Tufts University
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# Effectiveness of the Isolite System vs. Rubber Dam Technique While Placing Pit and Fissure Sealants in Pediatric Patients

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# Abstract

***Introduction*:** With the wide use of pit and fissure sealants for caries prevention it is important to highlight the fact that isolation is a key factor for pit and fissure sealant retention and success. However, means for proper teeth isolation may be challenging during pit and fissure sealant application especially for the pediatric patients. This has led many healthcare professionals to seek alternative methodologies for proper tooth isolation.

***Purpose:*** The aims of this clinical study were to compare the chair time and patients' acceptance to the Isolite system (IS) *vs* Rubber Dam (RD) during pit and fissure sealant placement in pediatric patients.

***Methods:*** Pediatric patients at the clinic in the Department of Pediatric Dentistry at TUSDM whose ages ranged between 7-16 years were recruited for the study. Pit and fissure sealants were placed on one permanent molar in each quadrant using IS on one side and RD on the other. Subjects were randomized to start with either IS or RD. Chair time for dental sealant placement was recorded for each side. Also, patient acceptance was rated by asking the patient to evaluate the noise, soft tissue stretching, overall comfort, system of choice in case of redo, gagging, taste and overall discomfort.

***Results:*** A total of 42 subjects (23 females and 19 males) were enrolled in the study. The average chair time was 19.36 minutes for placement of pit and fissure sealants in the RD side, and 10 minutes for the IS side ($P<.001$). Sixty-nine percent of the subjects were more comfortable using IS while 31% found RD more comfortable ($P= .019$). Seventy-four percent preferred using Isolite if they had to have the procedure again,

while 26% prefered rubber dam (*P*=*.002*). Twenty-six percent of the patients responded that they did not have any discomfort with either of the two systems, while 74% responded positive for discomfort experienced. Fifty-seven percent reported more discomfort with rubber dam, while 17% reported more discomfort with Isolite (*P* = .003).

***Conclusion:*** Isolite is a viable alternative to the conventional rubber dam. The use of Isolite is associated with reduced chair time and greater patient satisfaction.

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# Introduction

Occlusal surfaces account for about 12.5% of the total tooth surface [1], and despite this small percentage, pit and fissure caries account for about 80-90% of dental caries in children's permanent teeth. Pit and fissure areas are hard to access with a toothbrush so it is easy for food and bacteria to become trapped and cause decay [2]. Several measures have been used to prevent dental decay, and the most commonly known and widely used measure is fluoride. Fluoride causes a notable reduction of caries, but unfortunately the enamel of pits and fissures were less likely to be affected by the systemic and topical use of fluoride. A survey conducted by the National Institute of Dental Research (NIDR) in 1986-1987 showed only 10% reduction of occlusal caries, compared to 60% reduction of proximal surfaces caries in a fluoridated community when compared to the general population (non-fluoridated community) [3]. A two-year longitudinal study was conducted on caries-free children in order to compare the effects of using fluoride rinse alone and using sealant placement in addition to a fluoride rinse regimen in addition, the results showed that 78% of the children who used fluoride rinse only were caries-free, 96% of children who used fluoride rinse with the additional benefit of pit and fissure sealants were caries-free [4]. The first 2-4 years after eruption of molars were assumed to be the most vulnerable period for molars to be affected by dental caries [5]. This assumption was supported by the findings of Vehkalahti et al. (1991), where an annual occlusal caries occurrence rate of 5.9% per year was evident, 15% of which occurred at age 8 and 10% at age 9 [6].

Efforts to prevent occlusal caries can be dated back to the early 1920s, a task

pioneered by Thaddeus Hyatt in 1924, who placed prophylactic class I amalgam fillings on molars soon after eruption [7]. In 1929, a more conservative approach was executed by Bodecker; mechanical eradication of fissures was suggested to transform deep fissures into shallower and thus more easily cleanable fissures, a concept later coined as a prophylactic odontomy [8]. Others replicated the previous two techniques for years until the introduction of acid etching techniques, which came about in the 1950s. Cyanoacrylate, the first sealant material to be used, it was not considered to be an acceptable sealant material due to its tendency for bacterial degradation when placed in the oral cavity [9]. By the late 1960's, a new material was created through the chemical reaction of bispehnol A with glycidyl methacrylate—resin, a dimethylacrylate termed BIS-GMA [9]. BIS-GMA, a viscous resin resistant to degradation, was capable of forming a strong chemical bond with etched enamel. BIS-GMA was granted approval for its usage in restorative dentistry, especially for pit and fissure sealants.

There is an important difference between restorative materials and pit and fissure sealants. Restorative materials contain filler particles such as quartz or porcelain, which are added to increase strength. Pit and fissure sealants, on the other hand, exist in two forms: unfilled resin or resin that consists of relatively lower number of fillers in its chemical composition. After its discovery in the 1970s, glass ionomer became popularly used as a pit and fissure sealant over BIS-GMA because of its ability to release fluoride in addition to its physiochemical bond to both enamel and dentin following acid conditioning [10]. However, glass ionomer demonstrated poor retention into pit and fissures, which led to minimizing its acceptance and instead rendering it

as an interim preventive agent when there are concerns about moisture control compromising the sealant placement [11]. Nowadays, dental caries are easily prevented by the use of dental pit and fissure sealants, which block the pits and fissures in molars of young children from carious attack. Dental pit and fissure sealants, when placed properly, serve three primary purposes: prevent caries from occurring, arrest caries development in early carious lesions and reduce the number of caries-causing bacteria. Studies have reported an 86% reduction in the amount of caries present after one year of sealant application, 78.6% after two years and 58% after four years [12-14].

Pit and fissure sealant usage has gradually increased over the years. In 2010, up to 50% of children had pit and fissure sealants placed on their molars, an upward climb of only 10% in 1980, 22.5% in 1986-1987 and 30.5% in 1999-2002. [15-17] Pit and fissure sealants have been shown to be safe and effective when applied correctly to teeth. The appropriate application protocol includes: isolation of the teeth, air polishing of the enamel surface of the teeth and etching with 35% phosphoric acid for 15 seconds [18]. However, the effectiveness of pit and fissure sealants was found to gradually decrease proportionately with time post pit and fissure sealants application. Studies have shown that the caries rate have increased from 4% after the first year of sealant application and may reach up to 31% after seven years post sealant application [13, 19, 20]. The main reason for decreased effectiveness is the loss of sealant retention, with a decrease in sealant retention from 92% after the first year post application to 66% after the seventh year post application (Table 1). [13, 19, 20] Despite the important role pit and fissure sealants played in the prevention of occlusal surface

caries, dental care providers did not use them as extensively as they are used today [21]. Some authors reasoned that the insufficient practice of dental pit and fissure sealants at the time was due to the emphasis on restoration rather than prevention of dental caries [14, 22]. Others suggested that some dental care providers were still not confident in the long-term outcome of sealant treatment [19]. A major concern regarding pit and fissure sealants is the sealing over of a carious tooth [13, 23]. Although, current protocols support placing pit and fissure sealants over active noncavitated occlusal caries lesions [22, 24, 25]. American Dental Association also recommends sealing over early non-cavitated carious lesion [11].

