Clinical Study on Injuv®

Demonstrates Improvement of Skin Moisture Content

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Abstract

The efficacy of a patented, low molecular weight hyaluronic acid complex in a soft gelatin capsule (Injuv[®]) was evaluated in a human clinical study. The moisture content and pH of the skin's surface were measured to assess the barrier function of the skin. After taking Injuv[®] for 30 days, the subjects in the test group showed significant improvement in skin moisture without any adverse effects.

Introduction

Hyaluronic acid (HA) is a natural biopolymer, non-toxic, and fully biocompatible with the human body. It is an essential compound for maintaining healthy skin, joints, and connective tissue. Almost fifty percent of the total HA found in the body is found in the skin. The most important biological function of HA is cellular hydration, since it has good water absorption and retention capability. Retaining and holding moisture is vital to healthy skin. HA helps regulate the life cycle of skin cells, increasing their longevity and increasing the efficiency of maintenance and repair.

The stratum corneum layer found in the epidermis is most important for the moisture balance of the skin. The living layers lying beneath are almost constantly hydrated. For many years it was thought that HA is found in significant concentrations only in the underlying dermis layers of the skin. Researchers now know that the visible epidermis also contains significant amounts of HA. The half-life of HA in the epidermis is less than 24 hours. Without the proper levels of HA in the upper layers of the epidermis, the skin appears dull and wrinkled.

In its natural state, the molecular weight of HA is impossible for the body to orally absorb. However, a process has been developed whereby HA is treated enzymatically to produce lower molecular weight polymers that are capable of absorption through oral administration. This process results in a low molecular weight HA (a unique formula branded as Injuv[®]), which easily enters the epithelial cells for absorption by the intestinal tract.

Retention Time (min)	Estimated molecular weight	Injuv, containing 75% Dextrin HPLC peak area (A1)	100% Dextrin HPLC peak area (A2)	75% Dextrin peak area (A2x75/100) = A3	Injuv (no Dextrin) (A1 - A3)	Ratio (%)
5.6	5000 (28 mers)	266073	309708	232281	33792	33.000
7.0	1520 (8 mers)	301923	335698	251774	50149	47.000
7.7	1140 (6 mers)	41476	40994	30746	10730	10.000
8.1	760 (4 mers)	23560	22755	17066	6494	6.000
8.5	380 (2 mers)	7486	3997	2998	4488	4.000
		Total = 640518			Total = 105653	

Table 1. HPLC data of enzmatically digested rooster comb powder dried in maltodextrin (Injuv[®])

Materials and Methods

Subjects:	107 volunteers between the ages of 30 to 50 years, (average ag
	Subjects were randomly assigned to receive Injuv [®] (test group
	group) using random number tables.
Product Sample:	Test group received Injuv [®] soft gels containing 70 mg HA con
•	cally digested rooster comb, standardized to 9% hyaluronic a
	group received placebo
Dosage Regimen:	According to a recommended dosage regimen, subjects were
	gels of Injuv [®] or placebo twice daily for 30 consecutive days,
	instructed to maintain their normal dietary and lifestyle habi
Dermatological exa	amination: Skin surface moisture content and pH were measur
	supplementation.
Analyzer:	SHP88 probe (Corneometer [®] with pH-meter wa
-	factured by Courage + Khazaka Electronic Gml

	compact device measures moisture and pH of t
Measurement:	The dermatological measurements were performed
	room under controlled temperature (23°C) and
	humidity) conditions.
Site of Measurement:	The midpoint of the glabella—the space betwee
	above the nose on the forehead.
Test Procedure:	Under quiet ambient conditions, a single exper-
	ed the measurements before and after administ
	placebo. The moisture content and pH were m
	on the forehead within 15 minutes after rubbing
	clean cotton soaked with distilled water.
Statistical Analysis:	The data from the test results was calculated ar
	statistical analysis software, SPSS10.0. The com
	was conducted by t-test, and comparison of the
	group before and after the test was conducted b



ge 44.79±6.44 years). p) or placebo (control

mplex from enzymatiacid (6.3 mg HA); Control

administered two soft during which they were

red before and after

vas employed, manubh, Germany). This the skin surface. ormed in a well-ventilated nd humidity (60% relative

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rienced operator conductstration of the sample or neasured at the test site ng the area with a piece of

and analyzed using comon mparison between groups e data from the same by paired t-test.

