Title of the study: Long Term Clinical Evaluation of a Posterior Glass Hybrid System vs. Composite Resin: a Controlled Clinical MultiCenter Study

NCT number: 02717520

Date: November 7th, 2019

Objective: To evaluate clinical effectiveness of a glass hybrid restorative material as a long-term restorative material in moderate and large size two-surface restorations versus a nano-hybrid composite resin material.

Study design: Split-mouth, randomized, prospective and multicentre study.

Methods:

Study population: Healthy patients in need of two surface restorations in the molar region of the same jaw.

Inclusion criteria:

1. Subject > 18 years.
2. Subjects with restorative treatments on vital teeth in posterior molar region.
3. Subjects with indication for restorative treatment on vital teeth in posterior molar region.
4. Restorations limited to two surfaces with one proximal cavity in occlusion.
5. Favourable and stable occlusal relationship between the remaining teeth.
6. Subject must be reliable, cooperative, and in the opinion of the Investigator, likely to be compliant with study procedures.
7. Subject provides written informed consent signed and dated prior to entering the study.

Exclusion criteria:

1. Subject with full dentures or crowns and bridges in oclussal contact with teeth indicated for restorative treatment.
2. Subject has a history of drug abuse, addiction to medication or alcohol abuse within the previous year.
3. Pulp exposure.
4. Known unavailability of subject for recall visit(s).
5. Allergy to any ingredient of a material.
6. Severe bruxing.
7. Subject has a clinically significant or unstable medical or physiological condition.
8. Female subject is pregnant or lactating or intends to become pregnant during the course of the study.
9. Subject not willing to participate in the study or not able to understand the content of the study

Intervention: Each patient enrolled in the study received one restoration with a glass hybrid material (EQUIA Forte, GC, Tokyo, Japan) and one with a nano- hybrid composite resin material (Tetric EvoCeram, Ivoclar Vivadent, Schaan, Liechtenstein), according to the manufacturers' instructions.

Clinical Evaluation

Recall Periods: One week after placement of the restoration (baseline), and yearly up to 5 years according to the FDI-2 criteria (Hickel et al. 2007; Recommendations for conducting control clinical studies of dental restorative materials. Clin Oral Invest. 2007; 11:5-33).

Statistical Analysis Plan

Descriptive statistics were primarily implemented. To test the performance of the restorative materials according to the FDI-2 criteria over the study period, Sign test is going to be used and the level of significance is set at $\alpha=0.05$.