



Original Article

บทวิทษฬกร

# Comparison of the retention rate of resin sealant between Prevocare™ plus a drying agent and Concise™ under field conditions

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## Abstract

**Objective** To evaluate the equivalence of the retention rate of resin sealant Prevocare™ (Chulalongkorn, Thailand), plus a post-etching drying agent, and Concise™ (3M ESPE, U.S.A.) placed under field conditions over a 36-month period.

**Materials and methods** One hundred and thirty-eight pairs of contralateral first permanent molars from 122 hill-tribe school children aged 6-12 years old in Chiang Rai province, Thailand, were selected. A matched pair experimental design was used in which Prevocare™ (opaque) plus post-etching drying agent and Concise™ were randomly allocated to one of the teeth within each pair. The treatment was performed by three pediatric dentists under field conditions. After 6, 12, 24 and 36 months, another dentist evaluated the retention and caries of the sealed molars. The data were analyzed by statistical programs SPSS (version 11) and STATA (version 7). A confidence interval approach was used to compare the retention of the two sealants. In this study, clinical equivalence of the two sealants was accepted when the retention rate difference at 95% confident interval was within 10%.

**Results** At 12 months, the retention rates of Prevocare™ plus post etching-drying agent and Concise™ were 87.4 and 85.8%, respectively. The mean difference of retention rates were 1.6% (95% CI-6.8, 9.9%). And finally at 36 months, the retention rates in both groups were decrease to 70.0 and 68.2%. The mean difference of retention rates were 1.9% (95% CI-9.0, 12.8%). At the end of the study, seven carious teeth were detected in the Concise™ group.

**Conclusion** The retention rate of Prevocare™ plus a drying agent was not inferior to that of Concise™ under field condition at 36 months follow-up.

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**Key words:** drying agent; field condition; resin sealant; retention

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## Introduction

Dental caries is a silent health epidemic affecting large populations in developing countries. In Thailand, it is reported that 56.9% of 12 year old children had carious teeth with an average DMFT score of 1.6. Of the teeth with dental caries, first and second permanent molars were the most affected teeth. Unfortunately, 45.7% of the carious teeth were left untreated.<sup>1</sup>

Dental caries is preventable with the use of personal daily oral hygiene practices such as tooth brushing with fluoride toothpaste and health care provider-based intervention, including pit and fissure sealants.<sup>2</sup> It is well established that fully retained pit and fissure sealants can protect teeth from bacterial metabolic acid attack with subsequent demineralization, and caries development. The effectiveness of sealants in reducing the occurrence of pit and fissure caries was reported as 92-96% at the end of 1 year and 67-82% after five years.<sup>3</sup> Despite these findings, the use of pit and fissure sealants in Thailand is low. Poverty is a major factor in inadequate access to oral health care.<sup>4</sup> From the National Survey, 39.1% of the children requiring sealants have been left untreated.<sup>1</sup> In the year 2000, Thai researchers at the Faculty of Dentistry, Chulalongkorn University developed a new sealant which was distributed commercially in 2005 under the brand name "Prevocare"<sup>TM</sup>.<sup>5</sup> Prevocare<sup>TM</sup> sealant is composed of aromatic and aliphatic dimethacrylate monomers, tertiary amine, and a light activator.<sup>6</sup> From a clinical study performed in a dental clinic setting, the retention rate of 5 Prevocare<sup>TM</sup> (opaque) at 1 and 2 year follow-ups was 95 and 88.7%, respectively. In these studies, Prevocare<sup>TM</sup> was clinically equivalent to Concise<sup>TM</sup> in terms of retention rates.<sup>7,8</sup> A study performed in a school-based setting with a high speed suction comparing Prevocare<sup>TM</sup> (Clear) to Delton<sup>®</sup>, indicated the retention of Prevocare<sup>TM</sup> was 94.5%, which was clinically equivalent to Delton<sup>®</sup> (93.7%) at the end of one year.<sup>9</sup>

