

Randomized, controlled trial comparing the retention of a flowable restorative system with a conventional resin sealant: one-year follow up

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Summary. This clinical trial evaluated the retention rate of a flowable restorative system (Bond 1 + Flow-It!) used as a pit-and-fissure sealant compared with a conventional filled resin sealant (Fluroshield) over a 1-year period.

Method. Using a half-mouth design, 160 sealants (80 in primary and 80 in permanent teeth) were placed on sound first/second primary molars and first permanent molars of 40 children aged between 4 and 7 years. For both primary and permanent dentitions, half the teeth ($n = 40$) were sealed with Fluroshield and half ($n = 40$) with Bond 1 + Flow-It!. Teeth were evaluated at baseline, 6- and 12-month intervals.

Results. For both materials, there was no total loss of sealants placed on either the primary or permanent molars over 1 year. From Fluroshield sealants placed on primary teeth, 33 were completely intact after 6 months and 31 after 1 year. From those placed on permanent molars, no loss of material was observed after 6 months, while partial loss was noticed on 5% of teeth at 1-year recall. For Flow-It! resin applied on primary molars, partial loss of material was observed in only 1 sealant after 6 months and in 2 sealants after 1 year. On permanent teeth, 100% retention rate was observed over a 1-year follow up. There was a statistically significant difference ($P < 0.01$) between the sealing materials on primary but not permanent teeth, and, overall, Flow-It! sealants presented a higher retention rate at both 6-month and 1-year evaluations. Significant differences ($P < 0.01$) between baseline and the other evaluation periods were also observed.

Conclusion. It may be concluded that the flowable restorative system yielded optimal retention on both primary and permanent molars. Its retention rate was significantly higher than that of the conventional pit-and-fissure sealant on primary teeth.

Introduction

Over recent decades dentistry has experienced outstanding scientific advances in restorative materials

and techniques, as well as in reviewing understanding of principles. These have allowed more efficient oral health management with greater emphasis on prevention [1]. Based on contemporary principles, noninvasive strategies have been preferred to invasive healing treatments. Efforts have been focused on reducing patients' caries risk, stimulating the adoption of preventive measures and highlighting the relevance of a partnership approach between patients and dentists for ultimate success in caries control [1,2].

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A remarkable decline of caries prevalence has been noticed worldwide, primarily owing to the increase of scientific knowledge on the aetiology initiation, progression and prevention of disease coupled with the widespread use of fluoride and adoption of a wide range of preventive measures [2–5]. Paradoxically, lifelong exposure to different sources of fluorides is thought by many to be largely responsible for a change in the pattern and progression of dental caries [3,5,6]. Even in populations with decreased caries prevalence, the relative importance of occlusal caries has significantly increased [7–10].

In this context, resin pit-and-fissure sealants have been considered an important adjunct to oral health care strategies and fluoride therapy in preventing occlusal carious lesions [11,12]. The sealing material acts as an effective mechanical obstacle to plaque retention, thus minimizing the harmful action of cariogenic microorganisms on enamel surface [11–13]. Nevertheless, the preventive benefit of this treatment relies directly upon the ability of the resin sealant to thoroughly fill pits, fissures and/or morphological defects and remain completely intact and bonded to enamel surface for a lifetime [11–14]. Otherwise, partial loss of the sealing material inherently leads to the occurrence of marginal microleakage and hence to caries development underneath the sealant. The outcomes of clinical evaluations have shown that, unlike glass ionomer sealants, for resin sealants the retention rate (rather than caries inhibition) constitutes the major criterion for success [11].

Various materials and techniques have been developed and/or proposed to improve the sealing of pits and fissures and enhance their longevity. The use of flowable resin composites as pit-and-fissure sealants, for instance, has been widely suggested [15–18]. The applicability of flowable restorative systems in dentistry has increased, mainly because of their beneficial properties, such as low viscosity [19], low modulus of elasticity [19,20] and ease of handling [21]. This allows the materials to be successfully placed even in ultraconservative preparations. It has been reported that their higher amount of filler particles provides lesser porosity [17], better wear resistance [15,22] and retention similar to that of conventional resin sealant pit-and-fissure sealants [17,18]. However, there would appear to be few research studies comparing the retention of such materials on pits and fissures with that of conventional sealants under clinical conditions [17,18].

Therefore, the aim of this clinical trial was to evaluate the retention rate of a flowable restorative system used as pit-and-fissure sealant and to compare this with a conventional filled resin-based sealant over a 1-year period.

