

## Bonded amalgam as a fissure sealant in low-income setting: A randomised controlled trial

Farhan Raza Khan,<sup>1</sup> Samreen Liaquat,<sup>2</sup> Ghazala Rafique,<sup>3</sup> Syed Iqbal Azam,<sup>4</sup> Arshad Hasan<sup>5</sup>

### Abstract

**Objective:** To compare one year retention rate of bonded amalgam sealants (BAS) with that of conventional resin-based sealant (RBS).

**Methods:** It was a parallel group, equivalence, randomised controlled trial done during March 2018 to December 2019 at the dental clinics of Dow University of Health Sciences, and the Jinnah Sind Medical University, Karachi, Pakistan on children aged 12-16 years, who were randomly assigned to one of the two treatment groups (BAS vs. RBS). Complete retention of the sealant at one year follow-up was labeled as success. Multi-level mixed effect logistic regression model was employed. Study was registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) # NCT NCT03130725.

**Results:** There were 137 teeth (23 subjects) in the BAS and 128 teeth (15 subjects) in the RBS group that were evaluated for sealant retention at 12 months follow-up. Among the BAS group, 100/137 (73%) sealants were completely retained whereas 110/128 (86%) were fully retained in the RBS group. Nearly, 22/137 (16%) BAS and 10/128 (7.8%) RBS were completely dislodged. In multivariable analysis, subject age >15 years and male gender were found to be significantly associated with the dislodgement of sealants.

**Conclusions:** At 12 months follow-up, the retention of bonded amalgam sealant (BAS) was significantly lower than that of the resin-based sealant (RBS).

**Keywords:** Bonded amalgam sealants, Resin-based sealants, Retention, Caries.

**RCT Registration:** [www.clinicaltrials.gov](http://www.clinicaltrials.gov) with # NCT NCT03130725.

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### Introduction

Dental caries is a microbial disease where cariogenic bacteria living on carbohydrates produce acid that leads to dissolution of inorganic component of teeth followed by enzymatic disintegration of organic part of teeth.<sup>1</sup> It is one of the common conditions which people encounter throughout their life. According to global survey of 2009, on an average 70% of children were reported with dental caries in USA.<sup>2</sup> Untreated dental caries in children adversely affects the quality of life resulting from dental pain, causing weight loss, anorexia, sleeping problems, and changes in behaviour.<sup>3</sup> World Health Organization (WHO) has reported that caries rates are higher among children in developing countries compared to the children residing in developed countries. World Oral Health report 2003 revealed that high dental caries patterns were observed in Asia and America. However, countries including Australia, Russia and China had moderate caries rate.<sup>4</sup>

Fissure sealant is an established preventive modality

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<sup>1</sup>Department of Operative Dentistry, <sup>2</sup>Department of Clinical Research, <sup>3,4</sup>Department of Community Health Sciences, Aga Khan University, Karachi, <sup>5</sup>Department of Operative Dentistry, Dow Dental College, Dow University of Health Sciences, Karachi, Pakistan.

**Correspondence:** Farhan Raza Khan. Email: [farhan.raza@aku.edu](mailto:farhan.raza@aku.edu)

against occlusal surfaces caries in posterior teeth.<sup>5</sup> The sealant material bonds either chemically or micromechanically to the tooth surface and forms a tight seal with the enamel surface thus prevent cariogenic bacteria from damaging the tooth structure by their acidic attack.<sup>6</sup> Agencies including Centre for Disease Control and Prevention (CDC), USA and American Dental Association (ADA) has recommended dental sealants for caries control in school based oral health programmes.<sup>7</sup> Sealant retention rate decreases over time. A systematic review and meta-analysis based on 110 reports<sup>8</sup> showed that 5-year retention rate of RBS is 64.7% (95% CI=57.1-73.1%).

