Laminine® and DIGESTIVE^{+++} Supplementation Improves Gut Health as Determined by Pilot Clinical Trial Showing Increased Short Chain Fatty Acids Production in the Colon, Especially Butyrate

A pilot clinical study was conducted to observe the efficacy of subjects consuming two dietary supplements, Laminine and DIGESTIVE^{+++} over a four-week period. DIGESTIVE^{+++} dietary supplement contains a prebiotic blend of fructooligosaccharides, Jerusalem Artichoke (90% inulin), Dandelion leaves, and Yacon root. Additionally, the DIGESTIVE^{+++} supplement contains the spore forming probiotic *Bacillus coagulans*. The product also contains a digestive enzyme blend to digest proteins (at various pH's), carbohydrates, lactose, and fats. The enzyme blend consists of Amylase, three different Proteases, Alpha-galactosidase, Glucoamylase, Lactase, Invertase, Lipase, Acid Maltase, Peptidase and Flaxseed oil.

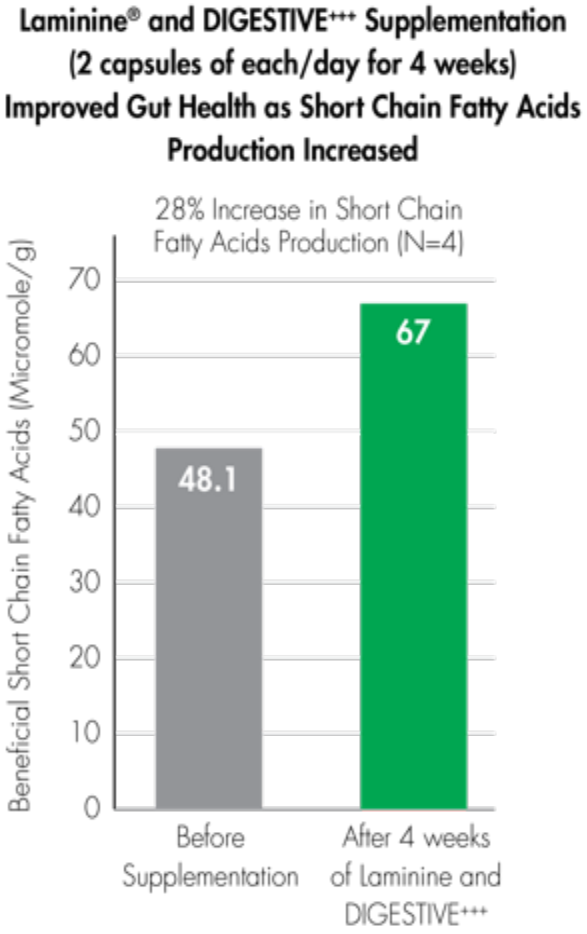
Subjects consumed 2 capsules of Laminine daily (one in the morning and one in the evening) and one capsule of DIGESTIVE^{+++} taken twice a day, (i.e. one capsule with each of the two heaviest daily meals). Ideally the DIGESTIVE^{+++} supplement should be taken 30 minutes before the meal but at least taken within the same hour of eating the meal, for a period of 4 weeks.

Subjects were asked to refrain from using other supplements prior to the study and to provide the doctors with initial baseline stool samples and again after 4 weeks supplementation. Data of the subjects upon completion of the trial from the Comprehensive Digestive Stool Analysis (Genova Diagnostics, Asheville, North Carolina) showed a substantial increase (28%) in both total Short Chain Fatty Acids (SCFAs) and 28% increase in butyrate production. Dietary carbohydrates, resistant starches and some fibers are substrates for fermentation that produce SCFA specifically acetate, propionate and butyrate, as end products. The rate and amount of SCFA production depends on the species and amounts of microflora present in the colon, the substrate source and gut transit time. SCFAs are readily absorbed. Propionate is largely taken up by the liver. Acetate enters the peripheral circulation to be metabolized by peripheral tissues. Butyrate is the major energy source of colonocytes.

Increased Butyrate Production is Found to be Supportive to Colon Health

Butyrate has been studied for its role in nourishing the colonic mucosa. It is the substrate of choice for colonocytes to increase their healthy functioning. Butyrate use by colonocytes has been indicated in the regulation of gross mutations in the mucosal cells' DNA leading to overgrowths of dysregulated cells, such as in the formation of tumors. It promotescell differentiation, cell-cycle arrest and apoptosis of mutated colonocytes. A greater increase in SCFA production and delivery, especially butyrate, to the distal colon has been shown to have a protective effect.