In previous studies, the retention rate of Delton<sup>®</sup> and Concise<sup>TM</sup> ranged from 44.1-97.6% at the end of 12 months.<sup>10-13</sup> However, in field studies done in Thailand, the retention rate of both Delton<sup>®</sup> and Concise<sup>TM</sup> at 12 months was only 19.62-72.2%.<sup>14-17</sup> The major cause of failure was insufficient moisture control. To control the moisture, in vitro studies investigated the use of an acetone based post-etching drying agent to minimize residual moisture and found sealant plus a post-etching drying agent significantly improved the sealant quality by increasing the penetration depth of the sealant into the fissures<sup>18</sup> and significantly reduced microleakage.<sup>19</sup> On the contrary, other in vitro studies revealed no significant microleakage reduction by using drying agent.<sup>20,21</sup> In addition, a clinical study reported the failure rate of a sealant (Ultra-Seal) plus a post-etching drying agent (Ultra-dent) was less than that using conventional technique (Ultra-Seal alone) but the results were not statistically significant at 12 months.<sup>22</sup> Thus, under field conditions, the use of a post-etching drying agent might be able to reduce moisture contamination and improve the sealant retention rate. However, there have been no studies to investigate the retention of Prevocare<sup>TM</sup> with the use of a post-etching drying agent as compared to a conventional product such as Concise<sup>TM</sup>. The purpose of this clinical study was to evaluate the clinical retention of Prevocare<sup>TM</sup> plus a post-etching drying agent and Concise<sup>TM</sup> under field conditions.

## Materials and methods

The research protocol for this study was approved by the Ethics Committee of the Medical School, Chulalongkorn University (Ethics No. 174/2004). In this study, one hundred and twenty-two hill-tribe school children age 6-12 years-old in Chiang Rai province, Thailand were enrolled by the inclusion criteria of cooperative children with pair sound teeth in the same arch. The teeth with enamel defect were

excluded. After obtaining written consent from the parents, a total of 138 pairs of contralateral first permanent molars were treated. A matched pair experimental design was used in which Prevocare™ (opaque) plus 2.5% acetone by weight post-etching drying agent (Chulalongkorn University, Thailand) and Concise™ (3M ESPE, U.S.A.) were randomly allocated to one of the molars within each pair and placed under field conditions using low speed suction and a mobile dental unit. The treatment was performed by three postgraduate pediatric dentists with chair-side dental assistance. The children's mouths were kept open by using a Molt mouth prop.

Each tooth was thoroughly cleaned with a prophylaxis cup using pumice and water. Additional debridement was done with a sharp explorer. Each molar to be sealed was isolated with cotton rolls and gauzes. Low-pressured suction was used. After the tooth was cleaned and isolated, the occlusal surface was etched for 15 seconds with 37% phosphoric acid, rinsed for 20 seconds, and then dried with oil-free compressed air for 10 seconds. In case of contamination after etching, the tooth was re-etched for 10 seconds. For the Prevocare™ group, after etching, rinsing, and drying, the 2.5% acetone-solution drying agent was applied on the tooth surface for 5 seconds and then dried with oil-free compressed air for 5 seconds. Both sealants were applied by a brush and light cured for 20 seconds each on the occlusal and buccal/lingual surfaces using 450 mw/cm<sup>2</sup> output visible light curing units (Optilux 400, Demetron Research Corporation, USA). Occlusal interference was checked using articulating paper and adjusted with a slow-speed white stone bur and flame shaped finishing bur.

### Clinical evaluation

The subsequent 6, 12, 24, and 36 month clinical evaluations were performed by a single examiner using a mouth mirror and an explorer under the light of the

mobile unit for field operation. The examiner was a dentist who was not involved in the treatment sessions. The sealant was evaluated for retention and margin integrity. On each surface the sealants were judged as "fully retained" if the primary groove was completely occluded by the sealant material, "partial loss" if the sealant material was clinically absent from any area of primary pits and fissures, and "complete loss" if the sealant material could not be detected with an explorer in any part of the primary pits and fissures.<sup>23</sup> The tooth was judged to be a "success" if the sealant was fully retained in all parts of the fissure system on all surfaces and a "failure" if there was partial or complete loss in any area of the pit and fissure system of any surface. If the tooth had cavitated dental caries, it was excluded from further participation in the study and restored.

