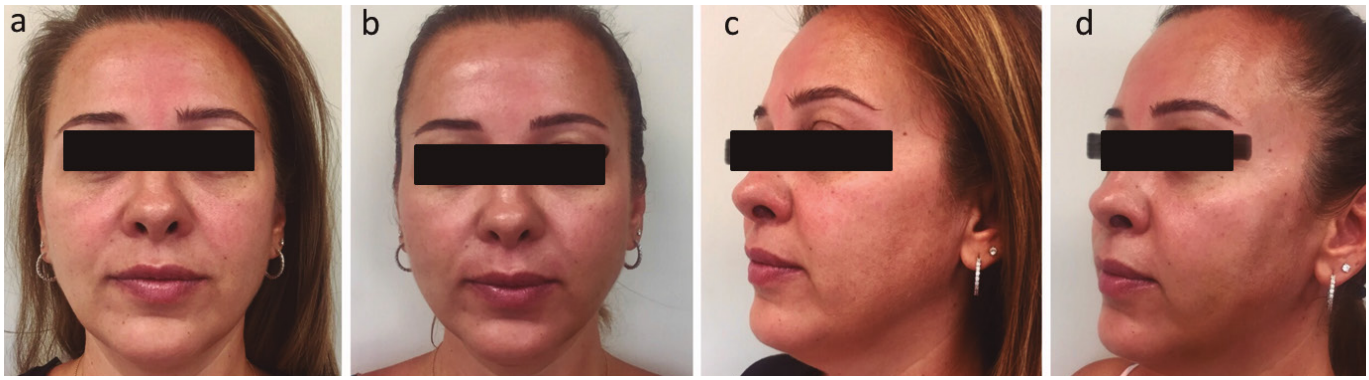

Figure 4 *- Patient view after 1 month PLLA/PCL Aptos thread application. a) Pre-treatment b) after 1 month-treatment c) Oblique view before treatment d) Oblique view after 1 month-treatment.*

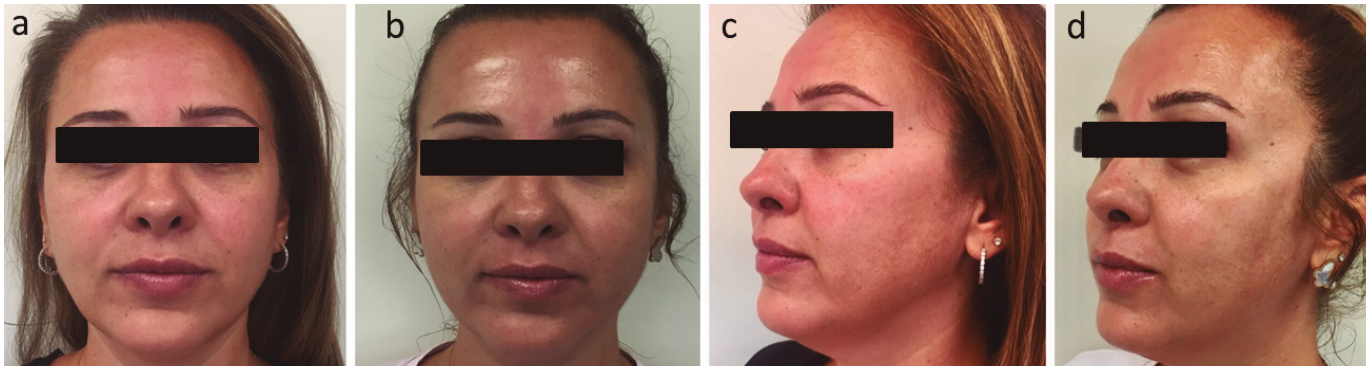

Figure 5 *- Patient view after 3 month PLLA/PCL Aptos thread application. a) Pre-treatment b) after 3 month-treatment c) Oblique view before treatment d) Oblique view after 3 month-treatment.*

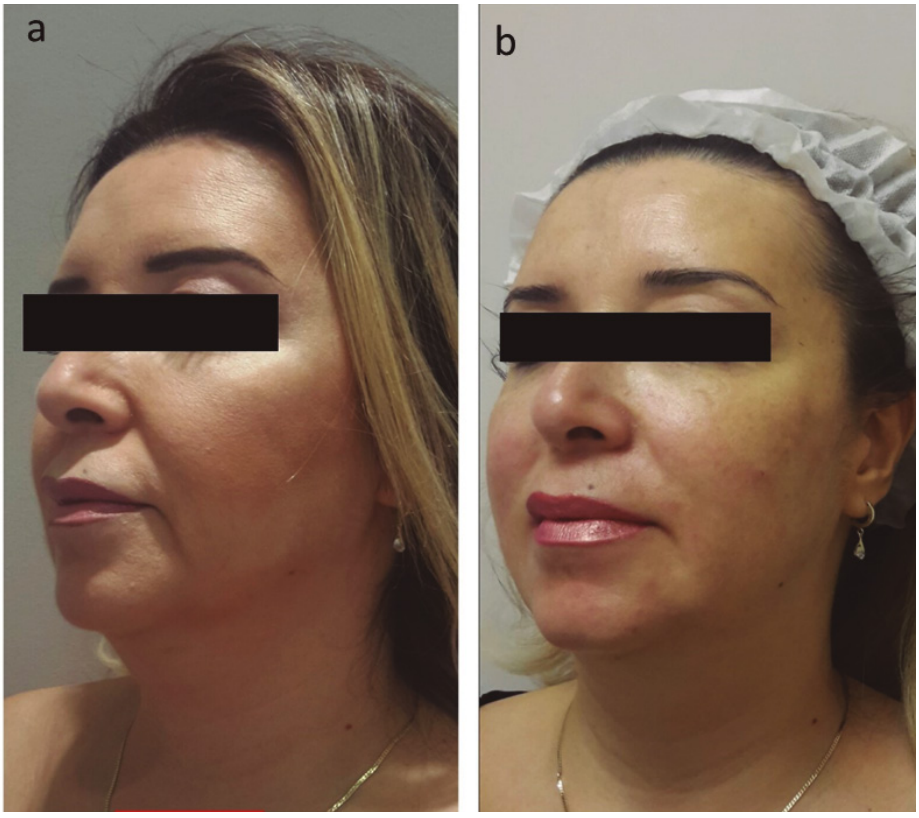

Figure 6 *- Patient view after PLLA/PCL Aptos thread and HIFU application. a) Pre-treatment b) the end of treatment.*

Discussion

The main reason for patients trying an aesthetic treatment is to counteract the symptoms of ageing. However, most facial treatments and methods offer relief only for some wrinkles or shrink-wrapped failing skin outwardly responding to the volume and forms of a fresh face. Injectable poly-L-lactic acid is a biodegradable artificial polymer for the improvement of lipoatrophy and is widely used in Europe. Sculptra was famously applied for improvement of nasolabial folds, lack of medial and lower face volume, jawline slack, and another type of facial ageing. Sculptra treatment is a minimally invasive and efficient method[16].