More About Skin Moisture Measurement Value Measurement of the skin's moisture is based on the internationally recognized Corneometer[®] method, a capacitance method. This measurement is based on the completely different dielectric constant of water (81) and other substances (mostly < 7). The measuring capacitor shows changes of capacitance according to the moisture content of the samples. A glass lamina separates the metallic tracks (gold) in the probe head from the skin in order to prevent current conduction in the sample. An electric field between the tracks with alternating attraction develops. One track builds up a surplus of electrons (minus charge) the other a lack of electrons (plus charge). The scatterfield penetrates the very first layer of the skin during the measurement and the capacitance is determined.

Interpretation of the Results

The effectiveness of water retention was expressed in terms of capacitance increase ratio (%). The following values are valid for healthy skin and normal room conditions (20°C and 40-60% air humidity) and will help determine the skin type:

Inner forearm
< 30
30-45
>45
-

The interpretation of the moisture values "very dry", "dry" and "sufficiently moisturized" was chosen according to the manufacturer's experience and is only a rough scale. The values will vary from the above scale due to environmental influences (temperature and relative humidity, geographical location and season).

More About Skin pH Measurement

The measurement of the pH value covers an important characteristic of any aqueous solution: its acidity or alkalinity. This value is determined by the concentration of hydrogen ions (H+, protons) and hydroxide ions (OH-). A pH-value may fall anywhere on a scale from 0 (strongly acidic) to 14 (strongly alkaline), with a value of 7 representing neutrality.

The pH value of the skin results from water-soluble substances contained in the stratum corneum and the secretion of perspiration and sebum (the hydrolipidic film of the skin), as well as the exuded carbonic acid.

The average pH value for women is 5.5, and is slightly lower for men (approx. 5). The pH value, of course, varies depending on the tested skin area and different external factors. This means the pH value of the skin is in an acidic range, it is also called the "acid protection layer" of the skin. It influences the bactericide and fungicidal effect of the skin, which is very important for health.

The following values are valid for healthy skin and normal room conditions (20° C and 40-60% air humidity) and will help determine skin type:

pH value	<3.5	3.8	4.0	4.3	4.5	5.0	5.3	5.5	5.7	5.9	6.2	6.5	>6.5	
Women	+	acidic	range	-	- normal			_	high skin pH-value +					
Men	+ aci	dic ran	ge -		normal				-	- high skin pH-value +				

