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Increase in Skin Modulus of Elasticity Following Administration of a Novel Combined Minimally Invasive Helium Plasma and Radiofrequency Energy

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ABSTRACT

The purpose of this paper is to present the first minimally invasive modality which can safely increase the modulus of elasticity of skin. Skin modulus of elasticity can be increased by administration of a percutaneous, minimally invasive helium plasma and radiofrequency energy. This single device emits the combined helium plasma and radiofrequency energies to heat the underlayer of the skin, the dermis. This device uses a narrow wand that is placed through a small port hole to allow for transfer of heat to collagen, a process termed subdermal coagulation. Changes in skin modulus of elasticity were documented following analysis of data collected from a prior study evaluating the effects of subdermal coagulation on tissue contraction during liposuction. Modulus of elasticity was calculated by dividing distraction forces by distance of distraction distances. Plotting the above stress and strain curve demonstrated linear increase in skin modulus of elasticity with each subdermal coagulation treatment pass. Analysis of this data provides insight into the efficacy of the combined, minimally invasive helium plasma and radiofrequency energies to increase skin modulus of elasticity.

Introduction

Elasticity is defined as the ability of an object or material to resume its normal shape after being stretched or compressed. The rubber in a balloon is an example of a material that is near 100% elastic. When an inflated balloon is compressed, it will quickly spring back to its original shape. In contrast, modeling clay is a 100% plastic material. When mechanical force is applied, it will retain the resulting shape even after the force is removed. Human skin is not completely elastic nor plastic. Skin deforms with applied force but returns to its original position after a slight delay when the force is removed. This combined elastic and plastic behavior of human tissue is called viscoelasticity. The viscoelasticity and other mechanical properties of human skin and connective tissue have been well studied and reported on in the literature [1-5]. The elastic and plastic behavior of skin, connective tissue, and other materials is most commonly graphically displayed on a stress-strain curve. The stress-strain curve is unique for a given material and is established by recording the amount of deformation or displacement of the material (strain) corresponding to a tensile or compressive load (stress). Figure 1 shows the total (unfilled squares, top curve), elastic (filled diamonds, middle curve), and viscous (filled squares, bottom curve) stress-strain curves established for human skin by Dunn and Silver [3,5]. As can be seen on the total stress-strain

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curve in Figure 1, the stress-strain behavior of skin is composed of three distinct phases. In the first phase corresponding to small deformations or displacements of the tissue (strain less than or equal to 0.4), the collagen fibers and fibrils in the tissue offer little resistance to deformation as they begin to uncrimp or unfold. In the second phase corresponding to higher deformations (strains between 0.4 and 0.8), the collagen fibers begin to offer resistance to the deformation and begin to carry the load of the force applied.