There are main directions for the application of PLLA: bone resorption, fat death and skin laxity; and at which layer of the face and at what level PLLA is determined depends on the patient's health[17-19]. Also, for skin laxity, the contrast happens–as PLLA needs to be practised just under the skin, into the subdermal level, with needles or cannulas, but with no fat in connecting tissues. It is in this layer that the best skin quality results can be achieved, which is the idea of this study[20,21].

Whenever PLLA is injected into a subdermal plane there is an improvement in skin quality of three types. The first being clear glow-luminosity produced by the hydration of the treated skin, providing the effect of a healthy, young and well-ageing skin. An addditional benefit is the reduction of skin atrophy associated with aging. Moreover, it reduces skin laxity by increasing skin adherence to lower-level tissue. This is normally due to the generation of collagen fibres resulting from the PLLA applications[22].

In the study carried out by Avelar et al.[23] three sessions were applied to the patients at intervals of 45-60 days. Notwithstanding PLLA being supported for many uses - bone resorption, fat loss and skin laxity - there is a regular increase in skin quality after treatment. However, not only is it necessary to know PLLA but also to define the level of injection.

In a previous study, a patient with poor skin quality was treated with a 12-week PLLA treatment. Due to the poor quality of the skin, the first and second treatments were applied for four weeks, allowing sufficient time for collagen restoration and repair. Four weeks after her initial treatment, the patient showed little or no cosmetic improvement. After the second treatment, an improvement of between 20% and 30% in tissue quality was observed according to the comparison of the photos of the patient before and after the treatment and the patient's opinion on the results of the treatment. Eight weeks after the second treatment, a third treatment was performed to resume collagen repair. No side effects related to treatment were observed. After completing the treatment, visual inspection and skin quality improvement resulted in significant results in terms of elasticity. In addition, as a result of the 12-week PLLA administration, an increase in fibrotic layer in the dermis and subdermal layer and skin shine were observed. In addition, collagen restoration resulted in a healthier skin, reduced pores and a more youthful appearance. No adverse effects were observed during the annual follow-up of the patient[24-28].

In another study, participants were treated with injectable PLLA or human collagen for 3 weeks. There is a 3-week period between treatments. For the members of the PLLA group, 3 injection sessions were completed. Three weeks after the last treatment with injectable PLLA, an important development was recognised in the wrinkle assessment scores compared to the baseline. Changes continued to appear until the 13-month evaluation period and were reported during the 19 and 25-month evaluation points. After the injection of PLLA, the number of nodules and papules was 7% and 9%, respectively. Further investigations can serve to maintain the advantage of injectable PLLA performance for aesthetic improvement of facial shape dysfunctions and help manage suitable patient choice criteria for treatment of this strategy[29,30].

In a similar study, 210 female participants were chosen to correct injectable (PLLA) age and disease-related facial volume deficits. The questionnaire was sent to patients treated with PLLA 6 months earlier or more. After the treatment, some of the patients had papules or nodules. After treatment, some of the patients had papules or nodules. One questionnaire was posted to 281 patients previously treated with PLLA for 6 months or more. PLLA was reconstituted by adding 5 mL of sterile water before injection and 1 mL of 1% xylokine before injection. Patients treated with PLLA had a recovery time of 24 months. The maximum improvement was seen after several treatment sessions[31].

In our study we evaluated the effect of PLLA. Similar to the results reported in the literature, PLLA use increased skin collagen. A skin increase of 42% was observed in the skin group with PLLA. This rate was higher in the HIFU and PLLA group. There was a moderate improvement in skin color. In particular, there was a significant improvement in the jaw line, and both groups had close rates in skin flexibility only.

In the PLLA group, a higher rate than in the HIFU and PLLA group was found. This can be considered as evidence that PLLA significantly increases skin elasticity and eliminates the signs of aging. In this study, it was observed that there was little recovery immediately after application. However, a high rate of improvement was achieved 1 month and 3 months after the treatment. This is in line with the studies in the literature.

Conclusion

In this study, we investigated the effect of PLLA/PCL Aptos thread treatment on 20 female patients. The treatment covers a period of 3 months. No side effects were reported by the patients. Evaluations were made through questionnaires and photographs. Both the patient and the physician evaulated the results and similar data were obtained.

- When the survey data were evaluated, an improvement of only 65% in the PLLA /PCL Aptos thread group and 76% in the combined treatment group was observed. These results showed close values in the evaluation of patients and doctors.
- Combined treatment with skin hydration and skin color gave better results.
- In the presence of fine lines, there was a moderate

improvement in PLLA/PCL Aptos thread application.
- A high improvement was observed in the jaw line and mouth lines. A smoother and taut image was obtained.
- As for skin elasticity, only PLLA/PCL Aptos thread application showed a better result than combined application.

In general, when the results are evaluated, it can be said that PLLA/PCL Aptos thread application is effective on skin quality. This effect depends on the time of the application and the patient's condition prior to the treatment. A minimal improvement immediately after the application but a high recovery after 3 months emphasize the importance of application time.

Abbreviations

PLLA: Poly-L-Lactic Acid
HIV: Human Immunodeficiency Virus
APTOS: Anti-Ptosis
SPSS: Statistical Package for the Social Sciences
VAS: Vısual Analog Scala
HIFU: High Intensity Focused Ultrasound

Conflicts of Interest

The author declares no conflict of interest.

