COMPARISON OF PHYSICAL PROPERTIES OF LOW-COST AND HIGH-COST SEALANTS AVAILABLE IN INDIAN MARKET- AN INVITRO STUDY

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ABSTRACT

Background: This study was intended to compare the physical characteristics of high-cost and low-cost sealants available on the Indian market as part of a non-inferiority experiment.

Methods: For this study exfoliated permanent teeth will be used as part of the experimental (invitro) study design, for a period of three months (July 2022 - September 2022). In order to analyse the physical properties, Fisher exact test was used, and independent t-test was used to compare groups.

Results: Mean Compressive stress at maximum force (Mpa) of Low-cost sealant was 198.09±54.59 and High-cost sealant was 202.40 ± 55.63 ($P < 0.001$). Compressive displacement(mm) at Break mean values were 3.57 ± 0.47 for Low-cost sealant and 3.70 ± 1.23 High-cost sealant respectively ($P = 0.003$**). In Cell line culture, percentage of cell viability of the low-cost sealant and high-cost sealant samples were 90 % and 84% respectively ($P = 0.007$**). Adaptability of the study groups were compared using Ovrebo and Raadal's scoring criteria based on dye penetration, which is found to be statistically significant ($P = 0.041$*).

Conclusions: Based on the results, this study indicate that a low-cost sealant has superior properties to that of a high-cost sealant, demonstrating the cost effectiveness, as well as providing evidence that affordable sealant material can be used to prevent dental caries at a variety of levels of healthcare.

1. INTRODUCTION

The 2017 Global Burden of Disease Report has raised concerns that dental caries is still a significant issue for dental public health worldwide, primarily in developing and underdeveloped nations1. It is evident that childhood dental caries is still inevitable that, affects 9% of the world's population. Dental caries has influence on an individual's quality of life (QOL), general health, access to healthcare, and sleep, mental activity, and self-esteem2. Despite various precautions, the onset and advancement of caries throughout the period of tooth formation is thought to be unavoidable3.

Pit and fissure on the occlusal surface of teeth are inaccessible areas that offer an ideal habitat for bacterial colonisation. Pit and fissure sealants are thought to effectively seal the tooth, limiting plaque adhesion and bacterial colonisation, according to evidence-based preventive measure4.

According to data from the National Health and Nutrition Examination Survey (NHANES) 2011–2012, dental caries was found in the permanent teeth of 37% of children between the ages of 2 and 8 who had primary teeth, 21% of children between the ages of 6 and 11 who had permanent teeth, and 58% of children between the ages of 12 and 19 who had primary teeth. About 90% of the caries in children and teenagers' permanent posterior teeth and 44% of the caries in their primary teeth are caused by pit and fissure caries5. Pits and fissures have a plaque-retentive characteristic that makes them challenging to clean, making them more prone to caries than smooth surfaces and possibly not being protected by fluoride treatment6.

To prevent the development of new caries or stop the progression of pre-existing, non-cavitated caries lesions, pit and fissure sealing is a proven, evidence-based preventative dental technique particularly effective in immature molars7. Different types of pit and fissure sealants are available depending on the sealant's compressibility, adaptability, and biocompatibility with the tissue surface, cost effectiveness, etc.

Due to the socioeconomic situation of the Indian population and the geographic obstacles that prevent many people from obtaining preventive treatments, the cost effectiveness of the program is particularly important. To fill this gap, we created a non-inferiority experiment with the goal of contrasting the physical characteristics of high- and low-cost sealants offered on the Indian market8. A dearth existed in scientific literature regarding the comparison of physical properties between Low-cost sealant and High-cost pit and fissure sealant. Thus, the purpose of this study is to compare the physical properties of a low-cost sealant with those of a high-cost sealant that is readily available in the Indian market.

MATERIAL AND METHODS

An invitro study was carried for a period for three months using Low-cost sealant (Conseal F) and High-cost sealant (Helioseal F). We intended to identify the physical properties such as biocompatibility, compressive strength and

Adaptability of two study products.A detailed proposal was submitted and, ethical clearance was given by the Institutional Review Board.The sealants were applied on the sample teeth at room temperature according to the manufacturer's instructions and the participants were grouped as follows

Group 1: Low-Cost Sealant – Conseal F

Group 2: High-cost Sealant – Helioseal F (Figure 1)

A pilot study was conducted on 10 samples (5 samples in each group). Compressive Strength, Biocompatibility and Adaptability were assessed for both study products to determine the sample size and feasibility of the study. The sample size was calculated using G-power software version 3.1.9.2(Heinrich–Heine–Universitat-Dusseldorf, Germany) based on the mean difference of the observations obtained from the pilot study. The required sample size was calculated as 20 with 10 in each group. We included all molar teeth extracted for periodontal purposes. The exclusion criteria included teeth with cracks, carious lesions, hypoplastic lesions and wasting diseases.

