Title:

3-year Evaluation of the Clinical Performances of a Self-adhesive Hybrid Resin Composite Compared to a Traditional Composite Resin Used for Direct Restorations of Non-carious Cervical Lesions (NCCLs): A Split-mouth Randomized Clinical Trial

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3-year Evaluation of the Clinical Performances of a Self-adhesive Hybrid Resin Composite Compared to a Traditional Composite Resin Used for Direct Restorations of Non-carious Cervical Lesions (NCCLs): A Split-mouth Randomized Clinical Trial

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Anticipated number of study sites: 1 study site.

Anticipated number of subjects: 50 (split-mouth design, i.e. Surefil one n=50, and Venous Pearl n=50).

Background and overall aim

Non carious cervical lesions (NCCL) are often restored due to dental sensitivity caused or for aesthetic reasons and in order to prevent further loss of mineralized tissue, with consequent pulp exposure. Numerous protocols of treatment have been proposed for V class cervical lesions. Treatment depends on the location and degree of dental materialized tissue loss, however, as soon as the lesion exposes the dentin, the restorative treatment may become necessary. Restorative therapy is often complicated by the absence of sufficient enamel tissue, dentin sclerosis and difficulty in isolation of the field. Furthermore, since the class V lesions tend to involve the anterior segments of the dental arches an incongruous restoration or pigmentations on the margins could affect the patients' smile. Current research is directed towards the development of new materials and the improvement of the adhesion between the restorative materials and the mineralized dental surface trying to respect as much as possible the healthy dental tissues, and to obtain an impeccable aesthetics. In fact, we know that an unsatisfactory aesthetics is the main cause of rebuilding a restoration in the anterior section, unlike the posterior sectors where the main motivation for reintervention is bacterial infiltration that causes secondary caries.

The aim of this study will be to demonstrate non-inferiority in terms of clinical performance and patient discomfort after direct restorative treatment of class V NCCL with Surefil one restorative material (Dentsply Sirona) in comparison with traditional paste composite "Venus Pearl" employed in combination with iBond universal adhesive (Kulzer Dental) during an observational period of 3 years.

Study objectives

Primary objective

The primary objective is assessment of restorative quality at 36 months follow-up using FDI and USPHS criteria.

Secondary objectives

The secondary objectives are to evaluate:

- Restorative quality at 6-, 12- and 24-months follow-up using FDI and USPHS criteria.
- Aesthetics at 6-, 12-, 24- and 36-months follow-up.
- Level of pain at 6-, 12-, 24- and 36-months follow-up.
- Time needed to perform the restoration.
- Safety

Study design

This is a split-mouth randomized clinical investigation conducted to evaluate clinical performances of a self-adhesive hybrid resin composite (investigational medical device Surefil) compared to a traditional composite resin, when used for direct restorations of non-carious lesions (NCCLs). The study consists of a 3-year long follow-up period.

Study population

All patients will be treated at the Department of Conservative Dentistry of the University of Bologna, Italy. Patients showing NCCL will be screened to assess if they are eligible for participation according to below criteria.

Inclusion criteria

For inclusion in the study subject must meet all of the following criteria:

1. Patients aging from 18 to 70
2. 40-60% women, 40-60% men
3. Patients who present at least 2 cervical lesions on canines and / or upper premolars on vital teeth
4. Patients who are not allergic or sensitive to the ingredients contained in the products
5. The test patient consents to the restorative treatment in line with the study´s criteria (informed consent)
6. Sufficiently understanding of the language

Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

1. Extremely low level of oral hygiene
2. Teeth with previous restorations
3. Not possible adequate isolation of the operating area
4. Patients with serious systemic diseases
5. Devitalized teeth or with pulpitis in progress
6. Periodontal problems on the elements to be restored

Materials employed in the study

Adhesives: iBond Universal Adhesive (Kulzer, Germany).

Composites:

- Surefil one (Dentsply Sirona, Germany)
- Venus Pearl (Kulzer, Germany)

Indication

Surefil one™ self-adhesive composite hybrid is a permanent bulk fill material for posterior restorations.

Data Analyses:

The differences between the two groups will be analyzed using a descriptive and inferential statistical analysis. The statistical analysis will be performed by the department of Biomedicinal and Neuro-Motor Sciences (DIBINEM) of the University of Bologna.

Study timetable

Anticipated study start:	Sep 2022
Anticipated completion:	Sep 2026