As we move towards more powerful and functioning cosmetic actives we need to better assess how they actually perfume in a more “real world” approach. Also, it is important that if panels are going to be using supportive products, such as mild soap and an SPF product, during the course of the study that we know more about their contribution, if any to the final results. It is important that supportive products be used to manage sun exposure and assist with compliance when studies are conducted in the winter months. Also, we need to be prepared, in the future to be able to run double blind controlled studies, so a model needs to be developed so as to be able to really determine the efficacy of the test product, when used with the supportive products rather than attempt to fool ourselves by running in, all the time, with soap only.

Background

Run-in period is a period before a clinical trial is commenced when treatment is standardized. The clinical data from this stage of a trial are only occasionally of value but can serve a valuable role in screening out ineligible or non-compliant participants, in ensuring that participants are in a stable condition, and in providing baseline observations. A washout period is a period before a clinical trial is commenced when treatment is either discontinued or withheld.

The question of whether a run in or a washout design is favorable in an anti-aging clinical study has not been fully examined as cost, presumed activity of ingredients and duration are often limiting factors when designing such research. We do know, based on this past winter in the North East that supportive products are very important for compliance and reasonable management of winter weather without impairing the ability to assess the performance of the test product.

Methods

We retrospectively reviewed our clinical study data base for anti-aging studies performed for 8 weeks with either a washout or run-in period. Studies included also had immediate hydration claims associated with the larger anti-aging study. To qualify for inclusion into our data base all studies must have used Moisture Meter (Delfin Tech) to measure hydration and Clarity Imaging Software (BTBP) to measure wrinkle severity. We reviewed hydration, initial hydration data and longer term wrinkle reduction to compare the two methodologies and explore factors leading to the use of either design. Careful attention had to be paid to these factors to insure a relevant and consistent database.

Results

We identified 18 clinical trials meeting our criteria for inclusion into this analysis. Twelve trials were included with a run-in and six with a washout period. All run-in studies had all subjects using Cetaphil
facial cleanser and SPF 15 daily as standard treatment, all washout studies used Camay bar soap as the only facial cleanser for washout period and where then switched to Cetaphil facial cleanser and SPF 15 at study commencement, i.e. after baseline readings were done. A total of 687 subjects’ data were reviewed. Seasonal start dates for both groups were equally distributed between winter and fall (New York, NY).

Baseline moisture levels and wrinkle severity scores were worse for those people with washout design resulting in higher percent improvements in both hydration (Figure 1) and wrinkle severity throughout the study time points. However, for the washout group it is not clear if these improvements were due to the study product or to the introduction of supportive products at baseline, whereas the changes seen in the run-in group can be attributed to the study product (figure 2). This situation presents researchers with a philosophical and scientific discussion on the appropriate method to be used.

Conclusion

Using a drying agent for washout results in an over estimation of product efficacy whereas run-in designs with proper supportive materials result in proper determination of product activity and efficacy. Therefore we recommend the utilization of a run-in design when immediate hydration and longer term anti-aging studies are combined. In general, this is, in our opinion, the best way to conduct a topical efficacy study for anti-aging parameters. If one wants to look for an immediate moisture spike then we suggest that the lower lateral legs be used following a week washout with soap such as Camay, as we have noted above.

Also, this model is one that can be used to conduct a double blind controlled anti-aging efficacy study. One can eliminate those with a strong positive response to the run in with the supportive products as their “conditions” can be well managed with the supportive products alone. Then, following the baseline evaluations, those qualified would be randomized into the control group, supportive products alone or with a “placebo”, or treatment, a strong scientific way to conduct cosmetic trials.

Figure 1
Figure 2

**Facial Hydration – Washout Effects**

- **Moisture Meter Value**
  - Washout
  - Baseline
  - Immediate

**Facial Wrinkle Reduction – Washout Effects**

- **Wrinkle Severity (0-100)**
  - Baseline
  - Week 4
  - Week 8
  - Week 12

Legend:
- **Dry Down**
- **Run-In**

- **Change noted likely due to study agents**
- **Change noted likely due to product use**