ANNEX 1. VAS questionary

BEFORE TREATMENT

EVALUATE SKIN MOISTURE

very dry and tense — moist and soft

0 1 2 3 4 5 6 7 8 9 10

YOUR SATISFACTION WITH SKIN COLOR

Very bad and many dark spots — very well no need any make up

0 1 2 3 4 5 6 7 8 9 10

FINE LINES EXISTING

Too many static fine lines all face — not any fine lines

0 1 2 3 4 5 6 7 8 9 10

SAGGING OF THE SKIN

JAWLINE

Very ondulated and saggy — very stright and tight

0 1 2 3 4 5 6 7 8 9 10

LINES AROUND THE MOUTH

Very deep folded — no lines

0 1 2 3 4 5 6 7 8 9 10

LINES UNDER EYES

Very deep folded — no lines

0 1 2 3 4 5 6 7 8 9 10

EVALUATE THE SKIN TENSION

Very loose and soft — very tight and firm

0 1 2 3 4 5 6 7 8 9 10

DURING THREATMENT

HOW IS THE PAIN

Worst pain ever need anestesia — no pain

0 1 2 3 4 5 6 7 8 9 10

IMMEDIATELY AFTER TREADMENT

EVALUATE CHANGING OF YOUR FACE
EVALUATE SKIN MOISTURE

very dry and tense — moist and soft

0 1 2 3 4 5 6 7 8 9 10

YOUR SATISFACTION WITH SKIN COLOR

Very bad and many dark spots — very well no need any make up

0 1 2 3 4 5 6 7 8 9 10

FINE LINES EXISTING

Too many static fine lines all face — not any fine lines

0 1 2 3 4 5 6 7 8 9 10

SAGGING OF THE SKIN

JAWLINE

Very ondulated and saggy — very stright and tight

0 1 2 3 4 5 6 7 8 9 10

LINES AROUND THE MOUTH

Very deep folded — no lines

0 1 2 3 4 5 6 7 8 9 10

LINES UNDER EYES

Very deep folded — no lines

0 1 2 3 4 5 6 7 8 9 10

EVALUATE SKIN TENSION

Very loose and soft — very tight and firm

0 1 2 3 4 5 6 7 8 9 10

DEGREE OF DISCOMFORT AFTER TREATMENT

Very bad and painfull — no discomfort

0 1 2 3 4 5 6 7 8 9 10

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aesthetic medicine

Review

Focus on biostimulation: diagnostic evaluation

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Abstract
In Aesthetic Medicine, any type of flaws (wrinkles, so-called cellulitis, overweight, etc.) must be evaluated from a medical point of view with a diagnostic approach.
The first Aesthetic Medicine visit, in compliance with the Italian Society of Aesthetic Medicine (SIME) recommendations, includes medical history and traditional clinical examinations aimed at identifying the patient's request, including a number of morphological and functional evaluations, i.e. morpho-anthropological and postural assessment, lower limb phlebological evaluation, hypodermal ultrasound, skin evaluation with cutaneous checkup according to Bartoletti-Ramette's method, psychological evaluation and blood chemistry. This approach allows to design a customized, preventive and site-specific treatment.
Aging is a phenomenon that affects the human face by provoking an array of complex changes over time, which include microscopic and macroscopic volumetric changes, exacerbated by the resorption of the deep three-dimensional structural support, gravity, subcutaneous fat redistribution, induced by bad habits or environmental factors.
The objective of this article is to provide a set of recommendations that readers can use to set up a diagnostic-therapeutic plan to implement a tailored preventive and corrective program.

Keywords
Skin aging, clinical evaluation, cutaneous check-up, physiological cutaneous aging, photo-induced aging

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Skin Aging

Facial skin aging is a phenomenon involving a set of microscopic and macroscopic complex volumetric changes. These changes can be explained by several factors, including deep three-dimensional structural support, subcutaneous fat redistribution, bad habits or environmental factors. Skin aging is caused by a disruption in the vascular and connective tissue architecture of the dermal and hypodermal layers associated with a reduction in the number and activity of fibroblasts[1]. It should be highlighted that skin aging is due to intrinsic factors, mainly responsible for physiological aging (intrinsic ageing)[2,3,4,5] and extrinsic factors responsible for photo-induced aging (extrinsic ageing)[2] (*Figures 1 and 2*).

Physiological Aging

Epidermal layer:
- Early keratinization
- Reduction in Langherans cells
- Irregular distribution of melanocytes
- Reduction in dermal papillae and epithelial crests

Dermal layer:
- Reduced thickness
- Disorganized and fragmented collagen and elastic fibers
- Reduced number of fibroblasts, mastocytes and Langherans cells

Figure 1 *- Physiological Aging.*

Photo-aging

Epidermal layer
- Skin thickening
- Epidermal damage (on keratinocyte nuclei)

Dermal layer
- Capillary dilation
- Sebaceous gland hyperplasia
- Collagen and elastin degradation
- Dermal damage with elastic fiber degeneration (solar elastosis)

Figure 2 *- Skin manifestations in photo-aging.*

One of the most important aspects is physiological aging which includes, at the epidermal level, early keratinization, reduction in Langerhans cells, irregular distribution of melanocytes, reduction in dermal papillae and epithelial crests; at the dermal level, reduced thickness, disorganized and fragmented collagen and elastic fibers, reduced number of fibroblasts, mastocytes and Langerhans cells. With regard to connective tissue, physiological aging causes a reduction in proteoglycans and glycosaminoglycans, thickened elastic and collagen fibers as well as elastin structural changes.
Another important issue is photo-induced aging that is characterized by skin thickening, capillary dilation, sebaceous gland hyperplasia, collagen and elastin degradation, epidermal damage (on keratinocyte nuclei), and dermal damage with elastic fiber degeneration (solar elastosis).
This aspect is responsible for visually evident cutaneous manifestations (*Figure 2*), including deep and irregular wrinkles, thick texture, resulting from the anarchic production of abnormal elastic tissue (elastosis), collagen loss and degradation, impaired vessel regeneration[5].

Wrinkles classification

- Linear wrinkles (frontal, peri-buccal, crow's feet)
- Glyphic wrinkles (from actinic damage due to elastosis)
- Creases (sleeping lines – vertical on the forehead)
- Crinkles (due to collapse of super-epidermal elastic fibers in elderly people in non-photo exposed areas)
- Naso-labial wrinkles (folds that delimit the border of muscular masses of the face: they delimit the orbicular oris muscle and masseter)

Figure 3 *- Kligman wrinkle classification.*

Kligman classification (*Figure 3*) distinguishes several types of wrinkles[6]: 1. Linear or expressional wrinkles: they are initially reversible, caused by the contraction of facial mimic muscles, run always perpendicular to the muscles; they are more marked in emotional and expressive people and are sub-divided into periocular wrinkles or "crow's feet", glabellar folds (frown lines), which run horizontally on the forehead, from the nose root in cranial-caudal and medial-lateral direction, and peri-labial ("smoking") wrinkles that are localized vertically on the upper lip and around the mouth; 2. Glyphic wrinkles: they are the clinical sign of actinic damage, caused by an accentuation of normal skin folding, run obliquely and perpendicularly to the other types of wrinkles, and are mostly localized on the chicks; 3. Sleeping lines (creases): they are created by prolonged facial positions, are initially reversible, run perpendicularly to linear lines, are usually localized on the forehead and chicks; 4: Ripples (crinkles): are small wrinkles found on the arms, thighs and gluteus muscles, related to physiological aging, due to collapse of subepidermal vertical elastic fibers (due to lack of adherence between dermis and epidermis); they are also present in non-photo-exposed regions in elderly people, but can be seen at all ages; 5: Naso-labial wrinkles are deep folds between the upper lip and the nose wings; they delimit the most important muscular masses of the face (especially the orbicular

