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Systematic Review

Advanced statistical methods for the analysis of data in cosmetic science studies

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ABSTRACT

Statistical analysis is fundamental to cosmetic research, enabling rigorous evaluation of product safety, efficacy, and consumer perception. Despite its importance, the selection and application of statistical methodologies in cosmetic studies remain varied and lack a comprehensive synthesis. This systematic review examines the statistical methods employed in clinical cosmetic research, focusing on both commonly used practices and advanced biostatistical techniques. Following PRISMA guidelines, a literature search was conducted using PubMed with the keywords "statistical + cosmetic products," restricted to studies published between January 2000 and April 23, 2025. After applying inclusion and exclusion criteria, 37 full-text articles involving human subjects and reporting statistical methodologies were included. Data on study design, sample size, outcome measures, and statistical methods were extracted and analysed. Parametric tests such as paired t-tests, independent t-tests, and ANOVA were commonly used for continuous outcomes, while non-parametric alternatives, including the Wilcoxon signed-rank test, Mann-Whitney U test, and Kruskal-Walli's test, were applied when normality assumptions were not met. Longitudinal data analysis frequently employed repeated measures ANOVA and mixed-effects models, with Bonferroni correction for multiple comparisons. Categorical data were analysed using chi-square tests, McNemar's test, Fisher's exact test, and logistic regression. More advanced methods, such as ANCOVA, Bland-Altman plots, two one-sided tests (TOST) for bioequivalence, and meta-analytic techniques using Cochran's Q and I^2 statistics, were also identified. Overall, cosmetic research demonstrates broad and largely appropriate statistical application, although improved reporting of assumptions and model specifications is recommended to enhance transparency and reproducibility.

Keywords: Statistics in cosmetics, Statistical methods, Cosmetic research, Skin, Parametric and non-parametric tests

INTRODUCTION

Biostatistics is a fundamental component of clinical research and plays a vital role in producing scientifically valid and reproducible results. In the field of cosmetic science, where research focuses on evaluating the safety, efficacy, and consumer perception of topical products and procedures, biostatistical methods provide the analytical foundation for evidence-based conclusions. As the cosmetic industry continues to integrate more rigorous clinical testing into product development, the correct application of statistical tools has become essential to ensure the validity and credibility of research outcomes.

Statistical methods are employed throughout the lifecycle of a cosmetic study from design and sampling to data analysis and interpretation. Descriptive statistics are commonly used in initial phase of analysis to summarize demographic characteristics, baseline measurements, and outcome variables. Measures such as mean, median, standard deviation, and frequency distributions help researchers understand central tendencies and variability within data. These summaries are critical when comparing groups or evaluating changes over time.

Inferential statistical techniques are used to draw conclusions about a population based on data from a

sample. In cosmetic studies, commonly used inferential methods include the student's t-test, independent t-test, and analysis of variance (ANOVA), which allow researchers to compare effects of different treatments or formulations. For e.g., ANOVA may be used to assess whether differences in skin hydration levels are statistically significant among users of 3 different moisturizers. When data do not meet assumptions required for parametric tests, such as normality/ homogeneity of variance, non-parametric alternative such as Mann Whitney U and Wilcoxon signed-rank test applied.[1]

Determining the appropriate statistical test depends on the distribution of the data. Parametric tests are valid when the data follow a normal distribution, while non-parametric tests are more suitable for skewed or ordinal data. The Shapiro-Wilk test is widely used in cosmetic research to assess whether the data conform to a normal distribution.[2-4,8] A significant result from this test indicates deviation from normality and helps guide researchers in choosing the appropriate statistical method. Ensuring this step is completed is vital for maintaining the integrity and reliability of the analysis.

In addition to hypothesis testing, the use of confidence intervals (CIs) is standard practice in reporting clinical data. A 95% confidence interval, for example, provides a range within which the true effect of an intervention is expected to lie with 95% certainty. Confidence intervals offer more information than p values alone, as they quantify the precision of an estimate and assist in determining clinical relevance.[5]

In systematic reviews and meta-analyses involving multiple cosmetic trials, random effects models are often applied. These models account for variability across studies, particularly in terms of population characteristics and study designs, and provide pooled effect sizes with confidence intervals. Such methods enhance the generalizability of findings and support broader conclusions about treatment efficacy.[6]

Despite the availability of a broad range of statistical tools, previous literature has indicated a tendency to rely heavily on descriptive statistics, with insufficient use of more advanced analytical approaches. In some cases, inappropriate test selection or failure to report key assumptions, such as normality testing, has been observed. These limitations can undermine the validity of the study's conclusions and reduce the quality of evidence available in the cosmetic sciences.