They were subjected to assessment of physical properties of study products. To assess the compressive strength 10 cylindrical specimens each of high-cost and low-cost pit and fissure sealant material were prepared in a cylindrical shaped stainless steel split mould measuring 6mm height and 4 mm width. The pit and fissure sealant material were filled up incrementally to the height of the cylindrical mould, followed by covering with a glass slide on top and another glass slide on bottom of the mould. The samples were light cured for 30 seconds, then demoulded and finishing was done using finishing burs. The cylindrical specimen samples were thermocycled for 1000 cycles using SD mechatronic cs4.4 thermocycler. After thermocycling, the samples were checked for compressive strength (Figure 1). For Biocompatibility Analysis (MTT Assay), 300 mg of 5 mm cylindrical blocks were prepared, and light cured. The prepared blocks were treated with DMEM- low glucose media formulated with 10 % FBS and 1% Penicillin/streptomycin. The media were collected after 24 hrs of immersion and treated with cells to test the compatibility. After 24hrs of culture, add the 10uL/100mL of MTT reagent (5 mg/mL stock) to cultured cells and then incubate for 4 h to allow formation of the formazan dye at 37. The medium is exchanged to DMSO (200 µL) and stand for 10min. The reaction product was transferred to a 96 well ELISA plate and A590 was measured with ELISA plate reader.The cells were cultured in DMEM low glucose/10% FBS/1% Penicillin; streptomycin. After two passages, 10000 cells per well were seeded in 48 well plate for cell viability and compatibility assays. The 20 molar tooth samples with the respective sealants after thermocycling (Figure 1) were sectioned buccolingually into 2 halves using Isomet 1000 precision saw. Then, it was viewed under Leica M 205 stereomicroscope under 20 X magnification for further analysis of adaptability.Based on the stereomicroscopic magnification x 20, the samples were scored using the following scoring criteria given by Övrebö and Raadal13

Score 0: No penetration of the dye seen in the section

Score 1: Penetration into the part around the sealant

Score 2: Penetration into the part below the sealant

Score 3: Penetration at the base of the fissure

All analyses were carried out using Statistical Package for Social Sciences (version 19, IBM, Chicago, USA). The data was subjected to normality test using Shapiro Wilk test. Quantitative datawere analysed using parametric tests of significance, thus independent sample t-test was used for Intergroup comparison of compressive stress. Biocompatibility and adaptability between the study groups were analysed using Fisher exact test.A p-value of <0.05 was considered as level of statistical significance.

2. RESULT AND OBSERVATIONS

Based on this study, the compressive strength of the study groups in which mean Compressive stress at maximum force (Mpa) of Low-cost sealant was 198.09±54.59 and High-cost sealant was 202.40 ± 55.63 and this difference hadvery high statistical significance (P = 0.000***). Compressive displacement at Break mean values were 3.57 ± 0.47 and 3.70 ± 1.23 for Low-cost sealant and High-cost sealant respectivelyand this difference showed highstatistical significance (P = 0.003**).

Intergroup comparison of biocompatibility between the study groups were represented in Table 2 which showspercentage of cell viability of the low-cost sealant and high-cost sealant groups were 90 % and 84% respectively, this difference was statistically highly significant (P = 0.007**). Figure 1 shows Cell count of control group, low-cost sealant group and high-cost sealant group obtained from Cell line culture.

Adaptability of the study groups were compared and presented in Table 3.On using Ovrebo and Raadal's scoring criteria based on dye penetration, 40% of Low-Cost Sealant samples was given Score 1 which is Penetration into the Part Around the Sealant whereas60% of Low-Cost Sealant samples and 20% of High-Cost Sealant samples were given Score 2 which is Penetration into the Part Below the Sealant; and 80% of High-Cost Sealant was given Score 3 which is penetration at the base of the fissure and this difference was statistically significant (P = 0.041*). Buccolingually sectioned tooth samples of the study groups viewed under Leica M 205 stereomicroscope under 20 X magnification for adaptability analysis is illustrated in Figure 1.