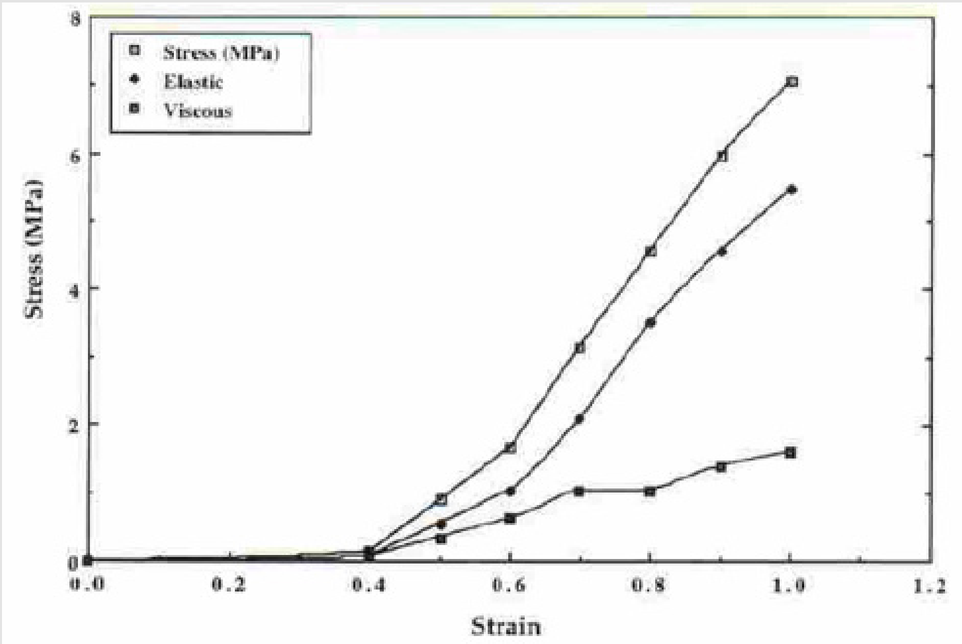

Figure 1: Total, Elastic, and Viscous Stress-Strain Curves for Human Skin [3,5].

The stress-strain relationship during this second phase is highly linear and is dominated by the elastic characteristics of the tissue and the collagen. Interestingly, there seems to be two separate linear stress strain relationships that can be described by an early and late phase. In the third phase corresponding to large deformations (strains greater than 0.8), the crosslinks between the collagen fibrils begin to yield and eventually failure of the tissue occurs (such as tearing). Analyzing the stress-strain curve of skin and connective tissue during the highly linear second phase described above can provide significant insight into skin elastic characteristics. For example, calculating the slope of this linear portion of the stress-strain curve provides a measure of the tissue's resistance to deformation by a mechanical force (slope = change in stress/change in strain). In material science and engineering disciplines, this resistance is most commonly referred to as the elastic modulus or the modulus of elasticity of a material. In reference to human skin and soft tissues, especially in cosmetic plastic surgery and dermatology, it is most commonly referred to as tissue firmness or tissue tightness. Changes in the firmness or tightness of skin and tissue will result in changes to the slope of this linear portion of the stress-strain curve.

Methods

A retrospective study was previously published on patients who underwent Renuvion J plasma skin contraction by the senior author (A.M.) at the Cosmetic Plastic Surgery Institute (CPSI) [6]. In this prior study, changes in skin firmness for six patients resulting from percutaneous, minimally invasive treatment of skin laxity using a novel helium plasma energy and radiofrequency emitting device, called Renuvion, made by Apyx Medical were measured. A force measuring device, a trigger meter, was used to quantify the amount of force needed to pull or distract skin away from the body at distraction distances of 0.5, 1.0, and 1.5 inches. Distraction force measurements were taken for each of these three distraction distances following liposuction and following each of 6 subsequent passes over nine (9) anatomical locations, including

1) Left/right arm,
2) Left/right lower back,
3) Left/right upper back,
4) Left/right medial thigh, and
5) Neck (total n=19) [6].

In the current study, the findings of the prior study were retroactively used to ascertain the effects of the combined energies of helium plasma and radiofrequency on skin modulus of elasticity.

In this study research, no contact with human subjects was required and calculations limited to prior information recorded by the investigator in such a manner that the identity of the human subjects could not be ascertained directly or through identifiers linked to the subjects. The investigator did not contact the subjects, and the investigator did not re-identify subjects. In the current study, measured distraction forces (stress) were plotted against the corresponding tissue distraction distances (strain). The slope of each line (with a no intercept linear model) was determined to yield the modulus of elasticity of skin for each stage of treatment. From post-liposuction through the 6th pass, the percent change in tissue firmness from pre-liposuction was analyzed using a linear regression model, where the difference between each consecutive treatment pass was compared. The threshold of determining statistical significance was set at a p-value < 0.05.