The purpose of this review is to examine the statistical methods most commonly used in cosmetic clinical research, evaluate their appropriateness, and highlight best practices in their application. By improving awareness and understanding of statistical methodology, this review aims to strengthen the overall quality, transparency, and scientific rigor of cosmetic studies.

METHODS

This systematic review was carried out following the guidelines of the preferred reporting items for systematic reviews and meta-analyses (PRISMA). The goal was to synthesize and evaluate the statistical methods utilized in studies related to cosmetics.

An extensive literature search was undertaken utilizing the PubMed database. The search strategy incorporated medical subject headings (MeSH) along with pertinent keywords associated with cosmetic studies and used statistical methods. The keywords applied were: "statistical + cosmetic products". The search was restricted to articles published from January 2000 to April 23, 2025.

The preliminary search resulted in 621 articles. After eliminating 4 duplicate entries, 617 distinct articles were left. These articles underwent a two-step screening process: (1) title screening, where 55 articles were included and 562 articles were excluded. (2) Following abstract screening, from 55, 37 articles were included and 18 articles were excluded. Particular emphasis was placed on whether the statistical techniques were clearly articulated. According to the set inclusion and exclusion criteria, in the end, 37 full text articles were selected for the final review, and comprehensive data extraction was carried out on all of these articles.

Inclusion criteria encompassed all full-text articles of clinical trials, meta-analysis, randomized control trials, reviews, and systematic reviews with outcome data available that involved human subjects in cosmetic studies, along with a description of statistical methods cited in the articles. Exclusion criteria consisted of non-human studies, pediatric populations, non-English publications, articles that did not discuss a statistical section, and studies with incomplete or absent data, as well as unpublished or non-peer-reviewed data.

Information gathered included study characteristics (title, authors, publication year, journal, study design, sample size), patient characteristics (age and sex), intervention specifics (statistical methods), and outcomes (incidence, efficacy measures, safety). We systematically documented results, capturing main findings.

All data were systematically recorded, and results were synthesized to discover trends and common statistical methodologies in cosmetics research.

The findings were reported in accordance with PRISMA guidelines, featuring a flow diagram that illustrates study selection process and tables that summarize essential characteristics and findings of the included studies.

These 37 articles listed include only those focusing on statistical approaches and do not cover articles related to introductory or background sections (Figure 1).

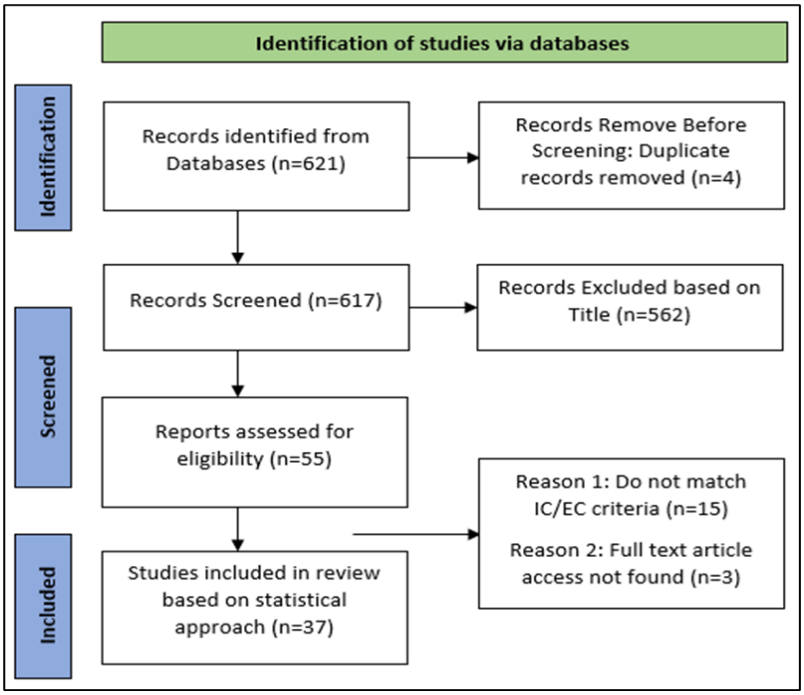

Figure 1: Prisma flow diagram.

