Tooth discolouration is caused by intrinsic and extrinsic staining and is a major concern for consumers. Intrinsic staining can be attributed to factors such as genetics, age, enamel wear exposing yellower dentine, high levels of fluoride, and developmental disorders, which can start before the tooth has erupted. Extrinsic staining is largely a result of environmental factors, including smoking, pigments in beverages or foods, some pharmaceuticals, or metals such as iron or copper. Coloured compounds from these sources are absorbed into the dental pellicle, or directly onto the surface of the tooth, causing a stain to appear.

A strong consumer desire for whiter teeth has driven the development of a range of oral care products with whitening capabilities, such as toothpastes, mouthwashes, varnishes, chewing gum and bleaching kits. Tooth whitening is any process that lightens the colour of teeth, and the efficacy of a whitening product is dependent on the type of tooth discolouration being treated (extrinsic or intrinsic staining).

Whitening products are formulated to include active ingredients which whiten teeth by different modes of action. The main whitening ingredients of toothpaste formulations are abrasives, such as silica and calcium carbonate, which remove stain surfaces by a mechanical mode of action.

A PCR test is an in vitro method designed to compare the ability of toothpaste formulations to remove surface stains. The ranking of toothpastes in this test has been shown to compare favourably with the results of controlled clinical trials. Hence a PCR test can be considered as reasonably predictive. A PCR test approach provides benefits to developers such as a cost-effective route to faster ranking of the cleaning performance of toothpastes.

CASE STUDY

IN VITRO TEST TO COMPARE THE ABILITY OF TOOTHPASTE FORMULATIONS TO REMOVE SURFACE STAINS USING A PELLICLE CLEANING RATIO (PCR) TEST

IN VITRO ORAL CARE PRODUCT TESTING

A pellicle cleaning ratio test (PCR) is an in vitro method designed to compare the ability of toothpaste formulations to remove surface stains. The ranking of toothpastes in this test has been shown to compare favourably with the results of controlled clinical trials. Hence a PCR test can be considered as reasonably predictive. A PCR test approach provides benefits to developers such as a cost-effective route to faster ranking of the cleaning performance of toothpastes.

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A PCR test is an in vitro method based upon work published by Stookey, Burkhard and Schmemehorn. The ranking of products in a PCR test has been shown to compare favourably with the results of controlled clinical trials. Hence a PCR test can be considered reasonably predictive. The benefit for manufacturers is that a PCR test provides a cost-effective and faster alternative for ranking the cleaning capacity of toothpastes.

Our Solution

Intertek CRS offers an optimized version of the PCR test which differentiates the ability of toothpaste formulations to remove stain. Test samples are prepared from bovine incisors by using high-precision saws to section suitable-sized specimens of tooth enamel. The enamel samples are embedded in polystyrene cuvettes using a methacrylate resin so that only the enamel surfaces are exposed. After polishing, the specimens are acid-etched to facilitate stain uptake and stained in a specially constructed staining rig for approximately 4 days (at 50°C) until a uniform stain has accumulated (mean L* values between 38 and 43). Colour (L*, a*, b*) values of the stained enamel samples are measured using a calibrated spectrophotometer and the data used to stratify the samples between treatment groups.

A V8 or M235D mechanical brushing machine is used to brush the samples with their assigned toothpaste slurry or the reference abrasive (ADA abrasion standard). Following brushing, specimens are stored in 0.01M Phosphate buffered saline for a minimum of 30 minutes, blotted dry and measured again for colour (L*, a*, b*).

Colour (L*, a*, b*) values are recorded before and after 800 brushing cycles. The overall removal of stain is calculated using the following CIELAB equation:

\[ \Delta E = \left( \Delta L^* \right)^2 + \left( \Delta a^* \right)^2 + \left( \Delta b^* \right)^2 \]

The Pellicle Cleaning Ratio (PCR) values for each toothpaste are calculated relative to the reference abrasive using the following equation:

\[ \text{PCR} = \left( \frac{\text{Test Paste Mean } \Delta E}{\text{ADA Reference Mean } \Delta E} \right) \times 100 \]

The graph below provides an example of the PCR values obtained from a PCR test.

![Figure 1: PCR data for each toothpaste and the reference abrasive](image-url)
A High PCR value indicates greater removal of stain. Figure 1 shows that toothpaste sample 1 achieved the highest PCR value (PCR 154), indicating that it was the most effective formulation at removing stain, followed by toothpaste sample 3. Statistical analysis of the data showed that these formulations were statistically superior to all other toothpaste formulations at removing stained pellicle.

Figures 2 and 3 provide illustrations of the samples before and after brushing with their assigned treatments.

Supporting your product development and claim substantiation

PCR testing is a cost-effective approach to benchmarking competitor products or new candidate formulations when conducted using a robust test method and the appropriate statistical analysis. Toothpaste formulations with stain removal agents can be screened and ranked using our modified PCR test, either to compare candidates with each other or to benchmark them against existing competitor products. Previous work has indicated that the ranking of products in this test compares favourably with the results of controlled clinical trials and hence may be considered as reasonably predictive, helping to guide product development and support marketing claims underpinning the launch of a new product.

Total Quality Assurance

Our Laboratory team can deliver Total Quality Assurance for our customers and has been a trusted partner for those manufacturing oral care products for many years. Intertek is a leading service provider in the oral care sector offering in vitro method development, bespoke models and rigorous screening of oral care products, supporting safety, product development, regulatory compliance and advertising claim support.

Our Oral Care Product Research Services

Supporting Product Development and Marketing Claims

- Testing of toothpastes, mouthwashes, tablets, toothbrushes, interdental brushes, whitening kits, delivery systems, novel cleaning devices
- In vitro models of cleaning efficacy
- Stain prevention / stain removal
- Abrasivity, tooth sensitivity, enamel erosion
- Remineralization / demineralization testing
- Scanning Electron Microscopy (SEM)
- Anti-plaque and anti-calculus
- Analytical and bioanalytical R&D support

Meet Our Expert

Gavin Thomas
Gavin Thomas MSc, Laboratory Manager
Clinical Research Services

Gavin has over 15 years of experience working within the in vitro oral care sector. He is currently the Laboratory Manager at Intertek Clinical Research Services and leads Intertek's team of scientists delivering a variety of in vitro methodologies for product evaluation and claim support, including enamel remineralization, stain prevention/removal and chemical whitening.

References