Isolation is one of the most important factors affecting pit and fissure sealants retention. Studies have reported a decreased bond strength of pit and fissure sealants when contaminated with saliva [11]. Saliva contamination of the tooth structure after the acid-etch conditioning prevents the formation of tags and thereby eliminates the potential for the mechanical retention [26, 27]. There are different techniques for tooth isolation while placing dental pit and fissure sealants: cotton rolls, dry-angles or the ADA recommended protocol using rubber dam isolation. Sanford Christie Barnum first invented the rubber sheet for isolation nearly one hundred and fifty years ago in 1864 [28]. A few years later, in 1882, White and Palmer introduced the rubber dam punch and the clamps used to hold the rubber dam in place [29]. Since that time, rubber dam isolation has been considered to be the best isolation technique among all the isolation techniques used for dental resin restorative materials or dental pit and fissure sealants [30-33].

Rubber dam usage has many advantages, which includes providing an aseptic environment and preventing microbial contamination during root canal treatment or restorative procedure. Microbial contamination was found to be reduced by 90-98% when a rubber dam was used for isolation [34]. Rubber dam isolation minimizes the potential risk of transferring infective microbes between the operator and the patient [35]. It also plays an important role in preventing any possible ingestion or aspiration of dental instruments during a dental procedure [36-40]. Rubber dam isolation can also prevent frequently occurring air emphysema when restoring Class V lesions in older patients [41]. Additionally, it protects the gingiva and the surrounding oral soft tissue from possible irritations created by any material or irrigation liquid used during the treatment [42, 43]. Retraction of the surrounding soft tissue serves as yet another significant advantage for any dental procedure performed under rubber dam [44]. Rubber dam isolation provides an excellent dry dental field, improves optimal restorative placement environment, prevents restoration microleakage and maximizes overall restoration longevity [31, 32, 45, 46]. The control of contamination improves the operator's quality of work and enhances the quality of the restoration itself [47]. In addition to these advantages, patients expressed more comfort during a dental procedure that was performed using rubber dam over one performed without it [48, 49]. Particularly in pediatric dental care, the rubber dam was considered to be an important aid in allowing positive pediatric patient behavior during dental treatment [30]. Conclusively, there are several advantages of rubber dam isolation that are serving for less malpractice claims from dental malpractice insurance companies [50]. Although, rubber dam isolation has been showing a huge importance in providing dental care, many dentists fail to use it in their daily restorative work [51].

The first survey for percentages of rubber dam usage in 1956 was as low as 2-4%, [52] but the percentage reached up to 10% in 1960 [52, 53]. In 1964, Wolcott and Goodman [54] found 23% of dentists reported that they use rubber dam isolation 30% or more of the time. Still, the percentages of rubber dam use was quite low, as Joynt et al 1988 [51], stated 10-17% of dentists only use rubber dam isolation for restorative procedures. In the United Kingdom, Marshal and Page in 1990 [55] found as high as 70% of the dentists ignore utilizing it for any dental procedure. This was confirmed by another survey carried out in the UK by Jenkins et al. 2001 [56], as 44.5% of the participating dentists stated that they never used a rubber dam, and less than 19% used it routinely. On the other hand, Hagge et al [52] in 1984, found that 52.4% of general dentists in US Air Force Dental Service use a rubber dam, 81-100% of the time they do operative procedure. The use of a rubber dam in academic settings was usually higher than its use in private practices or private clinics; 98% of the final year students responded using it, but only 32% of the students had used it on children, and 62% of the students believed that their use of the rubber dam would decrease after they graduate from dental school [57]. Teaching rubber dam techniques during undergraduate dental school was found adequate by about 98.5% for adult patients, but only 72% were confident placing it for children [58]. The most recent studies about rubber dam use varies but in general the percentages are still low. For example, in 2008, Hill and Rubel [59], found around 39% of the dentists never used rubber dam isolation for composite restorations. Roshan et al. [60] 2003, concluded in their study that rubber dam isolation is still not highly emphasized in undergraduate teaching; only 5% of dentists use rubber dam routinely while treating children. On the other hand, the most recent survey for rubber dam use in pediatric dentistry residency programs and private

pediatric dentistry practices was relatively high compared to previous studies. In fact, more than 80% of the respondents stated that they use it frequently if not always during daily practice [30]. Another study in 2010 by Gilbert et al [61] looked into procedure case notes rather than surveys and found more than half the dentists (63%) fail to use a rubber dam for any restorative procedure. The overall impression about rubber dam use is that despite its importance; it is still not used to the extent that it should be [60, 62].

Dentists appreciate the importance of the rubber dam. Patient safety is the most important benefit, followed by better moisture control, and a reduction in bacterial contamination [63]. Reasons behind the lack of rubber dam use are not entirely clear [57]. The most common reason was patient acceptance towards rubber dam [30, 55, 63]. Hill et al 2008 [59], found that most reasons behind the lack of rubber dam use included inconvenience and belief that it is unnecessary. Another important factor to influence the use of rubber dam is its placement time. Heiss [64] in 1971 found that the average time required for rubber dam placement may reach up to one minute and 46 seconds. Similar statistics were found in a study by Stewardson and McHugh in 2002 [49], where the mean time required for rubber dam placement was 1.27 min (range: 0.25-8 min) for experienced dentists and 4.65 min (range: 1-30 min) for undergraduate students. The majority of pediatric dentists agree on the importance of the use rubber dam isolation for composite restorations, while a smaller percentage can agree on its significance in fissure sealant procedures [63].

The application of rubber dam is not always possible in the dental clinic. For example, in the case of partially erupted teeth or due to governmental regulation that

vary from state to state regarding the use of rubber dam by dental hygienists or trained dental assistant. In terms of cost effectiveness, some researchers advocated sealant placements by trained dental auxiliaries, in order to reduce the cost by as much as 80%.[65] Therefore, cotton roll isolation was an acceptable and a highly preferred alternative for rubber dam isolation. In comparison to two-handed dentistry, four-handed delivery is associated with a 9% increase in the retention rate of pit and fissure sealants [66].

The most recent tooth isolation technique is the Isolite system, developed in the US. The Isolite utilizes high-speed suction, which is applied using a disposable silicone attachment that combines a bite-block with a cheek and tongue retractor. The Isolite provides suction, retraction, a bite-block and has a built-in LED light (Figures 1,2). Isolite ensures a secure treatment field without contamination by providing a continuous vacuum, protraction of check and tongue and secure mouth opening, in addition to partial illumination of the oral cavity. Isolite also provides retraction for one side of the oral cavity, allowing the practitioner to have access to two quadrants (upper and lower) at the same time. This may be beneficial to the practice in terms of chair time, as it will reduce the time for rubber dam removal from one quadrant to another. Quite often when working with an assistant, the blockage of the operator's visual field might occur in several occasions during the preparation or the restoration placement; with Isolite, this obstruction factor will be eliminated. Isolite will also provide a very convenient isolation system for dental students, where having dental assistant is not always possible.

There are limited numbers of studies evaluating the Isolite system in clinical

practice. Collette et al evaluated patient satisfaction and efficacy of the Isolite system during sealant placement. The study showed better time efficiency with the Isolite system when compared to cotton roll isolation [67]. However, patients reported minor discomfort with the Isolite system [67]. To date, no study has compared the Isolite system to the rubber dam. Moreover, no clinical study has compared the retention of pit and fissure sealants placed using the two different isolation techniques.