RESULTS

A variety of statistical methodologies were employed across the included 37 studies, tailored to data type, study design, and research objectives.

In a prospective, randomized, double-blind study (n=44) assessing topical bakuchiol and retinol creams for photoaging, skin fatigue and hydration were analysed using paired t-tests or Wilcoxon signed-rank tests based on data distribution, while wrinkle and fine line assessments applied repeated measures ANOVA with Bonferroni correction.[7] Similarly, skin mechanical parameters (R0-R8) following Calendula officinalis cream were measured via cutometer and evaluated using paired t-tests for preparation comparison and two-way ANOVA for time intervals (n=21).[8] Roflumilast cream for atopic dermatitis (n=50) was assessed using Cochran-Mantel-Haenszel test for vIGA-AD success at week 4.[9] In a 1-week sun exposure study comparing sunscreen users (n=22) with non-travelers (n=17), normality was tested via Kolmogorov-Smirnov, with paired t-tests for within-subject changes, ANOVA with post hoc tests for between-group comparisons, and linear regression and Bland-Altman for inter-lab vitamin D variation. Pearson's chi-square was applied to categorical data.[10]

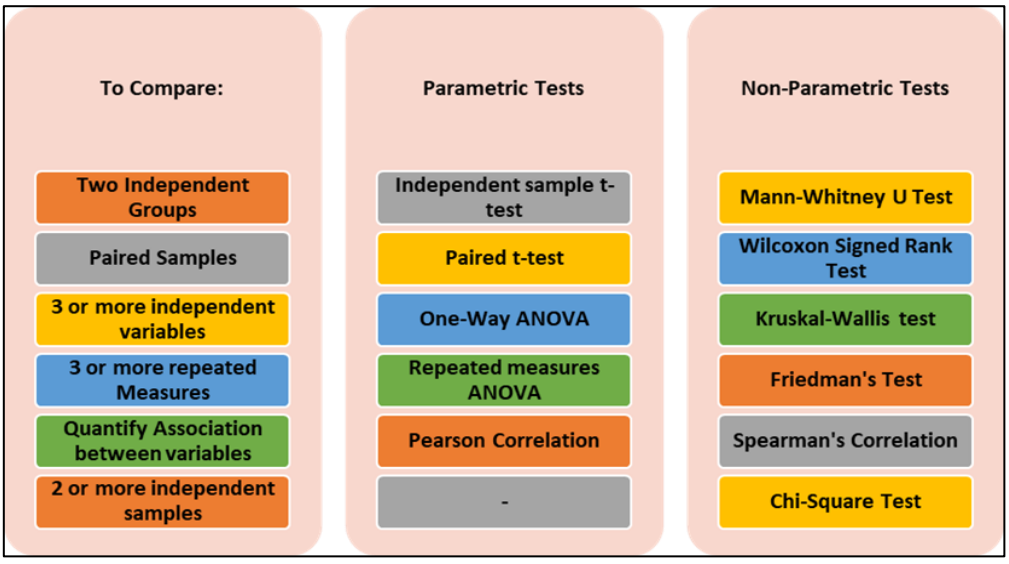

Figure 2: Classification of statistical procedure.

A randomized trial (n=49) on skin barrier, moisturization, dryness, and erythema index (EI) used ANCOVA with treatment as fixed effect and subjects as random effect.[11] A comparative melasma study of 3% tranexamic acid and 4% hydroquinone assessed mMASI, PtGA, melanin/erythema indices, and adverse events, analysing matched data using Wilcoxon or paired t tests, group comparisons with Mann-Whitney U or independent t-tests, and categorical data with McNemar and chi-square tests.[12] Another study compared ATPC and placebo creams in preventing ≥grade 2 HFS or HFSR, assessing melasma via Mexameter® (MI, EI), mMASI, and PtGA, with statistical analysis by Student's t-test and chi-square test ($p<0.05$).[13]

Homemade cosmetic product use involving essential oils across various product types was analysed with Shapiro-Wilk for normality, Kruskal Wallis test for group differences, and Dunn's post hoc with Bonferroni correction.[2] Sunscreen behaviours in Danish men and women were analysed using Pearson's chi-square for categorical SPF use patterns, Mann-Whitney for sunscreen quantities by gender and setting, independent t-tests for parking durations, and Spearman's correlation for sunscreen use by age. Wilcoxon signed-rank test compared missed areas post single vs. double application.[1]

