Clinical testing for a booming men's sector

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The male grooming industry is growing at a rapid pace. Entire aisles of drug stores are dedicated to men's grooming products. Product demand in the skin care, hair care, and fragrance industries has grown dramatically and is expected to keep pace in the coming years. Whether this growth stems from celebrity advertising or social media influence, one thing is clear: men have come a long way from the days of merely using a soap bar as face and body wash. The modern man stands ready and willing to invest in skin and hair products that maintain their health and youth.

Globe News Wire reports the men's grooming market worldwide will reach $183.2 Billion by 2027, with the U.S. market alone estimated at $38 Billion, and China Forecast to grow at 6.9%.[1] As men continue to open their wallets for new and improved grooming products, brands catering to this market are stepping up to meet those needs by expanding offerings to include anti-ageing, SPF and anti-acne products. Customisation of products is proving equally important, such as specialised regimens for every combination of skin and hair.

At Princeton Consumer Research (PCR), we offer premier clinical research testing facilities with expertise in clinical testing for men's grooming products. Specifically, we offer clinical testing for the following classes of products:

- Personal Cleansing Products: soaps, shower gels, body washes
- Sweat & Odour Control Products: anti-perspirants and deodorants
- Shaving Products: shaving creams, before and after shave lotions, shave gels and balms
- Skin Care Products: cleansers, moisturisers, anti-ageing products
- Hair & Beard Care Products: shampoos, conditioners, styling products (pomades, putties, clays, waxes, gels)

Figure 2: Efficacy testing of a deodorant product in the laboratory. The odour judge is sniffing the subject's armpit.

Companies are legally required to promote products based on proven claims rather than lofty descriptions. Companies also need their products to meet the demands of savvy customers. Today's customers can no longer be lured by visually appealing marketing campaigns alone. They require scientifically substantiated claims backing their products of choice. All the while, the introduction of novel ingredients into grooming products is pushing the boundaries of the scientific claims themselves.

After manufacturers test for package compatibility and product integrity, new products land at Princeton Consumer Research for clinical testing. Clinical testing at PCR begins with client consultation to create a customised study design. Our knowledgeable experts and trained study staff, often under the supervision of dermatologists, then execute the clinical trial, collect data, and statistically analyse trial outcomes.

At PCR, we offer both safety and efficacy testing. Safety testing of these products involves a determination of potential skin and eye irritation or allergic reaction. Common methods of evaluation include Human Repeat Insult Patch testing ("HRIPT"), cumulative irritation testing, and photo-reactivity testing. The correct study design for any given product will depend on client needs and the product being tested.

Efficacy testing focuses on ensuring product claims are clinically proven and supported by strong results. Adverse events occurring during efficacy trials are collected to further substantiate product safety. Efficacy testing may be used to authenticate cleansers, shaving products, moisturisers, anti-ageing products, antiperspirants, deodorants as well as products for hair and scalp. We also offer total hair and skin regimen test for multiple products. Below, we offer a description of sample study designs that may be used for efficacy testing of these products.

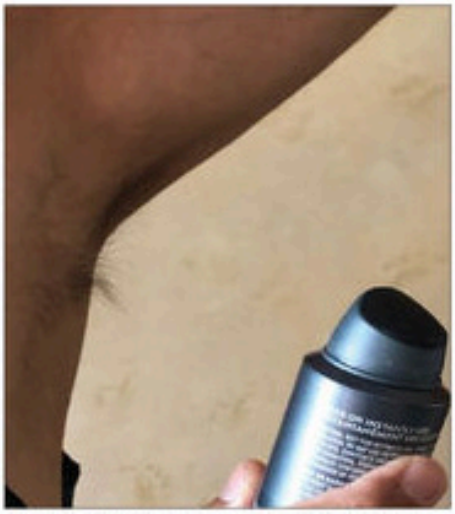

Figure 1: Efficacy testing of an antiperspirant spray product in the laboratory. The product is being sprayed on to subject's armpit area by trained staff.

Personal cleansing products

The forearm-controlled application technique ("FCAT") or leg-controlled application test ("LCAT") are used to estimate the relative irritation potential of personal cleansers. The FCAT and LCAT study designs use an exposure protocol based on consumer washing habits, offering an efficient means to evaluate cleanser mildness. The testing industry has relied on short-duration, exaggerated protocols that reach outcomes beyond those observed under normal use conditions to predict the relative irritation potential of personal cleansing products. At PCR, we understand the challenge is to choose appropriate test conditions that provide a reasonable level of product discrimination without sacrificing consumer relevance. By testing multiple products on each subject, the LCAT and FCAT helps minimise confounding effects. For example, an exaggerated leg, arm or hand wash can be used to verify claims such as "gentle", "mild", and "non-drying". On the other hand, a kinetic study design provides results detailing the effectiveness of a product over a short period of time: 1, 8 or 24 hours. These studies help to verify claims such as "moisturising formula" and "provides up to [X] hours of moisturisation".

