Lactobionic Acid, A Bionic Acid Enhances Skin Clarity and Provides Skin Plumping and Firming Effects

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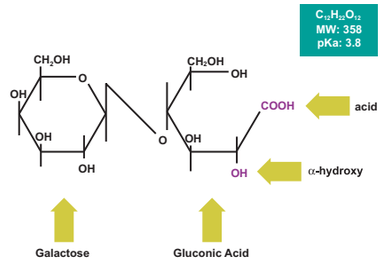
Introduction

Lactobionic acid has numerous beneficial properties due to its **polyhydroxy bionic AHA structure** and its known **antioxidant** effects, making it ideal for use in skin care.[1] The compound is an **excellent humectant**, is **non-irritating** to skin and provides skin **smoothing and moisturizing** benefits.[2] It is capable of forming a thin hydrofilm, which provides unique aesthetics to a topical formulation.

Lactobionic Acid



One of two molecules comprising lactobionic acid is gluconic acid. **Gluconic acid** has been shown to provide significant anti-aging effects when incorporated into formulations as gluconolactone.[3] **Galactose**, the second molecular constituent of lactobionic acid, is a chemically neutral sugar found in the body that is utilized by skin during glycosaminoglycan and collagen syntheses, and cell migration; studies indicate that it may enhance wound healing.[4-7]

Lactobionic acid is a major constituent of organ preservation fluids for use during transplantation procedures. This is due to lactobionic acid's ability to **chelate iron and suppress oxidative tissue damage** during organ storage and tissue reperfusion.[8,9]

In addition to the potent antioxidant benefits of lactobionic acid which may play an important role in helping to prevent aging-related skin effects, studies in the field of organ preservation have revealed that lactobionate is a cryptic **inhibitor of matrix metalloproteinase (MMPs) enzymes.**[10] MMP enzymes are responsible for degrading the skin's extracellular matrix and overall structural integrity causing wrinkles, skin laxity and telangiectasia.[11]

Cutaneous anti-aging effects of lactobionic acid have been previously studied in combination with gluconolactone.[2] The effect of lactobionic acid alone on anti-aging parameters has not been previously reported.

Objective

This poster will present clinical study results of a topical cream formulation containing **8% lactobionic acid** to evaluate the anti-aging effects of lactobionic acid.

Study Conduct

- **Design:** prospective, direct-comparison to baseline scores (for visual grading & firmness) and to untreated control skin (for skin thickness & biopsies); protocol received IRB approval and informed consent was executed
- **Subjects:** 31 women, 39-60 years of age, Fitzpatrick types II and III (29 Caucasian, 2 Asian), presence of mild-moderate periocular fine lines, periocular coarse wrinkles and mottled hyperpigmentation on the face
- **Product Application:** lactobionic acid, 8% cream, pH 3.8 was applied twice daily to the face and 3 times daily to one forearm; one forearm remained untreated as a control for forearm measurements
- **Clinical Evaluations:**
  - **Clinical Grading** (weeks 0, 6, 12): scores were collected visually by a trained evaluator using a 0 to 10 scale with 0.25 point increments for the following parameters:

Parameter	Site for Grading	Low Extreme of Scale	High Extreme of Scale
Fine Lines	Eye area	0 = None	10 = Severe
Coarse Wrinkles	Eye area	0 = None	10 = Severe
Pore Size	Cheek	0 = Invisible	10 = Very Large
Laxity	Cheek	0 = Firm, unpliable	10 = Loose, pliable
Roughness	Cheek	0 = Soft, smooth	10 = Rough, coarse
Sallowness	Face	0 = Light, non-yellow	10 = Dark, matte
Clarity	Face	0 = Dull, matte	10 = Clear, radiant
Mottled Pigmentation	Face	0 = Even tone	10 = Mottled, uneven tone