Staninec and co-investigators studied bonded amalgam sealant and inferred that the effectiveness of BAS was like that of conventional RBS.<sup>9</sup> Furthermore, clinical evaluation of BAS showed that it not only prevented dental caries but in addition of being readily detectable, demonstrated low marginal leakage, lowered postoperative sensitivity and had adequate retention. It has been suggested that amalgam can be used as a fissure sealant in permanent teeth. Staninec et al. have also shown that the amalgam sealants are not only durable, but their consistency and handling characteristics are also dentist-friendly.<sup>10</sup>

The objective of this trial was to compare the 12 months

retention rate of amalgam sealants with that of resin sealants in children aged 12-16 years.

## Methodology

A parallel group randomized controlled trial was done to compare the retention rate of bonded amalgam sealants with the resin-based sealants during March 2017 to December 2019. An allocation ratio of 1:1 was taken into consideration. The trial sites were the dental clinics of the Dow University of Health Sciences and the Jinnah Sind Medical University, Karachi, Pakistan. The trial protocol was registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) with # NCT NCT03130725. The CONSORT guidelines were followed for the trial.

Children aged 12 to 16 years who visited dental clinics of the two university hospitals and were willing to participate in the study were assessed for the eligibility. Children who were permanent residents of Karachi and had DMFT score of at least 2 were included in the study. Teeth were clinically assessed for the presence of

cavitated carious lesions before the sealant placement. Only caries-free and completely erupted teeth were included in the study.

Participants in both study groups were given baseline education regarding the maintenance of oral hygiene using pamphlets in the local language. Oral hygiene instructions and tooth brushing technique were explained to the study participants.

We randomly assigned 51 children having 354 sealant eligible permanent molars and premolars (as shown in Figure-1) satisfying the inclusion criterion into BAS (30 children; 177 teeth) and RBS (21 children; 177 teeth) groups. Standard clinical protocol of sealant application was followed. All the sealants were placed by dentists having more than 5 years of clinical experience. Interventional product contained three ingredients: 1) Etching Unietch (37% phosphoric acid) used in semi gel form. 2) Adhesive (Adper Single Bond, 3M-ESPE, USA and 3) Sealant material (either flowable resin material (ClinPro 3M-ESPE, USA or Amalgam (Tytin spherical high copper alloy, Kerr, USA).

