Clinical Efficacy and Safety Evaluation of Two Abrasive Agents for Use in Microdermabrasion Devices

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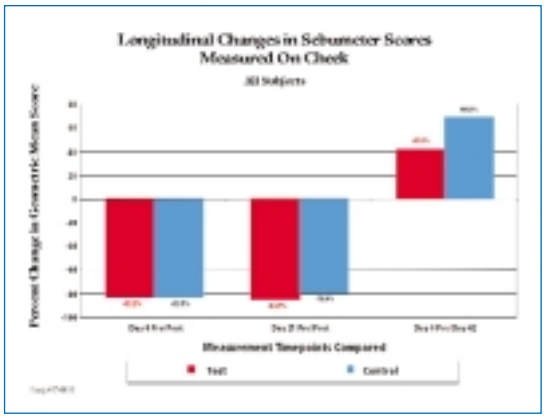
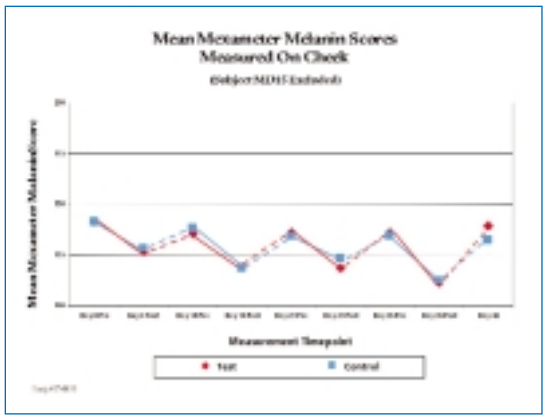
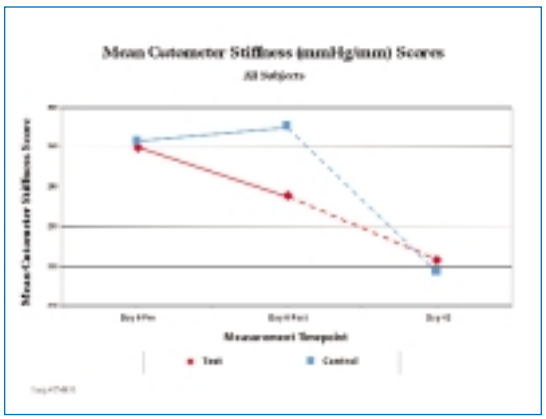
Abstract

The primary objective of this clinical study was to evaluate the safety and efficacy of sodium bicarbonate as a microdermabrasion agent after a seven-week period, relative to that provided by aluminum oxide.

Thirty-five adult female subjects completed this seven-week clinical study. Subjects who met the inclusion criteria and signed the informed consent form were enrolled in the study. This study consisted of two sections: (1) a histological evaluation of the upper/inner arms after a single use, and (2) a seven-week (six microdermabrasion) extended evaluation of the face. Subjects received both sodium bicarbonate and aluminum oxide microdermabrasions in a split-fashion design (left and right arms and/or face) in sections one and two of the study. Parameters evaluated in the second section of the study included sebumeter scores, mexameter erythema, and melanin scores, cutometer parameters including stiffness, compliance, laxity, elastic deformation, and elasticity. Additionally, subjects completed a self-assessment instrument evaluating their skin, and provided feedback concerning their satisfaction with the treatments on take-home questionnaires.







Introduction

The history of facial skin resurfacing can be found as far back as ancient Egypt when abrasive alabaster masks were used to revitalize the skin.

Many methods are now used to improve skin quality including dermabrasion, chemical peels, laser resurfacing and microdermabrasion. Microdermabrasion, which abrades the skin using a high pressure flow of crystals, is an effective treatment for the skin with minimal risk and rapid recovery.

There are several different types of crystals which can be used for microdermabrasion. Most commonly, a fine aluminum oxide crystal is used. This study evaluated and compared the more typical aluminum oxide and a new sodium bicarbonate crystal available from Church and Dwight. Several parameters were evaluated by the physician at this single center trial, including a patient satisfaction questionnaire.

Objective

The primary objective of this clinical study was to evaluate the safety and efficacy of sodium bicarbonate as a microdermabrasion agent after a seven-week period, relative to that provided by aluminum oxide.

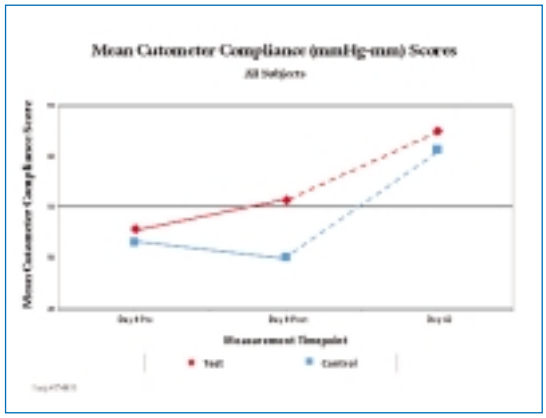
The study consisted of two sections, a single exposure histological evaluation, and an extended evaluation period in which a variety of instrumental and visual measurements were taken from subjects who displayed facial photo damage or melasma during the study.

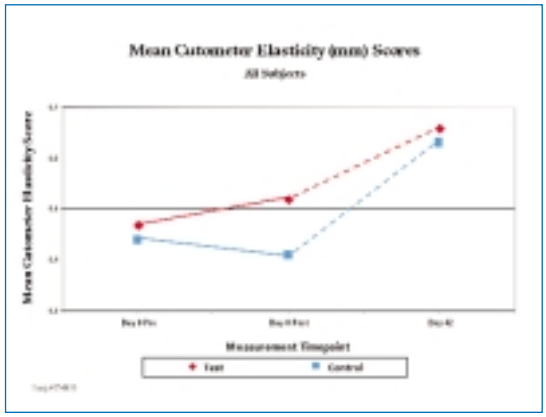
Analytical Methods

Population: 35 Adult Female Subjects
Test Products: Sodium Bicarbonate (Church & Dwight Company, Inc., Princeton, New Jersey)
Control: Aluminum Oxide
Methods

- A histological evaluation of upper/inner arms after a single use
- A seven week (six microdermabrasion) extended evaluation of the face

Subjects received both sodium bicarbonate and aluminum oxide microdermabrasion in a split fashion design (left and right arms and face).





Conclusion

All subjects, whether treated with the Test or Control, showed overall similar sebumeter data. There was a statistically significant lower post-treatment score on the cheek treated with Test material as compared to the Control. There were statistically significant increases in erythema after both Control and Test treatments. There were no statistically significant differences in the two treatments when melanin pigment was measured.

All subjects subjectively felt improvements with both the Test and Control treatments. Further, based on verbal feedback reported to the study personnel, the Test system was felt to be less abrasive and more comfortable on the skin than the control system.

In conclusion, the Test and Control produced similar results after standard microdermabrasion. However, the Test material is likely to be more acceptable because of the less abrasive effect on the skin.

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Dr. David Goldberg, personal communication,
March 9, 2004

This study was sponsored by:
CHURCH & DWIGHT CO., INC.
Princeton, NJ 08543

Poster #101, AAD, Summer 2004