In all of these study designs, the cleansing product is applied to the skin. The product

is compared to water, soap, an older formulation, or a competitor's product or various formulations. Clinical grading is used to measure product harshness, skin penetration/skin residue. Corneometer is used to measure the skin's hydration, Sebumeter to measure the skin's sebum content, and tape stripping to measure the depth of product penetration.

Sweat & odour control products

A variety of antiperspirant and deodorant options exist in today's market. Consumers looking to freshen underarms, prevent odour caused by the bacterial breakdown of sweat or impede perspiration have their choice of sticks, gels, wipes, and sprays. While deodorants only mask or neutralise the body odour caused by bacteria, antiperspirants temporarily suppress the flow of sweat. The hall mark for sweat and odour protection is a combination antiperspirant-deodorant.

At present, aluminium salts are the only FDA-approved chemical antiperspirant. However, high concentrations of aluminum used to prevent sweating have proven irritating for consumers. There is high demand for products free of aluminium, fragrances, dyes, lanolin, parabens, and other potentially irritating ingredients.

A general study design for antiperspirant products involves a brief evaluation of the subject's underarms conducted by trained study staff to confirm acceptability. Subjects who qualify for the study are given a mild non-antimicrobial soap to use while participating in a 2-3 weeks' washout period. Upon return, subjects have their vitals like blood pressure, temperature recorded, and if qualified, subjects participate in an approximate 80-minute hot room procedure for sweat collection. If they continue to qualify, subjects producing sufficient sweat following the collection period are randomised to treatment with the test product to one designated axilla versus the placebo product in the other axilla. The formulation is applied once daily for 4 consecutive days using the same designated underarm for the test product and placebo product. Approximately 8 hours and 24 hours following the fourth application, subjects return to the test site for an 80-minute hot room session for sweat collection. Successful products should show reduction in the amount of sweat.

For Deodorant efficacy we have trained sniffers (odour judges) for evaluating odour.

Figure 3: Shaving razors can often leave men struggling with irritated facial skin and razor bumps. New botanically infused creams and gels can help prevent these issues, providing men with younger looking and healthier skin.

Shaving products

Men's skin care is mandated by the regular need to remove facial hair. Problems can arise with improper hair removal which causes irritation and razor burn. New shaving products, techniques and ingredients with known skin protectant properties are constantly being introduced to improve male skin health. Such products work either by softening hair or by improving hydration of facial skin before, during or post shaving and by improving the skin barrier function. Shaving products on the market today may include:

Shaving Soaps: Shaving Soaps produce lather on rubbing and help in effective shaving. They have ingredients like vitamin E, aloe and coconut oil which help soften the hair and the skin.

Figure 4: The Corneometer and Sebumeter probes pictured here are used to measure skin hydration and sebum on subject's skin respectively.

Shaving Creams: Shaving Creams are often used for an effective shave and are sold as aerosol foam or gel. Shaving creams are made with hydrating ingredients like glycerin (with its humectant properties), aloe and oatmeal that help the razor in gliding easily across the skin and emollients like shea butter and lipids that help support and restore the skin barrier.

Pre-shave Products: Pre-shave lotions and creams are products used just before wet shaving or electric shaving. Such products usually contain an astringent to reduce any infection of cuts and scrapes in a closer shave and protective antioxidants like vitamins like A, C and E.

After-Shave Products: These are products intended to be used after shaving. They contain alcohol which helps close pores and prevent razor burn.

We test shaving razors, shaving creams, brushes, pre- and post-shaving products, and total shaving regimens, with particular emphasis on men who experience razor bumps. New shaving products often include a blend of soothing and anti-inflammatory plant ingredients. Clinical study design typically involves subjects aged 20 to 65. During the clinical trial, clinical grading by trained skin graders is employed to detect skin roughness, skin tone, skin radiance, razor bumps and lesions. The grading is completed at baseline, 30 minutes post shaving, and two- and three-days' post shaving. Skin hydration measurements with Corneometer are conducted and digital photos of the skin may be taken for analysis. Self-assessment questionnaires to evaluate product efficacy and tolerability by subjects are often included as they provide valuable feedback for our clients.