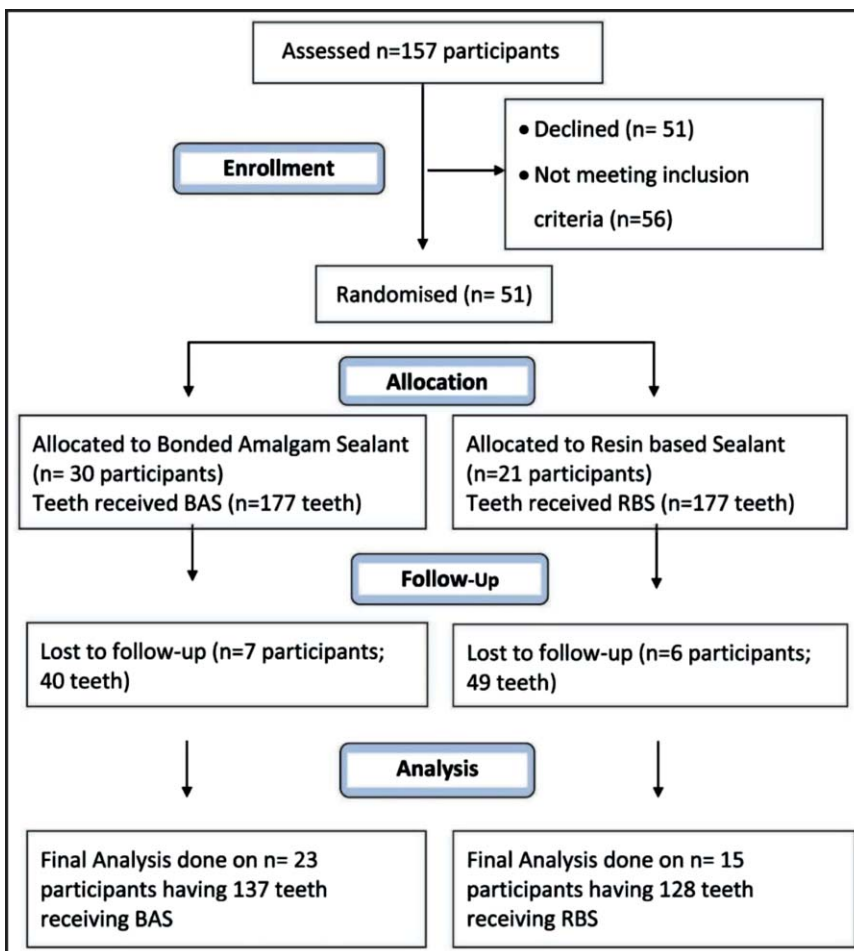


Figure-1: Study flow diagram as per CONSORT requirements NCT03130725.

For BAS, teeth were cleaned using three-in-one syringe and dried with cotton gauze and air spray. Etchant was applied on the cleaned tooth surface for 20 seconds, washed and dried with air water spray. Auto cured adhesive was applied and air thinned. Small capsule of amalgam alloy was mixed in the amalgamator and then applied directly onto the intended tooth surface. Amalgam was packed into the pits and fissure using small ball burnisher. After five minutes of initial setting time, the excess was removed using sterile cotton pellets.

The primary outcome was the retention of sealant material at 12 months follow-up (categorized into three categories: complete retention; partial retention and dislodgement). The outcome was ascertained by visual and clinical examination using mouth mirror and dental explorer. Blinding of the outcome assessor was not possible owing to the nature of intervention. Complete retention was labelled when the sealant material was found completely occupying the pits and fissures. Partial retention was

categorized when fissures were partially visible. Failure or dislodgment was considered when the fissures were completely visible.

The sample size was estimated by using NCSS PASS.<sup>11</sup> A total of 177 teeth in each arm were needed to achieve 5% significance level. This number provided the study an ability to detect a 30% clinical difference between groups with a power of 80 % and alpha 2.5% in each arm.

The group allocation was done using random number table. Even number last digit received BAS and odd numbers consequently received RBS. Both parties (study participants and the investigators) were aware of the treatment allocation. Owing to the physical nature of the intervention, it was not possible to conceal the treatment.

Clinical history, oral hygiene status and outcome were recorded on the study proforma by a trained dentist. Assent from the children and informed consent from the parents were obtained in Urdu language and retained for the record purpose. Patients and parents were assured that the individual level data will be kept confidential, and no personal identifiers of the participants will be disclosed. The investigators were responsible for the data monitoring, its audit and the quality.

**Data analysis:** Data were analyzed on SPSS 23.0. Frequency distribution of all the categorical variables (gender, maternal education, education of father, family's monthly income, frequency of tooth cleaning, method of tooth cleaning, cleaning of teeth at night, previous history of dental treatment) were determined. As data were taken at more than one level, therefore, multilevel logistic regression was used. Level of significance was kept at 0.05. Teeth characteristics were treated as primary level and patient characteristics were considered at secondary level. Tooth was taken as the unit of analysis. Missing data were excluded from the analysis. Interim analysis done at the 6 months follow-up.

