- Official Title: Esthetic Outcomes of a Newly Developed Dental Composite and Adhesive System: a Randomized Clinical Trial
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Objective: The aim of this randomized, split mouth clinical trial is to evaluate and compare the esthetic outcomes and patient satisfaction of a simplified newly developed dental composite system (system A) for the esthetic region to a nanohybrid composite system (Filtek Supreme Ultra-system B) placed in class III, IV and V lesions. Even though dental composite systems have been used extensively for the anterior region, clinicians face challenges with shade selection and longevity of the material over the years. This new system has been developed to improve the esthetic outcomes and patient satisfaction by enhancing the blending capability of the material.

Design: This is a randomized, split-mouth study (*ClinicalTrials.gov identifier-NCT03716349*). The study population consists of adult subjects (ages 18-99) that had one pair of class III, IV, or V lesions necessitating restorations. Subjects cannot have fewer than 20 teeth, rampant/controlled caries activity, bruxism, or undergoing or in need of TMJ therapy, or known allergies to methacrylate-based materials.

Methods: Consented subjects will have two restorations placed in their mouth, one restoration using system A and one restoration using system B. Randomization will be done as 1:1, in which each tooth will a 50% chance of being assigned to the restoration using System A or a 50% chance of being assigned to a restoration using system B. Subjects will voluntarily complete questionnaires at study visits.

Statistical Analysis Plan: For system A and system B, the primary outcome is patient satisfaction of the restoration's appearance using the Visual Analog Scale of 0-100 with 0 being a poor result and 100 being an excellent result, specifically at the 5-year visit. Descriptive statistics, including mean, standard deviation, minimum, maximum, median, and frequency distributions, will be compiled to profile the baseline, 6-month, 12-month, 24-month, 36-month, and 5-year clinical categories (such as retention rate, marginal adaptation, marginal discoloration, etc.) for each material. A paired-sample t-test or a non-parametric Wilcoxon signed-rank test (as the assumption of normality is not valid), a chi-square or Fisher's exact test will be conducted to detect the differences in the ratings of the two materials at the baseline, 6-month, 12-month, 24-month, 36-month, and 5 years. A McNemar's test, a paired-sample t-test or a non-parametric Wilcoxon signed-rank test, and chi-square or Fisher's exact test will be used to evaluate and compare the performance of materials between the baseline and each time period. Moreover, Mixed model or GEE (Generalized Estimating Equation) will be performed to explore the associations between clinical categories such as retention rate and independent variables (time and material). All tests will employ a 0.05 level of statistical significance. SAS for Windows (v9.1, SAS Institute Inc, Cary, NC, USA) will be used

for the data analysis. A continuous outcome time-to-failure survival analysis will also be performed including both censored and uncensored data.