Test plan
Clinical trial of two fissure sealants -

Version 3.0

September 01, 2021

Synopsis

Title:	Clinical trial of two fissure sealants
Testing institute:	1. Polyclinic for Conservative Dentistry and Periodontology, LMU Munich, Munich (Germany) 2. Graeser Dental Practice, Friedbergstrasse 7, 8820 Wädenswil (Switzerland)
Sponsor:	Ivoclar Vivadent AG, Bendererstr. 2, 9494 Schaan (Liechtenstein)
Clinical indication:	Fissure sealing for caries prevention in children and adolescents
Aim of the study:	Comparison of two different fissure sealants
Target criteria: **Primary endpoint:**	Retention rate of the applied fissure sealants
Secondary endpoints:	Occurrence of caries
Study design:	Two-center, randomized, prospective, blinded study in a "split-mouth" design
Test products	The medical devices to be tested (Helioseal F and Helioseal F Plus) are assigned to class IIa. CE marking is available.
Treatment plan:	Sealing of at least one pair of teeth per test subject Follow-up after 7-28 days, 6 months, 1 year, 2 years, 3 years
Selection of patients	From the patient pool of the trial centers
Inclusion criteria	Inclusion criteria for a patient - Indication for sealing the fissures - ASA status 1 - All dentin lesions in need of restoration have been repaired - Consent of the parents and the patient - Detailed instruction and demonstration of age-appropriate oral hygiene, accompanying prevention concept. - Age: 5-13 years (Wädenswil) - Age: 5-18 years (Munich) Inclusion criteria for tooth pair to be sealed - 1st or 2nd permanent molars

Exclusion criteria	Exclusion criteria for a patient - No consent of the parents / patient - Allergy and known intolerance reactions to methacrylates or other components of dental sealing/restorative materials Exclusion criteria for tooth pair to be sealed - Molars with clinical cavitations on the occlusal surface (UniViSS occlusal score ≥ M) - molars with untreated dentin lesions according to the clinical examination. If necessary, a bitewing radiograph is indicated. - Premolars, permanent anterior teeth with sealable pits, deciduous molars - Extensively restored teeth where sealable parts of the occlusal surface are included in the restoration. - - Teeth with hypomineralization or other structural disorders or shape anomalies
Methodology:	- Cleaning the tooth surfaces and fissures with cleaning paste (Proxyt green) and a rotating brush - Removal of paste residues by water rinsing - Blow the tooth surface dry well with a strong stream of air - Relative draining (LMU Munich) / rubber dam (Graeser dental practice) - Conditioning with a 37% phosphoric acid etching gel - Sealing of fissures and pits o Test group: Helioseal F Plus o Control group: Helioseal F

Statistical analysis	The retention of the fissure sealants used is analyzed using survival curves (Kaplan-Meier), with the proportion of intact fissure sealants serving as the primary endpoint. Caries infestation and incidence serve as secondary endpoints. The study design was chosen to test for non-inferiority of the newly developed sealant (Helioseal F Plus). The nQuery Advisor 6.0 program (Statistical Solutions, Saugus, MA, USA) was used to estimate the number of cases and a scenario for the non-inferiority of two fissure sealing techniques was calculated. The underlying assumptions are: The underlying assumptions are: - Study objective: To demonstrate the non-inferiority of the experimental therapy compared to the established standard therapy - Main outcome measure: Proportion of intact fissure sealings - Conjoined samples (split-mouth design) - Alpha level: 5% (two-sided) - Power: 80% $$n_a = n_b = \left(\frac{p_a(1-p_a)}{k} + p_b(1-p_b)\right)\left(\frac{z_{1-\alpha/2} + z_{1-\beta}}{p_a - p_b - \delta}\right)^2,$$ N= 55 pairs of teeth per group As a result of the case number estimation, 55 pairs of teeth per site should be included. Due to an expected drop-out of about 10%, additional patients must be included, so that a number of 61 tooth pairs per group and 122 in total seems appropriate. Therefore, at least 120 pairs of teeth are planned at the start of the study, with at least 60 pairs of teeth to be sealed in each study center.
number of patients:	120 pairs of teeth (60 per study location)
Schedule:	Recruitment: Following approval (from the end of Q2 2018) Baseline examination & sealing (T0; from the end of Q2 2018) Follow-up examination I 7-28 days after T0 Follow-up II 6 ± 1 months after T0 Follow-up III 12 ± 2 months after T0 Follow-up IV 24 ± 2 months after T0 Follow-up V 36 ± 2 months after T0
Risk category according to Art. 20 ClinO	Category A