

Study Title:

**A Clinical Trial Comparing Isolite® Vs Cotton Roll Isolation in the Placement
of Dental Sealants**

Clinical Trials ID: 201502801

Documents attached:

**Study Protocol
Statistical Analysis Plan**

Date: 9/1/2019

STUDY PROTOCOL: MATERIALS AND METHODS

Children attending the College of Dentistry Department of Pediatric Dentistry Clinics, 6-16 years of age were invited to participate in this study. Inclusion criteria for the study included two matched permanent contralateral (non-carious, not previously sealed or restored) fully erupted premolars and/or molars, cooperative children. Matched contralateral pairs of first and second molars/premolars were randomized to receive sealants with Isolite® or cotton roll isolation. Pits and fissures were scored for staining (stained or not stained) and depth (wide and shallow, normal, or deep and narrow) prior to sealant placement. Calibrated pediatric dentistry residents placed all sealants. Moisture contamination was recorded at the time of placement. Patient and operator acceptability and satisfaction were collected after sealant placement by direct reporting of both groups. Time for sealant placement was also recorded for each side in minutes. This study was approved by The University of Iowa Institutional Review Board (IRB # 201502801) and has been registered with The ClinicalTrials.gov #NCT02668874.

STATISTICAL ANALYSIS:

Descriptive statistics were used to provide meaningful insight regarding patients' and providers' acceptability and satisfaction. The exact binomial test was used to assess acceptability of one isolation technique over the other, namely we tested whether specific proportions of acceptability of the cotton roll isolation technique differed significantly from 50%. The nonparametric Wilcoxon signed-rank test was used to test the potential difference in the distribution of procedural time. Retention, marginal adaption and caries incidence rates were compared across isolation techniques using McNemar Test (or equivalently the exact binomial test). Mandibular versus maxillary rates and molars versus premolars rates were compared via Fisher exact tests. Retention, marginal adaption and caries incidence rates were also reported for others subsamples of interests. All analyses were conducted using a 5% significance level.