DryShield vs Cotton Roll Isolation During Sealants Placement: Efficiency and Patient Preference

NCT#: NCT02995369
Protocol ID: 2016-7229
Version Date: 12/7/2016

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Elements of Protocol

Introduction and background

In a survey conducted by the National Center for Health Statistics in 2011-2012, approximately 37% of children aged 2–8 years had experienced dental caries in primary teeth. Dental caries among children aged 2–5 was nearly 23% compared with 56% among those aged 6–8. Of children aged 6–11, 21% had experienced dental caries in permanent teeth. Dental caries among children aged 6–8 was nearly 14% and was twice as high for children aged 9–11. Among adolescents aged 12–19, 58% had experienced dental caries in permanent teeth. The prevalence of dental caries experience was higher among adolescents aged 16–19 (67%) compared with those aged 12–15 (50%).[1] Pit and fissure caries account for 80 to 90 percent of all caries in permanent posterior teeth, and 44 percent in primary molars.[2]

Pit-and-fissure sealants can be used effectively to prevent caries. By micromechanically bonding to the teeth, they provide a physical barrier that keeps microorganisms and food particles from collecting in susceptible pits and fissures, thus preventing caries initiation and arresting caries progression.[2]

It has been shown that sealants placed on the occlusal surfaces of permanent molars in children and adolescents reduced caries up to 48 months when compared to no sealants. Moreover, their placement reduces caries incidence of 86 percent after one year and 57 percent at 48 to 54 months.[3] The effectiveness of sealants for caries prevention depends on long-term retention, which is largely a function of meticulousness of application: keeping the tooth surface free from saliva contamination during application and polymerization is critical[4]. Low retention of sealants has been attributed to insufficient moisture control. [5] Therefore, proper isolation of the teeth is one of the most important steps when placing sealants to ensure their retention. [6]

Several techniques can be used to isolate teeth when applying sealants. The gold standard for isolating teeth has been the rubber dam. However, it often requires the use of a local anesthetic before its placement. Cotton roll isolation (CRI) has been widely used as an alternative to rubber dam isolation for sealant placement, and is the most common method among pediatric dentists. [7] CRI requires placing cotton rolls along the buccal mucosa, especially over the parotid glands ducts for maxillary teeth. For the mandibular teeth, the cotton rolls are placed in the buccal vestibule and the floor of the mouth (between the lower buccal mucosa and underneath and/or between the tongue). With this technique, a high-speed evacuation of saliva and water is used. Although very effective, CRI can be a challenging technique especially when used in young children: the cotton rolls can be cumbersome for both the patient and the clinician[8]; additionally, the cotton rolls

have to be changed after and/or during each quadrant as they absorb saliva very quickly.[6]

A previous study demonstrated that new moisture control systems such as Isolite, produce sealant retention rates comparable to cotton roll isolation or rubber dam, while decreasing procedure time.[6,9] DryShield (DS) has recently been introduced as an all-in-one isolation system. It is similar to the Isolite as it combines the tasks of fluid evacuation, tongue and cheek retraction, and serves as a bite block, but differs in that it's autoclavable and does not provide illumination. Its design allows it to suction and isolate half the oral cavity at a time. Therefore, it should presumably facilitate sealants placement under a more controlled environment, while reducing chair time for the dentist. Colette et al. evaluated patient satisfaction and efficacy of the Isolite during sealant placement, and showed better time efficiency with the Isolite system when compared to cotton roll isolation, some minor discomfort associated with the Isolite, with no significant patient preference for the Isolite or cotton roll isolation.

Research questions/objectives

The goals of this study are to determine if 1) placement times of pit and fissure sealants using the DryShield system differ from those when using the cotton roll isolation technique; and 2) there is a significant difference in patient preference between Dryshield and the cotton roll technique.

Study design

This is a split-mouth, randomized controlled trial study. When patients meeting the inclusion criteria arrive for their sealants application appointment at one of the four pediatric dental clinics of Montefiore, the study protocol will be explained, and patients and parents will be given the option of participating. Once the informed consent has been obtained (patient assent and parental consent), the patients will be randomized into four groups with randomization ratio 1:1:1:1, with each patient acting as their own control. The four groups are a result of randomizing the side receiving one of the interventions (CRI v. DS) as well as the order of application (first v. second). Randomization will be determined using a random number generator in SAS, that will produce envelope inserts with the allocation codes for that subject. Sealed envelopes containing inserts will be labeled with sequential numbers and the next envelope in the sequence will be opened in conjunction with the next subject who qualifies. The four groups are:

Group 1) Sealants placement using CRI on the left side, followed by sealants placement using DS on the right side

Group 2) Sealants placement using CRI on the right side, followed by sealants placement using DS on the left side

Group 3) Sealants placement using DS on the left side, followed by sealants placement using CRI on the right side

Group 4) Sealants placement using DS on the right side, followed by sealants placement using CRI on the left side

One operator will apply all the pits and fissure sealants in a given subject.

Subjects

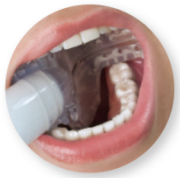
The target population will include healthy (ASA I/II), deemed able to cooperate children who present to one of the Montefiore pediatric dental clinics for an intake or a recall visit who are determined to benefit from sealants application, or patients who present solely for a sealant application appointment, when their examination was done at a previous date (within 6 months). The sample of patients will range from 5 to 14 years of age. They will be selected based on their cooperative behavior displayed during their visit or recorded at the previous encounter (classified as 3 or 4 according to the Frankl Behavioral Rating Scale). Patients included in the study need to have at least one erupted caries-free permanent molar in each quadrant. Subjects must be able to speak English or Spanish. There will be no exclusions based on race, gender, and ethnicity. Uncooperative, medically compromised patients requiring fewer than four sealants on permanent molars will be excluded. Those who do not provide appropriate assents or consents will be excluded. There are no risks nor benefits for participating in that study. Children participating will only benefit from the sealants application planned as part of their treatment.

