Clinical Evaluation of IPS Empress inlays luted with a self-adhesive resin cement: two year report

Reference: CED 2007 #0013

Investigators
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Aim of the Study
Aim of this prospective controlled clinical study is to compare the clinical performance of two different resin cements (RelyX Unicem, 3M ESPE and Variolink II low/Syntac, Ivoclar Vivadent) for luting IPS Empress inlays and onlays.

Study Design at a Glance
Design: Prospective, randomized, controlled clinical study, Split mouth design
Test Material: Self-adhesive RelyX Unicem Maxicap (3M ESPE) (RX-Group)
Control Material: Variolink II low in combination with the multi-step adhesive Syntac Classic (Ivoclar Vivadent) after Total Etching (SV-Group)
Number of patients included: 30
Number of IPS Empress restorations included: 83 (70 Class-II inlays, 13 onlays); 43 inlays/onlays luted with RelyX Unicem; 40 inlays/onlays luted with Variolink II low/Syntac Classic

Pretreatment of restorations: Etching with hydrofluoric acid and silanating; in the control group appliance of Heliobond (Ivoclar Vivadent) to the restorations
Number of blinded Examiners: Two
Evaluation criteria: Modified USPHS criteria
Statistical evaluation: Mann-Whitney Test, Kaplan-Meier, Log Rank-Test

Status of Study
Baseline 1 year report (√) 3 year report (√) 4 year report (-)
Year 1 Year 2 Year 3 Year 4
6 months report (-) 2 year report (√) 4 year report (-)

Inlay luted with RelyX Unicem at Baseline: Tooth 47
Inlay luted with RelyX Unicem after 2 years: Tooth 47
Results

**Number of patients/restorations involved in 2-year recall:** 30/82 restorations (43 RelyX Unicem; 39 Syntac/Variolink II)

**Failures:** One in the Syntac/Variolink II group due to marginal enamel chipping (detected at 6 months recall)

**Scores (Alpha I/Alpha II/Bravo/Charlie/Delta) [%]** with Alpha I=Excellent, Alpha II=Good, Bravo=Sufficient, Charlie=Insufficient, Delta=Poor:

- **Surface Roughness:** RelyX (98/2/0/0/0), Syntac/Variolink II (100/0/0/0/0), Color Match: RelyX (84/16/0/0/0), Syntac/Variolink II (92/8/0/0/0), Marginal Integrity: RelyX (0/67/33/0/0), Syntac/Variolink II (5/92/3/0/0), Integrity Tooth: RelyX (23/68/9/0/0), Syntac/Variolink II (49/46/5/0/0), Integrity Inlay: RelyX (63/12/25/0/0), Syntac/Variolink II (56/18/26/0/0), Proximal Contact: RelyX (100/0/0/0/0), Syntac/Variolink II (90/10/0/0/0), Hypersensitivities: RelyX (100/0/0/0/0), Syntac/Variolink II (100/0/0/0/0).

![Graph showing evaluation criteria](image)

Alpha I, Alpha II, Bravo → clinically acceptable; Charlie, Delta → clinically not acceptable

After two years, both materials showed clinically acceptable results for all evaluation criteria. No significant differences were found between Syntac/Variolink II low and RelyX Unicem regarding surface roughness, color match, integrity inlay and hypersensitivities.

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**Conclusions from Report**

“The self-adhesive resin cement RelyX Unicem showed acceptable clinical behaviour after two years of clinical service.” (Taschner at al., CED 2007).

No hypersensitivities were reported for both materials used, RelyX Unicem and the control material as well.

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**Related Clinical Evaluations**