  - **Pinch Recoil** (weeks 0, 6, 12) measurements were taken of the under eye area to assess skin elasticity by pinching the skin and recording time with a stopwatch (in hundredths of a second) to full recovery of the skin. The measurements were performed in triplicate, and the average score was reported. Pinch recoil is a recognized indicator of skin resiliency and firmness[12]
  - **Total Skin Thickness (plumping) Measurements** (weeks 0, 12) were collected on the outer forearms using a hinged pinching device and digital calipers as previously described.[13] Duplicate measurements representing a two-fold thickness of skin were taken and averaged at baseline and endpoint for both the treated and untreated control arms
  - **Irritation/Safety Grading** (weeks 0, 6, 12): global evaluation of objective irritation and safety was conducted for dryness, erythema and edema and subjective irritation scores were collected for burning, stinging, itching, tightness and tingling. Scale: 0–3 (none, mild, moderate, severe)
  - **Digital Photography** (weeks 0, 12) was collected using standardized lighting and positioning
  - **Self-Assessment** (weeks 0, 6, 12) was collected via questionnaires
  - **3-millimeter Punch Biopsies** were collected at endpoint on the forearms of several study participants. Biopsies were stored in 10% formalin and subsequently processed for histological assessments

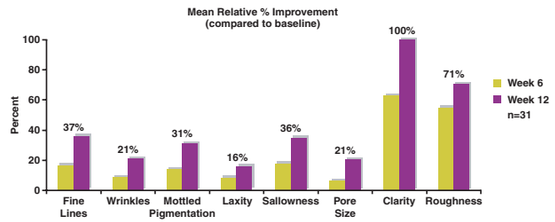
Statistics

- Clinical grading and pinch recoil: mean values were compared to baseline scores using a paired *t*-test, p≤0.05
- Total skin thickness: mean values were compared to baseline scores using a paired *t*-test, p≤0.05. Comparisons between treated and untreated test sites were made using ANOVA with Fishers LSD for pair-wise comparisons
- Self-assessment questionnaires were tabulated and a top box analysis was performed

Results

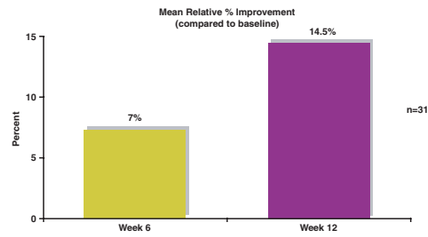
- 31 of 33 subjects completed the study. 2 subjects discontinued the study for reasons unrelated to the test product

Anti-Aging Effects



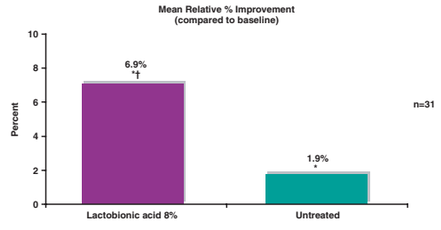
Clinical grading revealed significant improvements in all of the graded parameters at 6 and 12 weeks compared to baseline, p<0.05

Pinch Recoil/Firmness



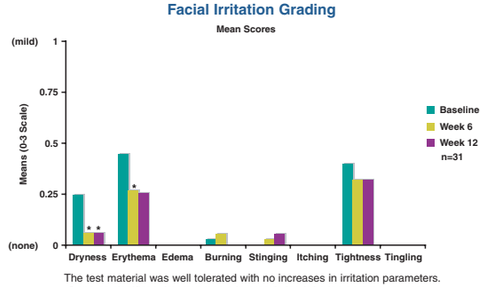
Firmness was significantly improved at 6 and 12 weeks compared to baseline, p<0.05

Skin Thickness Measurements on Forearms



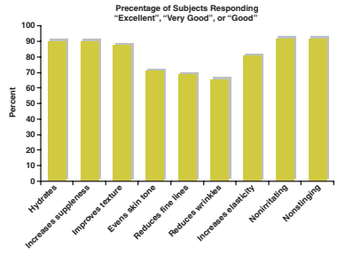
*Significant increase in skin thickness (plumpness) compared to baseline, p<0.05. †Significantly thicker than untreated (p=0.0001)

Facial Irritation Grading



The test material was well tolerated with no increases in irritation parameters. *Denotes significant improvements in preexisting irritation parameters compared to baseline, p<0.05

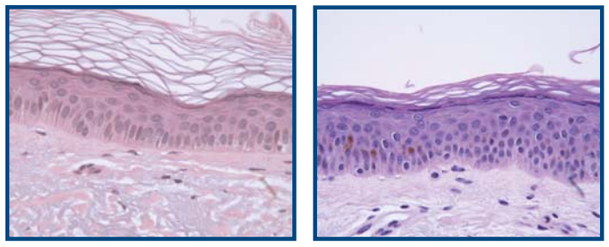
Self-Assessment



Significant self-assessed skin improvements were noted. These findings support the clinical grading and efficacy measurements.