SCFAs are being indicated in initial animal and human studies to regulatenormal gastrointestinal function and structure. The increase of these components is an indicator that the gut is reestablishing a healthier microbiomerelieving some irritable bowel disturbances and creating a healthier gut lining.

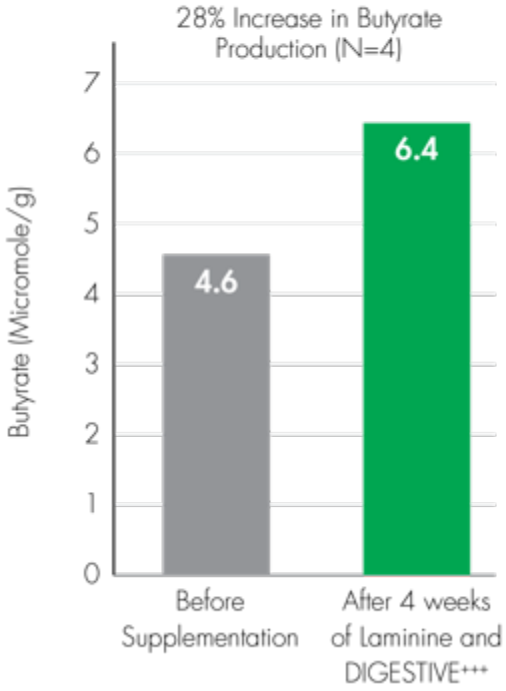


Benefits ofShort Chain Fatty Acids (CFAs)

Short Chain Fatty Acids (the total combination of butyrate, acetate, and propionate) are produced by anaerobic bacterial fermentation of dietary fibers such as fructooligosaccharides and inulin which remain undigested until reaching the area of the colon. The colon bacteria utilize these fibers as a fuel source and then produce SCFAs. These, in turn, provide an optimal energy source for the cells lining the digestive tract and colon. SCFAs:

- Provide energy for cells lining the digestive tract.
- Act as normalizing agent by removing sodium and water from the colon.
- Improve colonic blood flow.
- Deter the colonization of pathogens in the bowel.
- Provide 5-30 percent of systemic daily energy requirements.
- Regulate ammonia uptake from the intestine.

Laminine® and DIGESTIVE+++ Supplementation
(2 capsules of each/day for 4 weeks)
Improved Gut Health as Butyrate Production Increased



Butyrate Supports NormalizedInflammation Response in the Bowel

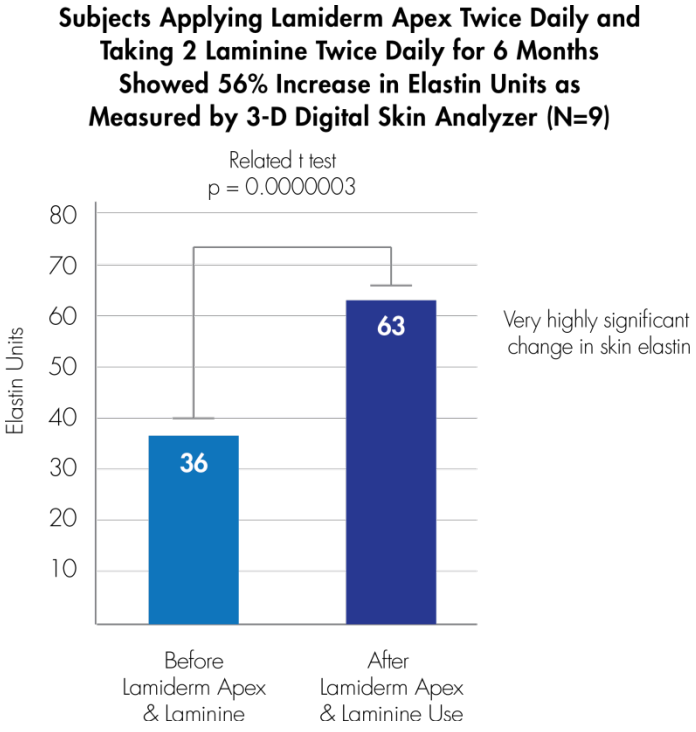
During the four-week study, an average 28% increase in butyrate production was shown in the subjects. The clinical indication of an increase in butyrate production supports normalized bowel inflammation. Butyrate is the choice fuel for the cells lining the colon. When cells lining the gut are properly nourished and healthy, inflammation is regulated. This provides a stronger integrity of the gut lining, which helps resist leaking and tears. In certain imbalances of the colon and GI tract, butyrate has been shown to regulate markers of inflammation. People that experience bowel disturbances and irritation including those with diarrhea tend to have lower total SCFAs.