Materials and methods

The research protocol was initially submitted to and approved by the local Ethics Committee (Ribeirão Preto School of Dentistry, University of São Paulo). Once the methodology had been approved, young patients of both sexes, ranging in age from 4 to 7 years, and seeking routine dental care at the Public Health Service in Marília (São Paulo State, SP, Brazil) were recruited to the study.

To be included in the trial, children were required to present with at least one homologous pair of intact, caries-free, fully erupted first/second primary molars and/or first permanent molars, with deep and retentive pits and fissures. At examination, the occlusal surfaces were first cleaned by pumice prophylaxis to remove the dental biofilm and stains. Then, careful visual inspection was carried out under good illumination on the clean, dry tooth surfaces. In addition, bitewing radiographs were taken using Funk X-ray equipment (10 mA and 60 KV, Funk Ltd, Ribeirão Preto, SP, Brazil) and apical radiographic films (KODAK, Ektaspeed Plus, EB – 31, size 2, Eastman Kodak Co., Atlanta, GA, USA). The films were exposed for 0.4 s with the aid of a film holder and developed using the time/temperature method. Unsatisfactory radiographs were repeated. Findings of both diagnostic methods (clinical and radiographic examination) were used to confirm the absence of decay.

To be admitted to the study patients were required to be willing and able to attend the scheduled appointments at specified study intervals for follow-up examinations. The nature and objectives of the trial as well as the possible discomforts and benefits were fully explained and all parents or guardians asked to sign the appropriate, approved informed consent documents prior to the investigation, according to Brazilian National Health Council's Resolution 196/96.

A total of 40 children were recruited, providing a sample size of 160 teeth (80 pairs), comprising 80 primary and 80 permanent molars (40 pairs of each tooth type).

Using a half-mouth design, a filled resin-based pit-and-fissure sealant (Fluroshield, Dentsply Caulk,

Table 1. Tested materials: compositions, specifications and manufacturers.

Material	Fluroshield	Bond 1	Flow-It!
Type	Resin-based pit-and-fissure sealant	Total-etch, single bottle adhesive system	Filled flowable resin composite
Principle	Bis-GMA, modified urethane,	PMGDM, HEMA, light curing initiator,	Ethoxylated Bis-GMA, TEGDMA,
Ingredients	triethylene glycol dimethacrylate, aluminium and barium borosilicate, phosphoric acid tetracyclic ester, sodium fluoride, N-methyl dietanolamine, camphoroquinone	acetone	photo initiator, accelerator, barium glass, UV stabilizer, inorganic pigments silica, TiO ₂
	Dentsply Caulk, Milfor, DE, USA	Jeneric-Pentron, Inc. Wallingford, CT, USA	Jeneric-Pentron, Inc. Wallingford, CT, USA

Milfor, DE, USA) was applied on randomly assigned upper/lower primary and permanent molars of one side of the mouth, and a single-bottle adhesive system (Bond 1, Jeneric/Pentron, Inc. Wallingford, CT, USA) used in association with a flowable resin composite (Flow-It!, Jeneric/Pentron, Inc. Wallingford, CT, USA) was applied to the contra-lateral side. From both groups of teeth (primary and permanent molars), half ($n = 40$) were sealed with Fluroshield and half ($n = 40$) were sealed with Bond 1 + Flow-It!. The two materials used for the study with their composition, specifications and manufacturers are shown in Table 1.

For both materials sealants were placed under careful isolation with a rubber dam to prevent salivary contamination and facilitate the operative procedures. A saliva ejector was used throughout the procedure. The dental surfaces were first cleaned with pumice/water slurry in Robinson bristle brushes at low-speed handpiece to remove salivary pellicle and the remaining dental biofilm. Next, the teeth were thoroughly rinsed and air-dried to remove pumice residues.

The occlusal surfaces were etched with 37% phosphoric acid gel (Gel Etchant, Kerr Corporation, Orange, CA, USA) for 30 s, rinsed with air/water spray for 30 s and dried with a mild oil-free air stream for 20 s until a uniform whitened surface with chalk-like appearance was obtained.

For teeth sealed with the flowable resin system, two coats of Bond 1 single-bottle adhesive were successively applied to the etched surface and light-cured for 20 s using a visible light curing unit with a 450 mW/cm² output (XL 3000, 3M/ESPE, St Paul, MN, USA). Afterwards, a uniform layer of Flow-It! was applied and light-cured for 40 s. For teeth sealed with Fluroshield, a uniform layer of the sealant was applied on etched occlusal pits and fissures using a disposable applicator and light cured for 40 s. Both

the resin composite and the resin-based sealant were carefully applied from the central fissure up towards the cusps in order to prevent voids, air entrapment or bubbles.