### Statistical analysis

The data were analyzed using the computer statistical programs SPSS version 11 and STATA version 7 to compare the differences between the two sealants. Clinical equivalence of the two sealants was defined as when the retention rate difference was within 10% using the 95% confidence interval approach.<sup>7</sup>

### Intra-examination reliability

Twenty percent of the samples were re-examined to determine intra-examiner reliability. Kappa statistics were calculated and the intra-examiner reliability was accepted at  $Kappa > 0.6$ .<sup>24</sup>

## Results

The study sample comprised 122 hill-tribe school children, 57 males (46.7%) and 65 females (53.3%), with a mean age of  $8.4 \pm 1.4$  years old and mean DMFT and dmft scores of  $1.3 \pm 0.8$  and  $3.5 \pm 2.9$ , respectively. Of the 122 participants, 119 (97.5%) returned at 6 months, 113 (92.6%) at 12 months, 105 (86.0%) at 24

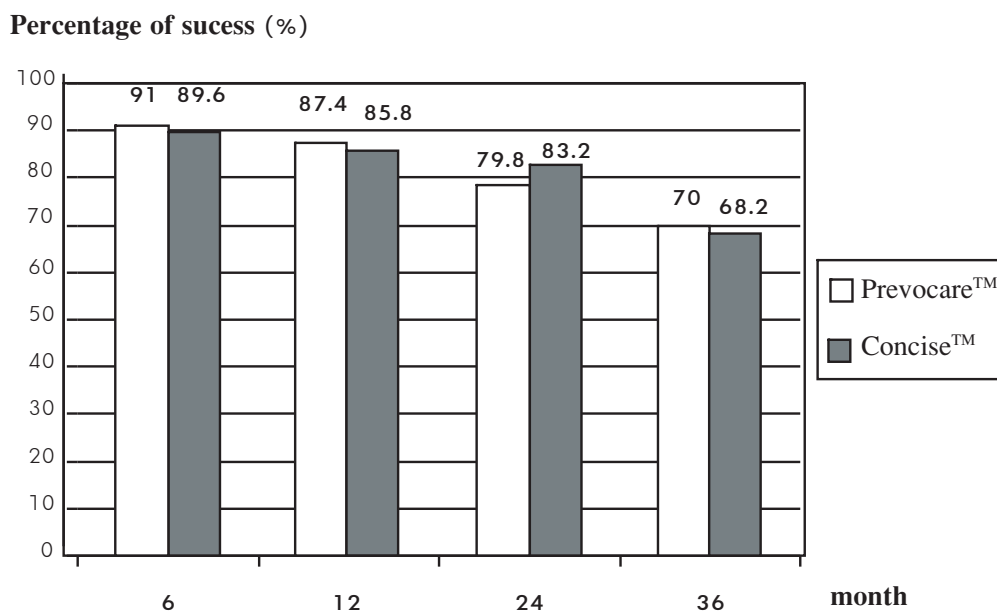
months, and 94 (77.0%) at 36 months, representing 134 (97.1%), 127 (92.0%), 119 (86.2%) and 107 (77.5%) pair sealants, respectively. Table 1 shows the distribution of the sealants between maxillary and mandibular molars at treatment and the four recall intervals. At the 36 month follow up, 7 carious teeth were found in the Concise™ group.