DIGESTIVE^{+++} contains the probiotic *Bacillus coagulans* which remains intact during the digestive process because it is one of the only spore forming lactobacillus types. The protective spore helps to keep the colonizing bacteria viable through digestion and has been shown in studies to remain in the colon as an effective probiotic. When the gut is more optimally colonized with good probiotics the gut lining is improved, gastrointestinal disturbances are minimized and healthy bowel function is restored. Supplementing with Laminine and DIGESTIVE^{+++} dietary supplements from LifePharm showed indication that Short-Chain Fatty Acids (especially butyrate for the colon) are being increased over a relatively short time. The formula created by LifePharm for a probiotic, prebiotic and digestive enzyme product was formulated with science-based trials evaluating each selected ingredient. Taking DIGESTIVE^{+++} and Laminine as directed was shown to support optimal digestive tract and colon health.

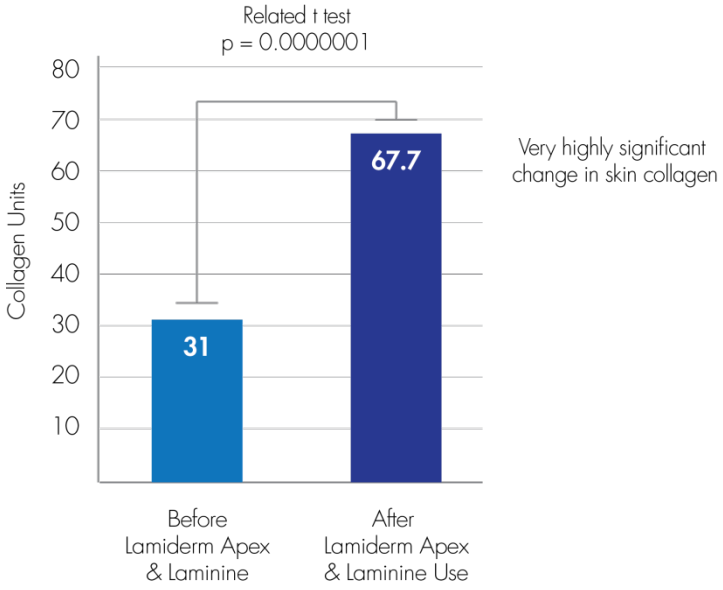
Subjects taking Two Laminine Dietary SupplementsTwice Daily and Applying Lamiderm Apex Skin Serum Twice Daily to the Face Showed Highly Significant Increases in Collagen and Elastin Units as Measured by 3-Dimensional Magnified Skin Analyses Photographs

A group of nine subjects (4 females and 5 males) were evaluated at baseline and after 6 months applying LamidermApex High Performance SkinSerum to their faces twice daily. Subjects also consumed 2 Laminine capsules twice daily for 6 months. Subjects were evaluated every month using the 3-D Skin Analyzer (GA-2000) which provides 3-dimensional real-time images. High resolution photographs (2560 x 1920) using a 5.0 Mega pixels sensor are stored in a specialized computer program. Photographs at baseline can be compared to photographs taken after the treatment phase for observing differences in the parameters of skin integrity. The images convert into unit readouts for Collagen, Elasticity, Sebum, Pores, Acne, Pigment, Sensitivity and Moisture. Investigators evaluated changes in Collagen and Elasticity units over 6 months.

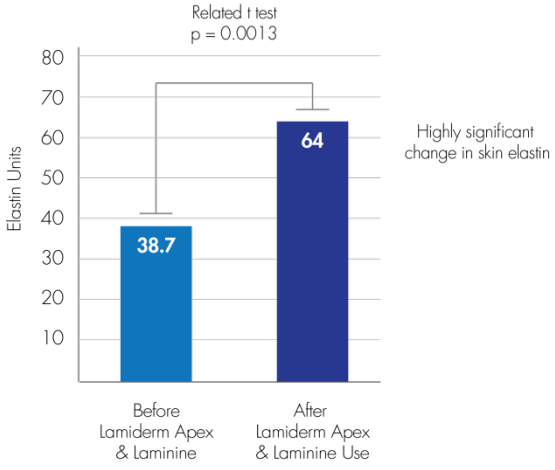
The results evaluated differences in the collagen units from baseline and after 6 months use of products. Statistical evaluations(related sample t tests) for all groups showed highly or very highly significant increase in collagen units for thegroup of 9 subjects and for the female group and the male group. The same was true for the elastin values measured by related samples tested, as all groups showed highly significant or very highly significant increases in elastin units. The results of the study indicated that applying Lamiderm Apex topically and leaving one application on the face overnight while consuming the dietary supplement Laminine, showed highly significant skin improvement in all subjects.

