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· 临床研究 ·

# 氟保护漆、玻璃离子与树脂类窝沟封闭剂预防低龄儿童窝沟龋效果观察

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**【摘要】** 目的 研究氟保护漆、玻璃离子与树脂类窝沟封闭剂预防低龄儿童窝沟龋的效果, 探讨在隔湿有限的情况下, 减少操作技术敏感性并能有效预防低龄儿童窝沟龋的方法。方法 3~5岁儿童370例, 采用自身对照设计, 口内8颗乳磨牙分布在4个象限中, 4个象限随机选择设置为空白组、氟保护漆多乐氟组、玻璃离子GC Fuji VII组、树脂类Clinpro™ Sealant组, 分别于6、12、24、36个月复查, 观察乳磨牙窝沟封闭剂的保留率和患龋率。结果 6、12、24个月时, GC Fuji VII组和Clinpro™ Sealant组的材料保留率差异无统计学意义; 36个月时, Clinpro™ Sealant组封闭剂的保留率高于GC Fuji VII组( $P < 0.05$ )。6个月时, 多乐氟组、GC Fuji VII组、Clinpro™ Sealant组患龋率均低于空白组, 差异有统计学意义( $P < 0.001$ ), 多乐氟组、GC Fuji VII组、Clinpro™ Sealant组三组患龋率差异无统计学意义, 12、24、36个月时, GC Fuji VII组和Clinpro™ Sealant组患龋率均低于多乐氟组和空白组, 差异有统计学意义( $P < 0.001$ ); 空白组和多乐氟组患龋率差异、GC Fuji VII组和Clinpro™ Sealant组患龋率差异均无统计学意义。结论 与单纯涂氟化物相比, GC Fuji VII组和Clinpro™ Sealant组均能较为持久有效地预防窝沟龋, 但在低龄幼儿配合欠佳、且无法获得良好隔湿的情况下, 采用玻璃离子型窝沟封闭剂(GC Fuji VII)的预防措施更为简便易行。

**【关键词】** 低龄儿童; 窝沟龋; 窝沟封闭; 氟保护漆; 多乐氟; 玻璃离子窝沟封闭剂; 树脂窝沟封闭剂; 患龋率; 保留率

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**Effect of fluoride varnish, glass ionomer and resin sealant on the prevention of pit and fissure caries in young children** LIU lei, HUANG Lixia, DI Lisha, SU Kui. Department of Pediatric Stomatology, Zhongshan City People's Hospital, Zhongshan 528400, China

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**【Abstract】 Objective** To study the effect of fluoride varnish, glass ionomer and resin sealant on the prevention of pit and fissure caries in young children, and to identify an a method to reduce the sensitivity of operation technique to prevent pit and fissure caries in young children with limited moisture isolation. **Methods** A self-control design was used to select 370 young children aged 3 to 5. Eight molars in the mouth were distributed in four quadrants, and each quadrant was randomly allocated to the blank group, fluoride varnish Duraphat group, glass ionomer GC Fuji VII group, and resin Clinpro™ Sealant group. The retention rate of pit and fissure sealant and the incidence of primary molar caries were observed in the 6<sup>th</sup>, 12<sup>th</sup>, 24<sup>th</sup> and 36<sup>th</sup> months respectively. **Results** In the 6<sup>th</sup> month, 12<sup>th</sup> month and 24<sup>th</sup> month, there were no significant differences in the material retention rate between the GC Fuji VII group and Clinpro™ Sealant group. In the 36<sup>th</sup> month, the retention rate of the Clinpro™ sealant group was better than that of the GC Fuji VII group ( $P < 0.05$ ). In the 6<sup>th</sup> month, the caries incidence in the Duraphat group, GC Fuji VII group and Clinpro™ sealant group



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was significantly lower than that in the blank group ( $P < 0.001$ ). There was no significant difference between the Duraphat group, GC Fuji VII group and Clinpro™ sealant group. In the 12<sup>th</sup> month, 24<sup>th</sup> month and 36<sup>th</sup> month, the incidence of caries in the GC Fuji VII group and Clinpro™ sealant group was lower than that in the Duraphat group and blank group ( $P < 0.001$ ), but there was no significant difference between the blank group and Duraphat group, and there was no significant difference in caries incidence between the GC Fuji VII group and Clinpro™ sealant group. **Conclusion** The GC Fuji VII and Clinpro™ sealant treatments continuously and effectively prevented pit and fissure caries compared with simple fluoride application. However, in cases of limited cooperation and poor moisture isolation in young children, the preventive measures of glass ionomer pits and fissure sealants (GC Fuji VII) are simpler and more feasible.