The percentage of fully retained sealants at 6, 12, 24 and 36 months was shown in Fig 1. In both groups, the highest retention was found at 6 months, then

gradually dropped at 12, 24 and 36 months. The percentage of successful sealants at 36 months in the Prevocare™ plus a drying agent and Concise™ groups were 70.0 and 68.2%, respectively. In Concise™ groups, 7 teeth with total loss developed carious lesion (1 tooth at 12 month period, and 6 teeth at 36 month period). The carious lesions were on 1 buccal surface, 4 occlusal surfaces, and 2 on both surfaces. From the equivalence study at 10% acceptable rate, the retention rate of Prevocare™ plus a drying agent was equivalent

**Table 1** The distribution of sealants between maxillary and mandibular molars at baseline and four recall intervals.

	<b>Baseline</b> (pairs/percent)	<b>6 months</b> (pairs/percent)	<b>12 months</b> (pairs/percent)	<b>24 months</b> (pairs/percent)	<b>36 months</b> (pairs/percent)
<b>Maxillary molars</b>	107/77.5	104/75.4	98/71.0	92/66.7	82/59.4
<b>Mandibular molars</b>	31/22.5	30/21.7	29/21.0	27/19.6	25/18.1
<b>Missing</b>	-	4/2.9	11/8.0	19/13.7	31/22.5
<b>Total</b>	138/100	138/100	138/100	138/100	138/100



**Fig. 1** The percentage of success, fully retained sealant of Prevocare™ plus a drying agent and Concise™

to Concise™ at the 6 and 12 months intervals but not certain equivalent at 24 and 36 months (Table 2). At each recall evaluation, the analysis of intra-examiner agreement showed that the intra-examiner reliability was acceptable. The Kappa statistics at 6, 12, 24, and 36 months were 0.88, 0.80, 0.79, and 0.80, respectively.

### Discussion

Pit and fissure sealant is an effective modality for caries prevention in the permanent dentition.<sup>3</sup> In order to protect the tooth from carious lesions, the sealant

must be fully retained.<sup>25</sup> The major factor influencing the retention of a sealant is meticulous moisture control.<sup>26</sup> In Thailand, the field dental service is organized to serve children in remote villages where they have little access to dental care. However, previous Thai field studies showed low sealant retention rates ranging from 19.6–72.2% at the end of the first year.<sup>14–17</sup> In our field study, the retention rates of Prevacare™ plus a drying agent and Concise™ at 12 months were 87.4 and 85.8%, respectively. The retention rates of Prevacare™ with conventional method in a clinical setting at 1 and 2 years were 95

**Table 2** The mean difference of success in retention rates of Prevacare™ plus a drying agent and Concise™

Material	N (teeth)	Mean (%)	Success rate span at 95% Confidence Interval (%)
6 months			
Prevacare™	134	91.1	86.1–96.0
Concise™	134	89.6	84.3–94.8
Mean difference of success		1.5	–5.1–8.1
12 months			
Prevacare™	127	87.4	81.6–93.3
Concise™	127	85.8	79.7–91.9
Mean difference of success		1.6	–6.8–9.9
24 months			
Prevacare™	119	79.8	72.5–87.1
Concise™	119	83.2	76.4–90.0
Mean difference of success		–3.4	–12.9–6.2
36 months			
Prevacare™	107	70.0	61.3–78.9
Concise™	107	68.2	59.3–77.2
Mean difference of success		1.9	–9.0–12.8

and 88.7%, respectively.<sup>7-8</sup> Under less controlled conditions such as mobile clinic, temporary facilities, and warm climate, the longevity of the sealants were lower than those placed in an ideal clinical setting.<sup>27</sup> However, our results were similar to other international field studies.<sup>28-30</sup> Using the mobile dental chair with low pressure suction, the retention rate of our field study was higher than previous Thai field studies.<sup>15-17</sup> A high sealant retention rate can be achieved with strict adherence to the manufacturer's technique guidelines and meticulous moisture control. The application of sealants is a simple procedure but must be performed precisely to the manufacturer's recommendations at each step. Additionally, the light curing unit should be checked periodically to ensure that the intensity of the light is 450 mw/cm<sup>2</sup>. In our study, the moisture was controlled by means of patient selection, intact triple syringe, and immobilization of the jaws by using a Molt mouth prop, and utilizing a chair-side dental assistant.