## Results

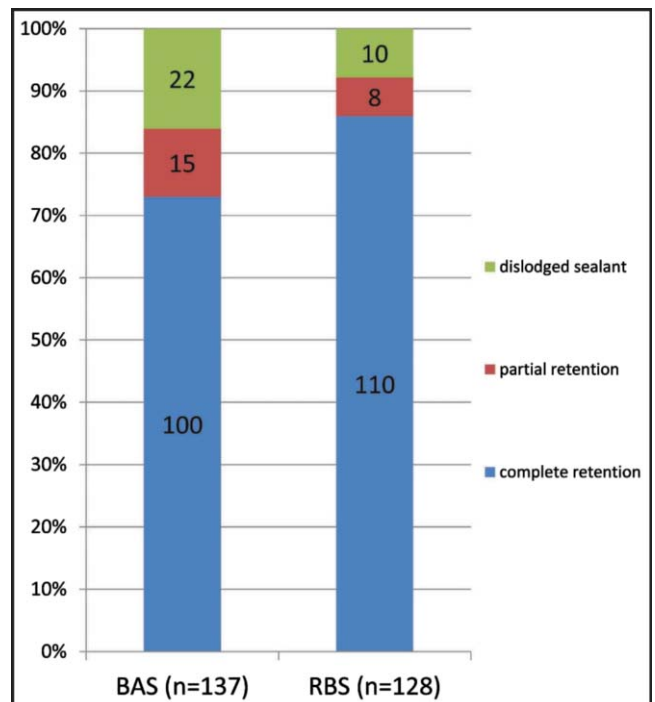
A total of 157 children were examined of which 106 were excluded for their unwillingness to participate or not satisfying the eligibility criteria. We selected 51 children (354 teeth) in the trial. Each participant contributed multiple teeth (on average 6-8 teeth) in the study. The study CONSORT flow diagram is shown as Figure-1.

The selected 51 participants were assigned treatment in a manner that there were 177 teeth in each treatment arm. At 12 months follow-up, seven subjects contributing to 40 teeth (22.6% data) were lost to follow up in the BAS group and six subjects contributing to 49 teeth (27.7 % data) were lost to follow up in the RBS group. Final analysis was

**Table-1:** Socio-Demographic characteristics of the study participants (baseline).

Variables (subject level data)	Categories	BAS (n=30)	RBS (n = 21)
Age	12 years	5(16.6%)	5(23.8%)
	13 years	7(23.3%)	5(23.8%)
	14 years	2(6.6%)	4(19.0%)
	15 years	11(36.7%)	3(14.2%)
	16 years	5(16.6%)	4(19.0%)
Gender	Male	10(33.3%)	6(28.5%)
	Female	20(66.6%)	15(71.4%)
Education of Mother	No Schooling	9(30%)	7(33.3%)
	Primary school	2(6.6%)	4(19.0%)
	Secondary school	13(43.3%)	2(9.5%)
	Intermediate	1(3.3%)	3(14.2%)
	Graduate and above	5(16.6%)	5(23.8%)
Education of Father	No Schooling/Primary school	10(33.3%)	8(19.0%)
	Secondary school	13(43.3%)	6(28.5%)
	Intermediate	5(16.6%)	2(9.5%)
	Graduate and above	2(6.7%)	5(23.8%)
Monthly Income in rupees	Less than 10,000	5 (16.6%)	3(14.2%)
	10,000-15,000	12 (40.0%)	7(33.3%)
	More than 15000	12 (40.0%)	4(19.0%)
	Not known	1 (3.3%)	7(33.3%)
Ethnicity	Sindhi	8 (26.6%)	5(23.8%)
	Punjabi	1 (3.3%)	10(47.6%)
	Saraiki	1 (3.3%)	2(9.5%)
	Other	14 (46.6%)	1(4.7%)
	Urdu speaking	6 (20.0%)	3(14.2%)

n refers to the number of participants.