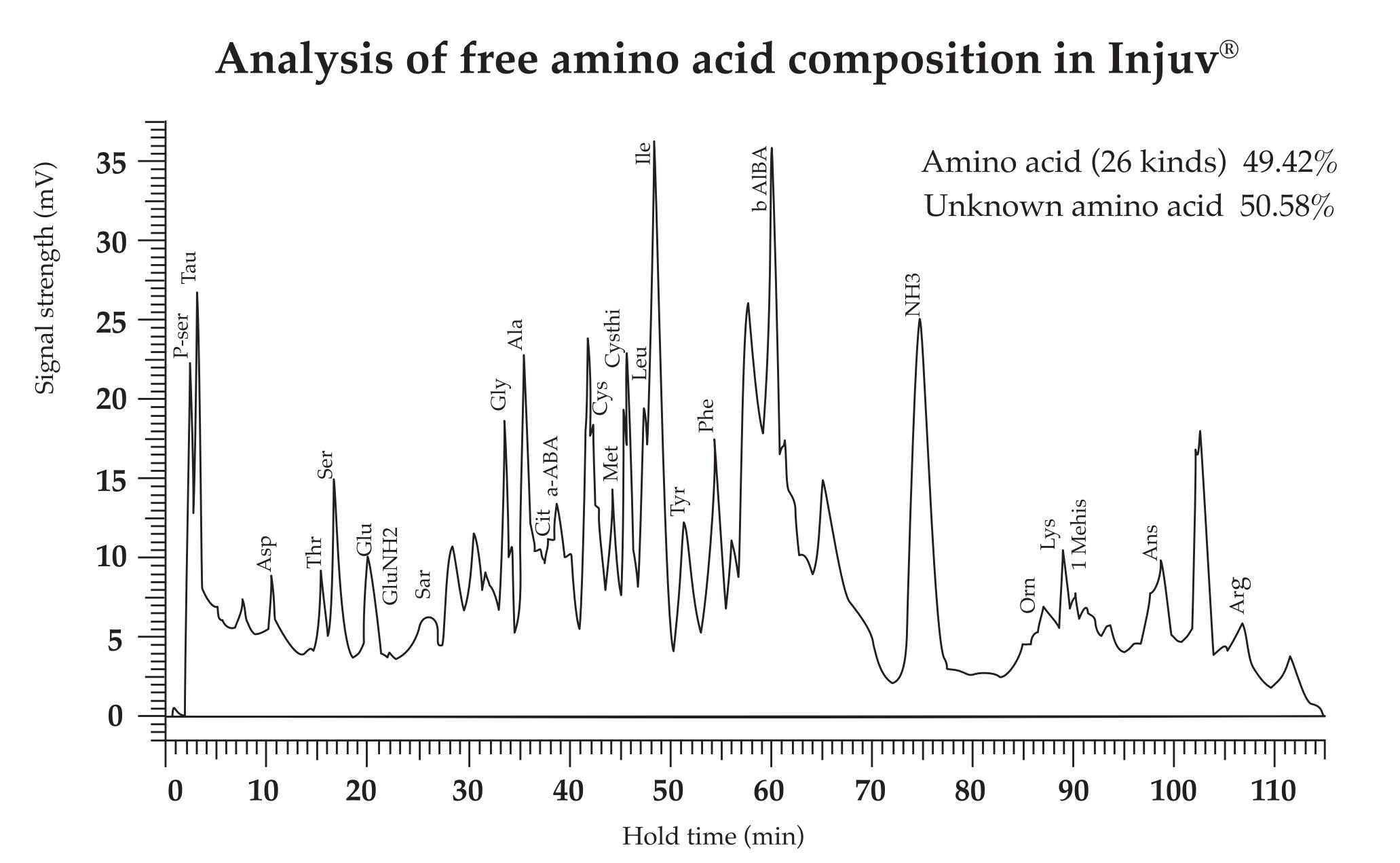
Relevant Charts/Graphs

Comparison of skin moisture content and pH value between Injuv-treated and control groups

		Mois	sture Content	pH Value		
Group	n	Baseline	Post-administration	Baseline	Post-administration	
Injuv-treated	52	46.60±9.75	67.53±18.60**##	5.20±0.64	5.53±0.64 ^{**##}	
Control	55	45.60±7.90	55.04±18.33	5.10±0.63	5.24±0.61**	

**: P<0.01 for self data comparison of the same group before and after test ##: P<0.01 for the comparison between test group and control group





Results

Significant differences were observed when comparing the moisture content data in the Injuv-treated (test) group before and after administration, as well as between the test and control groups. The examinees of test group showed an improvement in skin moisture. When comparing the data for the blood biochemical index before and after the test, there were no obvious changes and there were no adverse consequences reported.