**【Key words】** young children; pit and fissure caries; pit and fissure sealant; fluorides; Duraphat; glass ionomer pit and fissure sealant; resin pit and fissure sealant; incidence of caries; retention rate

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**【Competing interests】** The authors declare no competing interests.

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低龄儿童喜甜食,又不能自觉有效清洁牙齿,是龋病的高发人群。第四次全国口腔健康流行病学调查结果显示,我国5岁儿童平均乳牙患龋率为71.9%,而10年前第三次全国口腔健康流行病学调查结果显示5岁儿童平均乳牙患龋率为66.0%,儿童患龋情况已呈现上升态势<sup>[1]</sup>。窝沟封闭技术是用高分子材料涂于牙齿表面,渗透入牙齿的窝沟点隙,覆盖并封闭窝沟,以预防牙体组织受到细菌代谢产物影响的一种有效的防龋技术,目前已广泛应用于临床<sup>[2]</sup>。氟制剂的应用也使青少年儿童的患龋率显著下降<sup>[3-4]</sup>。

目前国内所采用的窝沟封闭剂以及氟保护漆种类繁多,应用于5岁以下低龄儿童时,由于其年幼且配合性差的特殊性而疗效不一。本研究对氟保护漆、玻璃离子型窝沟封闭剂、树脂类窝沟封闭剂预防低龄儿童(5岁以下)乳磨牙窝沟龋的效果进行分析评价,旨在选择一种操作环境隔湿条件有限时,操作技术敏感性较低并能较为持久有效预防低龄儿童窝沟龋的方法,为基层开展口腔保健提供依据。

## 1 材料和方法

### 1.1 研究对象

2017年1月至2018年1月于中山市人民医院儿童口腔科门诊就诊并持续随访到2021年1月,年龄3~5周岁的儿童。

纳入标准:双侧上下共8颗乳磨牙临床冠完全萌出无牙龈覆盖,咬合面深窝沟,卡探针,易累积食物残渣,临床视诊及探诊检查无龋坏,监护人同

意加入该实验,且签署知情同意书。

排除标准:乳磨牙牙冠未完全萌出,窝沟较浅,牙冠有着色或可疑龋坏,伴有牙釉质发育不全或有氟斑牙,或曾经进行过乳磨牙窝沟封闭或其他防龋措施者。共纳入病例370例,其中男202例,女168例,共纳入牙齿数目2960颗。本研究通过中山市人民医院医学伦理委员会批准。

### 1.2 研究方法

1.2.1 分组及操作步骤 采用随机分配的方法,将符合标准的研究对象按四个象限区分(每个象限2颗乳磨牙)分别分配到试验组与空白组,具体如下:每个研究对象的口内8颗乳磨牙分布在4个象限中,4个象限随机选择设置为空白组、氟保护漆组、玻璃离子型窝沟封闭剂组、树脂型窝沟封闭剂组。

空白组为对照组,试验初始不做任何处理,但需密切随访,若观察期间一旦出现可疑龋时,应及时行预防性充填治疗或常规龋齿充填。

氟保护漆组(多乐氟组)采用多乐氟氟化钠护齿剂(Colgate,美国),操作步骤:①清洁牙齿,用探针去除窝沟点隙内软垢,将小毛刷置于低速手机上清洁窝沟,冲洗干净,气枪吹干;②用小毛刷头均匀蘸取多乐氟涂抹于牙面,避免气泡。

玻璃离子型窝沟封闭剂组(GC Fuji VII组),采用GC Fuji VII(手调装粉色版,GC公司,日本),操作步骤:①清洁牙齿,同氟保护漆步骤;②隔湿,在棉卷隔湿(未用强吸辅助)、吹干牙面的同时,由1名助手调拌GC Fuji VII,用挖匙将材料送入口内,均匀涂抹于窝沟处,自然固化40 s。