**Figure-2:** Retention of sealant material in the two study groups at 12 months' follow-up.

**Table-2:** Baseline characteristics of the participants in the treatment arms.

Variables at participant level	Categories	BAS (n = 30)	RBS (n = 21)
Previous history of dental treatment	No treatment	24 (80%)	17 (80.9%)
	Other treatments (Extraction, Filling and Pulpectomy /Root Canal)	6 (20%)	4 (19.0%)
Plaque Index	-	2.02 (0.44)	1.67 (0.54)
Method of cleaning	Once a baby brush (Manual/Electric)	27 (90%)	19 (90.4%)
	Others (Fingers, Miswaak/ Dandaas, Soft cleaning cloth, Rinsing with water)	3 (10%)	2 (9.5%)
Betel nuts	No(reference)	7 (23.3%)	6(28.5%)
	One pack/day	6(20%)	3(14.2%)
	Two pack/day	8(26.6 %)	3(14.2%)
	Three pack/day	2(6.7%)	2(9.5%)
	More than three pack/day	2(6.7%)	5(23.8%)
	Rarely	5(16.7%)	2(9.5%)
Dietary consumption	No Bar/Day (reference)	3 (10%)	6 (28.5%)
Chocolate	Daily Intake	27(90%)	15 (71.4%)
Ice cream	No ice cream/Daily (reference)	5 (16.7%)	7 (33.3%)
	Daily Ice cream eater	25 (83.3%)	14(66.6%)
Sweets	No sweets/day (reference)	4 (13.3%)	5(23.8%)
	Daily sweets eater	26(86.6%)	16(76.2%)
Drinks	No drinks/daily (reference)	16(53.3%)	8(38.1%)
	Yes/daily	14(46.7%)	13(61.9%)
	No burger/daily (reference)	11(36.7%)	5(23.8%)
	Yes/daily	19 (63.3%)	16(76.2%)
Burger	No pizza/daily (reference)	21(70%)	11(52.3%)
Pizza	Yes pizza/daily	9 (30%)	10 (47.6%)
Medicine	No (reference)	27 (90%)	19 (90.5%)
	Yes	3 (10%)	2 (9.5%)
Fluoride toothpaste	Yes (reference)	19 (63.3%)	18 (85.7%)
	No	11 (36.7%)	3 (14.3%)
Fluoridated water use	Yes (reference)	26 (86.7%)	15 (71.4%)
	No/Don't know	4 (13.3%)	6 (28.6%)

n refers to the number of participants.

**Table-3:** Risk factors affecting retention using Crude Odds Ratio with 95% Confidence Intervals.

	Factor	Crude Odds Ratio (95% CI)	Model 1	Model 2	Model 3
Group	RBS (ref)	1	1	1	1
	BAS	0.57 (0.34,0.95)	0.57 (0.34,0.95)	0.54 (<0.01,175.64)	0.56 (0.37, 0.95)
Gender	Male (ref)	1	1	1	1
	Female	0.027 (0.003, 0.20)	0.02 (0.003,10.19)	0.024 (0.001, 0.20)	0.012 (0.001, 11.28)
Age	12 years (ref)	1	1	1	1
	13 years	0.89 (0.37, 2.39)	0.89 (0.33,2.39)	0.83 (0.32, 2.4)	0.82 (0.16,4.22)
	14 years	1.08 (0.34, 3.42)	1.08 (0.34,3.42)	1.09 (0.56,3.9)	1.14 (0.17, 7.30)
	15 years	0.28 (0.11, 0.69)	0.28 (0.115,0.69)	0.29 (0.111, 0.75)	0.11 (0.003, 3.45)
	16 years	3.08 (0.74, 2.82)	3.08 (0.74,12.82)	3.5 (0.85, 3.8)	5.31 (0.35, 79.17)
Frequency of teeth cleaning	Once/day (ref)	1	1	1	1
	Twice a Day	0.83 (0.50, 1.39)	0.83 (0.50, 1.39)	0.82 (0.28,2.41)	0.83 (0.048,14.3)
Plaque index		1.75 (1.10, 2.78)	1.75 (1.10,2.78)	2.25 (0.41,12.20)	2.25 (0.41, 12.2)
Chocolate	No (ref)	1	1	1	1
	Regular intake	1.69 (0.92, 3.06)	1.03 (0.57,1.86)	1.76 (0.058, 53.29)	1.75 (0.10,29.32)
Ice cream	No (ref)	1	1	1	1
	Regular intake	1.03 (0.57, 1.86)	1.03 (0.57, 1.86)	1.04 (0.53, 2.02)	1.04 (0.45, 2.39)
Fluoride in water	No (ref)	1	1	1	1
	Yes	3.61 (1.49, 8.74)	3.61 (1.49,8.74)	3.85 (1.29, 8.8)	3.17 (0.008,16.06)
Hypo- mineralized tooth	No (ref)	1	1	1	1
	Yes	0.071 (0.009,0.532)	0.71 (0.009, 0.53)	0.064 (0.01, 2.1)	0.064 (0.002, 19.23)
Use of medicines in childhood	No (ref)	1	1	1	1
	Yes	0.59 (0.19, 1.80)	0.59 (0.19, 1.80)	0.57 (0.17, 2.2)	0.58 (0.001, 28.2)