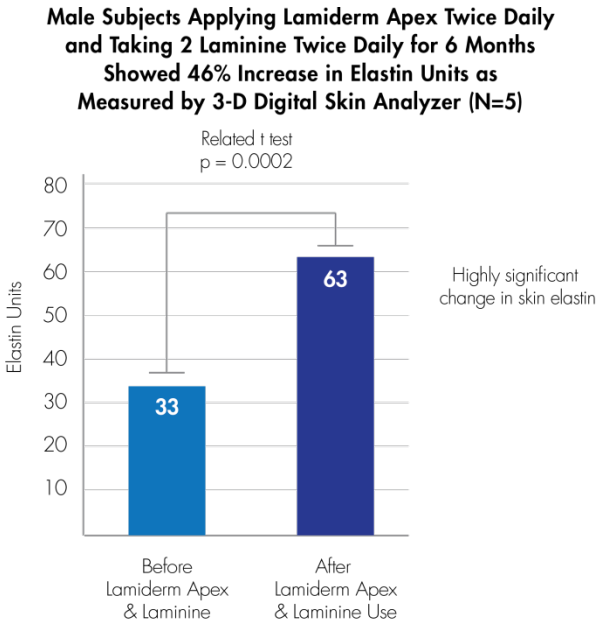


Subjects Applying Lamiderm Apex Twice Daily and Taking 2 Laminine Twice Daily for 6 Months Showed 46% Increase in Collagen Units as Measured by 3-D Digital Skin Analyzer (N=9)

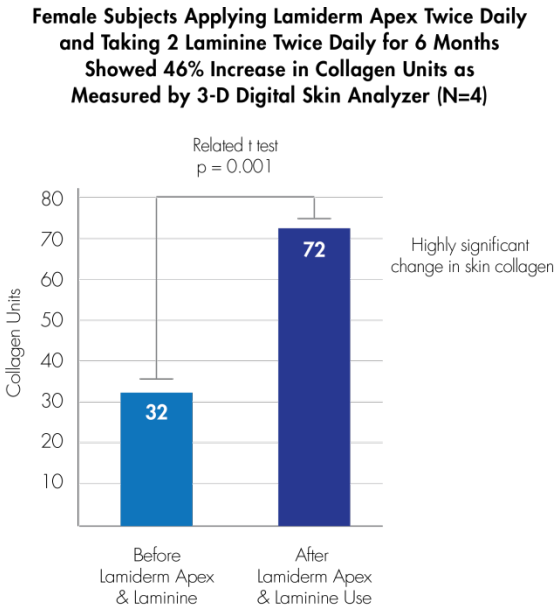


Female Subjects Applying Lamiderm Apex Twice Daily and Taking 2 Laminine Twice Daily for 6 Months Showed 60% Increase in Elastin Units as Measured by 3-D Digital Skin Analyzer (N=4)



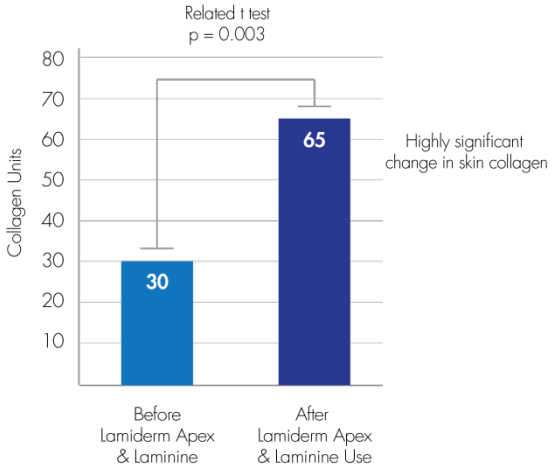


3D Analyzer Magnified Photographs with Contrast Images (left-hand corner) Showing Changes in Skin Elastin for a Male Subject



3D Analyzer Magnified Photographs with Contrast Images (left-hand corner) Showing Changes in Skin Collagen for a Female Subject

Male Subjects Applying Lamiderm Apex Twice Daily and Taking 2 Laminine Twice Daily for 6 Months Showed 46% Increase in Collagen Units as Measured by 3-D Digital Skin Analyzer (N=5)



Overview of Safety and Efficacy Study of Lamiderm Apex Serum Application Twice Daily in 20 Female Subjects ages 35 to 65

A study conducted by Dermatest GmbH Laboratory for Allergologic and Dermatologic Research (Munster, Germany, 2017) evaluated the safety and efficacy of Lamiderm Apex High PerformanceSkin Serum. Twenty subjects applied Lamiderm Apex to a clean face in the morning and again at night before bed. State-of-the-art dermatologic testing instruments validated effectivity of LamidermApex increasing wrinkle reduction, fading dark spots and increasing elasticity all at highly significant differences before and after Lamiderm Apex application.