The aims of the study are:

1. Determine the difference, if any, in chair time when using the Isolite system compared to rubber dam isolation

2. Assess patient satisfaction and acceptance toward the Isolite isolation system when compared to rubber dam isolation system.

# Specific Aims and Hypothesis

To evaluate patient acceptance, placement time and sealant retention of the Isolite System (IS) compared to Rubber Dam (RD) isolation technique.

Hypothesis 1: The chair time using Isolite system has a shorter chair time than that using Rubber dam isolation.

Hypothesis 2: The Isolite system have higher patient acceptance rate when compared to Rubber Dam isolation.

# Materials and Methods

The study design was a prospective split mouth, clinical trial. The study had two groups, a test group who received sealants on one side using Isolite dental isolation system (Experimental group), and one side received sealants under rubber dam isolation (control group). A sample size calculation was performed using nQuery Advisor (version 7.0). Assuming that the proportion of subjects who prefer the Isolite system is 75% compared to 25% who prefer rubber dam, a sample size of 36 subjects is adequate to obtain a power greater than 80%. A total of 42 subjects were recruited due to an estimated attrition rate of 15%. Randomization schedule was generated using R 2.11.1. The randomization was intended to randomize placement of experimental side first or the control side first for each subject. The Institutional Review Board (IRB) of Tufts University School of Dental Medicine approved this study.

**Subject characteristics:**
The inclusion and exclusion criteria for recruiting patients to this study are as follow:

1) Inclusion Criteria

a) Healthy children, with no medical or developmental compromising conditions.

b) Children and adolescents between ages 7-16 years old.

c) Both male and female were selected for the study.

d) Child, parents/ guardian willing to participate in the study.

e) Patient fluent in speaking English.

f) No mental handicaps or mental disorders.

g) The candidate most require 4 pit and fissure sealants on non-cavitated permanent molars (2 maxillary right and left, 2 mandibular right and left) with normal anatomy and enamel.

h) Cooperative patients.

2) Exclusion Criteria

a) History of chronic disease (e.g., epilepsy, ectodermal dysplasia, cardiac anomalies).

b) Parent/guardian unwilling to provide informed consent or child unwilling to provide informed assent.

c) Unable to return for follow-ups.

d) Requiring less than 4 pit and fissure sealants on permanent molars.

e) Partially erupted molars.

**Operators calibration:**

Two operators placed the pit and fissure sealants, after both operators have had training and calibration.

**In the first visit:**

Informed consent/assent were obtained. The subjects and their guardians instructed to read the informed consent, given ample time to have any questions answered, before consenting and assenting to the study. Medical history and demographic information also

collected. Inclusion/exclusion criteria were evaluated. Two calibrated operators placed pit and fissure sealants, but the same operator placed all the pit and fissure sealants in one subject.

**Standard clinical procedure:**

**Isolite Isolation procedure:**

The correct size of the disposable Isolite mouthpiece selected following Isolite mouthpiece sizing "Rule of Thumb" (Figure 3). Patients' lips were lubricated with petroleum jelly. After that, the isthmus (narrow part in the middle of the Isolite plastic mouthpiece), placed at the corner of mouth and the patient was instructed to open widely. The Isolite mouthpiece was inserted while folding cheek shield forward toward tongue retractor, and sliding the isthmus into cheek. The bite block was placed on the occlusal surface and the patient was asked to bite. Finally, the cheek shield was tucked into the buccal vestibule and the tongue retractor into the tongue vestibule.

**Rubber Dam isolation procedure:**

Gingival soft tissue around the tooth dried, and topical anesthesia 20% benzocaine gel applied for 1 minute according to the manufacturer instruction. The latex-free rubber dam was punched and aligned with the quadrant to be treated. The wingless clamp appropriate for use on molars was selected, flossed and held in the forceps to be placed securely on the tooth. The rubber dam was then held in both hands, and the index fingers used to stretch out the punched hole and slipped over the bow of the clamp and pulled onto the tooth. The frame was applied and the seal verified.

**Placement Time comparison:**

Placement time was measured using a stopwatch to compare the time required for pit and fissure sealants placement using Isolite, compared to pit and fissure sealants placed using rubber dam. The time necessary for the application of topical anesthesia was included in placement time measurements for the rubber dam side. For the Isolite device, placement time included the time required to assemble the Isolite rubber head, including any necessary adjustments..

**Sealant placement procedure:**

After isolation, the tooth was cleaned with pumice, using a low speed handpiece. After the surfaces were cleaned and rinsed thoroughly, the tooth was dried and checked for any remaining debris using explorer and under 2.5x dental magnification loupes. The tooth was then etched for 20 second with 35% phosphoric acid. The etched surface then rinsed for approximately 10-15 seconds to remove all organic particles from the micropores. A high-speed evacuator was used for the rubber dam isolation. The tooth then dried thoroughly for 15 seconds and evaluated for a frosty, white appearance. Manufacturer recommended drying agent PrimaDry® (Ultradent Products Inc., South Jordan, UT) was applied and left for 5 second. The tooth was then dried by gently blowing the area with air. Opaque white UltraSeal XT® plus resin sealant (Ultradent Products Inc., South Jordan, UT) was used. Manufacturer's instruction followed while placing the light-cure pit and fissure sealants. After applying the pit and fissure sealant to the surface, the curing light was held as close as possible without touching the surface. Pit and fissure sealants were cured for 30 seconds. Isolation of the teeth maintained until

the sealant was checked by sight under the same magnification loupes for complete coverage of all pits and fissures. Pit and fissure sealants were checked for retention by attempting to dislodge the pit and fissure sealant with an explorer, and in case of any pit and fissure sealant dislodgment the sealant reapplied and this particular tooth was noted to have initial dislodgment under this isolation system. Finally occlusion was checked and if needed adjusted using a flame shaped white polishing bur.

**Research-related procedure:**

**Patient satisfaction questionnaire:**

A 7-item questionnaire was used to measure subjects' acceptance to the different isolation techniques. This was modified from a recent study, which evaluated the efficacy and patient acceptance of the Isolite system[67]. The questionnaire was administered at the end of the visit (Table 3).

## Statistical Analysis

Data were entered into an Excel spread sheet. Descriptive analyses and hypothesis testing were conducted using R 2.11.1 (R Foundation for Statistical Computing) and SPSS version 19 (IBM, Armonk, New York). The distribution of the data was normal and continuous data were summarized as means, ranges and standard deviations for a parametric approach using the paired *t*-test. Binary data from the patient satisfaction questionnaire were approached using the exact binomial test. The chair time difference between the rubber dam and Isolite systems was compared between the two operators using an independent-samples *t*-test to evaluate for an operator effect. Finally, a between-operators comparison of relative comfort experience (rubber dam versus Isolite) was made using a cross tabulation and the Chi-square test to assess for an operator effect.

# Results

The study population comprised 23 female and 19 male age range, 7–16 years; (average, 12.3 years). The average age among male was 13.2 years and that among female was 11.4 years.

The Chi-square test was performed to determine whether there was any significant difference between operators in terms of patient preference for the most comfortable isolation system. Using a *P-Value* of 0.05 as the cut off, no significant difference was found between the two operators (*P-Value* =.739).