oris muscle and the masseter). They are formed when the anterior fascial attachments between the skin and the Superficial Musculo-Aponeurotic System (SMAS) become weaker, which results in the collapse of excess skin. Another important aspect that affects skin aging is a change in the structure of dermis, characterized by a reduction in the cellular component that is submerged in the extracellular matrix formed by the fundamental substance.
The fundamental, or amorphous, substance consists of glycosaminoglycans (GAGs) and proteoglycans which are glycosaminoglycans bound to large proteins (LP) and fibrillar proteins. The GAGs, D-glucosamine or D-galactosamine are polysaccharides consisting of disaccharide units, each containing one amino hexose. Commonly-known GAGs are hyaluronic acid and heparin, while the most abundant GAGs in the skin are hyaluronate and dermatan sulphate. In young dermis, there is a prevalence of chondroitin-4-sulfate and chondroitin-6-sulfate, while in adult dermis, there is a prevalence of keratan sulfate with depletion of hyaluronic acid[7]. It is of note that in dermis all GAGs, with the exception of hyaluronic acid, are bound in large amounts to fibrous proteins thus forming proteoglycans. Proteoglycans are the intercellular 'concrete' that fills the space between the cells of most tissues, including articular cartilage and dermis. This aspect seems to be particularly important, as GAGs play a crucial role in the fundamental substance of dermis and articular cartilage thus optimizing its structure. In fact, they are guarantors of isoionia, isoosmia, isotonia of the fundamental substance; thanks to their molecular structure they can fight the positive charges of lytic enzymes such as hyaluronidase, protease, elastase, glucuronidase. The fundamental substance is the environment where fibroblasts, the cells for the synthesis of elastin, collagen and glycosaminoglycans are submerged[8].
With regard to this, skin aging involves the so-called "escape" of glycosaminoglycans of dermis, including hyaluronic acid, with a reduction in cellular synthesis reactions and an increase in catabolic reactions with subsequent dehydration and impairment of the functions of the fundamental substance. The last important aspect is the alteration of the micro-circle that causes a metabolic change due to which the high-energy producing aerobic glycolytic metabolism switches to a low-energy producing anaerobic metabolism. The ATP availability is reduced with consequent impairment of anabolic metabolism and reduced biosynthesis of glycosaminoglycans and collagen. Therefore, we observe a reduced synthesis of collagen Type I / collagen Type III typical of young age as well as a generalized extracellular atrophy in intrinsically aged skin; moreover, photo-aged skin is characterized by catabolic and anabolic remodeling events specific for the matrix components[9]. The reduced bioavailability of ATP slows down cellular mitoses with subsequent reduction in skin thickness, while the reduced ability of GAGs to fix cations is responsible for the alteration of the micro-circulation and non-enzymatic glycosylation of collagen.

Patient Clinical Evaluation in Aesthetic Medicine

In Aesthetic Medicine, any type of flaws (wrinkles, so-called cellulitis, overweight, etc.) must be evaluated from the medical point of view with a diagnostic approach.
The first Aesthetic Medicine visit, consistently with the recommendations of the Italian Society of Aesthetic Medicine (SIME), includes medical history and traditional clinical examinations aimed at identifying the patient's request, and includes a number of morphological and functional evaluations, including psychological evaluation, morpho-anthropological and postural evaluation, phlebological evaluation of lower limbs, adipose tissue ultrasound, skin evaluation with cutaneous checkup according to C.A. Bartoletti-G. Ramette's method, and blood chemistry (*Figure 4*).

Morphological and functional evaluations

1) Psychological evaluation
2) Morpho-anthropological evaluation
3) Postural evaluation
4) Phlebolymphology evaluation of lower limbs
5) Adipose tissue ultrasound
6) Physical ability evaluation
7) Skin evaluation (Cutaneous Check-up)
8) Blood-chemistry

***Figure 4** - Morphological and functional evaluations.*

This approach allows to design a customized, preventive and site-specific treatment.
In particular, cutaneous checkup according to C. A. Bartoletti/G. Ramette's method includes inspections at naked-eye, magnifying lens, natural light, cold light, Wood's light, corneometry, sebometry, pHmetry, 15% lactic acid sensitivity test and evaluation of reactivity with dermographism.
The evaluation obtained by cutaneous checkup, in particular with instrumental examination, is crucial to formulate a correct diagnosis, to make a cosmetological prescription and to define appropriate treatments for the prevention and management of skin aging. This procedure helps identify the skin biotype, classify the phototype, make a functional balance, determine the degree of skin aging and monitor skin values over time. The diagnostic path allows to implement a tailored preventive and corrective program. It is recommended to use official methods that have been implemented for at least two years and are supported by referenced scientific evidence, published in indexed journals and involving an appropriate number of patients.
According to SIME recommendations, the Board of experts agrees that the interventional approach to patient-reported flaws includes a diagnostic evaluation, a phase of normalization of abnormal parameters, a patient education program on the importance of daily skin care at home and at the clinician's, of preventive and corrective treatment based on a shared plan of action, of monitoring of results and the related

corrective measures when any changes occur.
Based on these considerations, skin biostimulation is one of the medical-aesthetical procedures used to fight or slow down the process of skin aging whose manifestation is the onset of wrinkles and folds.
The word biostimulation (from the Greek "βίος" (bíos), life and from the Latin "stimulate", spur) refers to a technique, method or practice that can trigger a response in a living system through the application of a stimulus. It is a site-specific intradermal injection treatment (face, neck, décolleté, hands, body) of substances aimed at stimulating fibroblasts, not only to produce elastin, collagen, hyaluronic acid, being therefore eligible to prevent, delay and affect chrono- and photo-aging. The crucial aspect of biostimulation is the protection of the physiology of the patient's skin, especially to provide elements useful to cellular regeneration, starting from the improvement of the entire tissue and the restoration of the structures that the aging processes and diseases impoverish through biochemical and biophysical procedures. Therefore, biostimulation carried out with a site-specific intradermal treatment allows to slow down skin aging by ensuring a better physiological skin brightness, elasticity and turgor[10].

Conclusions

In summary, before implementing any therapeutic techniques, it is important to collect medical history and carry out traditional clinical examination aimed at identifying what is the patient's request, through a number of morphological and functional evaluations, including morpho-anthropological and postural assessment, phlebological evaluation of lower limbs, hypodermal ultrasound, skin evaluation with cutaneous checkup according to Bartoletti-Ramette's method, psychological evaluation and blood chemistry. This approach allows to design a customized, preventive and site-specific treatment.

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aesthetic medicine

Case Report

Delayed onset filler complications on the face: a case report

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Abstract
All injectable fillers can produce unexpected adverse reactions. Liquid injectable silicone (LIS) is a widely used filler. A common adverse event caused by LIS is inflammation, which may occur as a response from the immune system to silica per se or its additives.
We report a case of a 71-year-old woman who presented swelling, induration and erythema, from the medial canthus of the left eye to the zygomatic/malar area 11 years after being treated with 2 infiltrations of LIS in the "marionette lines". Initially she was treated with surgery, to remove the largest inflammatory nodule. Four years after the first intervention, the patient presented a subcutaneous nodule in the contralateral malar area. High frequency ultrasound (HUS) showed that the lesions were distributed extensively in the dermis of almost the entire facial region. Due to the esthetic consequences (scars) of an extirpation, a new surgery was not considered. Therefore, the patient was treated with Minocycline, showing a significant clinical improvement.
Granuloma induced by silicone should be considered as a differential diagnosis in patients with a history of cosmetic injections that develop facial swelling. In our opinion, monotherapy with minocycline is a good alternative treatment for patients with facial granuloma.

