Microneedling + ZO® Accelerated Serums

Clinical Pairings - Safety Study

SAFETY STUDY SUMMARY

- ZO® Skin Health conducted a series of robust safety studies supporting the safe use of a ZO® Accelerated Serum following a microneedling treatment.
- The studies were performed by board-certified dermatologists and included control and test sites which were located on the subject's back.
- Both the control and test sites were observed for signs of edema, erythema, and other abnormalities of the skin following a microneedling treatment delivered at the maximum depth (range of 2–2.3 mm).
- All safety studies reported that ZO® Accelerated Serums were safe in a clinical pairing following the microneedling treatment and that no adverse events (irritation or hypersensitivity) were reported or clinically observed by the study investigator.

STUDY OBJECTIVE

To evaluate and compare the safety of ZO® Skin Health Accelerated Serums used immediately following a microneedling procedure versus the microneedling procedure alone.

Three separate safety studies were performed for:

- Microneedling + Brightalive® Serum Accelerated
- Microneedling + Rozatrol® Serum Accelerated
- Microneedling + Firming Serum Accelerated

STUDY DESIGN

A single center, baseline controlled, monadic test site trial performed by a Board-Certified Dermatologist

- *A single center study* is a study that is performed and completed at one study location.
- *A monadic test* meaning only one product (or in this case, one ZO® Accelerated Serum) was tested in isolation.
- *A controlled study* is an experiment or clinical trial in which the treatments are rigorously controlled. In this case, each individual patient had two test sites demarcated on their back for comparison purposes. In the ZO® microneedling study, the two test sites were:
  - The **treated site** which received the microneedling treatment and ZO® Accelerated Serum.
  - The **control site** which only received the microneedling treatment.

STUDY FINDINGS

For the following clinical protocols:

- Microneedling + Brightalive® Serum Accelerated
- Microneedling + Rozatrol® Serum Accelerated
- Microneedling + Firming Serum Accelerated

- **Did not elicit any irritation** or hypersensitivity
- **Did not elicit edema, erythema, or other abnormalities** that are uncommon with the microneedling procedure– there was no clinically significant difference in adverse skin response between microneedling alone compared to microneedling followed by one of the ZO® Accelerated Serums mentioned above (Brightalive® Serum Accelerated, Rozatrol® Serum Accelerated, Firming Serum Accelerated).

Microneedling + ZO® Accelerated Serums

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MICRONEEDLING + ZO® ACCELERATED SERUM PROTOCOL

Both sites (control & test) site received the following protocol, except for **Step 6** which was only performed on the test site.

STEP 1	Cleanse the intended test site with Gentle Cleanser.
STEP 2	Apply 5% Lidocaine cream to the test site, cover the test site with Saran wrap or equivalent, and wait at least 20 minutes.
STEP 3	Cleanse the test site with Gentle Cleanser and wipe the test site with an alcohol wipe.
STEP 4	Apply the microneedling pen at a maximum depth (range of 2–2.3 mm) to administer one pass of the microneedling pen. Pinpoint bleeding should be achieved within 1-2 minutes. Wipe skin with an alcohol wipe to remove any blood.
STEP 5	Wipe test site with an additional alcohol wipe.
STEP 6 *(*This was only performed on the test site)*	Apply 2 mg/cm2 of ZO ®Accelerated Serum (Brightalive® Serum Accelerated, Rozatrol® Serum Accelerated or Firming Serum Accelerated) to the test site, rubbing lightly into the skin. Allow to dry for at least 15 minutes.
STEP 7	Apply a thin layer of 1% Clindamycin Phosphate gel directly onto the test site. Allow the test site to dry for at least 5 minutes before allowing the patient to dress. The test site will not require bandaging.

SPECIFIC STUDY DETAILS

- 57–day single center, monadic, controlled clinical safety study
- The number of subjects and Fitzpatrick skin types for each study are below:
    - **Microneedling + Brightalive® Serum Accelerated:** 18 subjects completed, Fitzpatrick Skin Types I-IV
    - **Microneedling + Rozatrol® Serum Accelerated:** 20 subjects completed, Fitzpatrick Skin Types I-IV
    - **Microneedling + Firming Serum Accelerated:** 23 subjects completed, Fitzpatrick Skin Types I-IV
- During the study period, 3 microneedling treatments were administered at a maximum depth (range of 2-2.3 mm) by a board-certified dermatologist at **baseline, 28 days, and 56 days.**
    - 1 day after each treatment, the dermatologist completed an erythema, edema and overall skin appearance assessment.
- A new microneedling head was used for each subject across all studies.