After the sealants were placed, the rubber dam was removed and the occlusion was checked with a carbon marker. Any premature contacts were removed to ensure the sealants did not produce occlusal interference.

The same examiner evaluated the sealants at three intervals: baseline (control), 6 and 12 months after placement. Visual inspection was carried out and the tip of a blind probe used to check the retention and condition of the sealants at evaluation. The retention rate was assessed following the criteria proposed by Tonn & Ryge [23]: TR – total retention, PL – partial loss and TL – total loss.

Data were submitted for statistical analysis using the Fisher and Cochran tests.

Results

The distribution of sealant retention rates at baseline, 6- and 12-month intervals is displayed in Table 2.

For both materials, there was no total loss of sealants placed on either primary or permanent molars, over 1 year.

Among the 40 Fluroshield sealants placed on primary teeth, 33 were completely intact after 6 months and 31 teeth were still fully sealed after 1 year. Among those placed on permanent molars, no loss of material was observed after 6 months, whereas partial loss of the sealant was noticed on two teeth at 1-year recall.

For Flow-It! flowable resin applied on primary molars, partial loss of material was observed in only one sealant after 6 months and in two sealants after 1 year. On permanent teeth, all 40 teeth remained fully sealed over a 1-year follow-up period.

Table 2. Distribution of retention rates.

	Primary teeth (<i>n</i> = 80)				Permanent teeth (<i>n</i> = 80)			
	Fluoroshield (<i>n</i> = 40)		Flow-It! (<i>n</i> = 40)		Fluoroshield (<i>n</i> = 40)		Flow-It! (<i>n</i> = 40)	
	6 months	12 months	6 months	12 months	6 months	12 months	6 months	12 months
TR	33 (82.5%)	31 (77.5%)	39 (97.5%)	38 (95%)	40 (100%)	38 (95%)	40 (100%)	40 (100%)
PL	7 (17.5%)	9 (22.5%)	1 (2.5%)	2 (5%)	0	2 (5%)	0	0
TL	0	0	0	0	0	0	0	0
Total	40	40	40	40	40	40	40	40

TR = total retention; TL = total loss; PL = partial loss.

There was a statistically significant difference ($P < 0.01$) between the sealing materials on primary but not permanent teeth. The retention rate of Flow-It! sealants was markedly higher than that of Fluoroshield sealants at both the 6-month and 1-year evaluations. There was a statistically significant difference ($P < 0.01$) between baseline and the other evaluation periods (6-month and 1-year) when the sealant results were combined.

Discussion

The aim of this clinical trial was to investigate sealant loss in young patients over a 1-year interval. As the literature has strongly emphasized, the most appropriate period for the placement of occlusal sealants is soon after eruption of the permanent molars, because recently erupted teeth are less mineralized than those exposed to oral environment for several years, and may thus be more prone to acid attack. In such conditions, early placement of sealants may prevent the development of carious lesions on occlusal pits and fissures [24]. Therefore, studies that aim to evaluate the clinical performance of occlusal sealants should be conducted with young subjects. Nevertheless, clinical trials involving children are extremely demanding to perform, as sealants are very technique sensitive. Success of the follow up is dependent also on parent cooperation and motivation to bring their children for follow up. In our study, all the patients attended the scheduled appointments up to a 1-year follow up. Regrettably, after the 12-month recall, the study had to be concluded as a result of an excessive dropout rate. The main reasons for dropouts included the family leaving the area, parents' lack of time and/or interest to take the children to the appointments and refusal to continue participating in the trial. These shortcomings clearly demonstrated that putting too much weight onto the families really could result in

loss from the studies. It is a relevant point that it is sometimes a cost to parents and guardians to attend regular recalls for a child.

The sealing of occlusal pits and fissures was introduced with a major purpose of preventing the ingress of food and bacteria, which create the acidic conditions that favour caries onset. Sealants of various types have been in use for more than 30 years, and several fissure-sealing programs have been investigated [25].

Some clinical studies have reported that the ability of resin sealants to control the initiation of occlusal caries is limited to the formation of a physical barrier, which prevents the metabolic exchange between the fissure cariogenic microorganisms and the oral environment [26,27]. Therefore, unlike glass ionomer sealants, whose success may also relate to other factors such as fluoride uptake, the effectiveness of resin sealants inherently relies on their retention and integrity over time [27,28].