In a study on chlorhexidine wash vs. no treatment, SSI rates were compared using relative risk (RR) with 95% CI, fixed-effect models for data pooling, and random-effects models based on heterogeneity (I^2).[14] Similarly, heterogeneity in hair dye poisoning was assessed via Cochran's chi-square and I^2, with pooled estimates using a random-effects model (DerSimonian and Laird).[6]

Study evaluated skin hydration (Corneometer® CM820), elasticity (Cutometer® SEM 575), and wrinkle area (Quantirides®) across time points (Days 0, 1, 7 and 28), using student's t tests and paired t tests.[15] Net TEWL changes from baseline analysed via repeated measures ANOVA and Tukey-Kramer post hoc testing ($\alpha=0.05$).[16] Test-retest reliability and associations between fragranced product use and safety attitudes were assessed using weighted Cohen's Kappa, polychoric correlations and ordered logistic regression with fixed effects.[17]

A UV detection sticker study used Pearson's chi-square or Fisher's exact test, with binary logistic regression adjusted for age and sex, and likelihood ratio chi-square for categorical associations.[18] In a placebo-controlled cellulite study, paired t tests analysed thigh circumference changes.[19] A dermatopharmacokinetic (DPK) study on metronidazole creams applied ANOVA to log-transformed AUC values (subject and treatment effects), with Schuirmann's TOST used for bioequivalence, and MSE estimating within-subject variability.[20]

A pilot study evaluating a skin whitening serum with SPF 50+ in melasma used clinical photography, mMASI, IGA, Bazin's scale, GAIS, SGAIS, and satisfaction scores. Data were reported as mean±SD and analysed using paired t tests and chi-square tests ($p<0.05$).[21] In comparing hyaluronic acid products for nasolabial folds, effectiveness was assessed using the Wrinkle severity rating scale and global aesthetic improvement scale, analysed with paired t-tests for within- and between-group changes ($p\leq0.05$).[22]

A mixed-effects ANOVA with unstructured variance-covariance matrix evaluated changes in mMASI and colorimetric parameters at weeks 6 and 12.[23] In lentigo maligna patients treated with imiquimod, relapse-free survival was analysed via Cox regression, with comparisons using exact Wilcoxon signed-rank tests.[24] The Miamo Renewal peel serum vs. mandelic acid and placebo was evaluated for erythema index, TEWL, hydration, roughness, and mechanical properties using descriptive statistics and paired t-tests.[25]

CEA and SSA scores were analysed intra-arm using Wilcoxon signed-rank tests; inter-arm comparisons (GAI scores, vessel size) were made using Wilcoxon rank-sum tests. Assessments also included pain scores and vessel grading.[26] In a photodamage study using topical fluorouracil, four photonumeric scales were rated by two raters with inter-rater agreement via Cohen's K and ICC. Kruskal-Walli's test compared outcomes across 6, 12, and 18 months.[27]

A study on sericin cream assessed VAS scores, hydration, pigmentation, and irritation using repeated measures ANOVA; quality of life was analysed using paired and independent t-tests.[28] In alopecia areata, scalp hair regrowth (SALT score) was compared between TR-M-PRP plus and placebo groups via two-sample t tests.[29] ASFS baseline changes were analysed using ANCOVA, adjusting for treatment, site, gender, and age ($p\leq0.05$).[30]

In a topical lesion treatment, the dynamic PGA was analysed using MMRM from T0 to T12, with product, site, and sequence as fixed effects and baseline as covariate.[31] Barrier function (TEWL) changes across test cream, control, and no treatment groups were analysed via ANCOVA, with subject as random effect.[32] A meta-analysis on sunscreen and melanoma risk calculated odds ratios and relative risks using fixed and random effects depending on heterogeneity.[33]

In the open-label safety study of Clascoterone cream, the IGA score and facial score were evaluated in terms of frequency and percentage. Descriptive statistics were also provided.[34] Changes in Corneometry values at multiple time points post-application of lamellar moisturizers were analysed using paired t-tests or Wilcoxon signed-rank tests.[35] Two studies evaluated a tinted SPF 30 facial moisturizer (DFM30). The first assessed its effect on skin barrier function in dry skin, using descriptive statistics, Shapiro-Wilk test for normality ($p<0.01$), and either Student's t-test or Wilcoxon signed-rank test for

comparisons ($p<0.05$). The second study analysed tolerability in rosacea-prone skin using Wilcoxon signed-rank test, McNemar's test, Binomial test, and paired t-tests, with $p<0.05$ for significance.[3]