Regarding the comparison of chair time differences between operators, the first operator had a mean difference of 9.046 minutes (rubber dam time – Isolite time) with SD=3.26, while the second operator had a mean difference of 9.683 minutes and SD=4.48. A two directional independent-samples *t*-test revealed that there was no significant difference (*P-Value* = .602) between the two operators in terms of time differences.

A two-tailed paired sample *t*-test revealed a significant difference in chair time using rubber dam (m = 19.36, s = 3.58) as compared to Isolite (m = 10.00, s = 1.77) (*P-Value*<.001).

**The participant response to the isolation system used**

Thirty-three patients (78.6%) found the Isolite to be more noisy than the rubber dam; the converse was true for 9 patients (21.4%). The exact binomial test showed that significantly greater number patients reported more noise during use of the Isolite as compared to the rubber dam (*P*<.001) (Figure 4).

Twenty-nine patients (69%) found more tissue stretch at the side of Isolite, while only 13 patients (31%) reported that they had more tissue stretch using rubber dam for isolation. Exact binomial test revealed that significant number of patients reported more tissue stretch while utilizing Isolite compared to rubber dam (Figure 5).

While comparing which isolation system was more comfortable to our patient population, 29 patients (69%) felt more comfortable during use of the Isolite, while only 13 patients (31%) reported more comfort during use of the rubber dam. This difference was significant (*P-Value* = .019) (Figure 6)

Thirty-one patients (73.8%) preferred to have the procedure performed using the Isolite in the future, while 11 patients (26.2%) preferred the rubber dam. This difference was statistically significant according to the exact binomial test (*P-Value* =. 002) (Figure 7).

Twenty-four patients (57.1%) reportedly felt no gag response with either approach, while 18 patients (42.9%) experienced a gag response at some point. Among these 18 patients, 10 patients felt more gagging with the Isolite; 8 patients felt more gagging when using the rubber dam. This difference was not significant (*P-Value* =. 814) (Figure 8).

Twenty-three patients (54.8%) reported that they did not taste any of the study materials; 19 patients (45.2%) reported that they had. Among this latter group, 5 patients experienced a more unpleasant taste with the Isolite, 14 with the rubber dam. This difference was not significant (*P-Value* = .063) (Figure 9).

Eleven patients (26.2%) reported no discomfort during the procedure; 31 patients (73.8%) reported occasional discomfort. Twenty-four patients felt more discomfort on the side treated using the rubber dam; 7 patients felt more discomfort on the side treated using the Isolite. This difference was significant (*P-Value* = .003) (Figure 10). Results are summarized in (Table 4).

# Discussion

This study was conducted using a split mouth technique. Patients had the pit and fissure sealants placed with rubber dam on one side of the mouth and Isolite system on the opposite side. Both systems were used during the same visit, which allowed the patient to easily compare both dental isolation systems. The questionnaires were asked immediately after sealant placement, thereby preventing a time gap between the actual experience and the survey. The results yielded two clinically significant findings. Patients preferred the Isolite to the rubber dam. Use of the Isolite also reduced the time necessary for sealant placement by 10 minutes, on average. Other factors that were compared included noise, soft tissue stretching, gagging, preference, and tasting of the materials.

The patients experienced more noise during treatment with the Isolite system as compared to the rubber dam. This was not surprising because the Isolite device utilizes constant suction. With use of the rubber dam, high-volume suction is used only intermittently during the procedure.

Reports of buccal mucosa and soft tissue stretching were more associated with use of the Isolite system. This may derive from the need for the patient to open his mouth widely to allow for insertion of the disposable silicon mouthpiece. In addition, the Isolite mouthpiece is typically positioned adjacent to the buccal mucosa. Rubber dam provides isolation for a single tooth, while the Isolite system provided isolation for both upper and lower quadrants simultaneously.

Most patients (69%) found the Isolite system to be more comfortable, despite the high noise reported and the tissue stretching experienced. The increase in patient comfort may be attributable to the reduced chair time or elimination of the pressure associated

with use of the rubber dam clamp, including insertion of the rubber dam sheet around the clamp.

When patients were asked about their preference for future pit and fissure sealant placements, the patients participated in the study indicated that they strongly prefers the use of Isolite system rather than rubber dam.

More than half (57%) of the patients felt no gagging with use of either of the isolation systems. The few who experienced gagging reported similar responses with the use of either system.

Experience of the taste of material during the procedure was also low; about half the patients (54.8%) reported that they did not taste any material during the procedure. The patients who reported taste during the procedure indicated that there was no difference between the sides that had pit and fissure sealants placed using rubber dam and the sides treated using Isolite.

With regard to overall discomfort, 26.2% reported no discomfort. Those who did experience discomfort reported higher levels with use of the rubber dam as compared to the Isolite. This finding coincides with the patient comfort level and the patient preferences for future treatment. Isolite offered a highly accepted isolation tool; regardless of the amount of tissue stretching, or noise level accompany its use. Subjects were requested to report both comfort and discomfort, as discomfort was about the entire procedure, while the comfort participants were only requested to give response about one of each isolation systems. The Isolite was preferred to the rubber dam, despite the associated noisiness and tissue stretching. The Isolite therefore represents a viable alternative for use in the application of pit and fissure sealants.

Although dentists are fully aware of the importance of rubber dam use, they are still not using it enough, especially for restorative or preventive procedures such as pit and fissure sealants [30, 63]. The overall rubber dam use tends to increase with time, especially with the growing understanding of its importance [30]. With time and frequent use of rubber dam dentists starts to feel more comfortable using it [49]. Patient discomfort was the reason cited most commonly by dentists who choose not to use the rubber dam[59]. On the other hand, when patient were asked in previous studies to give their response about rubber dam, they did not show any resistant to its use, and they were not negative towards it, and majority of patients prefer to use it in the future [49]. Wolcott and Goodman [54] reported that dentists who use rubber dam more often tend to face fewer patient rejection, and they came to the conclusion that patient motivation to use rubber dam will be reflected by the dentist presentation of rubber dam to patients. It have been also interesting that investigators found less use of rubber dam when they looked into records [61] than what is reported by dentists in surveys [30]. Hill et al. [59]mentioned that dentists tend to give the correct answer rather than the true answer whenever these surveys were conducted at large dental meetings, and the response rate for mail-out surveys are quite low which impact the sample size for any survey.

Slawinski and Wilson[30] demonstrated that pit and fissure sealants are the least procedure to be performed under rubber dam when introduced in an office settings rather than in hospital under general anesthesia. Their findings matched the findings by Soldani and Foley [63] in the UK. Patients under general anesthesia are more likely to require different procedures rather than pit and fissure sealants that are placed in an office setup without the use of local anesthesia. Time factor is also an important factor that may

preclude use of rubber dam during pit and fissure sealants application. When Isolite system was used, the chair time was minimized by an average of 10 minutes. This is a significant reduction of the time required for pit and fissure sealants placed, especially in private dental offices. When cotton roll isolation was used for placing pit and fissure sealants, Isolite was able to minimize the chair time whereas no clamp is placed around the tooth and no rubber dam sheet need to be inserted around it and no frame is required to stretch the sheet around [67].

Despite patients' acceptance or chair time minimization, the Isolite may provide and maintain a dry field is an important factor for sealant retention.