Study procedures

When presenting for their scheduled intake or recall appointments, and it has been determined during the examination that the patient would benefit from sealants application, parents of potential subjects meeting the inclusion criteria will be asked if they would like their child to participate in the study. The same will be done for patients coming exclusively for their sealants placement. Informed consents and assents will be obtained at the time of the visit targeted for sealants placement. One operator will apply all the pits and fissure sealants in a given subject with the help of a dental assistant. In each patient, the DS and the CRI will be used to seal maxillary and mandibular molars (either on the left or right side, first or second). The correct size of the autoclavable DS mouthpiece will be picked according to the manufacturer's recommended guidelines.

MOUTHPIECE SIZES

Age Consideration	Dentition Guidelines	Size
7–8 years of age and younger	Primary or mixed dentition	Pedo
9 years of age to young teen	Fully-erupted permanent 1st molars	Small
Teens to adults	Existing permanent 2nd molars	Medium
Adults	Permanent dentition with large vertical opening	Large



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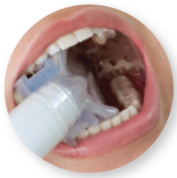

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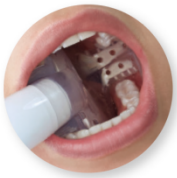

Correct Fit

In the DS group, no other suction device will be used. In the CRI intervention, a Molt mouth prop will be used to help the patients keep their mouth open; an assistant will handle a high-speed suction as well as a saliva ejector.

After the molars are isolated, the technique used for sealant application will be exactly the same for both isolation systems. The teeth will be cleaned using a prophylaxis cup and pumice, rinsed thoroughly, etched with 40% phosphoric acid gel for 15 seconds, rinsed thoroughly, air dried, and sealed with Embrace Wetbond pit and fissure sealant by Pulpdent as per standard protocol, and light cured for 20 seconds. Following placement and curing, the sealants will be checked for proper retention and voids with an explorer. In the case of any voids, defects or material dislodgement, the results will be recorded and the sealant reapplied. The time for sealant application will be recorded with a stopwatch by the dental assistant as follows for the two techniques: the insertion of the isolation aids (DS or CRI) in the oral cavity will constitute the start time, and the end time will coincide with the time when the isolation aids are removed from the oral cavity after the sealants application.

A seven-item survey will be used to evaluate patients' acceptance and satisfaction of CRI and DS. This modified close-ended questionnaire was previously developed and used in a study, which evaluated the efficacy and patient satisfaction associated with the use of Isolite and CRI by Colette et Al. The items will reflect issues of comfort, noise, taste, tissue stretching. The pediatric dental attending will ask the patient each question verbally in the same sequence at the end of the visit.

Patient's preference questionnaire: Cotton roll isolation vs DryShield

Date: MM/DD/YY

Child ID:

Start time of DS: End time of DS:

Start time of CRI: End time of CRI:

Randomization Group:

Please circle the appropriate answer (to be read to subject):

1.	Which system made the most noise?	CRI	DS
2.	Which system stretched your mouth, cheeks, and lips the most?	CRI	DS
3.	Which system was the most comfortable	CRI	DS
4.	If we did the procedure again, which system would you prefer?	CRI	DS
5.	Did either system made you feel as if you needed to gag?	No	Yes
	If yes, which system made you feel like you needed to gag the most	CRI	DS
6.	Did you taste any of the materials used?	No	Yes
	If yes, with which system did you taste the materials the most?	CRI	DS
7.	Did either system cause any discomfort?	No	Yes
	If yes, which system caused the most discomfort?	CRI	DS

Statistical analysis

Estimates of the mean time to completion of the procedure were 398 for CRI and 340 for IS (Collette, 2009). Because the within subject standard deviation was not provided in the Collette 2009 and Lyman 2012 articles, we assumed a standard deviation for the paired/split-mouth design between CRI and IS to be 100 seconds. For an overall α=.05 (as per Lyman) considering two main hypotheses (DS v. CRI; right v. left), then 31 subjects are required for a two-tailed test with 80% power. It is expected that the distribution of differences from right to left, as per a split-mouth randomized design, will be somewhat normally distributed and CRI .

Descriptive statistics will be presented as means and standard deviations for normally distributed data, or medians and ranges if continuous and nonnormal.

Relative frequencies will be presented for dichotomous variables by group, intervention order and side. The statistical analysis is similar to that for a cross-over design in which a side by treatment interaction and first/second application by treatment interaction have to be considered in the analysis. The analysis will be done using a general linear model that accounts for pairing within subject and the interactions described. Preferences for treatment will be presented as proportions along with 95% or 99% confidence intervals as per the predetermined α level.

Implementation plan/timetable

The researcher will perform enrollment of subjects, obtain informed consent and assent, collect data, and perform data entry, management and analysis. Subjects will be enrolled at each of four Montefiore Pediatric Dental Clinics, including 1516 Jarrett Place, 5500 Broadway, 951 Prospect Avenue, and 3444 Kossuth Avenue. Numbers will be assigned to each patient to ensure patient privacy and all other identifiers will be removed. Patient enrollment and data collection will begin once IRB approval is obtained

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