Conclusion

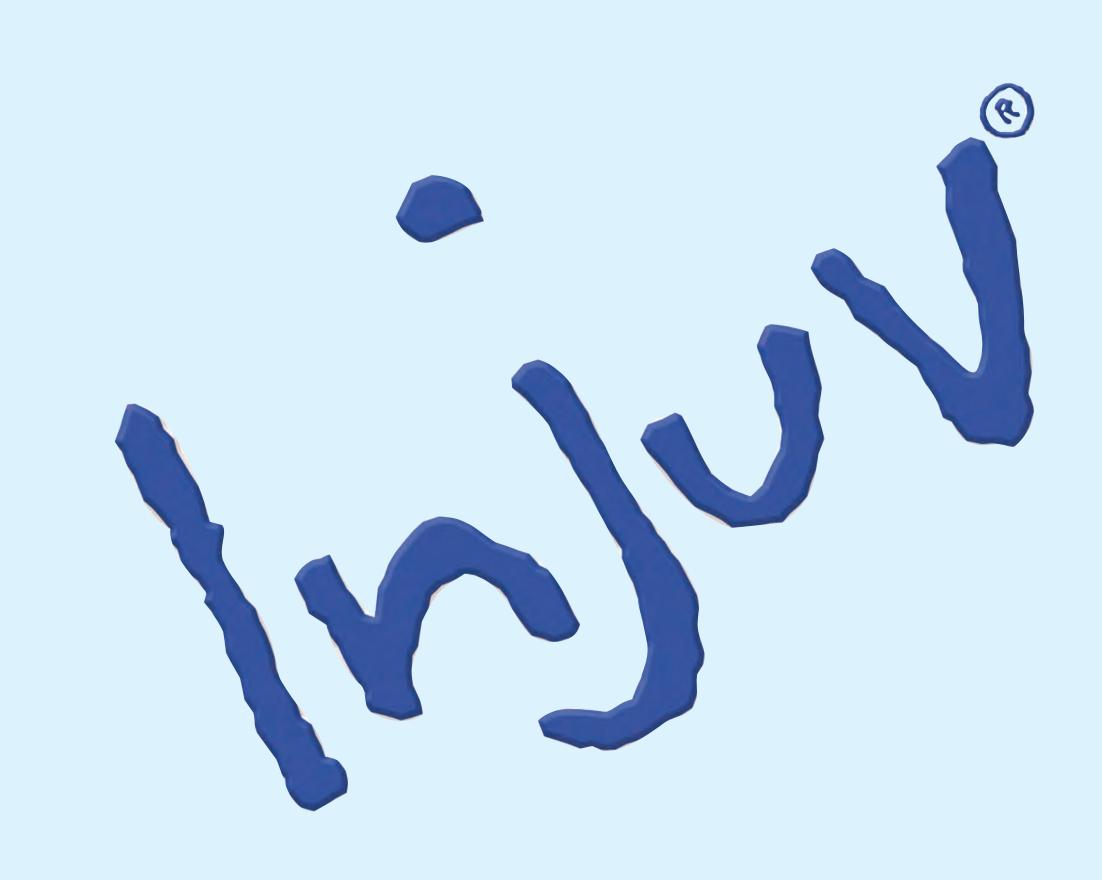
The examinees in test group took Injuv[®] continuously for 30 days and showed significant improvement in skin moisture, compared to their status before the test and when compared to the control group. This dietary supplement has the effect of retaining moisture in the skin.

The moisture and pH value depend on age. A child's skin moisture is very low; that of an adult (between the ages of 20-40 years) is at its maximum, while a senior's skin moisture content becomes lower again due to the decreasing storing capacity of the stratum corneum. The pH value increases with age.

Hyaluronic acid is one of the most important and useful substances in the body. Since the amount of HA synthesis decreases with age, it is being used in most high quality cosmetic products for its effectiveness in preventing dryness of skin and hair. Dietary supplements containing HA, such as Injuv[®], combine the essential structural support and protection of this marvelous macromolecule with the rejuvenating power of its moisturizing and purifying properties. Injuv[®] is a clinically tested cosmeceutical with proven absorption and bioavailability that hydrates from the inside out.

References

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