## Limitation:

A limitation of this study was the lack of long-term evaluation of sealants retention placed under both isolation systems. A follow up study will be conducted to evaluate the retention of these sealants.

# Conclusion

Isolite system offers an effective alternative to rubber dam that provides shorter chair time during pit and fissure sealants placement procedure. Results also show higher patients' acceptance to the Isolite system compared to rubber dam isolation.

# Clinical Considerations

Although the rubber dam is considered the standard of care for dental isolation, pit and fissure sealants is the least procedure rubber dam is used for. Isolite system offers an effective alternative to the rubber dam Isolation during sealants placement. This new approach reduces chair time, which is of the utmost importance to dentists employed in a private practice. The Isolite is also associated with greater patient satisfaction as compared to rubber dam isolation.

# Recommendations

The pit and fissure sealants retention is a crucial factor in the evaluation of Isolite effectiveness. The pit and fissure sealants retention will be evaluated in a separate follow up study.

# Figures

**Figure 1.** The Isolite system with the mouthpiece connected. (Courtesy: Isolite system owner's guide).

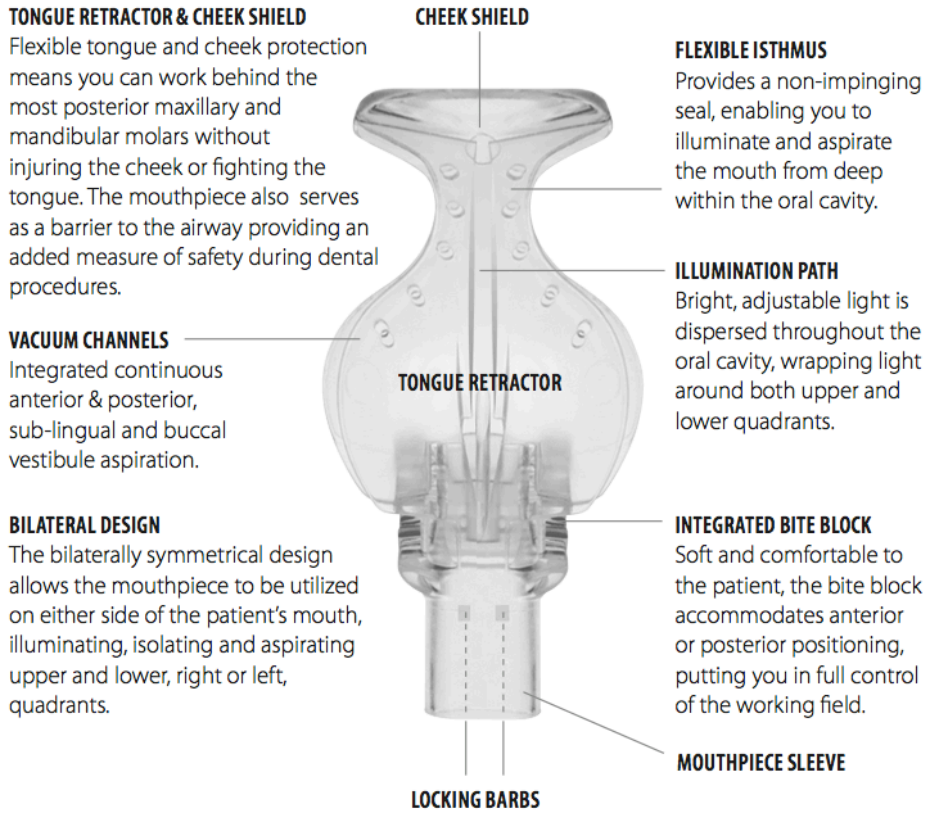


**Figure 2**. Isolite mouthpiece components. (Courtesy: Isolite system owner's guide).

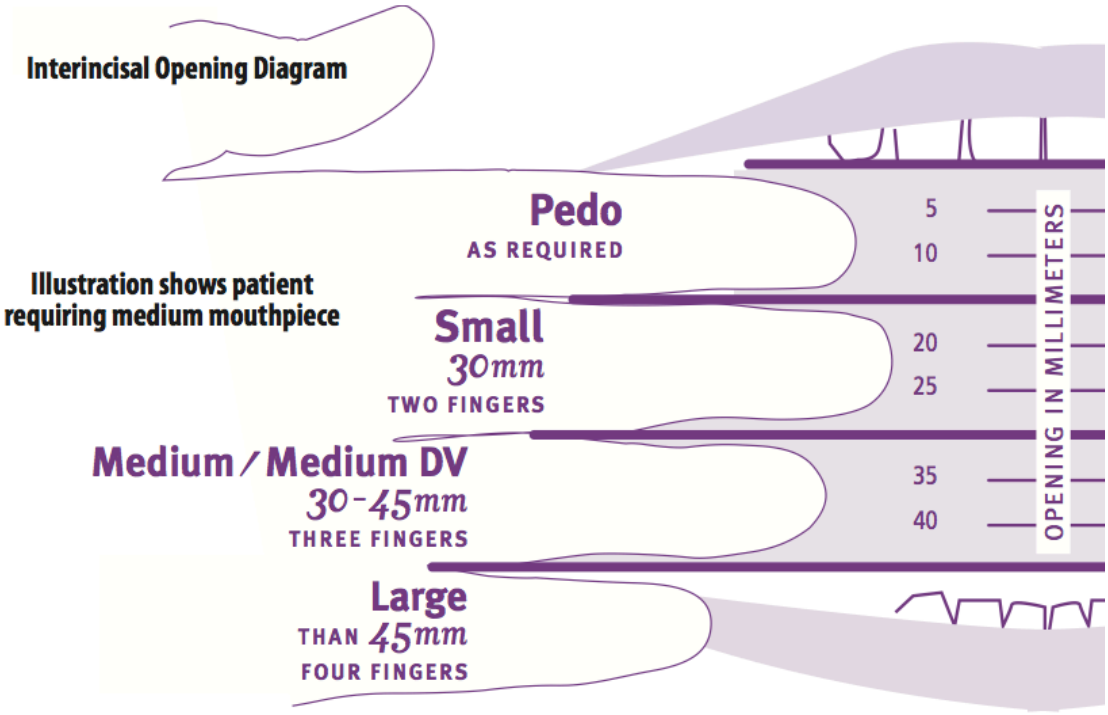


**Figure 3**. Isolite mouthpiece sizing "Rule of Thumb". (Courtesy: Isolite system owner's guide).

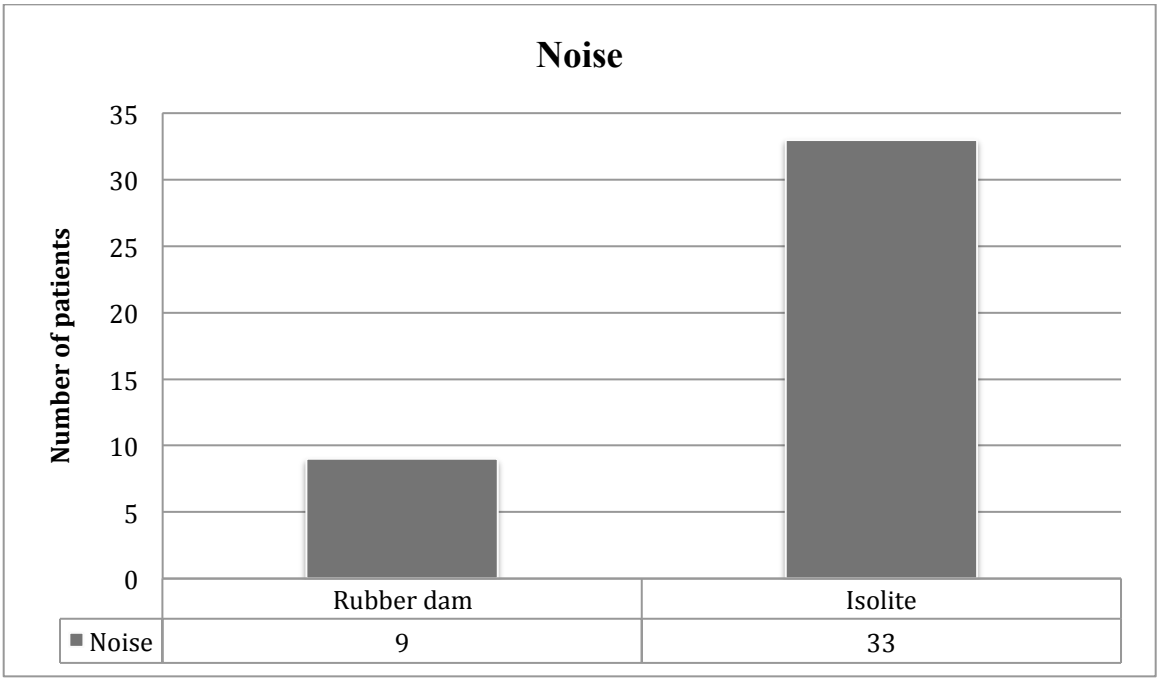


**Figure 4.** Patients' response to which system made the most noise (rubber dam or Isolite) *P-Value* < .001

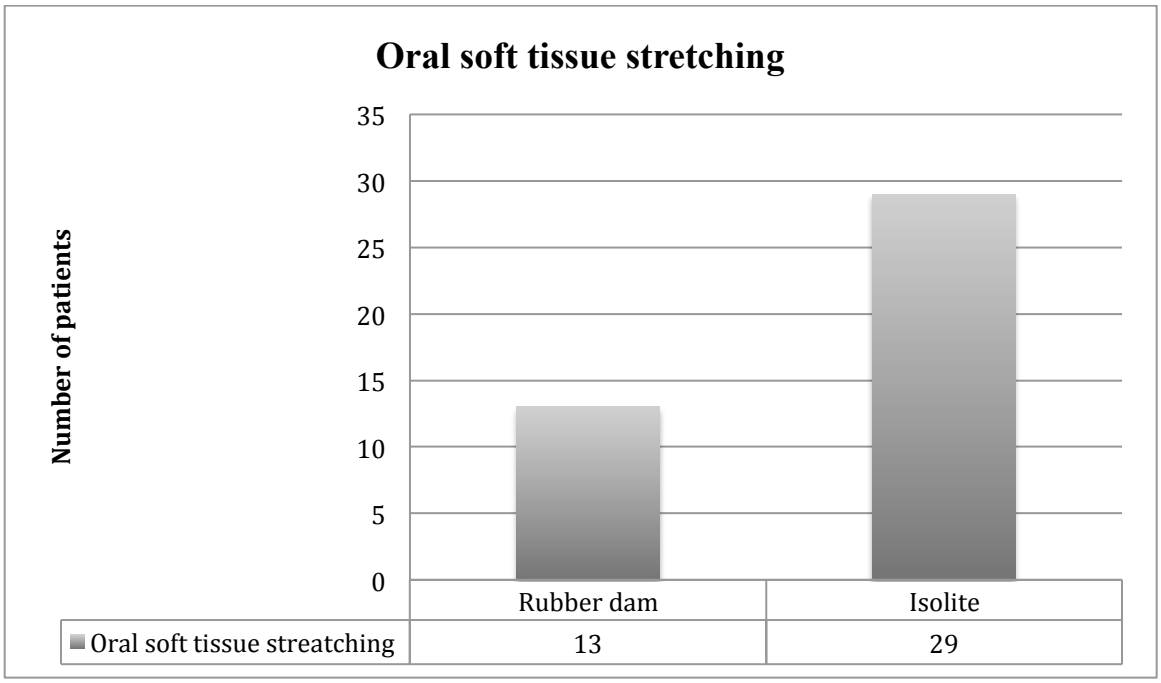


**Figure 5.** Patients' response to which system stretched your mouth, cheeks, and lips the most (rubber dam or Isolite*) P-Value* = .019.