done on 38 participants (Figure-1). Frequency distribution of the participants in the two groups are shown in Tables 1 and 2.

There were 137 teeth (23 subjects) in the BAS and 128 teeth (15 subjects) in the RBS group that were evaluated for sealant retention at 12 months from placement. Complete retention of sealants was observed in 100/137 (73%) in BAS and 110/128 (86%) in the RBS group. Partially retained sealants were observed in 15/137 (11%) and 8/128 (6.2%) teeth in BAS and RBS, respectively. Regarding failures, 22/137 (16%) in BAS and 10/128 (7.8%) in RBS were completely dislodged (Figure-2).

Following variables were significant at the bivariate analysis: type of sealant, age of child, gender, tooth brushing frequency, consumption of ice creams and chocolates etc. Presence of fluoride in water and presence of hypo-mineralized teeth were negatively associated with the sealant retention. Moreover, the use of childhood medicines was also statistically significant (OR=0.59; 95% CI: 0.19-1.80).

All independent variables were retained in the statistical model to determine association between the independent variables and the outcome. Initially three models were made. First model had tooth level variables, second model included patient level characteristics whereas the third model was constructed by including both the teeth and participant level variables (Table-3). At combined level, the main exposure (BAS vs. RBS) had no effect over the retention of the sealant. (OR= 0.56; 95% CI: 0.37- 0.95).

## Discussion

The present study showed significantly inferior retention at 12 months follow up of BAS compared to RBS. There were 22/137 (16%) sealant failures in the BAS group compared to 10/128 (7.8%) in the RBS (Chi-square p-value 0.03). It's interesting to note that there was no significant difference in the retention of two sealants in the first six months. However, with time, a substantial proportion of BAS experienced dislodgment from the tooth surface. This could be due to deterioration of the bond between the adhesive resin and the silver alloy particles.

Staninec<sup>10</sup> has shown that in terms of retention, BAS is comparable to RBS (mean difference of only 0.08). Staninec's five-year long clinical trial also demonstrated that both RBS and BAS are retentive.<sup>11</sup> However, in the present study, one year follow-up showed that BAS had only 100/137 teeth (73%) with retained sealant. This was not at par with the RBS 110/128 teeth (86%). This

difference could be attributed to poor isolation technique (cotton wool roll isolation) employed in the present study as no additional funding was available for rubber dam. Another explanation could be poor bonding of amalgam alloy with the adhesive.

For RBS, the present study showed 86% retention. This is similar to other studies. Mejare and Mjor<sup>12</sup> conducted a clinical trial to compare the retention of RBS and reported retention rate of over 90%. Poulsen et al.<sup>13</sup> too have reported a retention rate of >82% for RBS.