Skin care products – moisturisers

Moisturisers are used to address a range of men's skin care needs – including protection, healing, and treatment. Moisturisers help prevent dry skin, improve appearance, heal irritated skin, and treat diseased skin. The most common ways to test moisturiser efficacy is to measure hydration and the skin's barrier function. Specifically, we measure trans-epidermal water loss ("TEWL") and skin surface hydration by electrical capacitance in already irritated skin or in skin irritation created by mechanical or chemical processes e.g. tape stripping or using sodium lauryl sulfate. Following this, the moisturiser product is applied and testing carried out to see if this product prevents irritation and assists in repairing the damaged barrier.

A decrease in TEWL in normal skin is sometimes found following application of a moisturiser. It should be noted that not all moisturiser formulations work equally, or even by the same mechanisms. When normal skin is studied, a commercially available moisturiser containing novel ingredients like peptides may prove superior to formulations without it, inducing a significant increase in hydration and/or in other stratum corneum ("SC") attributes by using kinetic and longer use designs.

Regimen testing can be effective in determining how well moisturisers work

TABLE 1

Claim	Assessment Options
Hydrating	Corneometer, Visual grading
Barrier protectant	TEWL
Non comedogenic	Cyanoacrylate biopsies, Visual grading
Brightening	Chromameter, Colorimeter, Visual grading
Smoothing	Tactile grading, Visual grading, 3D imaging or replicas, Visioscan
Firming	Visual and Tactile grading, Cutometer
Elasticity	Tactile grading, Cutometer
Anti-ageing	Visual grading, Non-invasive instruments and VISIA®
Pores	Visual grading, and VISIA®

with other skin care products. For example, irritation ratings and digital photography methods used at PCR demonstrate how a skin care regimen that includes a facial hydrating serum or toner can be more effective on dry skin than a moisturiser alone.

Skin care products – anti-ageing products

The anti-ageing arena is expanding for men. The addition of new ingredients is allowing men to swap leathery, wrinkled, dried out skin for healthy, glowing, and hydrated skin. Anti-ageing products claim to have hydrating, smoothing, brightening, lifting, and firming effects. These products may also claim to reduce fine lines, wrinkles, and pores. Currently, alpha hydroxy acids (AHAs), vitamin A derivatives, and non-comedogenic formulas continue to be particularly popular in men's anti-ageing products.

The scope of anti-ageing product study designs is wide ranging with a simplistic study design comprised of expert visual grading and self-perception questionnaires to evaluate the subject's lines, wrinkles, dryness, tactile roughness, and skin softness. More complex anti-ageing study designs may include clinical grading, non-invasive instruments and advanced photography with VISIA® Canfield imaging system.

Table 1 offers a few examples of claims and measurement options used in corresponding efficacy trials.

Figure 5: The VISIA image is analysed for lines on the subjects face in an anti-ageing study design that correspond to a thickness of 0.28 – 0.34mm.

Hair & beard care products

Smart consumers are constantly looking for cost-effective ways to find products that deal with "bad-hair-days". Every store shelf in the world resembles a conga-line of products claiming to help with everyday issues like frizz, volume and shine, and proven claims for scalp and hair health. Consumers are searching

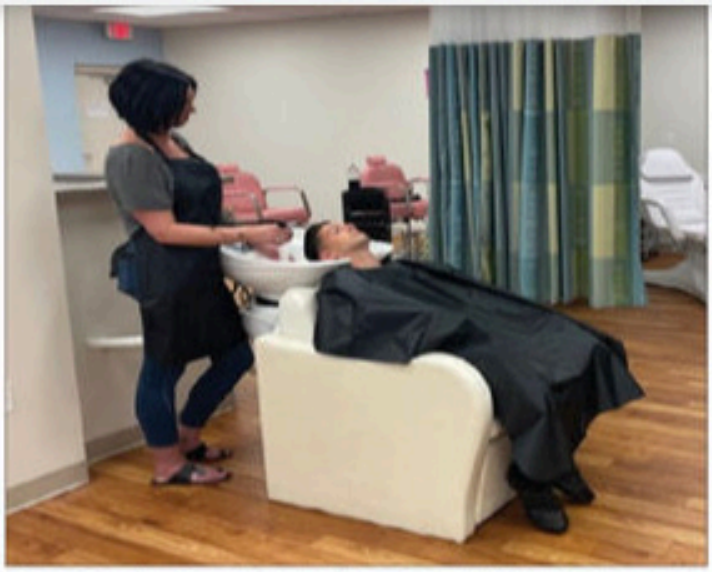

Figure 6: Testing of a scalp product in a controlled laboratory environment by a trained technician.

Figure 7: Testing of a heat protectant hair product on a study volunteer in a controlled laboratory environment.

for that one product that makes them feel incredible and leaves them with a picture of how they see their hair should look, in their minds eye.

Most consumers feel it is important for hair to preserve and maintain its cleanliness, softness, volume and shine. Experts are recognising that a healthy scalp is the key to maintaining healthy hair.