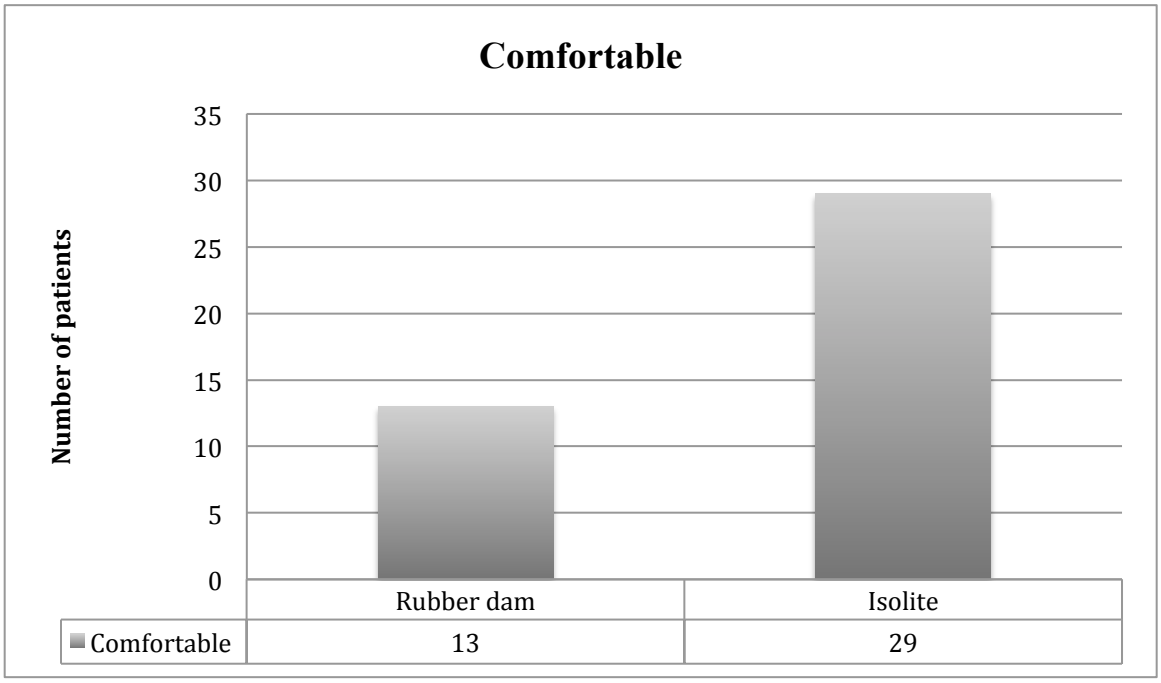


**Figure 6.** Patients' response to which system was the most comfortable (rubber dam or Isolite) *P-Value* = .019.

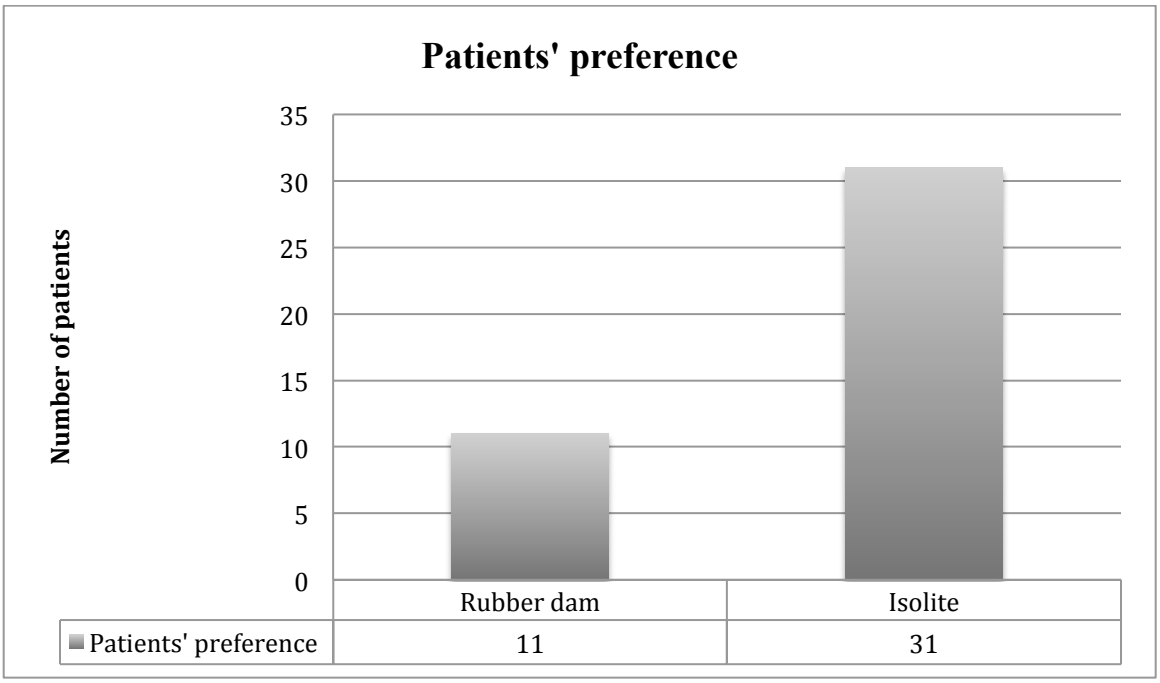


**Figure 7.** Patients' responses to question "if we did the procedure again, which system would you prefer?" *P-Value* = .002.

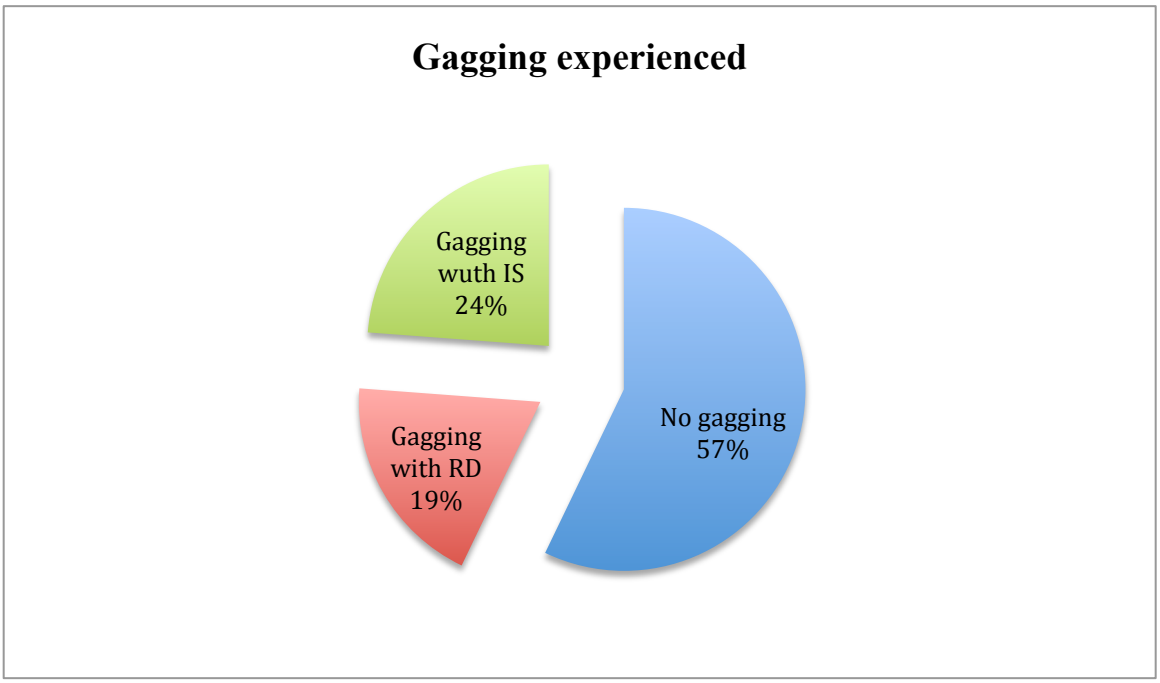


**Figure 8.** Patients' responses to question "did either system make you feel as if you needed to gag? And which one was the most" (rubber dam or Isolite) *P-Value* = .814.