树脂型窝沟封闭剂组(Clinpro™ Sealant组),采

用 Clinpro™ Sealant 窝沟封闭剂(3M ESPE, 日本), 操作步骤: ①清洁牙齿, 同氟保护漆步骤; ②隔湿, 吹干牙面涂酸蚀剂, 酸蚀 1 min, 冲洗, 吸唾器吸走冲洗液, 棉卷隔湿, 干燥牙面, 涂窝沟封闭剂, 光照 40 s。本研究由同一人进行窝沟封闭操作。

1.2.2 随访 分别于 6 个月、12 个月、24 个月、36 个月复查, 观察乳磨牙龋病的发病率和窝沟封闭剂的脱落率。

复查时采用单盲法, 由非进行窝沟封闭操作的医师实施窝沟封闭完整性和患龋情况的检查。保留情况分为: 完全脱落、部分保留、完全保留, 封闭剂保留率的统计以牙为单位, 封闭剂保留率 = 封闭剂保留牙数(部分保留+全部保留)/复查牙数 × 100%。

龋齿的诊断标准采用国家卫计委 2015 年发布的《口腔健康调查 检查方法》, 具体方法如下: 在人工光源下, 以视诊结合探诊的方式进行, 必要时行 X 线检查, 检查器械包括平面口镜和 CPI 探针, 可借助棉签或喷枪去除软垢, 检查顺序从 54、55 开始, 至 64、65, 再到 74、75, 最后 84、85; 对两名复查医师进行乳磨牙窝沟封闭完整性和龋齿诊断的标准的一致性检验 ( $Kappa \geq 0.85$ )。

### 1.3 统计学分析

所得数据经 GraphPad Prism8 软件进行数据分

析, 保留率采用卡方检验, 以  $P < 0.05$  为差异有统计学意义, 患龋率采用卡方分割法的多个样本率间的多重比较, 检验水准公式如下所示:

$$\alpha' = \frac{\alpha}{[k(k-1)/2]+1}$$

式中:

k-实验组个数

根据以上公式, 代入  $\alpha = 0.05$ ,  $k = 4$ , 计算得出  $\alpha' = 0.00714$ , 以  $P < 0.00714$  为差异有统计学意义。

## 2 结果

本研究基线时共纳入 370 例, 男 202 例, 女 168 例, 随访 3 年, 共失访 38 例, 失访患者的情况未列入统计学分析中。

各个时间段材料保留率如表 1 所示。比较 2 种封闭材料保留率发现, 6、12、24 个月时, GC Fuji VII 组和 Clinpro™ Sealant 组的材料保留率差异无统计学意义, 而在 36 个月时, GC Fuji VII 组和 Clinpro™ Sealant 组的材料保留率差异有统计学意义, Clinpro™ Sealant 组的材料保留率优于 GC Fuji VII 组的保留率 ( $P < 0.05$ )。

表 1 不同时间段 2 种材料的保留率

Table 1 Retention rate of two materials in different periods

Time	Retention rate	Type of sealant				$\chi^2$	P
		Blank	Duraphat	GC Fuji VII	Clinpro™ Sealant		
6 months (n=740)	Completely lost	-	-	24 (3.24)	17 (2.30)	1.229	0.268
	Partly retained	-	-	56 (7.57)	50 (6.75)		
	Fully retained	-	-	660 (89.19)	673 (90.95)		
12 months (n=732)	Completely lost	-	-	66 (9.02)	52 (7.10)	1.807	0.179
	Partly retained	-	-	117 (15.98)	104 (14.21)		
	Fully retained	-	-	549 (75.00)	576 (78.69)		
24 months (n=708)	Completely lost	-	-	159 (22.46)	136 (19.21)	2.265	0.132
	Partly retained	-	-	185 (26.13)	161 (22.74)		
	Fully retained	-	-	364 (51.41)	411 (58.05)		
36 months (n=664)	Completely lost	-	-	230 (34.64)	184 (27.71)	7.426	0.006
	Partly retained	-	-	219 (32.98)	222 (33.43)		
	Fully retained	-	-	215 (32.38)	258 (38.86)		

Sealant retention is divided into the following categories and counted by teeth: completely lost, partly retained and fully retained. Retention rate of sealant = the number of partly or fully retained sealants/the number of all the rechecked teeth × 100%

