

## Instrumental non-invasive assessments of cosmetic efficacy

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Efficacy of cosmetic products and procedures can be assessed by *in vitro* studies, volunteer self-assessment, clinical expert evaluation and objective instrumental measurements. One or more of these approaches may be selected for assessing cosmetic ingredients, final formulations and medical interventions. Most instrumental assessments are highly valuable because their sensitivity and objectivity are indisputable. However, their specificity does not lessen the importance of a global assessment best obtained by a non-instrumental expert evaluation.

For all bioengineering methods, it is wise to rule out any possible direct interaction between the method used and the product or procedure to be tested. Prior to making measurements, the apparatus should be calibrated, either according to reference values or to relevant internal standards. Besides these adjustments and calibrations, it is essential to know the sensitivity, reproducibility, and range of variation of the parameters to be measured. Reliable devices and reproducible measurements are mandatory in order to assess efficacy over a period of time. Indeed, consistency among multiple measures of the same attribute increases the confidence of the observations.

In general, data gained by instruments add quantification to the subjective perception by the consumer, the patient and/or the expert evaluator. Non-invasive measurements may also reveal changes in the functional properties of the skin which are not obtained by the visual or tactile examination. This situation is an advance in knowledge when it describes a relevant aspect. Unfortunately, it may represent 'hype' in some instances. Any significant difference yielded by instrumental methods between two cosmetic treatments but lacking clinical support suggests discrepancies between the two assessments, not only regarding the sensitivity but also in what they actually measure. The global three-pronged approach using instruments, trained assessors and self-assessments provides a good opportunity to evaluate the cosmetic effects and increase the confidence of the conclusions.

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The specificity and sensitivity of most bioengineering methods are high but they may suffer from a series of biases. For instance, environmental factors can affect most of the measurements. The interpretation of the data needs adequate expertise to understand both the technical aspects and the physiological and microanatomical parameters under consideration. Of course, a proper use of non-invasive instruments provides the possibilities of demonstrating the actual cosmetic effect in a cost-effective way. To be most useful, the outcome parameter to measure must have relevance for the objective of the study, be clearly defined and be as objective as possible. When multiple parameters are used, the critical ones should be identified and justified by reference to publications, guidelines or recommendations by regulatory authorities. It is easy to place a probe onto the skin and obtain a reading on a digital display. However, it is important that the study generates information that can be interpreted meaningfully. In particular, care should be taken in the selection of volunteers and patients (age, gender, typology ... ) and of the test site on the body. The test design must also clearly identify the type of comparison to be made distinguishing the before–after, the active–untreated and the active–vehicle (placebo) modalities.

Surrogate parameters sometimes are used to assess the efficacy of topical products. These are not a direct measure of the benefit of the product and special attention is required to recognize such parameters. However, carefully chosen and validated surrogate parameters often provide answers to questions that would typically require much larger trials if the specific targeted end point was assessed. One example of such a parameter is the determination of electrical properties of the skin as a measure of the stratum corneum hydration.

Sound and relevant information can only be obtained when respecting specific guidelines. As a rule, a multi-pronged approach is used for unravelling the complexity of skin biology. It increases the validity of the assessment. The European Group for the Efficacy Measurements of Cosmetics and Other Topical Products (EEMCO) endeavours to offer comprehensive technical guidance.<sup>1–4</sup> The topics presently covered by the group are listed in Table 1.

**Table 1** EEMCO guidelines.

Topic	References
Dry skin, xerosis	Serup, <sup>5</sup> Piérard <sup>6</sup>
Stratum corneum hydration	Berardesca <sup>7</sup>
Skin colour	Piérard <sup>8</sup>
Skin topography	Lévêque <sup>9</sup>
Skin tensile properties	Piérard, <sup>10</sup> Rodriguez <sup>11</sup>
Skin greasiness	Piérard <sup>12</sup>
Transepidermal water loss	Rogiers <sup>13</sup>
Skin microcirculation	Berardesca <sup>14</sup>
Skin surface pH	Parra <sup>15</sup>

Instrumental non-invasive assessment of cosmetic efficacy is valuable because it is objective and quantitative. It is often most useful when combined with subjective assessment both by volunteers and by a clinical expert.

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