

1. J Clin Dent. 2002;13(2):77-81.

A study to assess the tooth whitening efficacy of a new dentifrice formulation variant containing a special grade of silica: a six-week study on adults.

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The objective of this double-blind clinical study was to investigate the tooth whitening efficacy of a formulation variant of a commercially available dentifrice (Colgate Total Plus Whitening Toothpaste) obtained by the addition of high cleaning silica, relative to that of its currently marketed formulation (Colgate Total Toothpaste). Following a baseline examination, qualifying adult male and female subjects were randomized into two treatment groups which were balanced for age, gender and level of extrinsic tooth stain. Subjects were instructed to brush their teeth twice daily (morning and evening) for one minute with their assigned dentifrice, using a soft-bristled toothbrush. After one, and again after two weeks' use of the assigned dentifrices, a randomly selected panel of subjects was examined for soft tissue findings. Examinations for extrinsic tooth stain were repeated for all subjects after six weeks' use of the study dentifrices. Ninety-seven (97) subjects complied with the protocol and completed the entire study. At the six-week examination, subjects assigned to the new dentifrice formulation group exhibited statistically significantly ($p < 0.05$) lower levels of extrinsic tooth stain area and extrinsic tooth stain intensity than did those subjects assigned to the Colgate Total Toothpaste group. Thus, the results of this double-blind clinical study support the conclusion that the new dentifrice formulation variant is efficacious for the removal of extrinsic tooth stain.

PMID: 11695211 [PubMed - indexed for MEDLINE]