各组患龋率的情况如表 2 及图 1 所示。6 个月时, 多乐氟组、GC Fuji VII 组、Clinpro™ Sealant 组均低于空白组, 差异有统计学意义 ( $P < 0.001$ ), 多乐氟

组、GC Fuji VII 组与 Clinpro™ Sealant 组三组间差异无统计学意义 ( $P > 0.00714$ ); 12、24、36 个月时, GC Fuji VII 组和 Clinpro™ Sealant 组均低于多乐氟组

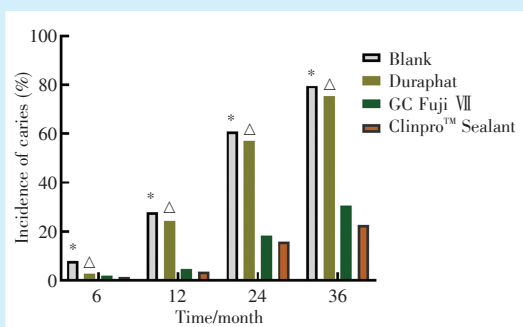
和空白组,差异有统计学意义( $P < 0.001$ ),空白组和多乐氟组间差异无统计学意义( $P > 0.007 14$ ),GC Fuji VII组和Clinpro™ Sealant组患龋率差异无统计学意义( $P > 0.007 14$ ),但GC Fuji VII组较Clinpro™ Sealant组操作更为简便易行。因为在实施操

作的过程中,GC Fuji VII组较Clinpro™ Sealant组相比仅需要棉卷隔湿,同时不需要光固化设备,对唾液环境要求不高,操作时间更短,患儿的舒适度更强,更为简单高效。

表2 不同时间段4组乳磨牙患龋率

Table 2 Incidence of caries of deciduous molars in the 4 groups in different periods  $n(\%)$ 

Type of sealant	Incidence of caries			
	6 months ( $n = 740$ )	12 months ( $n = 732$ )	24 months ( $n = 708$ )	36 months ( $n = 664$ )
Blank	59 (7.97)	203 (27.73)	426 (60.17)	511 (76.96)
Duraphat	21 (2.84)	181 (24.73)	403 (56.92)	489 (73.64)
GC Fuji VII	13 (1.76)	51 (6.97)	137 (19.35)	196 (29.52)
Clinpro™ Sealant	9 (1.22)	43 (5.87)	113 (15.96)	174 (26.20)
$\chi^2$ (Blank vs. Duraphat)	19.08	1.71	1.54	1.96
$P$ (Blank vs. Duraphat)	< 0.001	0.191	0.215	0.162
$\chi^2$ (Blank vs. GC Fuji VII)	30.89	110.10	246.30	300.10
$P$ (Blank vs. GC Fuji VII)	< 0.001	< 0.001	< 0.001	< 0.001
$\chi^2$ (Blank vs. Clinpro™ Sealant)	38.54	125.10	293.50	342.40
$P$ (Blank vs. Clinpro™ Sealant)	< 0.001	< 0.001	< 0.001	< 0.001
$\chi^2$ (Duraphat vs. GC Fuji VII)	1.93	86.56	211.80	258.80
$P$ (Duraphat vs. GC Fuji VII)	0.165	< 0.001	< 0.001	< 0.001
$\chi^2$ (Duraphat vs. Clinpro™ Sealant)	4.90	100.40	256.40	298.90
$P$ (Duraphat vs. Clinpro™ Sealant)	0.027	< 0.001	< 0.001	< 0.001
$\chi^2$ (GC Fuji VII vs. Clinpro™ Sealant)	0.74	0.73	2.80	1.81
$P$ (GC Fuji VII vs. Clinpro™ Sealant)	0.390	0.394	0.094	0.178



\*: compared with the Duraphat group, GC Fuji VII group and Clinpro™ sealant group,  $P < 0.001$ ;  $\Delta$ : compared with the GC Fuji VII group and Clinpro™ sealant group,  $P < 0.001$

Figure 1 Comparison of caries incidence associated with three materials in different periods

图1 不同时间段3种材料患龋率比较

### 3 讨论

一直以来,各种氟化物以及不同材料、性能窝沟封闭剂的应用使儿童的患龋率显著下降,这些已经被大量研究所证实<sup>[5-7]</sup>,而对于5岁以下的低龄儿童,由于其年幼且配合性差的特殊性,疗效尚未明确。