The findings of this clinical study demonstrated that the flowable resin restorative system investigated yielded an optimal performance in sealing the occlusal pits and fissures of both primary and permanent teeth at least over a 1-year follow up. Similar outcomes have been reached in previous studies [17,18], which reported that flowable resin materials presented a retention rate comparable to that of conventional pit-and-fissure sealants.

In this project, statistical analysis revealed significant difference between the tested sealing materials on primary teeth, with the flowable restorative system presenting markedly better retention than the conventional resin-based pit-and-fissure sealant. It may be speculated that, as pits and fissures are significantly shallower on primary teeth, a sealing material used in conjunction with an adhesive system prior to its placement might result in enhanced retention. The outcomes of one recent study [29] have revealed that a low-viscosity resin composite

also provides efficiency of higher penetration in shallow-wide fissures than the conventional resin sealant.

One *in vitro* study [30] has evaluated the microleakage and the penetration depth of three types of materials and advocated that, among the tested systems, Tetric Flow flowable resin yielded the best results in sealing deep fissures of noncarious bicuspid. It has also been reported that a flowable resin used as pit-and-fissure sealant presented a lower surface porosity than the conventional resin-based sealant [17], perhaps improving retention in consequence.

An earlier *in vitro* investigation comparing a flowable resin used as pit-and-fissure sealant and a conventional resin-based sealant with respect to the marginal microleakage revealed that the flowable resin provided marginal sealing at the enamel/sealant interface similar to that of the conventional sealant associated or not with an adhesive system [16].

The lack of clinical evaluations assessing the retention of flowable composite resin on primary teeth prevents a comparison with findings of previous research.

One interesting feature disclosed in this study was that there was no total loss of the sealants for either of the tested materials, regardless of the type of tooth (primary or permanent). These findings are supported by the results of previous studies [11,31,32], which have reported a higher percentage of sealant partial loss and no or little total loss. Such results might be attributed to such factors as the use of rubber dam and the sealing technique [33].

The findings of this clinical study suggest that flowable resin composites in association with adhesive systems may be used to successfully seal occlusal pits and fissures. Nevertheless, because of disparities in the formulation, characteristics and physical properties of the current flowable restorative systems, further long-term *in vivo* investigations are needed. Research should investigate the feasibility and real benefits of using such materials as sealants before any recommendation for their routine application in dental care can be made.

Conclusions

Based on the outcomes of this randomized, controlled trial, it may be concluded that the flowable restorative system yielded optimal retention on both primary and permanent molars. Overall its retention

rate was higher than that of the conventional pit-and-fissure sealant on primary teeth.

Résumé. Cet essai clinique a évalué, sur une période d'un an, le taux de rétention d'un système de restauration fluide (Bond 1 + Flow-it!) utilisé en tant que scellement de puits et fissures comparé à un scellement de sillon conventionnel à la résine (Fluroshield).

Méthode. Utilisant un protocole sur hémi-bouche, 160 scellants (80 sur dent temporaire et 80 sur dent permanente) ont été placés sur des premières molaires permanentes et premières/secondes molaires temporaires de quarante enfants âgés de 4 à 7 ans. Pour chacun des deux types de denture, la moitié des dents ($n = 40$) a été scellée avec Fluoshield et l'autre moitié ($n = 40$) avec Bond 1 + Flow-It!. Les dents ont été évaluées au départ et à 6 et 12 mois d'intervalle.

Résultats. Il n'y a pas eu de perte totale de scellants placés sur les molaires permanentes ou temporaires, sur une période de un an, quelque soit le matériau. Après six mois, 33 des scellants Fluoroshield placés sur les dents temporaires sont restés intacts et 31 après un an. Aucune perte de ce matériau n'a été observée sur dent permanente après 6 mois, tandis qu'une perte partielle a été notée sur 5% des dents au contrôle de un an. Une perte partielle de la résine Flow-It appliquée sur les molaires temporaires a été observée au niveau d'un seul scellant après 6 mois et de deux scellants après un an. Au niveau des dents permanentes le taux observé de rétention était de 100% à un an. La différence entre les deux matériaux de scellement était statistiquement significative ($p < 0,01$) au niveau des dents temporaires, mais pas au niveau des dents permanentes. D'une façon générale, les scellements au Flow-It ont présenté un taux de rétention plus élevé aux évaluations à 6 mois et un an. Des différences significatives ont également été notées entre l'évaluation de départ et les autres périodes d'évaluation ($p < 0,01$).

Conclusion. Il peut être conclu que le système de restauration fluide a fourni une rétention optimale à la fois sur les molaires temporaires et permanentes. Son taux de rétention sur les dents temporaires était significativement plus élevé que celui du scellement de puits et fissures conventionnel.