Table 1. Intergroup comparison of the Compressive strength of the study groups

Groups	**N**	**Compressive stress at maximum force (Mpa)**	**Unpaire d T test value**	**p-value**	**Compressive displacement at Break (Standard)** [mm]	**Unpaired T test value**	**p-value**		
		Mean	**SD**			**Mean**	**SD**		
Low-Cost Sealant	10	198.09	54.59	4.975	.000***	3.57	0.47	3.230	.003**
High-cost Sealant	10	202.40	55.63			3.70	1.23		

**P<0.01 shows high statistically significance

***P<0.001 shows very high statistically significance

Table 2. Inter-group comparison of percentage of cell viability of the study groups in Biocompatibility Analysis (MTT Assay)

Groups	**% Of Cell**	**p-valueF**
Low-Cost Sealant	90%	0.007**
High-Cost Sealant	84%	

[F] Fisher exact test

**P <0.01shows high statistical significance

Table 3. Inter-group comparison of adaptability of the study groups based on Ovrebo and Raadal's scoring criteria

SCORE	Groups		p-valueF
	Low-Cost Sealant N (%)	High-Cost Sealant N(%)	
0	0(0.00%)	0(0.00%)	.041*
1	4(40.00%)	0(0.00%)	
2	6(60.00%)	2(20.0%)	
3	0(0.00%)	8(80.0%)	

[F] Fisher exact test

*P<0.05 shows statistically significance

DISCUSSION

National oral health policy conscripted by the Indian Dental Association (IDA) in 1986,also accepted as an integral part of National Health Policy (NHP) by the Central Council of Health and Family Welfare in 1995focuses on comprehensive oral health care with greater emphasis on promotive and preventive measures 14and also promotes availability of quality assured oral health products for the Indian population at affordable costs. The present study has been designed to assess and compare the physical properties of Low- cost sealant with that of high- cost sealant (available in Indian market) under in-vitro conditions. Compressive strength, biocompatibility and adaptability are the most significant physical properties which determines the preventive effect of pit and fissure sealants.

In a previous study15research was done on the role of enamel powder, dentin, and cementum of natural tooth as thematerial of pit and fissure sealant and their physical properties and shape. They separated enamel, dentin and cementum from a tooth, downsized them into the size under 45 in diameter and put them into 3M's sealant, GI cement, and resin cement with different content ratio to produce specimens and reported compressive strength of the control group wasmeasured as 39.98 Kg/cm2 as the highest in all experimentalgroup and a little less in sealant with 0.07g of enamel ordentin powder group, otherwise, relatively low oncompressive strength in the other groupand the adaptability wasestimated as the highest as 4.26 Kg/cm2 with the material of ESPE concise of 3M.Present study reported compressive stress at maximum force (Mpa) of Low-cost sealant was 198.09±54.59 and High-cost sealant was 202.40 ± 55.63.

Wright JT et al16 studied the physical properties of preventive sealants in 2016 and found that the adaptability was 4.90 µm in study group which was higher than that of the control group by 0.64µm.

Current study used Ovrebo and Raadal's scoring criteria based on dye penetration which stated that 40% of Low-Cost Sealant samples had Score 1 which is Penetration into the Part Around the Sealant whereas60% of Low-Cost Sealant samples and 20% of High-Cost Sealant samples had Score 2 which is Penetration into the Part Below the Sealant; and 80% of High-Cost Sealant had Score 3which is penetration at the base of the fissure.The Low-cost sealant, Conseal F, with its low viscosity can flow more quickly and deeply into the prepared pits and cracks with the ideal low viscosity.Helioseal-F includes a fluorosilicate glass that releases fluoride ions, promotes mechanical block with fluoride action for twofold defence. Clinically, Helioseal-F forms a smooth surface initiating prevention to growth of bacteria.

This study is a first of its kind to compare the Physical properties between Low-cost and High-cost sealants reporting that Low-cost sealant is non-inferior to High-cost sealant with respect to their physical properties which can influence their preventive effect towards pit and fissure caries. This study methodology was designed as per standard guidelines provided byInternational Organization for Standardization17, they have provided specific guidelines forconducting and standardising tests fordental materials to enable investigators to interpret andcompare reproducible results that would support in-vivo testing.Experts independently did the microscopic examination and scoring.

Limitations of the current study includes that it is invitro study and may not exactly reveal the properties of the sealants in the oral cavity. Harleen et al18 reported thatalthough in vitro tests do not completely predict howdental materials will behave in the oral cavity, these testsare still valuable; most research into dental compositebond strength is carried out in vitro because it is difficultto expose the materials and subsequently retrievethem from the oral environment. According to theInternational Organization for Standardization (2003),thermocycling is the best process for mimicking thermalchanges in the oral environment during in vitro studies17, and our samples were subjected to thermocycling before analyse. Future in-vivo research can enhance this study results further.

CONCLUSION

One of the major focuses of National oral health policy is to provide affordable, safe and quality oral health care services at all health facilities. This study results reveals that low-cost sealant is non-inferior to that of high-cost sealant proving the cost effectiveness of low- cost sealant available in Indian market, thereby providing evidence for the use of affordable sealant material for the prevention of dental caries at various level of health care. This study also opens vista for various future research.

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