<p style="text-align: center">Study Protocol with Statistical Analysis Plan</p>

TİTLE: Retention and Caries-Preventive Outcomes of Glass Ionomer–Based Fissure Sealants in Children: A 24-Month Split-Mouth Randomized Controlled Trial

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RCT: The study was approved by the Medical Ethics Committee of Izmir Katip Celebi University, under report No. 14/100

STUDY PROTOCOL:

This randomized, controlled, double-blind clinical trial was approved by the Ethics Committee of Izmir Katip Celebi University (Approval No: 14/100). Informed consent was obtained from parents, and the study adhered to CONSORT guidelines. A total of 200 healthy children (ASA I), aged 6–12 years, each with two fully erupted permanent mandibular first molars (400 teeth), were enrolled. Using a split-mouth design, one molar received a high-fluoride glass ionomer–based sealant (Fuji Triage, GC Corp., Tokyo, Japan; control), while the contralateral molar was treated with either a CPP-ACP–containing sealant (Fuji VII EP, GC Corp.) or a nano-fluorohydroxyapatite–based sealant (GCP Glass Seal, GCP Dental, The Netherlands). Sample size was calculated using G*Power 3.1.9.7, assuming an effect size of 0.40, $\alpha = 0.05$, and power $= 0.80$, yielding a minimum of 88 teeth per group. Considering a 15–20% potential loss, the final sample included 400 teeth. Inclusion criteria comprised children demonstrating cooperative behavior (Frankl scores 3–4) and having deep fissures without caries (ICDAS II; DIAGNOdent ≤ 15). Exclusion criteria included systemic disease (ASA $\geq$ II), uncooperative behavior, enamel defects, or inability to attend follow-ups. Bitewing radiographs excluded proximal caries. Two calibrated examiners (Cohen's k ≥ 0.8) conducted the study. Screening of 295 children included health history, caries risk assessment (Cariogram software, Malmö University), and inclusion of those with moderate caries risk. Randomization was two-phased: material pairing (Fuji Triage–GCP Glass Seal / Fuji Triage–Fuji VII EP) was determined using an online randomizer, while tooth allocation (right/left) was assigned by coin toss. Blinding was maintained for participants and evaluators. Before sealant application, baseline data (age, sex, oral hygiene, ICDAS II, and DIAGNOdent scores) were recorded. Teeth were cleaned and isolated; materials were applied per manufacturers' instructions. For Fuji materials, cavity conditioner was used for 10 s, followed by sealant placement, coating, and 20 s LED curing. GCP Glass Seal involved EDTA cleaning, 60 s light-curing, and surface coating with GCP Gloss. All restorations were inspected for marginal adaptation and polymerization, and occlusion was adjusted. Oral hygiene instructions were provided. Follow-up evaluations were conducted at 3, 6, 12, 18, and 24 months by a blinded examiner. Retention, marginal integrity, discoloration, and secondary caries were assessed using modified USPHS criteria. Retention was graded (1 = complete, 2 = partial, 3 = total loss); further caries evaluation (ICDAS II and DIAGNOdent) was performed for scores 2–3.

STATİSTİCAL ANALYSİS PLAN

Data were analyzed using IBM SPSS v21. Descriptive statistics were expressed as mean ± SD or percentage. Normality was assessed with the Kolmogorov–Smirnov test. Non-parametric tests (Friedman, Kruskal–Wallis with Bonferroni correction) were used where appropriate. Categorical data were analyzed using Fisher-FreemanHalton, Pearson chi-square, or Fisher's exact tests. Kaplan–Meier curves and log-rank tests compared material survival. Statistical significance was set at $p < 0.05$.