Zusammenfassung. Diese klinische Studie untersuchte die Retentionsrate eines fließfähigen Restaurationssystems (Bond 1 + Flow-it!) als Fissurenversiegelung im Vergleich zu einem konventionellen gefüllten

Versiegelungsmaterial (Fluroshield) über einen Zeitraum von einem Jahr.

Methode. In einer Halbseitenstudie wurden insgesamt 160 Versiegelungen (80 bei bleibenden Molaren, 80 bei Milchmolaren) auf kariesfreien Milchmolaren bzw. ersten bleibenden Molaren bei 40 Kindern (Alter von 4–7 Jahren) gelegt. Jeweils die Hälfte der Milchzähne sowie der Hälfte der bleibenden Zähne wurde mit dem Restaurationsmaterial versiegelt, die andere Hälfte mit dem Versiegelungsmaterial. Die Zähne wurden zu Studienbeginn untersucht, nach 6 Monaten und nach 12 Monaten.

Ergebnisse. Bei beiden Materialien konnte kein totaler Retentionsverlust beobachtet werden, weder bei bleibenden Molaren noch bei Milchmolaren. Von den Fluroshield-Versiegelungen der Milchmolaren waren nach 6 Monaten 33 und 31 nach 12 Monaten völlig intakt. Bei den auf bleibenden Molaren gelegten Versiegelungen war kein partieller Retentionsverlust nach 6 Monaten und nur bei 5% der Zähne nach 12 Monaten zu erkennen. Bei den Flow-It Versiegelungen an Milchmolaren wurde bei einer Versiegelung nach 6 Monaten und 2 Versiegelungen nach 12 Monaten ein Teilverlust registriert, bei den bleibenden Molaren in keinem einzigen Fall während der 12 Monatsbeobachtung. Der Unterschied zwischen beiden Materialien war statistisch signifikant ($p < 0.01$) für die Milchmolaren, nicht jedoch für die bleibenden Molaren. Insgesamt schnitt Flow-It besser ab hinsichtlich der Retention nach 6- und 12 Monaten. Weiterhin waren die Unterschiede zwischen Ausgangsuntersuchung und den 6-Monatergebnissen sowie nach 12 Monaten statistisch signifikant ($p < 0.01$).

Schlussfolgerung. Es kann gefolgert werden, dass fließfähiges Komposit eine optimale Retention sowohl in Milchmolaren als auch bleibenden Molaren erreichen kann. Die Retentionsrate war höher als ein konventionelles Kontroll-Versiegelungsmaterial aufwies.

Resumen. Este ensayo clínico evaluó el porcentaje de retención de un sistema restaurador fluido (Bond 1 + Flow-it!) usado como un sellador de fosas y fisuras, comparándolo a un sellador de resina con relleno (Fluroshield) durante el periodo de un año. **Método.** Usando un diseño de boca partida, se colocaron en primeros/segundos molares primarios y en primeros molares permanentes de cuarenta niños entre 4–7 años de edad, 160 selladores (80 en dientes temporales y 80 en dientes permanentes). Tanto en dentición primaria como permanente, la mitad de los dientes ($n = 40$) se selló con Fluroshield

y la otra mitad se selló con Bond 1 + Flow-It!. Los dientes se evaluaron basalmente y en intervalos a los 6 y 12 meses.

Resultados. Para ambos materiales, durante un año, no hubo pérdida total de sellador colocado tanto en molares primarios como permanentes. De los selladores Fluroshield colocados en los dientes primarios, 33 estaban completamente intactos después de 6 meses y 31 después de un año. De los colocados en molares permanentes, no se observó pérdida de material después de 6 meses, mientras que la pérdida parcial de material se observó en el 5% de los dientes al año de revisión. Para la resina Flow-It! aplicada en los molares primarios, se observó la pérdida parcial de material en sólo un sellador después de 6 meses y en 2 selladores después de un año. En dientes permanentes, se observó el porcentaje de 100% de retención al año de seguimiento. Hubo una diferencia estadísticamente significativa ($p < 0,01$) entre los materiales de sellado en temporales, pero no en dientes permanentes y en general, los selladores Flow-It! presentaron un porcentaje de retención más alto tanto en las evaluaciones a los 6 meses como al año. También se vieron diferencias significativas ($p < 0,01$) entre la evaluación basal y los otros períodos de evaluación.

Conclusión. Se puede concluir que el sistema restaurador fluido produjo retención óptima tanto en molares primarios como permanentes. Su porcentaje de retención fue significativamente más alto que el del sellador de fisuras convencional en dientes primarios.

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