In a large cohort (n=346) evaluating 0.05% isotretinoin with sunscreens, normality and variance were tested via Shapiro-Wilk and Bartlett's tests; if assumptions failed, permutation tests or Wilcoxon Rank Sum were used for between-group comparisons, and logistic regression (adjusting for center and stratum) analysed categorical outcomes with odds ratios and 95% CI.[4] Farrington and Manning's method tested noninferiority in phase 3 trials at a 2.5% one-sided significance level and recurrence rates were calculated for patients and lesions during follow-up.[5]

Phase III and IV datasets were merged for comparative and correlational analyses. Spearman's rank correlation assessed relationships between percentage improvement and SAT-RFR item 1. The McNemar paired test compared oxymetazoline arms in phase IV and phase III trials.[36] In a phase 3 study, group differences in IGA scores were tested via Pearson's chi-square; SCORAD, EASI, pruritus VAS, and sleep scores were analysed using two-sample t-tests or Wilcoxon rank-sum tests.[37]

Table 1: Statistical test and study findings.

Statistical test	Study findings	References
Paired t-test	Skin hydration (Corneometer® CM820), skin mechanical parameters (R0-R8), elasticity (Cutometer® SEM 575), wrinkle area (Quantirides®) across time points, thigh circumference changes, mMASI, IGA, Bazin's scale, GAIS, SGAIS, and satisfaction scores, EI, TEWL, Roughness, and mechanical properties, quality of life, corneometry values at multiple time points post product application	7, 8, 15, 22, 28 and 35
Independent t-test	Group comparisons for melanin/erythema indices, quality of life, scalp hair regrowth (SALT score), skin barrier function of group comparisons, SCORAD, EASI, pruritus VAS, and sleep scores	3, 12, 13, 28, 29 and 37
ANOVA	Skin wrinkles and fine lines, between-group comparisons, Bioequivalence, mMASI and colorimetric parameters, VAS scores, hydration, pigmentation, and irritation	7, 8, 20, 23 and 28
Cochran-Mantel-Haenszel test	Post-treatment comparison	9
Kolmogorov-Smirnov	To check normality of data	2-4 and 10
Pearson's chi-square	Categorical data	10
ANCOVA	Skin barrier, moisturization, dryness, and erythema index, ASFS, barrier function (TEWL) change	2, 11 and 16
Wilcoxon signed-rank test	mMASI, PtGA, adverse events, compare post single vs. double application of product, Intra-arm comparison (CEA and SSA scores), corneometry values at multiple time points post product application, group comparisons	1, 3, 12, 13, 26 and 35
Mann-Whitney U/Wilcoxon rank-sum test	Group comparisons for mMASI, PtGA, adverse events, comparison by gender category, Inter-arm comparisons (GAI scores, vessel size), between-group comparisons, SCORAD, EASI, pruritus VAS, and sleep scores	1, 4, 12, 26 and 37
McNemar test	Categorical data, arm comparison	12 and 36
Pearson's Chi-square test	Categorical data, group differences in IGA	1, 6, 12, 13, 17 and 21
Kruskal Wallis	For group differences, compare outcomes across timepoints	2 and 27
Spearman's correlation	Product use by age, relationships between percentage improvement	1 and 36
Relative risk with 95% CI	SSI rates	11, 14 and 33
Random-effects models based	Subjects as random effect on skin barrier, moisturization, dryness, and erythema index, relative risks	6, 11, 32 and 33
Fixed-effect models	Treatment as fixed effect on skin barrier, moisturization, dryness, and erythema index, data pooling, relative risks	11, 14 and 33
Tukey-Kramer test	Net TEWL change	16
Weighted Cohen's Kappa	Reliability and associations, inter-rater agreement	17 and 27
Mixed models for repeated measures (MMRM)	PGA at different timepoints	31
Frequency and percentage	IGA score and facial score	34
Logistic regression	Categorical outcomes	4

DISCUSSION

This review highlights a robust and methodologically varied use of statistical techniques in research related to cosmetics. Among the 37 studies analysed, researchers applied a wide range of statistical tools that were aligned with the study type, research objectives, and the nature of the data being assessed. The findings reveal a consistent reliance on both parametric and non-parametric tests, with careful selection based on data distribution and study design.