Wrinkle depth was measured with the PRIMOS optical 3D portable in-vivo measurement device, which measures the skinfold depth of a single wrinkle. The wrinkle reduction differences in the 20 subjects were measured by a paired t test and found to be statistically significant (Wilcoxon matched pairs test, $p<0.001$) with the averaged wrinkle decrease of 31.77%. Because wrinkle reduction may involve collagen fibers production, the 3D Skin Analyzer values may correlate to enhanced collagen units from the 3D scanner.

The Dermatest clinical trial measured skin elasticity using a standard cutometer (Cutometer MPA 580 Fa. Courage+Khazaka electronic GmbH). The changes observed were found to be statistically significant (Matched samples t test, $p<0.001$) for the 20 subjects and resulted in an averaged increase in elasticity of 14.62% after 4 weeks application of the LamidermApex serum. The cutometer elasticity values could be correlated to the elastin units of the 3D Skin Analyzer.

The Dermatest clinical trial examined the lightening of age spots before and after the 4-week application period using spectrophotometry. Age spots (Lentiginesseniles, Lentiginessolares) are blemishes on the skin associated with aging and exposure to ultraviolet radiation from the sun. The

skin color pigment melanin is responsible for the occurrence of age spots. These spots range in color from light brown to red or black and are located on areas most often exposed to the sun, particularly on hands, arms, shoulders and the face. Nearly 90% of all people older than 60 years have age spots on their skin. The used spectrophotometer CM 700d (Konika Minolta Sensing) allows high-resolution measurements using standard illuminate type C (Commission Internationale de l'Eclairage: International Commission for Illumination). A sensor cell measures the spectral reflection for different wave lengths or a narrow range of wavelengths of the evaluated dark spot. The reflection data is calculated to provide standard color values enabling the numerical depiction of the results. In the twenty subjects evaluated for a 4-week application of Lamiderm Apex Skin Serum, the results showed an average lightening of 7.40% which was statistically significant (Matched pairs t test, $p<0.001$).

Laminine contains a 9-day fertilized chicken egg extract and quality proteins (shark cartilage and pea). Recent investigations showed the LifePharm proprietary Egg Extract contained several growth factors, as well as, fibroblast growth factor 2. These are transforming growth factor B-1 (TGFB-1) and platelet derived growth factor (PDGF). These were identified to stimulate collagen, elastin and fibronectin (wound repair fiber) production in human dermal fibroblast cultures (Lloyd K, Suyanto W, Hinek A, 2016). Fibroblasts are the most abundant cells in skin and connective tissues with the primary function to secrete collagen and elastin for tissue strength, texture and functionality. Fibronectin fibers increased by 350% in human dermal fibroblasts when treated with LifePharm Proprietary Egg Extract. Fibronectin is the extracellular matrix fiber that is responsible for wound repair and scar reduction.

Lamiderm Apex High Performance Serum also contains a proprietary blend of extracts from the fruits of blueberry, pomegranate, strawberry, kiwi, and cranberry known for antioxidant protection and reversal of UV damage. A proprietary extract of Alpine herbs and plants has shown effectivity in inhibiting melanin production and to lighten age spots. Vitamin C is also an effective skin lightening agent. An extensive research report evaluated all ingredients at their effective concentrations in the product and met European standards of highest quality and safety.

Lamiderm Apex High Performance Serum was given the 5 Star Excellent Rating by Dermatest GmbH as it was Dermatologist tested for clinical safety and nonallergenic. There was no irritation caused by long term application of the serum. Because it was shown effective at highly significant levels for wrinkle reduction, dark spot reduction and increasing elasticity it was given the Excellent rating as well for effectively improving skin. Laminine supplementation may stimulate skin elasticity and collagen production by delivering growth factors and nutrients from the blood supply to the skin. Laminine provides high-quality proteins, amino acids, peptides, vitamins,phospholipids and nutrients important for nourishing cells of all types. Protein supplements have been shown to influence the texture, elasticity and thickness of human skin in clinical trials. The synergistic combination of consuming the oral supplement and applying the Lamiderm ApexSkin Serum shows strong indication of supporting wrinkle reduction, increased elasticity (firmness) and for fading dark spots.

Disclosures

References

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