Evaluation of New Alkasite Based Restorative Material for Restoring Non-Carious Cervical Lesions- Randomized Controlled Clinical Trial

Keywords

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ABSTRACT

Two different restoration materials, an alkasite-based resin composite and a resin-modified glass ionomer cement were used to assess restoration of non-carious cervical dental lesions. This split mouth randomized controlled trial included 40 patients. After randomization both sides of the dental arch were restored with either an alkasite-based (Cention N, Ivoclar Vivadent) or a resin-modified glass ionomer cement (Voco GmbH) restoration. The placed fillings were evaluated by blinded additional operators 1, 6 months and 1 year after to the USPHS criteria (retention, marginal integrity and discoloration, anatomical form and secondary caries). Data were analyzed using Kendall's Coefficient of Concordance test and Chi-square tests using SPSS software (SPSS Inc., Version 20) (P=0.05). As for retention and anatomic form both materials performed similar after one month. However, the retention and anatomic form for alkasite based restorative Cention showed significantly better results after 6 months (p=0.013/p=0.003) and one year (p=0.026/p=0.008). The resin modified glass ionomer restoration showed higher discoloration after 6 months (p=0.025) and one year (p=0.018), while Cention performed better regarding marginal integrity at all time intervals. No secondary caries occurred. Alkasite based restorative materials displayed superior technical, mechanical and aesthetical performance in a follow-up period of one year and can therefore be recommended as an alternative to resin-modified glass ionomer cements.

INTRODUCTION

The prevalence of non-carious cervical lesions (NCCLs) is continuously increasing among the general global population and is becoming an important factor to be considered for long-term dental health.[1,2] NCCLs are categorized as dental hard tissue loss in the cervical tooth part, as a result of multifactorial and unclarified aetiology non than caries.[3,4] Among possible etiological factors, erosion, abrasion and tooth flexure have been implicated as a cause for the formation of NCCLs.[5-7] Abrasion can be caused by improper brushing frequency and technique, excessive brushing force application and tooth paste abrasiveness and is defined as the abnormal wear of tooth substance or structure by a mechanical

process.[6] Abrasion on the other hand results from occlusal loading and is presented as disruption of the enamel crystal at the cervical region, secondary to tooth flexure.[8] The resulting cervical lesions shape varies from grooves, U- or dish shaped to large wedge-shaped defects with sharp angles of the internal and external margin.

Complications of the NCCLs include biological factors, such as dentinal hypersensitivity, pathological changes in the pulp, plaque retention and/or aesthetic problems.[9-11] In clinical practice, the restoration of NCCLs is a challenge because most of the time, the cervical margin is located in cementum or dentin. This characteristic makes the cervical margin more susceptible to microleakage, difficulty in bonding of restorative materials, postoperative sensitivity and also favors the incidence of carious lesions. Also, the dentin found in the NCCLs is more sclerotic making bonding of adhesive restorations difficult.[12,13]

Additionally, the higher failure rates of restorations in these lesions can be attributed to the role of mechanical stresses due to occlusal loading at the cervical margin leading to cuspal flexure and lack of mechanical retention.[14] Hence, selection of restorative material for restoring NCCLs is very critical. Numerous studies have investigated the clinical behavior of resin composite and glass ionomer cement in restoring NCCLs. Resin modified glass ionomer cement (RMGIC) has shown promising result in restoring NCCLs when compared composite resin.[15-17] This is due to the fact, that in NCCLs no cavity preparation is performed and dentin bonding capacity is evaluated. Furthermore, the degradation of the adhesive bond of adhesives allows continuous transudation of dentinal fluid and do not provide hermetic seal of deep dentin.[13]

Cention N (Ivoclar Vivadent) is a newly introduced alkasite based restorative material which utilizes an alkaline filler, capable of releasing acid-neutralizing ions. It is a tooth-colored dual cure material indicated for direct restorations. Till date, no clinical studies have evaluated for the effectiveness of Cention N in restoring NCCLs. Hence, the aim of this clinical trial was to evaluate the effectiveness of RMGIC and Cention N cements in restoring NCCLs. The null hypothesis tested was that there would be no difference in the efficacy of RMGI and Cention N cements in restoring NCCLs in terms of clinical performance.