Results

Figure 2 provides an example of the linear stress-strain curves for each stage of treatment for one of the anatomical locations (right arm) treated in the study. The slopes of all lines shown in Figure 2, which represent the modulus of elasticity of skin at each stage of treatment, are listed in Table 1. The skin firmness or modulus of elasticity values listed in Table 1 were determined for all 19 anatomical locations treated in this study and averaged. The summary data for all anatomical locations is presented below in Table 2. Figure 3 presents a graph of the mean tissue firmness values listed in Table 2 for each stage of treatment. Figure 3 demonstrates a linear increase in skin firmness or modulus of elasticity with each subsequent pass of Renuvion treatments. The summary statistics of the change in skin firmness values for each stage of treatment compared to the previous stage of treatment is presented in Table 3. On average, a single treatment pass with the Renuvion energy device increased the firmness of the tissue by 11.5g/in. The changes in skin firmness for all treatment stages were statistically significant (P-Value<0.05) when compared to that of the subsequent stage demonstrating that a maximal effect was not achieved within six treatment passes. The average skin firmness for each anatomic location and each stage of treatment in the study is shown in Table 4. The back locations had the highest initial firmness while the neck and medial thighs had the lowest. The back locations also saw a more significant increase in firmness per treatment pass with an average of 15.8g/in increase per pass when compared to 9.9g/in, 9.5g/in, and 11.4g/in for the neck, medial thighs, and arms respectively.

Table 1: Skin Modulus for the Treatment Stages of the above right arm.

Stage of Treatment	Tissue Firmness (g/in)
Post-Liposuction	61.3
After 1 Pass with Helium Plasma	73.6
After 2 Passes with Helium Plasma	86.3
After 3 Passes with Helium Plasma	97.6
After 4 Passes with Helium Plasma	109.7
After 5 Passes with Helium Plasma	126.3
After 6 Passes with Helium Plasma	133.1

Table 2: Tissue Firmness Values (g/in) for All Anatomical Locations by Stage of Treatment.

Location R = Right L = Left	Pt #	Post-Lipo	P1	P2	P3	P4	P5	P6
Neck	1	92.3	111.3	118.6	123.9	114.1	143.7	151.9
Lower Back, L	2	214.1	226.7	253.4	263.6	278.4	298.1	319.9
Lower Back, R	2	229.4	262.0	268.4	283.0	294.1	314.0	345.6
Upper Back, L	2	222.1	234.0	253.0	275.6	286.1	304.3	314.9
Upper Back, R	2	241.7	254.3	265.4	279.3	286.1	298.9	306.0
Medial Thigh, L	3	64.4	73.1	83.4	98.1	119.3	131.4	140.1
Medial Thigh, R	3	81.4	89.4	96.3	104.0	112.1	120.6	131.4
Medial Thigh, L	4	68.0	73.4	85.1	101.6	114.1	126.4	131.7
Medial Thigh, R	4	61.4	71.7	80.1	97.4	112.6	122.0	132.0
Medial Thigh, L	5	82.4	87.0	92.9	98.1	101.4	108.7	155.4
Medial Thigh, R	5	72.7	88.1	95.9	103.1	109.7	117.3	121.9
Medial Thigh, L	6	146.9	156.3	165.6	171.3	176.4	183.4	186.7
Medial Thigh, R	6	93.3	98.4	103.4	109.1	118.7	125.3	127.3
Arm, L	3	71.0	86.7	101.3	112.6	125.6	138.6	146.6
Arm, R	3	61.3	73.6	86.3	97.6	109.7	126.3	133.1

Arm, L	4	120.6	130.3	138.6	148.7	162.0	171.1	179.1
Arm, R	4	112.6	120.1	128.3	137.6	147.1	159.1	171.6
Arm, L	7	128.7	164.0	195.0	202.4	212.9	223.4	227.7
Arm, R	7	187.6	200.3	211.9	217.7	221.9	229.4	235.4
Averages	N/A	123.8	136.9	148.6	159.2	168.6	181.2	192.5

Table 3: % Change in Tissue Firmness By Stage of Treatment.

Stage of Treatment Comparison	Mean Difference (SD) g/in	P-Value
Pass 1 – Post-Lipo	13.1 (5.5)	<0.0001
Pass 2 – Pass 1	11.7 (4.8)	<0.0001
Pass 3 – Pass 2	10.6 (3.9)	<0.0001
Pass 4 – Pass 3	9.4 (4.3)	<0.0001
Pass 5 – Pass 4	12.6 (4.3)	<0.0001
Pass 6 – Pass 5	11.4 (7.0)	0.0003

Table 4: Average Skin Firmness by Anatomic Location and Stage of Treatment.