Keywords
Liquid injectable silicone, granuloma, minocycline, siliconoma, iatrogenic allogenosis

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Introduction

Several types of injectable materials have been used for facial rejuvenation and soft tissue augmentation. The popularity of facial fillers has grown substantially worldwide due to its effectiveness and safety as a non-surgical procedure. The ideal injectable material should offer good esthetic results with lasting effects, be safe, biocompatible and stable at the place of implantation, with minimal complications and no risk of migration[1]. However, this kind of product has yet to be discovered. All filling substances, to a greater or lesser extent, have some adverse effect[2].

Depending on their permanence in the tissues, cosmetic fillers are classified in two categories: temporary or permanent[3]. All injectable fillers can produce unexpected adverse reactions, from small to large responses, with severe complications. Temporary agents may induce serious complications, which usually resolve spontaneously over a variable period of time. Permanent fillers can also generate minimal adverse reactions such as pain, swelling, erythema, ecchymosis; and large responses such as nodules or granulomas that do not resolve spontaneously[4].

Liquid injectable silicone (LIS) is a product without odor or color, composed of polymerized dimethyl-siloxane chains[5]. Its popularity is based on the fact that it is permanent, economical, minimally antigenic and non-carcinogenic[6]. Although it is used as a facial filler material, it has not been approved by the US FDA for this application[1]. In some cases, it has been associated with displacement or migration which can occur after many years, leading to an accumulation of particles and nodular granulomas at sites far removed from the points of injection[7]. These granulomas are also called "siliconomas", and were described for the first time in 1964[8].

The inflammation induced by LIS may occur as a response from the immune system to silica per se or its additives (or contaminants) such as platinum, an amorphous aggregate of silica, or fumed silica8. Previous studies support the fact that a small fraction of the granulomas formed in reaction to silicone injections are infectious[9]. In addition, patients are not always aware of the material that has been injected or recall if they have previously received treatment with another compound[10].

We present a case of "iatrogenic allogenosis". Its definition was established by Coiffman in 2012[11] as a term that defines the disastrous results produced by several permanent substances, months or years after being injected. It is called "Allogenosis", because it is caused by allogenic substances, that is, foreign to the organism; and "Iatrogenic", because it is caused by medical intervention.

The goal of this article is to report a case of filler migration with foreign body granulomas (siliconomas) at a distant site, and to raise awareness of the late complications of soft tissue filler injections.

Case

A 71-year-old woman was referred to our department due to a 3-year history of facial swelling, induration and erythema, from the medial canthus of the left eye to the zygomatic/malar area. She mentioned 2 infiltrations in the "marionette lines", 11 years earlier, ignoring the type of compound or the amount used for infiltration. We assumed that it was silicone.

During the physical examination, she presented small erythematous nodules in both malar and nasal root areas, at the level of nasolabial folds. The largest nodule, located diagonally from the canthus of the left eye to the middle area of the infraorbital rim, presented induration and erythema. There were no palpable lymph nodes and the rest of the physical examination was normal. Blood tests were within normal values.

A facial magnetic resonance (MRI) was performed, showing the presence of filler material in both zygomatic/malar areas (*Figure 1*).

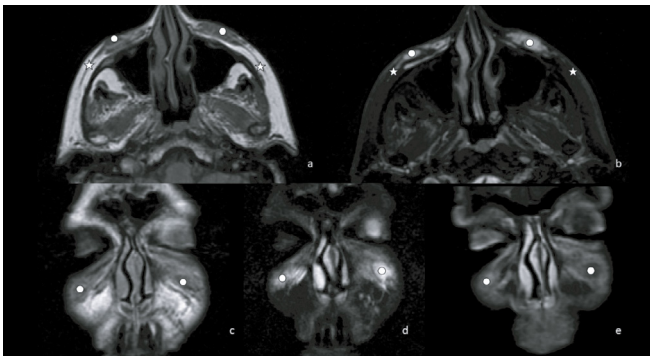

Figure 1 *- Craniofacial MRI of the patient. a) Axial T1; b) Axial T2 Fat-Sat; c) Coronal T1; d) Coronal T2 Fat-Sat; e) Coronal T1 Fat-sat with gadolinium. Circle: presence of filler material in both zygomatic/malar areas of subcutaneous localization. Star: presence of filler material above the musculoaponeurotic system (SMAS).*

Surgical removal of the largest inflammatory nodule was performed. Pathology was consistent with the formation of a foreign body granuloma secondary to silicone, and the presence of another permanent material (*Figure 2*).

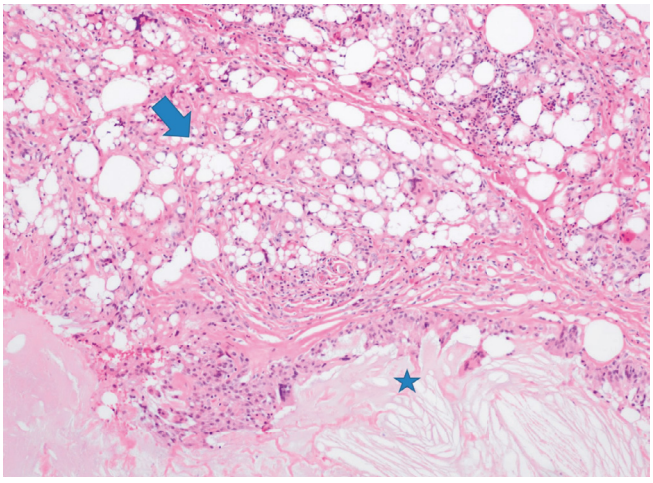

Figure 2 *- Histology of the patient's largest nodule showing silicone granulomas. Arrow: presence of numerous vacuoles of exogenous material and microvacuolated histiocytes. Star: granulomatous reaction with multinucleate giant cells to exogenous acellular material .*

Autologous fat infiltration (lipofilling) was subsequently performed to correct the hypotrophic defect.
Four years after the first intervention, the patient presented a subcutaneous nodule in the right malar region and nasal root, of approximately 2 x 2 cm, with overlying erythema. A new MRI was performed showing a collection of subcutaneous material in both malar/zygomatic areas with left predominance (*Figure 3*).
Surgical removal of the right malar lesion was performed again, with good scarring.
Two years after the last intervention (16 years after being treated with silicone), the patient kept the small residual erythematous nodules described above and swelling, and began to develop new facial nodules, one at the level of the medial canthus of the right eye and nasal root, approximately 2 x 1.5 cm; and some about 5 mm in the right and left "marionette lines". These lesions did not have clinical signs of infection (*Figure 4*).
We performed a high frequency ultrasound (HUS) (*Figure 5*) in which we observed image in "snowstorm", which suggested the presence of a permanent material, typical of silicone.
Since the lesions were distributed extensively in the dermis of almost the entire facial region, due to the esthetic consequences (scars) of an extirpation, a new surgery was not considered.
She started treatment with Minocycline 100mg / day. Within 4 weeks of treatment, the swelling and erythema improved substantially. During the following weeks, the nodules became softer and smaller; however, small nodules around the left eye were still visible. Minocycline was continued and a follow-up visit 4 months after initiation of therapy showed a significant clinical improvement (*Figure 6*).