Hair care products come in two forms – leave-in products like oils and mousses or rinse- off products like shampoos and conditioners. Scalp actives include products with special ingredients like coal tar, zinc pyrithione, selenium sulfide, salicylic acid or mineral oil) for treating specific problems like scalp dryness/flakiness, or conditions like dandruff, alopecia, seborrheic dermatitis. These ingredients are added in various cosmetic products like nourishing shampoos, conditioners and oils. Dietary supplements (flax, fish oil supplements, rich in omega-3 fatty acids are known to help fight dryness or zinc supplements along with vitamins A, B, C or E are used for maintaining healthy hair, nails and skin).

Hair evaluations are routinely offered for assessment of hair density, thickness, moisture, frizz control, static, manageability, combing forces, shine, volume, breakage, softness, suppleness, color, curl effect, curl retention, gloss, anti-loss/growth products and hair photo protectors. Scalp evaluations include dryness/flaking, hydration, irritation, inflammation, erythema, pruritus, oiliness, fatty acids, cytokine levels, overall scalp analyses in vivo digital photography/microscopy. We offer a systematic measurement of scalp clinical and physiological parameters. Typically, a clinical study to test an anti-hair loss or hair-growth product is designed for 3-6 months on volunteers with mild to moderate hair loss. Methodologies for evaluation of loss include non-invasive techniques (hair counts, pull tests, pluck tests, standardised wash test, photographs, dermoscopy, hair weight, phototrichogram, trichoscan, microscopy and invasive techniques, such as a scalp biopsy. Effects studied include decrease of the telogen hair density, increase of the anagen hair density, increase of the growth coefficient (A/T) ratio at baseline, midpoint and at end of treatment phase. For hair replenishment products, trained evaluators assess the subjects' hair for attributes of shine, volume, thickness, softness, and general appearance/ condition at baseline and after 8 to 12 weeks approximately. The Brush Friction Count Method (BFCM) is employed and intact and broken hair are each counted. Macro photographs are taken of an area on the head with thinning hair and assessed for hair growth and count at baseline and/ or at midpoint and at end of treatment period. Also, self-evaluation by subjects for any perceived improvements of specific criteria can provide useful information about the product.

Dandruff and Scalp Seborrheic Dermatitis (SD) are scalp conditions both caused by a yeast called *Malassezia* and result in flaking, erythema, itching and inflammation. The study design may include one or all of the following: visual grading for erythema and flaking, non-invasive instrumentation like squamometry, digital photos along with self-perception questionnaires. Recently, clients are asking for inclusion of scalp microbiome because of its influence on scalp health, and involvement in the pathophysiology of scalp-related disorders. As the scalp surface provides a distinct microenvironment, studying pH, sebum level, hydration, trans-epidermal water loss (TEWL), dandruff severity, as well as the dysbiosis in the cutaneous microbiome assumes great importance. Thus, a systematic measurement of scalp clinical and physiological parameters along with the scalp microbiome and associated functional pathways can help reveal important information.

Beard oils are popular and help hydrate, add shine, tame astray hair, reduce itching during early growth, and provide nourishment of both facial hair and facial skin thereby help in keeping the beard neat and tidy. Ingredients like almond, grape seed and jojoba oil all are rich in vitamin E which keeps hair and skin soft and smooth. Shea butter helps to keep beards soft and healthy looking. Clove oil because of its antiseptic/antibacterial properties is increasingly being added to products and helps keep the beard clean and the face break out free. The damage with use of blow dryers for hair can be corrected with products called heat protectants which cover the cuticle and form a shield locking in moisture and nourishment and decreasing the damage.

Testing efficacy of hair care regimens is becoming increasingly common and includes testing of shampoo, scalp and conditioner treatments, scalp/hair serums, beard care products including dietary supplements. This involves a greater understanding of the complexity of the formulations individually and when used in combination and choosing from various criteria and techniques mentioned above for a good scientific right fit study design.

Conclusion

At Princeton Consumer Research, we continue to provide safety and efficacy testing services for male grooming products. As the male grooming industry becomes increasingly complex and expansive, we recognise the need for effective, timely, and science-based clinical testing. Our testing services range from simple to complex, allowing us to provide the best study design and clinical trial execution for companies and budgets of all sizes. PCR is constantly expanding its knowledge base and utilising experience gained over the years to keep up with the evolving trends. We are here to offer the best service to help our customers with rational and well thought out strategies for testing their products and helping them with their timely product launches. **PC**

Reference

1. https://www.globenewswire.com/newsrelease/2020/08/20/2081562/0/en/Global-Men-s-Grooming-Products-Industry.html