Location	N	Post-Lipo	P1	P2	P3	P4	P5	P6
Neck	1	92.3	111.3	118.6	123.9	114.1	143.7	151.9
Back	4	226.9	244.3	260.1	275.4	286.2	303.8	321.6
Medial Thigh	8	83.8	92.2	100.3	110.4	120.6	129.4	140.8
Arm	6	113.6	129.2	143.5	152.8	163.2	174.7	182.3

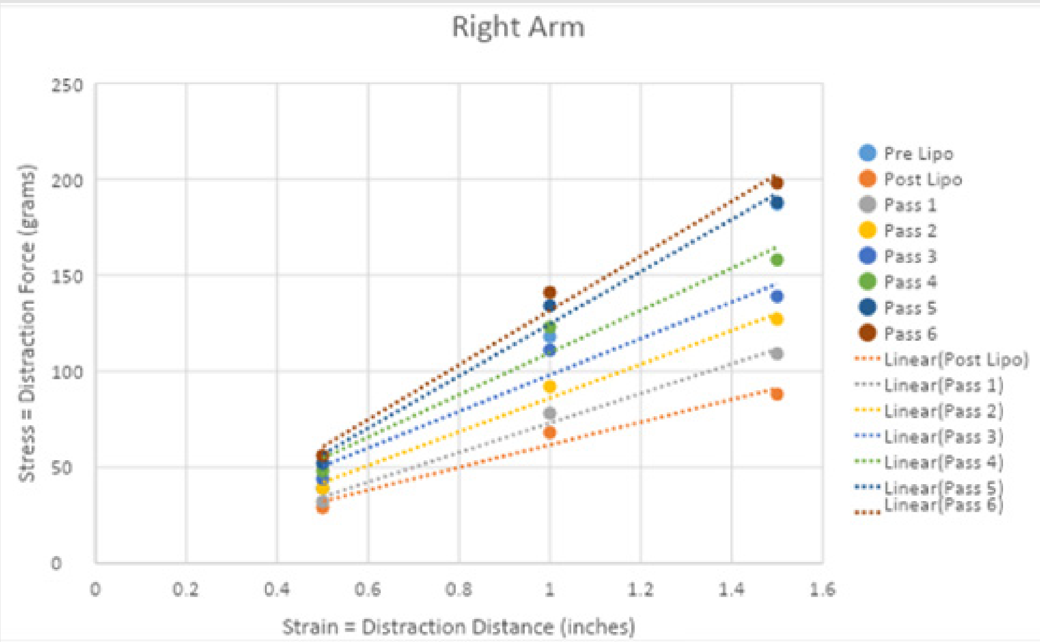

Figure 2: Stress-strain Curves for the Treatment Stages of an Arm.

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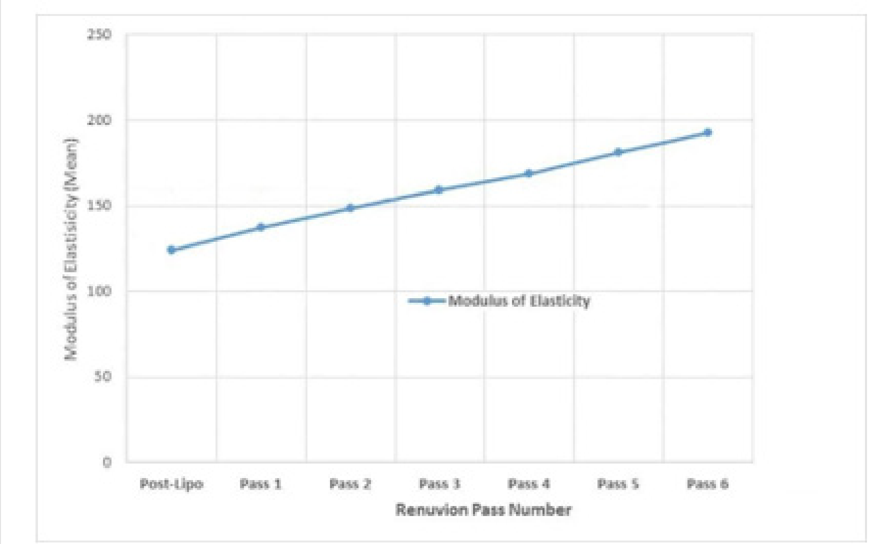

Figure 3: Mean skin Firmness Per Stage of Treatment.