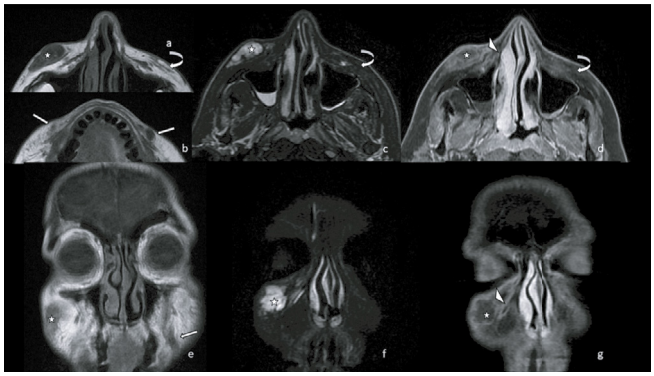

Figure 3 *- Craniofacial MRI of the patient, four years after surgical removal of the largest inflammatory nodule and lipofilling of the hypotrophic defect. a) Axial T1 Upper cut at malar level; b) Axial T1 lower cut at the level of dental arch; c) Axial T2 Fat-Sat; d) Axial T1 Fat-sat with gadolinium, e) Coronal T1; f) Coronal T2 Fat-Sat; e) Coronal T1 Fat-sat with gadolinium. Star: collection of subcutaneous material in the right malar/zygomatic area. Curved arrow: trabecular subcutaneous fat at the left malar. Straight arrow: two-sided material of left predominance. Arrowhead: collection on the right cheek with peripheral contrast when administering gadolinium.*

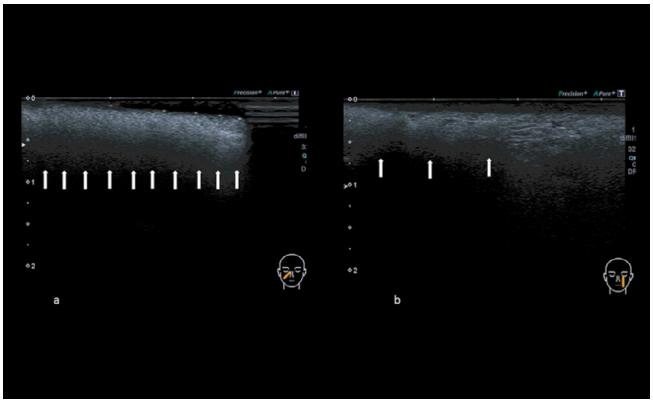

Figure 5 *- HUS image of the face of the patient. a) Right Malar region: it occupies the whole malar region; b) Left Malar region: small isolated remnants observed. Arrows: image in "snowstorm".*

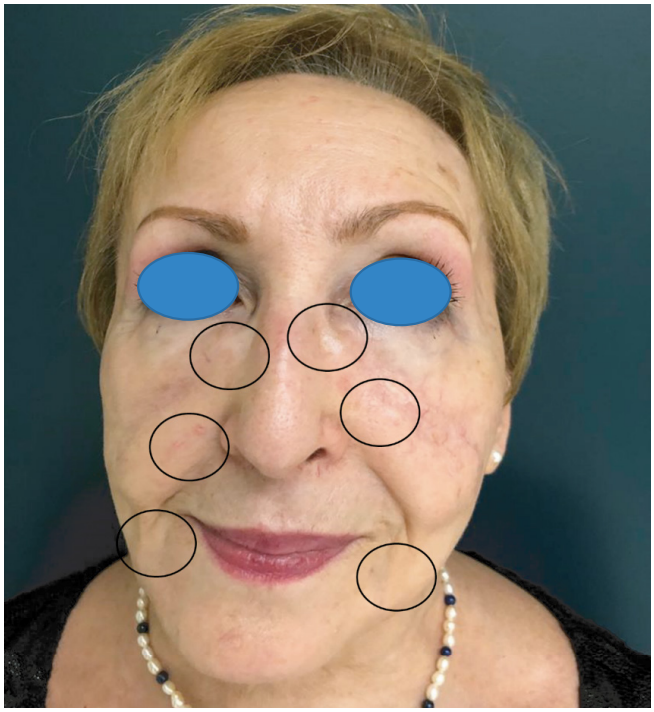

Figure 4 *- The 71-year-old woman with multiple "siliconomas" (circled), 16 years after being treated with silicone.*

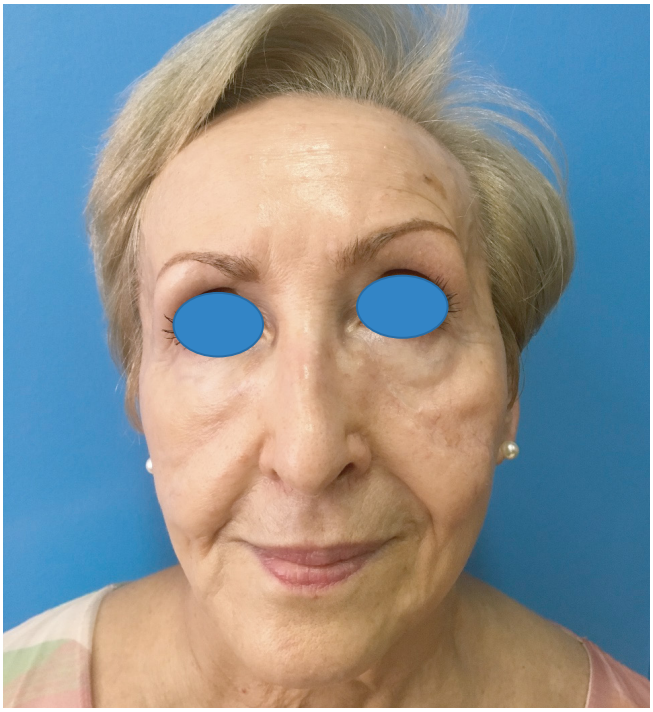

Figure 6 *- Patient after the treatment with minocycline. No presence of facial nodules could be observed.*