Llodra et al. studied the factors that could influence the clinical effectiveness of sealants. They observed sealants retention was high in areas supplied with fluoridated drinking water.<sup>14</sup> Our findings are also somewhat similar to their results as we too observed a positive effect of fluoridated water consumption as well as use of fluoridated tooth paste with the sealant retention (Table-2). In our study, females experienced more sealant dislodgment. Biologically, there is no clinical plausibility for such an observation. Such statistical significance might have resulted due to sampling errors as there were unequal numbers of participants in the two treatment groups. Folke et al. has also reported an insignificant association of gender with the sealant retention.<sup>15</sup>

Other possible reasons behind low sealant retention (particularly in the BAS) may be due to dietary factors. Most children in the study sample were not taking healthy diet. Consumption of betel nut and other abrasive food items were common in children of low socio-economic status in South Asian culture. All participants in the present study were mainly from the low socio-economic stratum (SES). It's known that people with low SES usually have high unemployment, increased family size and poor oral hygiene.<sup>16</sup> Other possible reasons behind poor retention of sealants could be that each participant contributed to multiple teeth in the sample. Moreover, a universally agreed upon definition of sealant retention is not there in the dental profession, therefore, for the study, we used the sealants retention guidelines advised by Deery.<sup>17</sup>

The lost to follow up in the present study were 7 participants; 40 teeth (22.6% data) in the BAS and 6 participants; 49 teeth (27.7% data) in the RBS groups, respectively. The differential attrition in the two groups could lead to difference in the retention rates for the study groups. In the present study, BAS fails to demonstrate its efficacy against RBS. However, with 73% retention at twelve months follow-up, BAS still can be used in management of incipient caries among high-risk children.

Use of amalgam sealants in resource restraint populations can reduce the cost burden of treatment, as amalgam is cheaper compared to RBS. Moreover, it's readily detectable on the tooth surface; a characteristic that can be useful in community-based surveys.

The present study was the first study one on amalgam sealants in south Asia. Using amalgam sealants paves the way of low-cost solution of dental caries management. The untreated dental caries may later need expensive treatments such as fillings or endodontic therapy. A considerable proportion of population in developing countries is unable to financially afford this treatment. This creates room for the use of amalgam sealants. However, this needs to be looked again in the context of the Minamata Treaty<sup>18</sup> which aims at reducing the release of mercury into the environment. The treaty advocates a phase-down in the use of amalgam. However, the domestic circumstances of each country and especially the economic position of the developing countries should be considered before following the legislation on such accords.

An established limitation of the present study is the lack of blinding of the data collector and data assessor. Due to nature of the intervention, all parties were ought to be aware of the treatment allocation. The clinical relevance of this study is that the resin-based sealants are commonly used for the prevention of pits and fissures caries and arresting incipient carious lesions. However, due to the cost of resin-based sealants, many children in the third world countries remain untreated. Amalgam sealants although are inferior to RBS with respect to retention, can still be employed as a viable option for these children. Amalgam based sealants are cost-effective and can be used as a dental public health intervention in the low-income populations.

## Conclusions

At six months evaluation, the retention of both sealants was comparable. However, at 12 months follow-up, the retention of bonded amalgam sealant (BAS) was significantly lower than that of the resin-based sealant (RBS).

**Ethics Approval:** All procedures performed in the present study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The reference of Ethics review committee of the Aga Khan University was #4445-CHS-ERC-16. The reference of institutional review boards

of the Dow University of Health Sciences (IRB-989/DUHS/2018/128) and the Jinnah Sind Medical University (F.2-81/2017-GENL-IRB/4521/JPMC).

**Informed Consent:** Informed consent was obtained from all parents/guardians of participants included in the study. We obtained the informed consent from the study participants in native language (Urdu).

**Disclosure and Consent to Publish:** Some of the data in the present paper was presented at MSc of Dr Samreen Liaquat. However, the one-year data were never shared, presented or published elsewhere. All authors have expressed their consent to publish.

**Disclaimer:** The AKU-URC grant covered dental materials, consumables and equipment needed for placing amalgam sealants and resin-based sealants but did not cover the procedure fee that is charged at the dental clinics. Hence, it was decided to carry out the trial at the public sector dental institutions (Dow Dental College and JSMU) where there is no separate fee for procedures. Therefore, IRB approvals from DUHS and JSMU were also taken after AKU-ERC approval. Dr Arshad Hasan did the oversee of the trial outside AKUH.

**Conflict of Interest:** All authors declare that there is no conflict of interest regarding this paper.

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