Paired t-tests and Wilcoxon signed-rank tests were the most commonly applied methods for within-group comparisons, especially in studies examining treatment effects over time on variables such as skin hydration, pigmentation, wrinkle depth, or trans epidermal water loss (TEWL).[3,7,8,10,12,15,19,21,25,28,35] These analyses were frequently preceded by normality testing using either the Shapiro-Wilk or Kolmogorov-Smirnov tests, indicating compliance with appropriate statistical procedures.[2-4,10] Likewise, in related studies, paired t-tests were used to compare continuous data between baseline and post-treatment measurements for skin hydration, while paired t-tests or Wilcoxon signed-rank tests were employed to evaluate changes within three different groups over multiple time points for skin hydration and TEWL outcomes.[38-42]

Between-group comparisons were frequently conducted using independent t-tests, Mann-Whitney U tests, or Wilcoxon rank-sum tests, depending on distribution.[1,4,12,22,26,39,37] Repeated measures ANOVA and ANCOVA were also widely used to account for time-dependent changes and to control for baseline values or covariates.[7,8,11,15,16,23,28,31,32] These methods strengthened internal validity, especially in trials involving multiple time points.

For categorical outcomes, appropriate use of Pearson's chi-square, McNemar's, and logistic regression was evident in analysing proportions, adverse events, and group differences.[1,3,4,10,12,13,18,36,37] Several studies used Cochran-Mantel-Haenszel and Fisher's exact tests for small or stratified samples, while odds ratios and relative risks were employed in safety and meta-analytic contexts.[6,9,14,18,33]

Advanced models such as mixed-effects models, MMRM, and ordered logistic regression were applied to accommodate repeated measures and ordinal data.[17,23,30,31] This reflects an evolving methodological sophistication in the field. Bioequivalence and pharmacokinetic studies applied regulatory-standard methods, such as Schuirmann's TOST and the log-transformed ANOVA.[20]

Some studies incorporated inter-rater reliability measures like Cohen's kappa and ICC for validating subjective assessments and clinical grading scales.[17,27] Studies involving sensor-based devices (e.g., Corneometer®, Cutometer®, Mexameter®) demonstrated appropriate statistical handling of continuous biometric data.

However, not all studies reported pre-analysis normality testing or variance checks, which could compromise the appropriateness of parametric test use.[12,13,21] Similarly, while Bonferroni or Hochberg corrections were used to address multiple comparisons in some studies, these adjustments were inconsistently applied.[2,7,36] A number of reports also lacked power calculations and confidence intervals, which are vital for interpretation and reproducibility.

Emerging areas, such as personalized skincare and digital diagnostics, may benefit from more advanced analytical techniques, including multivariate analysis and machine learning. While current studies show foundational statistical rigor, there is clear opportunity to strengthen methodological consistency and adopt modern data analysis tools for complex, high-dimensional data.

In summary, the reviewed literature demonstrates a thoughtful and largely appropriate application of statistical methodologies in cosmetic studies. The use of standard and advanced statistical tools reflects a commendable level of analytical proficiency within the field. Moving forward, continued efforts toward methodological transparency and the adoption of innovative analytical strategies will be essential in maintaining the integrity and progression of research in cosmetic science.

CONCLUSION

Statistical evaluations are fundamental to establishing the safety, efficacy, and dermatological benefits of cosmetic products. The reviewed literature demonstrates a methodologically sound application of both parametric (e. g., ANOVA, paired and independent t-tests) and nonparametric (e.g., Kruskal-Wallis, Mann-Whitney U, Wilcoxon signed-rank) tests for analysing continuous variables, as well as appropriate models for repeated measures and longitudinal data, including mixed-effects and repeated measures ANOVA with adjustments for multiple comparisons. Studies involving categorical outcomes consistently utilize chi-square tests, Fisher's exact test, McNemar's test, and logistic regression. The incorporation of advanced methods such as ANCOVA, Bland-Altman analysis, polychoric correlations, kappa statistics, and bioequivalence assessment via TOST further reflects the field's commitment to robust and contextually relevant analysis. Despite this strong foundation, consistent reporting of statistical assumptions, effect sizes, and model specifications remains an area for improvement. Moving forward, the selection and transparent application of statistically appropriate methods aligned with study design and data type will be essential to enhancing the reproducibility, reliability, as well as scientific value of cosmetic research.

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