Discussion

The principle of thermally-induced contraction of collagen through denaturation and coagulation of soft tissue is well known in medicine and has been used to achieve beneficial results in ophthalmology, orthopedic applications, the treatment of varicose veins, and cosmetic plastic surgery procedures. Once tissue is heated to the appropriate temperature, protein denaturation of collagen and subsequent contraction occur resulting in a reduction of volume and surface area of the heated tissue. More recently, the use of thermal-induced collagen/skin contraction has been expanded to minimally invasive, percutaneous procedures. The combined helium plasma and radiofrequency energy device used in this study has combined the removal of subcutaneous fat using liposuction with skin and soft tissue heating to reduce the skin laxity. The device is placed in the same subcutaneous tissue plane as a liposuction cannula and is used to deliver thermal energy to coagulate the underside of the dermis and subcutaneous septal network and fascia.

The coagulation of all skin and subcutaneous tissues where collagen molecules are found results in increase in skin modulus and reduction in skin laxity. Although percutaneous, tissue heating devices have proven effective in achieving soft tissue contraction, the evidence has been primarily limited to volume or surface area changes as measured through photographic analysis of before and after images [7-9]. Measurement of the changes in the biomechanical properties of the skin resulting from soft tissue coagulation and contraction has proven more difficult. The desire to establish the biomechanical changes of the epidermis resulting from topical treatments and moisturizers in dermatology has resulted in multiple commercial measurement devices and a significant volume of peer-reviewed scientific literature. One commercially available device with considerable supporting peer-reviewed evidence measures tissue firmness by applying a suction force to the tissue and measuring the corresponding amount of tissue distraction or displacement resulting from the application of the suction [10].

This device has been established as an effective tool for evaluating biomechanical changes of the superficial layers of the skin. Since the helium plasma energy device focuses treatment on the underlying skin dermis and subcutaneous fibro septal network, the superficial measurements of the commercially available suction device have proven insufficient for quantifying changes resulting from treatment. The force measurement method used in this study utilized the well-established scientific measuring principles of the suction device but allowed for quantification of firmness changes in the deeper layers of the skin and underlying connective tissue. The data resulting from this study demonstrates the ability of the Renuvion device to change the firmness of the treated tissue and the ability of the measurement method to quantify these changes. Review of the data for each of the 19 treated anatomical locations demonstrated an increase in skin firmness following liposuction.

Each subsequent treatment pass with the Renuvion device resulted in increased tissue firmness. On average, the tissue firmness began to exceed the pre-liposuction value with the third treatment pass. All 19 anatomical locations treated saw an increase in skin firmness throughout the six treatment passes used in this study. One potential benefit of quantifying the changes in the biomechanical properties of the treated tissue is to utilize the information to establish a relevant endpoint for treatment. For example, a leveling of the tissue firmness values with subsequent treatment passes would indicate a point of diminishing returns for further treatment. In this study, this point was not achieved within six treatment passes. This is evidenced by the firmness values of the sixth treatment pass being statistically higher than the firmness values measured for the fifth treatment pass for all 19 treatment locations. Further study is warranted to establish the number of passes needed to reach a treatment endpoint corresponding to a maximal treatment effect.

Conclusion

This study demonstrates that the minimally invasive, percutaneous delivery of a novel combined helium plasma and radiofrequency energies provides an effective modality to decrease the skin laxity. Skin firmness, a biomechanical property, can be established by measuring the forces (stress) required to distract tissue to certain distances (strain) which establishes skin modulus of elasticity. We document the first, safe application of thermal energy that can be used to increase the modulus elasticity of skin.

Financial Disclosure Statement

I am the lead author on this page and am a paid trainer for VASER® by Solta Medical and RENUVION ® by Apyx Medical. The other authors declare no conflicts of interest in regard to the research, authorship, or publication of this article.

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