Selected Characteristics of a New Vinyl Polysiloxane Impression Material: A Randomized Clinical Trial

#2638

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Introduction

The precision, fit, and clinical success of indirect dental restorations depend on the accuracy of the final impression (Fig 1a-e). A final impression free of bubbles, voids, and tears is still considered one of the most challenging procedures in restorative dentistry. Vinyl polysiloxane impression materials (PVS) (a.k.a. addition reaction silicones) have favorable physical properties, accuracy, dimensional stability, and biocompatibility. Recently, new materials with improved material characteristics such as flow and wetting ability were developed (e.g., Affinis, Coltène/Whaledent, Altstätten, CH) and their advantages verified in laboratory studies. It is unknown, however, whether those properties will also lead to successful application in vivo.

Objectives

This study evaluated the ability of a new PVS impression material to achieve satisfactory final impressions for indirect fixed restorations when used by inexperienced clinicians (3rd year dental students) as compared to a widely used PVS impression material.
The Null-Hypothesis was tested: there is no difference between impression materials.

Methods

115 patients treated in the LSU School of Dentistry Junior Student Clinic for indirect fixed restorations in posterior (premolar/molar) teeth and meeting the inclusion criteria were randomly assigned to either one of two groups. In Group A (n=62), Affinis was used as the impression material (treatment group). The standard impression material in our clinics, a widely-used PVS impression material, was utilized in Group B (control, n=53) Preparations of the abutment teeth were made according to accepted universal guidelines for tooth preparation. Position of tooth, type of preparation, preparation finish line (Class I-V), and gingival bleeding score were recorded (Impression evaluation sheet, Fig 2). After application of a standardized cleaning and tissue-retraction protocol ("double cord technique"), a final impression was obtained with a one-step impression technique and a perforated metal tray. Manufacturers' recommendations on working and polymerization times were followed strictly.
Two calibrated examiners evaluated the first impression of the most distal abutment tooth at a magnification of x10 for acceptability (no voids or bubbles).

Criteria for success/failure
1 no voids or bubbles – "acceptable impression"
2 voids or bubbles – "unacceptable impression"

Figure 1a-e: Clinical example of a study case

Impression Evaluation Sheet
Date _____
Patient name _____ **Chart#** _____
Abutment tooth/teeth - prepared # ___ **evaluated #** ___

Type of Preparation
Inlay ☐ Onlay ☐ Crown ☐

Preliminary Measurements
Preparation finish line (most apically)
Class I (supragingval) ☐
Class II (epigingival) ☐
Class III (1 mm subgingival) ☐
Class IV (2 mm subgingival) ☐
Class V (3 mm or more subgingival) ☐

Gingival Bleeding Score
0 (no bleeding) ☐
1 (minor bleeding spots) ☐
2 (some bleeding, controllable) ☐
3 (excessive bleeding) ☐

Impression material
Express ☐ **Affinis** ☐

Evaluate only the most posterior abutment tooth
1 "acceptable impression" - no voids or bubbles ☐
2 "unacceptable impression" - voids or bubbles ☐

Student name/signature
_____
Instructor/Evaluator name/signature

Figure 2: Evaluation sheet

		Unaccept.	Acceptable	Total
Group B	Frequency	21	32	53
	Percent	18.26	27.83	46.09
	Row Pct	39.62	60.38	
Group A	Frequency	5	57	62
	Percent	4.35	49.57	53.91
	Row Pct	8.06	91.94	
Total	Frequency	26	89	115
	Percent	22.61	77.39	100.00

Table 3: Detailed Results

Test	Chi-Square	DF	Pr > ChiSq
Likelihood Ratio	16.9998	1	<.0001

Table 4: Logistic regression model (significant)

Parameter	DF	Estimate	SError	Chi-Square	Pr > ChiSq
Intercept	1	1.5912	0.7301	4.7501	0.0293
material	1	2.0124	0.5444	13.6625	0.0002

Table 5: Materials significantly different

	Point	95% Wald	
Effect	Estimate	Confidence Limits	
material	7.481	2.574	21.747

Table 6: Odds Ratio Estimates

		Class I	Class II	Class III	Class IV	Class IV
Express	Frequency	8	23	21	0	1
	Percent	6.96	20.00	18.26	0.00	0.87
	Row Pct	15.09	43.40	39.62	0.00	1.89
Affinis	Frequency	7	29	17	8	1
	Percent	6.09	25.22	14.78	6.96	0.87
	Row Pct	11.29	46.77	27.42	12.90	1.61
Total	Frequency	15	52	38	8	2
	Percent	13.04	45.55	33.04	6.96	1.74

Table 1: Frequency preparation finish line

		No	Minor	Some	Excessive
Group B	Frequency	18	23	8	3
	Percent	16.22	20.72	7.21	2.70
	Row Pct	34.62	44.23	15.38	5.77
Group A	Frequency	21	30	8	0
	Percent	18.92	27.03	7.21	0.00
	Row Pct	35.59	50.85	13.56	0.00
Total	Frequency	39	53	16	3
	Percent	35.14	47.75	14.41	2.70

Table 2: Frequency gingival bleeding score

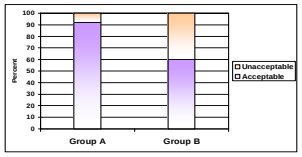

Figure 3: Percentage of accept. impressions

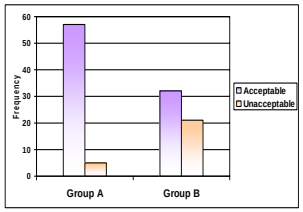

Figure 4: Frequency of accept. impressions

Fisher-Freeman-Halton test was used to test for associations between material and type of preparation, preparation finish line, and gingival bleeding score. Logistic regression was used to determine the effect of material on success of the impression (acceptable/unacceptable). All statistical summaries and analyses were performed using SAS Version 8.1 (SAS Institute, Inc.). Contingency table analysis (Fisher-Freeman-Halton Test) was done using the FREQ procedure. Logistic regression was performed using the LOGISTIC procedure. All statistical tests were performed at the 5% significance level and p-values less than or equal to 0.050, after rounding to 3 decimal places, were considered statistically significant.
Original power analysis revealed a sample size of 310 to detect a 10 % difference. Since these calculations were solely based on estimations, interim analysis was performed 6 months after initiation of the study and it was agreed to halt the study if interim analysis finds statistical significance.

Results

Fisher-Freeman-Halton test revealed significant association only between type of material and preparation finish line (p=0.0385). Affinis was more frequently used in cases where the preparation finish line was at least 2 mm subgingival. Regardless, 92% of the impressions made in Group A were acceptable; as compared to 60 % of the impressions made in Group B.
Material was highly significant in the logistic model (p<0.001) with impressions made with Affinis being nearly seven and a half times more likely to result in an acceptable impression (OR=7.481; 95% CI for OR: 2.574, 21.747). Detailed results and analyses are displayed in tables 1-6.

Conclusions

Within this study's limitations, the new PVS impression material Affinis provided very significantly higher chances to obtain an acceptable impression than the control material.

This study was supported by a Grant from Coltène Whaledent.