Patient selection plays an important role in the retention of sealants.<sup>31,32</sup> In our study, all of the participants were co-operative children with a mean age of 8.4 ± 1.4 years old. Walker *et al.* found that sealants placed in the first permanent molars of 6, 7 and 8 year-olds required more retreatment than those in older children.<sup>32</sup> Factors contributing to these failures might be the stage of tooth eruption and the patient's behaviour. The use of a chair-side assistant for each operator is critical for sealant success. Four-handed dentistry is essential for adequate isolation and efficient sealant placement.<sup>33</sup> Moreover, the use of jaw movement restriction can play an important role in preventing saliva contamination. It is well documented that sealant failures can be expected to be 5 to 10% yearly.<sup>27</sup> In the present study, the retention of sealant decreased 19.9-20.5% by the final recall at 36 months.

Since comparison between the two methods, the clinician prefer to use the results that could be

recognized clinically. Jones advocated that the clinical equivalent should be used to test the efficacy of a new method compared to the original one.<sup>34</sup> To compare the retention of Prevocare<sup>TM</sup> with post-etching drying agent and Concise<sup>TM</sup>, the clinical equivalence at the 95% confidence interval was used. In our study, the mean difference of success rates of Prevocare<sup>TM</sup> with a drying agent was equivalent to Concise<sup>TM</sup> at the 12 month period. The mean difference of success in retention rates of both sealants was between -5.1 to 8.1, within the 95% confidence interval. However, at 24 month periods, the mean retention rate was not equivalence. And also, at the end of 36 month periods, the mean retention rate of Prevocare<sup>TM</sup> plus a drying agent and Concise<sup>TM</sup> were 70.0 and 68.2%, respectively. The difference of success of Prevocare<sup>TM</sup> with a drying agent and Concise<sup>TM</sup> was not within 10%. (-9.0 to 12.8%). Some teeth in Prevocare<sup>TM</sup> group got better retention rate as some did not. So, it can be concluded that the retention rate of Prevocare<sup>TM</sup> plus a drying agent was not inferior to that of Concise<sup>TM</sup>. At the end of our study, both groups had cases with total loss of sealants, but seven teeth in the Concise<sup>TM</sup> group developed carious. The caries protection in Prevocare<sup>TM</sup> plus a drying agent might be from retained resin tags. A previous *in vitro* study revealed that post-etching drying agent results in longer resin tags.<sup>18</sup> In the field condition situations with compromised moisture control, the use of drying agent may be an additional option. However, the additional step of post-etched drying agent requires more chair time, further study should be conducted to compare the retention rate of Prevocare<sup>TM</sup> with the conventional method.

Under field dental service, a high retention rate of sealant could be achieved by means of good application technique, patient selection, and meticulous moisture control including the use a chair-side assistant, and a jaw immobilization device. The retention of Prevocare<sup>TM</sup> plus a drying agent was shown not inferior to the conventional resin sealant, Concise<sup>TM</sup> at 36 months.

## Conclusion

At the 36 month follow-up, the retention rates of Prevocare™ plus a drying agent and Concise™ were 70.0 and 68.2%, respectively. Under field condition, the retention rate of Prevocare™ plus a drying agent was not inferior to that of Concise™.

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# การเปรียบเทียบอัตราการยึดติดของเรซินผนึกหลุม และร่องฟันระหว่างชนิดพรีโวกแคร์ร่วมกับสาร ทำให้แห้งและชนิดคอนไซส์ในการศึกษาภาคสนาม

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## บทคัดย่อ

**วัตถุประสงค์** เพื่อศึกษาความเท่าเทียมของอัตราการยึดติดของสารผนึกหลุมและร่องฟันชนิดเรซิน “พรีโวกแคร์” (จุฬาลงกรณ์ ประเทศไทย) ร่วมกับสารทำให้แห้ง กับสารผนึกหลุมและร่องฟัน “คอนไซส์” (3M ESPE สหรัฐอเมริกา) ที่ช่วงระยะเวลา 36 เดือน ในการปฏิบัติงานภาคสนาม