Discussion

Complications due to injection of LIS are rare. They include chronic cellulitis, nodules and subcutaneous plaques, foreign body reactions, and migration of silicone[12]. Treatment of silicone-induced granulomas has been based on case reports, proved difficult to manage and was in many cases unsuccessful. The treatment must be individualized[13].
Erythema, swelling, induration, pain, deformity and hyperpigmentation may also appear[14]. Some authors propose that complications due to LIS are due to the use of adulterated silicone, large volume injections or because of administration by inexperienced/untrained professionals[11,15].
Subsequent to injection, silicone is encapsulated in the fibrous tissue due to the host inflammatory response, resulting in increased volume. Histologically, silicone-induced granulomas contain multinucleated giant cells and histiocytes that are seen in the dermis and subcutaneous cellular tissue, together with polymorphic pseudocystic spaces representing LIS particles[16]. Our case presented a similar pattern.
In addition, another exogenous material different from silicone could also be observed in the histopathological exam of the patient, similar to what has been published by Wang et al[9], who suggest that granulomas can also be induced by the injection of adulterated silicone or when injected in conjunction with other substances.
A large volume of injection results in silicone migration thereby leading to granuloma appearance in areas distant from the site of infiltration[8]. Due to this, our patient presented granulomas in the zygomatic area and medial canthus of the eye, even though the silicone was injected into the “marionette lines”.
The pathogenesis of granuloma formation is uncertain. Granulomas may be caused by a generic response to a foreign body, or to an adulterant in the silicone or by an infectious process. One of the proposed hypotheses is that liquid silicone can act as a niche for bacterial proliferation. Non-tuberculous mycobacteria at the subcutaneous level have been reported in adulterated liquid silicone. Additionally, bacteria can form a biofilm around the silicone[15].
Treatments range from surgical resection for localized granulomas to treatments with oral or systemic corticosteroid[10], minocycline[18], 5-fluorouracil[19] or isotretinoin[20], among others. In cases in which a surgical removal is necessary, the patient may present scars. In addition, sometimes it is necessary to remove thick layers of tissue and the cosmetic result may not be satisfactory[12]. This happened to our patient, who presented a hypotrophic scar after surgical removal of the “siliconoma”, subsequently needing a new procedure to correct the defect. Antibiotics, especially minocycline, have been used successfully due to their anti-inflammatory, immunomodulatory and antigranulomatous effects, as well as their coverage for mycobacteria[21]. Suchismita et al[14], have reported a case treated with doxycycline (100 mg every 12h for 3 months) with improvement of granulomatous reactions at 3 months. We report the successful treatment of multiple silicone granulomas of the face (siliconomas) with a low dose minocycline regime (100mg/day).
Current studies suggest that high frequency ultrasound (HUS) is an economical, useful and non-invasive diagnostic tool to determine the nature and type of material and to identify the injection site and quantity of injected filler[22].
Grippaudo et al[23] demonstrated that the use of HUS helps to identify the place and quantity of silicone injected into the soft tissue. In ultrasound, permanent fillers such as silicone show “snow storm” image with posterior acoustic shadow[22]. In this case HUS allowed to identify the actual location and confirm the type of filler injected in the soft tissue of the face.
Granuloma formation by silicone should be considered as a differential diagnosis in any patient with a history of cosmetic injections who develops facial swelling. In our opinion, monotherapy with minocycline is a good alternative treatment for patients who present facial granuloma.

Conflicts of Interest

The author declares no conflict of interest.

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Letter to the Editor

The web, end user safety and false myths

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Abstract
EC Regulation 1223/2009 has established precise norms for the protection of cosmetic product end users. However, the web and the ever-changing consumer needs have led to the development of gray areas in the application of the Regulation, which exposes end users to a number of risks.

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When EC law-makers decided to regulate the cosmetic sector with Regulation 1223/2009 to establish precise rules for cosmetic manufacturers, they certainly did not foresee how much and fast the web would change and the huge amount of information, sometimes incorrect, that goes around on it and which led to a rapidly growing trend: DIY homemade cosmetics.

The Cosmetic Regulation establishes strict norms - and sanctions for those who break them - aimed at protecting end users on three aspects: the ingredients used, the manufacturing process, the labelling describing the product. Conversely, homemade cosmetics shirk the laws governing commercial cosmetic products and stand as a sector with no rules and which exposes the unaware users to a number of serious consequences.

Homemade cosmetics are the consequence of misleading and inaccurate information that has been spread over the web and the media on certain ingredients used in cosmetics, supposedly dangerous or anyway inappropriate for skin, thus unnecessarily demonised. On the one hand, this generated mistrust for everything that appeared artificial and industrially processed or manufactured and, on the other hand, it led to the exasperation of the idea that everything that is natural is also healthy. This new trend triggered a number of personal care enthusiasts, who unfortunately lack specific professional qualifications, to disseminate increasingly sophisticated recipes through the web, developed through home-based, unprofessional testing, in kitchens and with the little household tools available - a phenomenon that has rapidly gone viral. The recipes of soaps, creams and deodorants, yet also nail polish and makeup, have spread rapidly over the web and entered the homes of "DIY cosmetic makers" through Youtube and internet blogs managed by the pioneers of homemade cosmetics. As it seems, the reliability and efficacy of the final product is basically given by the number of positive reviews that each recipe obtains, not by rigorous and scrupulous laboratory testing that guarantees product safety and efficacy, as it should be.

Therefore, self-manufactured cosmetics face a number of limitations. Firstly, there is the purchase and imprudent use of ingredients, which can be harmful if not handled with the proper precautions and may not always meet the required quality standards. The purchase of ingredients, especially by inexperienced cosmetic makers, on the internet from non-certified ingredient manufacturers or suppliers can indeed prove to be a very bad idea. In addition, besides sourcing ingredients whose quality is impossible to verify, there is a high risk of inaccurately measuring and combining those ingredients to form the recipe, especially if using household tools, which are clearly inadequate – clearly, far too many risks that may compromise the quality of the final product. Another aspect not to be underestimated is ensuring microbiological stability of the cosmetic product, which is definitely not in the ability of homemade cosmetic makers because safety tests cannot be carried out at home. Finally, also the containers the final products are stored in can release substances that alter the final product, if the quality of such containers is not proven and certified.

If "DIY cosmetic makers" use the cosmetics they make on themselves, no particular law is being broken. On the other hand, if homemade products are used by other people, given as gifts (as certain bloggers like to underline) or marketed through private stores, there may be some serious legal consequences. In the event that the cosmetic product causes damage to the end user, for instance a bad allergic reaction, though regulation 1223/2009 cannot be enforced, civil law will apply instead - in Italy, it would be article 2043 of the Civil Code - on the grounds that anyone who causes damage to third parties is obliged to pay compensation. Unfortunately, in this case the burden of proof lies with the injured party, with the consequent difficulty in identifying the culprit. In addition, besides the combination of ingredients, damage to the user may also occur due to the poor quality of a single ingredient, which may have been purchased anywhere in the world, clearly making it even more difficult to trace back where it came from in the first place.