本研究结果显示,多乐氟在6个月内仍有不错的防龋效果,这与Mekky等<sup>[8]</sup>和Gözetici等<sup>[9]</sup>的研究基本一致,其原理是口腔内游离的氟离子能抑制

牙菌斑内变形链球菌的活性,减少致龋菌代谢糖而产生的乳酸,从而改变牙菌斑生物膜性状;同时氟离子还能在龋损发生的早期促进牙釉质再矿化,抑制龋病发展<sup>[10]</sup>。但是随着氟化膜的脱落,释放的氟越来越少,防龋效果持续下降,需要定期涂氟保证氟化物的浓度,才能起到更有效的防龋效果<sup>[11]</sup>。

24个月时,GC Fuji VII组与Clinpro™ Sealant组材料保留率、患龋率差异均无统计学意义,这与

Alirezai等<sup>[12]</sup>的Meta分析结果“传统树脂型窝沟封闭剂与玻璃离子作为封闭材料的龋齿发生率比较差异无统计学意义”一致。而Hosida等<sup>[13]</sup>、Feroz等<sup>[14]</sup>的研究也表明了玻璃离子与釉质本身能产生化学性的结合,在室温下能快速固化形成有一定强度和硬度的机械性屏障,阻隔了乳磨牙窝沟点隙里细菌生物膜的酸性环境,抑制了龋损的发生发展。同时Par等<sup>[15]</sup>还发现了玻璃离子可以缓慢而长久地释放氟化物,促进早期龋的再矿化,防龋途径更优秀。

36个月时,GC Fuji VII组封闭剂的脱落率高于Clinpro™ Sealant组,这是因为玻璃离子硬度不够,耐磨性较差,抗折强度差,在同等条件下玻璃离子材料较树脂基质封闭剂磨耗更多<sup>[16-17]</sup>,尤其乳磨牙完全建立咬合后,其保留率随着咀嚼磨耗的增加而进一步降低。但是GC Fuji VII组患龋率并没有因为脱落率的增加而出现患龋率的增加,这二者之间并不矛盾。扫描电镜下观察封闭剂完全脱落的牙标本时发现点隙沟裂深处仍可残存玻璃离子材料,持续发挥其机械屏障和缓慢释放氟的作用。同时也有研究显示,封闭剂脱落后牙釉质里吸收的氟在一段时间仍有防龋作用<sup>[18]</sup>。另外,因为玻璃离子组份里含有水分,具有较低的湿敏性<sup>[19]</sup>,在固化的过程中,表面形成了一层水凝胶层,在隔湿环境较差的情况下也能应用<sup>[20]</sup>,而不像树脂封闭剂一样,隔湿条件不良的情况下窝沟封闭剂脱落率明显增高<sup>[21]</sup>。对于唾液分泌旺盛的低龄儿童,使用玻璃离子型窝沟封闭剂显得更为合适,疗效更佳。但是需要关注的是,无论使用哪种材料进行窝沟封闭,随着材料本身脱落率的增加,患龋风险势必也有所增加,所以对于已经进行过窝沟封闭操作的低龄儿童也应注意定期随访,一旦出现封闭剂脱落但仍具有明显卡探针的深窝沟的乳磨牙应及时重新行窝沟封闭,以避免龋病进一步发展。

本研究结果表明,氟化物的应用可以明显降低牙齿患龋的几率,但需定期涂氟,保持口腔环境的氟浓度,而对于乳磨牙的深窝沟,采用玻璃离子型窝沟封闭剂(GC Fuji VII组),使用时无需酸蚀,对隔湿环境要求低,操作简单,易于被儿童接受,并且能自行凝固,其疗效并不弱于隔湿要求高、需要光固化机且耗材费用较高的树脂型窝沟封闭剂,更有利于在基层大规模开展治疗。综上,与单纯涂氟化物相比,GC Fuji VII组和Clinpro™ Sealant组

均能较为有效地预防窝沟龋,但在低龄幼儿配合欠佳、且无法获得良好隔湿的情况下,采用玻璃离子型窝沟封闭剂(GC Fuji VII)的预防措施更为简便易行,为基层开展低龄幼儿的乳磨牙口腔保健提供了新的证据。

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