The combination of cleansing motion and potential chemical triggers can induce reactions in individuals with sensitive skin, but facial skin must be maintained in a hygienic state. With 51.4% of women and 38.2% of men reporting sensitive skin reactions in the first epidemiological study of sensitive skin (Willis et al. 2001), continuing research and product development are imperative to finding appropriate solutions for both cleansing motion and chemical cleansing.

A handheld, mechanically driven treatment tool with a counter-oscillating head was developed to cleanse skin using alternate means to conventional scrubbing with hands, cloth, or tissues. The round, counter-oscillating head utilizes interchangeable, antimicrobial, medical-grade silicone treatment surfaces of varying topographies (see Figure 1).

**Objectives**

1. Evaluate if three treatment cleansing surfaces on a counter-oscillating mechanically driven treatment device and two accompanying treatment cleansers were sufficiently well-tolerated for subjects with sensitive skin
2. Evaluate whether there were observed improvements in facial skin

**Methods**

In the first study, eighty female subjects with sensitive skin confirmed by the dermatologist investigator were enrolled in an IRB-approved clinical study. Subjects were randomly and equally assigned to treatment groups comprised of four combinations of treatment surface and treatment cleanser type: 1) normal/normal, 2) normal/sensitive, 3) firm/normal, and 4) firm/sensitive. Baseline efficacy and tolerability with the device, assigned treatment surface, and treatment cleanser combination were evaluated 10–20 minutes after first use. Subjects were given instructions for self-assessment diaries and returned at Weeks 1, 2, and 4 to complete the same investigator assessments as given at baseline. The gentle treatment surface was developed to have even more flexible topography than other treatment surfaces. A second clinical study assessed the tolerability and efficacy of this new topography following the first study method, using a gentle treatment surface with sensitive treatment cleanser on thirty sensitive-skin subjects.

**Results**

Seventeen subjects in the first study required reassignment to the normal/sensitive group, four to the firm/sensitive group (only changed treatment cleanser), and two made up a new group: normal treatment surface with another cleanser for sensitive skin. At Week 1, among the firm/normal group, there was statistically significant improvement in facial skin dryness (p<.001) which also occurred in the normal/normal group (p=.006). There was also statistically significant improvement in radiance among the firm/sensitive (p=.026) and normal/normal (p=.024) groups. By Week 4, normal/sensitive, firm/normal, and firm/sensitive groups all showed statistically significant improvement in smoothness and softness (p<.05). The firm/normal group showed statistically significant improvement in pore quality and overall appearance (p<.05), and the firm/sensitive group showed statistically significant improvement in texture and radiance (p<.05).

In the second study, among the gentle/sensitive group, there was statistically significant improvement in how subjects rated facial skin smoothness (p=.041) and cleansing (p<.001) immediately after one use. In addition, the dermatologist investigator rated highly statistically significant improvement to skin softness, smoothness, texture and facial cleansing (p<.001). By the end of Week 1, there was highly statistically significant improvement in skin softness, smoothness, texture, clarity, radiance, dryness, overall appearance and cleansing ability (p<.001); this extended to skin firmness by the end of Week 2. The four skin attributes with the highest percent improvement are graphed on the left. No tolerability issues arose with the gentle/sensitive combination.