**วัสดุและวิธีการ** ทำการศึกษาในเด็กนักเรียนชาวไทยภูเขามืออายุระหว่าง 6-12 ปี จำนวน 122 คน ในจังหวัด เชียงราย ประเทศไทย โดยคัดเลือกฟันกรามแท้ซี่ที่หนึ่งในขากรรไกรเดียวกันจำนวน 138 คู่ฟัน เพื่อจัดตัวอย่าง เข้าศึกษาด้วยวิธีสุ่มอย่างง่าย จัดให้ฟันข้างหนึ่งได้รับการผนึกหลุมและร่องฟันด้วยพรีโวกแคร์ชนิดซุนร่วมกับ สารทำให้แห้งภายหลังการปรับสภาพผิวเคลือบฟันด้วยกรดและฟันอีกข้างได้รับการผนึกหลุมและร่องฟันด้วยคอนไซส์ การผนึกหลุมและร่องฟัน ทำโดยทันตแพทย์สำหรับเด็ก 3 คน โดยใช้เก้าอี้สนาม ติดตามผลการยึดติดของวัสดุ และการเกิดฟันผุโดยทันตแพทย์อีกคนที่ระยะเวลา 6 12 24 และ 36 เดือน นำผลการวิจัยมาทดสอบทางสถิติด้วย โพรแกรมเอสพีเอสเอส (เวอร์ชัน 11) และสตราต้า (เวอร์ชัน 7) เพื่อทดสอบความเท่าเทียมกันของสารทั้งสองชนิด โดยยอมรับความแตกต่างของอัตราการยึดติดของสารทั้งสองชนิดในช่วงความเชื่อมั่นร้อยละ 95 ในระดับไม่เกินร้อยละ 10

**ผลการศึกษา** ในระยะ 12 เดือน พบว่าฟันที่ได้รับการผนึกหลุมและร่องฟันด้วยพรีโวกแคร์ร่วมกับสารทำให้แห้ง สารภายหลังการเตรียมผิวเคลือบฟันด้วยกรด และกลุ่มคอนไซส์มีอัตรายึดติดสมบูรณ์ร้อยละ 87.4 และ 85.8 ตาม ลำดับ ผลต่างเฉลี่ยของอัตราการยึดติดของสารผนึกหลุมและร่องฟันทั้งสองมีค่าเป็นร้อยละ 1.6 (ช่วงความเชื่อมั่น ร้อยละ 95 อยู่ในช่วง -6.8, 9.9) เมื่อสิ้นสุดการทดลองที่ระยะเวลา 36 เดือน พบว่าในกลุ่มพรีโวกแคร์ร่วมกับสาร ทำให้แห้งมีอัตราการยึดติดสมบูรณ์ลดลงเหลือร้อยละ 70.0 และในกลุ่มของคอนไซส์มีอัตราการยึดติดสมบูรณ์ ลดลงเหลือร้อยละ 68.2 ผลต่างเฉลี่ยของอัตราการยึดติดของสารผนึกหลุมและร่องฟันทั้งสองมีค่าเป็นร้อยละ 1.9 (ช่วงความเชื่อมั่นร้อยละ 95 อยู่ในช่วง -9.0, 12.8) โดยพบรอยผุในกลุ่มคอนไซส์ 7 ซี่

**สรุป** ในการศึกษาภาคสนามพบว่าเรซินผนึกหลุมและร่องฟันชนิดพรีโวกแคร์ร่วมกับสารทำให้แห้งมีประสิทธิภาพ ในการยึดติดไม่ด้อยกว่าเรซินผนึกหลุมและร่องฟันชนิดคอนไซส์ที่ระยะเวลา 36 เดือน

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**คำสำคัญ:** การยึดติด; การศึกษาภาคสนาม; เรซินผนึกหลุมและร่องฟัน; สารทำให้แห้ง

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