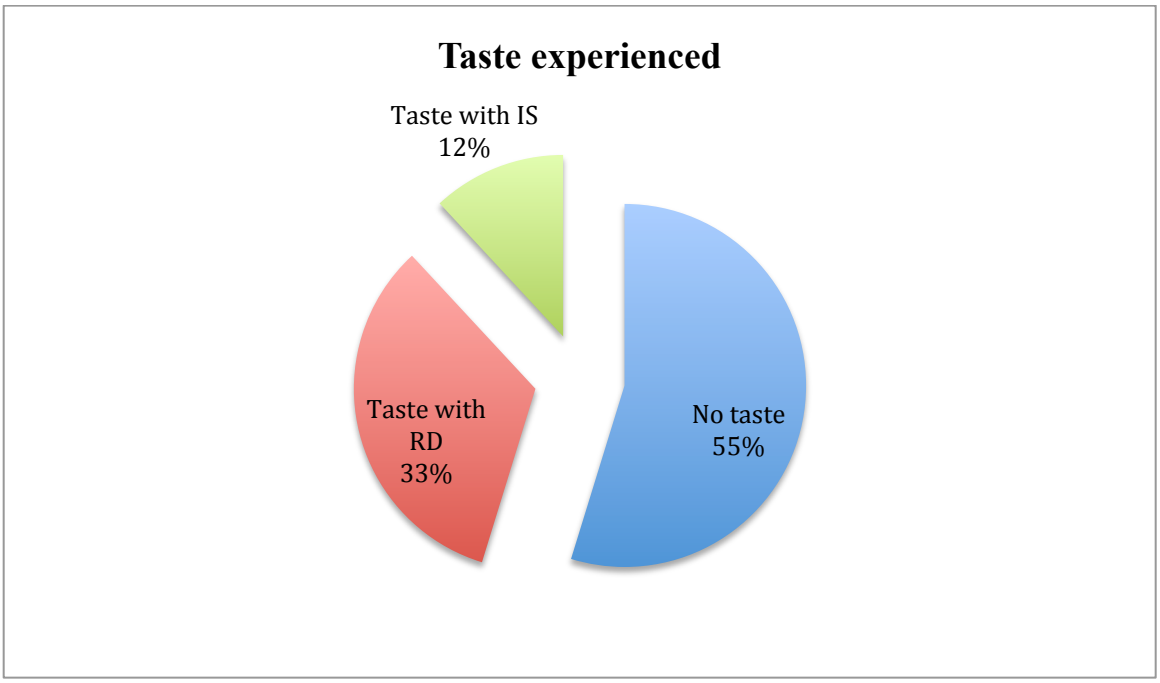


**Figure 9.** Patients' response to question **"**did you taste any of the materials used? And which one was the most" (rubber dam or Isolite) *P-Value*=.063.

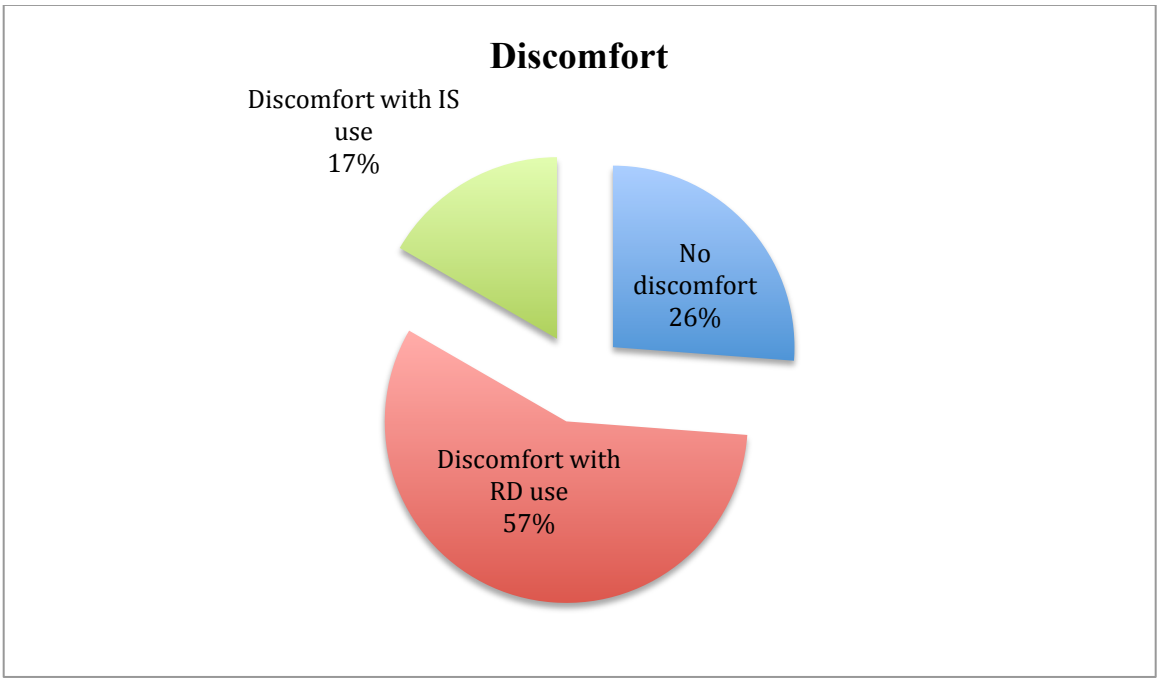


**Figure 10.** Patients' response to question **"**did either system cause any discomfort? And which one was the most?"(rubber dam or Isolite) P-Value=.003.

# Tables

| Length of time | Complete retention | Caries rate | Effectiveness |
|---|---|---|---|
| 1 year | 92% | 4% | 83% |
| 2 years | 85% | 7% | 81% |
| 3 years | 71% | 14% | 69% |
| 5 years | 67% | 26% | 55% |
| 7 years | 66% | 31% | 55% |

**Table 1:** Dental pit and fissure sealants retention and its relation to caries rate and sealant effectiveness. (Courtesy: Pediatric dentistry Infancy through adolescence. Mosby; 4th edition)

| Appointment Procedures | Visit 1 Screening /pit and fissure sealants placement | Visit 2 3 months recall | Visit 3 6 months recall | Visit 4 12 months recall |
|---|---|---|---|---|
| Consent Form | X | | | |
| Demographics | X | | | |
| Medical History | X | | X | X |
| Inclusion/Exclusion Criteria | X | | | |
| Sealant placement | X | | | |
| Intraoral photographs | X | X | X | X |
| Chair time measure | X | | | |
| Isolite VS Rubber dam questionnaire | X | | | |
| Sealant retention evaluation | | X | X | X |
| Adverse Event Assessment | | X | X | X |
| Gift Card | X | X | | |

**Table 2.** Summary of the procedures performed during the first visit and every recall visit.

| Please check the appropriate box in response to each question: | | | |
|---|---|---|---|
| 1. Which system made the most noise? | | ○ RD | ○ Isolite |
| 2. Which system stretched your mouth, cheeks, and lips the most? | | ○ RD | ○ Isolite |
| 3. Which system was the most comfortable? | | ○ RD | ○ Isolite |
| 4. If we did the procedure again, which system would you prefer? | | ○ RD | ○ Isolite |
| 5. Did either system make you feel as if you needed to gag? | ○ No | ○ Yes | |
| If yes, which system made you feel like you needed to gag the most? | | ○ RD | ○ Isolite |
| 6. Did you taste any of the materials used? | ○ No | ○ Yes | |
| If yes, with which system did you taste the materials the most? | | ○ RD | ○ Isolite |
| 7. Did either system cause any discomfort? | ○ No | ○ Yes | |
| If yes, which system caused the most discomfort? | | ○ RD | ○ Isolite |

**Table 3.** The questionnaire asked to every patient after the pit and fissure sealants application.

| | Rubber Dam | Isolite | P-Value |
|---|---|---|---|
| Chair time<br>Mean (SD) | 19.36 min (3.58) | 10.00 min (1.76) | P<. 001 |
| Noise experienced<br>N (%) | 9 (21.5%) | 33 (78.6%) | P<. 001 |
| Stretching experienced<br>N (%) | 13 (31%) | 29 (69%) | P = .019 |
| Comfort<br>N (%) | 13 (31%) | 29 (69%) | P = .019 |
| Preferences<br>N (%) | 11 (26.2%) | 31 (73.8%) | P = .002 |
| Gagging experienced<br>N (%) | 8 (19%) | 10 (24%) | P = .814 |
| Taste experienced<br>N (%) | 14 (33%) | 5 (12%) | P = .063 |
| Discomfort<br>N (%) | 24 (57%) | 7 (17%) | P = .003 |

**Table 4.** Summary of data; the first row shows the mean for chair time using each isolation system and the standard deviation, the remaining rows show the patient response to each question in the questionnaire.

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