

CLINICAL TRIAL DESIGN AND BASELINE OUTPUT: MULTI-MODE SYSTEMS WITH DIFFERENT ADHESION STRATEGIES

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INTRODUCTION Multi-Mode (MM) are contemporary generation of simplified adhesives indicated for use under different application strategies.

OBJECTIVE Describing the randomized clinical trial (RCT) design and baseline output of MM adhesives applied by Self-Etch (SE; with non-etched or etched enamel) and Etch-and-Rinse (ER) strategies, analysing NCCL restorations for two-years (2016-2018).

MATERIAL and METHODS Prospective, double blind RCT approved by UFP Ethics Committee, National Clinical Trials Ethics Committee (NCTEC-20150305), Infarmed (EC/011/2015), NCT02698371, in 38 patients with 210 restorations (Admira Fusion®; nanohybrid-ormocer composite) randomly allocated according to 6 groups (Adhesive systems; adhesion strategies) of 35 restorations (Table 1). All restorations done by one operator and evaluated (aesthetic, functional and biological parameters) at baseline (one month after restoration) by 3 calibrated examiners (ICC≥0.952) using USPHS and FDI criteria.

Table 1 – RCT GROUPS, restorations (n), adhesive systems and adhesion strategies

RCT groups	G1 Control	G2 Control	G3	G4	G5	G6	TOTAL
n	35	35	35	35	35	35	210
ADHESIVE SYSTEM (Batch Number)	Futurabond®DC (1532592)		Futurabond®U (1543141)		Adhese®Universal (U35131)		Admira Fusion®
ADHESION STRATEGY	SE	SE Etched enamel	ER	SE	ER	SE	
Orthophosphoric acid (35%)	X	✓	✓	X	✓	X	

RCT design included NCCL characteristics (Tables 2 and 3). Baseline reports the restorations/adhesion strategies efficacy (success rate); Statistical analysis with nonparametric tests using alpha=0.05.

RESULTS

Median age: 55.5years (24-63-years-old), 21(55.3%) male (T. Mann-Whitney; p=0.508).

NCCL in 176 (83.8%) pre-molars and 34 (16.2%) molar teeth; three to six restorations by patient; 210-NCCL restorations characteristics: Dentin sclerosis categories (Table 2): 146 (69.5%) One, 35 (16.7%) Two, 8 (3.8%) Three and 21 (10%) Four, no significant differences found per group (Chi²-test; p=0.353).

Table 2 – RCT design: NCCL characteristics (Tooth type, Dentin sclerosis and Cavity geometry) allocated to control and study groups

NCCL Characteristics	NCCL distribution in control (G1, G2) and study groups (G3 to G6)						p (Chi ²)		
	All	G1	G2	G3	G4	G5		G6	
Tooth type	Pre-molar tooth	176 (83.8%)	29 (82.9%)	32 (91.4%)	32 (91.4%)	27 (77.1%)	30 (85.7%)	26 (74.3%)	0.252
	Molar tooth	34 (16.2%)	6 (17.1%)	3 (8.6%)	3 (8.6%)	8 (22.9%)	5 (14.3%)	9 (25.7%)	
DENTIN SCLEROSIS*	Category 1	146 (69.5%)	29 (82.9%)	24 (68.6%)	26 (74.3%)	20 (57.1%)	23 (65.7%)	24 (68.6%)	0.353
	Category 2	35 (16.7%)	4 (11.4%)	7 (20%)	5 (14.3%)	7 (20%)	5 (14.3%)	7 (20%)	
	Category 3	8 (3.8%)	0 (0%)	1 (2.9%)	0 (0%)	3 (8.6%)	4 (11.4%)	0 (0%)	
	Category 4	21 (10%)	2 (5.7%)	3 (8.6%)	4 (11.4%)	5 (14.3%)	3 (8.6%)	4 (11.4%)	
CAVITY GEOMETRY**	Acute (<45°)	84 (40%)	13 (37.1%)	17 (48.6%)	14 (40%)	14 (40%)	15 (42.9%)	11 (31.4%)	0.903
	Severe (45° to 90°)	60 (28.6%)	9 (25.7%)	11 (31.4%)	11 (31.4%)	9 (25.7%)	8 (22.9%)	12 (34.3%)	
	Obtuse (>45°)	66 (31.4%)	13 (37.1%)	7 (20%)	10 (28.6%)	12 (34.3%)	12 (34.3%)	12 (34.3%)	

Source *Ritter AV, Heymann HO et al. 2008; **Perdigão, Kose et al. 2014

NCCL-Cavity geometry 84 (40%) Acute, 60 (28.6%) Severe and 60 (31.4%) Obtuse, no significant differences found per group (Chi²-test, p=0.903). No differences in tooth type (pre-molar/molar) per RCT groups (p=0.252). Median NCCL estimated volume (Height x Width x Depth) of 30.3 (18.0-49.1) mm³ (Table 3), no differences detected per group (p=0.081), but cavity estimated volume of pre-molar teeth were significantly smaller than the molar ones (p<0.001).

Table 3 - NCCL Cavity Estimated Volume (mm³) according to RCT groups, tooth type and intra-oral location

RCT Group	G1	G2	G3	G4	G5	G6
Me (P25-P75)	32 (19.2-45)	24 (18-37.5)	22.5 (15.6-40)	39.4 (24-62.5)	30 (15.8-55)	37.5 (18-54)
min-max	3.8-132	6-140	6-81.2	6-120	9-112	9-105
p=0.081 (Kruskal-Wallis T.)						
Tooth type Intra-oral Location	Pre-molar	Molar	Maxilla pre-molar	Mandibular pre-molar	Maxilla molar	Mandibular molar
Me (P25-P75)	27 ^b (17.5-41.1)	58.9 ^a (35.4-75.4)	24 ^b (15-39.5)	30 ^b (18-48)	60 ^a (29-83.6)	57.8 ^a (36.8-74.7)
min-max	3.8-140	14-120	3.8-140	6-120	21-120	14-105
p<0.001 (Mann-Whitney T.)			p<0.001 (Kruskal-Wallis T.)			

^{a,b} Different letters indicate significant differences in the median value according to the Mann-Whitney test (2 groups) or multiple comparison groups.

At baseline (Table 4) all restorations showed 100% aesthetic, functional and biological success rates in RCT groups.

Table 4 – BASELINE Success rates, by USPHS and FDI (Alpha / Bravo Ryge* scores and level 1, 2 and 3 Hicel* and colleagues) for NCCL restorations with MM, SE and ER adhesion strategies (p > 0.05)

Clinical parameters	G1-control FBDC; SE	G2-control FBDC; etched-enamel	G3 to G6
Aesthetic	100%	100%	100%
Functional	100%	100%	100%
Biological	100%	100%	100%

*Source: Hicel et al., 2007 and Cvar and Ryge, 2005.

DISCUSSION

Efficacy of different adhesion strategies are usually evaluated in NCCL restorations. No differences were found in NCCL characteristics by RCT groups. RCT designs should include NCCL features when evaluating clinical performance of adhesive's strategies.

CONCLUSIONS NCCL characteristics were similar in RCT groups. MM adhesives with different strategies showed baseline excellent performance.

CLINICAL IMPLICATIONS Restoration evaluation at mean/long term are mandatory to determine clinical performance of MM adhesion strategies.

KEYWORDS

Multi-Mode adhesive
Self-Etch adhesive
Universal adhesive
Non-Carious Cervical Lesions
Randomized Clinical Trial
Composite Restorations



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