Histology Results

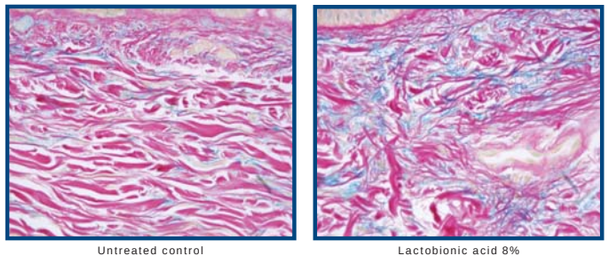
Epidermal Structure: 400x



Untreated control | Lactobionic acid 8%

Increased viable epidermal thickness and a more compact stratum corneum

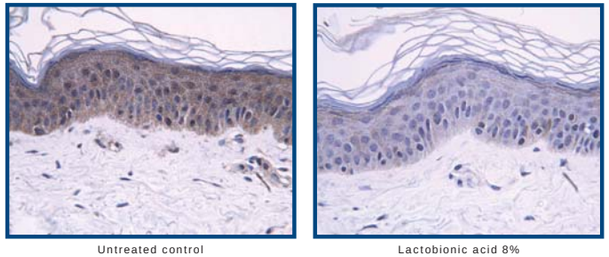
GAGs: 400x



Untreated control | Lactobionic acid 8%

Increased density of dermal colloidal iron staining (blue color) representing glycosaminoglycans/acid mucopolysaccharides (GAGs)

MMP9: 400x



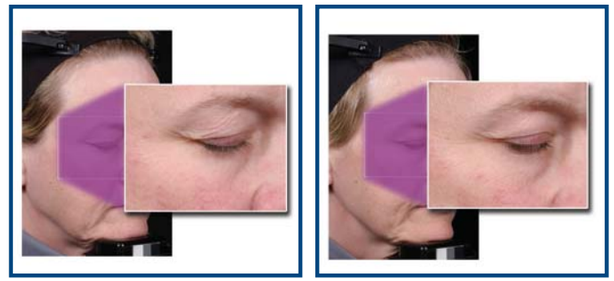
Untreated control | Lactobionic acid 8%

Decreased density of MMP9 staining (brown color) within keratinocytes

Clinical Photographs

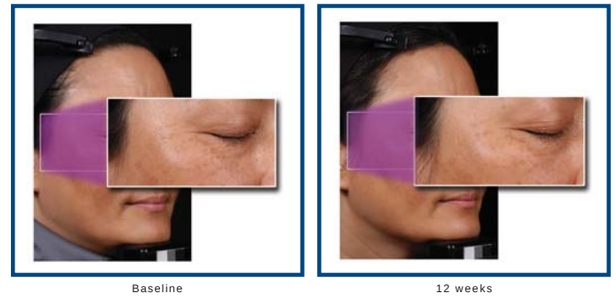
Baseline | 12 weeks

Improvements to skin laxity and texture at 12 weeks



Baseline | 12 weeks

Diminished periocular fine lines and improved eyelid texture at 12 weeks



Baseline | 12 weeks

Diminished periocular fine lines and smoother texture at 12 weeks

Summary

Lactobionic acid is a polyhydroxy bionic acid with numerous skin care benefits. It is a potent moisturizer and antioxidant, and is nonirritating to skin. This study reveals significant anti-aging effects of an 8% formulation. Benefits presented in this poster include:

- Clinically graded improvements in skin texture, clarity and roughness
- Increased skin firmness and elasticity
- Increased skin thickness/plumping
- No irritation
- Self-assessed improvements in skin texture, suppleness, degree of hydration and elasticity
- Histological effects

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