The hope for the future is to put the spotlight on the need to define the rules for DIY cosmetics, a trend that is silently but rapidly growing in popularity in Italy and all over Europe.

Courses and Congresses

2019

13 - 14 September - Paris (France)
40th National Congress SFME
French Society of Aesthetic Medicine
Palais des Congrès de Paris
President: J.J. Legrand
Email: info@sfme.info
Web: www.sfme.info

26 - 29 September - Warsaw (Poland)
22nd World Congress of Aesthetic Medicine
Organized by: Polish Society of Aesthetic and Anti-Aging Medicine
Hilton Warsaw Hotel and Convention Center
President: A. Ignaciuk
Web: www.icaam.pl

4 - 6 October - Lima (Peru)
1st Scientific Congress of Aesthetic and Anti-Aging Medicine
Scientific Association of Aesthetic Medicine (ASOCIME)
San Isidro Disctrict, Lima
President: I. Ogata Matayoshi
Email: info@asocime.com.pe
Web: www.asocime.com.pe

11 - 12 October - Santiago (Chile)
13th Congress of Aesthetic Medicine of Chile
Chilean Association of Aesthetic Medicine (SOChME)
Hotel Intercontinental, Santiago
President: G. Marzullo
Email: contacto@creativaproducciones.cl
Web: www.congresomedicinaestetica.cl
www.sochme.cl/

18 - 20 October - Almaty (Kazakhstan)
11th International Congress of Aesthetic Medicine, Plastic Surgery and
Aesthetic Gynecology in Kazakhstan and Central Asia
Kazakhstan Association of Aesthetic Medicine and Plastic Surgery
Reception House "Bakhshasaray"
President: G. Zhumatova
Email: info@estetic.kz
Web: www.esteticcongress.kz
estetic.kz

25 - 26 October - Toronto (Canada)
CAAM 16th Annual Conference
Canadian Association of Aesthetic Medicine
Hilton Toronto / Markham Suites Conference Centre
President: J. Carroll
Web: www.caam.ca

26 - 27 October - Tbilisi (Georgia)
5th International Congress of Aesthetic Medicine
Georgian Society of Aesthetic Medicine
The Biltmore Hotel, Tbilisi
President: E. Ugrekhelidze
Email: info@gsoam.ge
Web: www.gsoam.ge

31 October - 2 November - Cascais, Lisbon (Portugal)
4th National Congress of Aesthetic Medicine
Portoguese Society of Aesthetic and Anti-Aging Medicine
Hotel de Oitavos
President: J. P. Vale
Web: www.spme.pt

6 - 8 November - La Paz (Bolivia)
2nd Bolivian Congress of Aesthetic Medicine
Bolivian Association of Aesthetic Medicine (ASOBOME)
Hotel Atix La Paz
President: D. Hurtado Terrazas
Facebook page

8 - 10 November - Long Beach California (USA)
16th AAAM Congress
American Academy of Aesthetic Medicine - AAAM
President: M. Delune
Email: delegate@aaamed.org
Web: www.aaamed.org

14 - 15 November - Algers (Algeria)
Congress of the Algerian Society of Aesthetic Medicine (SAME)
President: M. Oughanem
Email: oughanem_m@hotmail.com

28 November - 1 December - Belek (Turkey)
3rd National Medical Aesthetic Congress
Turkish Association of Medical Aesthetic Medicine
Kaya Palazzo Golf Resort Hotel, Belek - Antalya
President: H. Subasi
Email: mestder@opteamist.com
Web: mestder2019.org

6 - 8 December - Moscow (Russia)
8th National Congress of Plastic Surgery, Aesthetic Medicine and Cosmetology
Russian Society of Aesthetic Medicine
President: O. Panova
Email: info@rs-am.ru
Web: www.rs-am.ru

2020

20 - 22 February - Malaga (Spain)
35th National Congress of the Spanish Society of Aesthetic Medicine
Palacio de Ferias y Congresos, Malaga
President: P. Vega
Email: seme2020@pacifico-meetings.com
Web: www.seme2020.org

13 - 14 March - Mexico City (Mexico)
17th Mexican Scientific Congress of Aesthetic and Anti-aging Medicine
Mexican Society of Aesthetic Medicine
Pepsi Center WTC, Mexico City
President: B. Miller Kobisher
Email: inscripciones@congressmcme.com
Web: congressmcme.com

2 - 3 May - New Delhi (India)
International Congress of Indian Society of Aesthetic Medicine
President: A. Rana
Web: www.indiansocietyofaestheticmedicine.com

15 - 17 May - Kiev (Ukraine)
13th European Congress of Aesthetic Medicine - UIME
Organised by Ukrainian Society of Aesthetic Medicine
President: V. Tsepkolenko
Web: usam.org.ua

20 - 22 May - Medellin (colombia)
12th Colombian Congress of Aesthetic Medicine
Colombian Society of Aesthetic Medicine
President: G. Arroyave Estrada
Email: acicme.com.co
Web: acicme.com.co

22 - 24 May - Rome (Italy)
41st SIME Congress
Italian Society of Aesthetic Medicine
Rome Cavalieri Congress Center
President: E. Bartoletti
E-mail: congresso@lamedicinaestetica.it
Web: www.lamedicinaestetica.it

28 - 30 May - Pretoria (South Africa)
15th Aesthetic Medicine Congress of South Africa
Aesthetic and Anti-aging Medicine Society of South Africa
President: D. Norval
Email: info@aestheticdoctors.co.za
Web: aestheticdoctors.co.za

13 - 14 June - Opatija (Croatia)
3rd Congress of the Croatian Society of Aesthetic Medicine (HUEM)
Hotel Milenij Opatija
President: E. Bunar
Email: congress@huem.eu
Web: huem.eu

15 - 17 October - Quito (Ecuador)
XIII Pan American Congress of Aesthetic Medicine - UIME
Organised by: Ecuatorian Society of Aesthetic Medicine
President: V. Tinoco Kirby
Email: medesteticapanam2020@gmail.com
Web: www.seem.com.ec

2021

4 – 6 March – Mexico City (Mexico)
23rd World Congress of Aesthetic Medicine - UIME
Organised by Mexican Scientific Society of Aesthetic Medicine
18th Mexican Scientific Society of Aesthetic and Anti-aging Medicine
Pepsi Center WTC, Mexico City
President: B. Miller Kobisher
Email: congreso@ippc.mx
Web: congressmcme.com/2021

aesthetic medicine