MATERIALS AND METHOD

STUDY DESIGN

This was a split mouth randomized controlled single-center clinical trial with two parallel experimental arms. The conducted trial was approved by the ethical institution committee (ICE 442/2018) and was thereafter registered in the Clinical Trial Registry of India (CTRI/2018/08/015252). All patients were informed regarding the benefits, risks, and alternative treatment choices before enrollment in the trial. They were also informed that not participating in this study had no consequences regarding their treatment whatsoever. After obtainment of patient's informed consent, this study was performed in accordance with the World Medical Association Declaration of Helsinki and the CONSORT guidelines (2010) for randomized trials.

PATIENT SELECTION

Patients, aged 18-60, who presented to the department of Conservative Dentistry and Endodontics, Manipal College of Dental Scienes, Manipal, India, with one pair of non-caries cervical lesions (NCCLs) on each side of the dental arch, were included in this clinical trial. Inclusion criteria's were, vital teeth, good oral hygiene, absence of periodontal disease and normal occlusion with interproximal contact. Non-vital teeth, cervical caries, discolorations, periodontitis, mobile teeth, poor oral hygiene and teeth with parafunctional wear or subgingival lesions were considered as exclusion criteria.

SAMPLE SIZE ESTIMATION

With 95% confidence interval and 90% power, total number of 30 patients were taken by including 20% error. With anticipation of 20% dropouts, a total number of 40 patients were selected.

CLINICAL PROCEDURE

All the patients were treated by only one operator who had 18 years of restorative experience and was trained to perform all procedures according to manufacturer's instructions. Oral prophylaxis was carried out in all the subjects before placement of the restoration. In each patient, both the materials were randomly allocated to either side of the dental arch using coin toss method. No mechanical preparation of the cavity surface was performed. Isolation was achieved using rubber dam (Hygienic; Coltène Whaledent, Altstätten, Switzerland). For resin-modified glass ionomer cement (Voco GmbH, Cuxhaven, Germany) group, appropriate shade was selected using VITA shade guide. Dentin conditioner consisting of 20% polyacrylic acid (GC America Inc, Alsip, Illinois US) was applied to the surface of the cavity for 20 seconds using a micro brush followed by thorough water rinse and careful air drying. The resin-modified glass ionomer cement powder and liquid (3.2:1g/g) was then dispensed on to the mixing pad and mixed with a plastic spatula according to the manufacturer's instructions. The cement mix was then placed on to the cavity with the aid of a suitable plastic instrument. The restoration was contoured and light cured for 20 seconds using LED curing lamp with power of 834 mW (3M ESPE, St. Paul, MN). For cavities deeper than 2 mm, the material was placed in layers. The restorations were finished under water cooling using fine and superfine diamond points (Horico Dental, Berlin, Germany). Polishing was carried out using sof-lex polishing discs (3M ESPE).

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For Cention N group, the cavity surface was etched with phosphoric acid (Eco Etch, Ivoclar Vivadent, Liechtenstein) for 10 seconds followed by thorough rinsing with water. Then the Adper Single Bond 2 (3M ESPE) bonding agent was applied in two layers and photo-polymerized for 20 seconds. Then one scoop of Cention N powder was mixed with one drop of liquid (4.6:1) according to manufacturer's instructions. The material mix was then placed on to the cavity, countered and light cured for 40 sec using LED lamp (3M ESPE). For cavities deeper than 2 mm, the material was placed in layers. Finishing and polishing of the restoration was done in similar way to that of resin modified glass ionomer cement restorations. All the subjects were instructed to use a soft brush with a non-abrasive toothpaste and were incited with the correct brushing technique.

CLINICAL EVALUATION

Clinical evaluation was conducted using an explorer and a mouth mirror with a good operating light by two additional blinded operators after 1, 6 months and one year of placement. Evaluation criteria were selected according to United States Public Health Service Criteria (USPHS) and were restoration retention, marginal discoloration and integrity, anatomic form and secondary caries *(Table 1)*.

STATISTICAL ANALYSIS

For each restorative material at different time periods, various parameters were evaluated using Kendall's Coefficient of Concordance test. Intergroup comparison for various parameters at different time periods was performed using Chi-square test. The analysis was undertaken using SPSS software, version 20 (SPSS Inc., Chicago, IL, USA) with the significance level present at $\alpha = 0.05$.

RESULTS

Recall rates registered were 100% for 1, 6 and 12 months. The evaluated parameters retention, marginal integrity, and discoloration of both used restoration materials are presented in Table 2. In Table 3 the aesthetical parameter anatomic form and the biological parameter secondary caries using both materials at all tested time points are illustrated. In case a restoration dislodge, it was considered as a clinical failure. At the time point of one month no significant differences could be observed using both tested materials ($p>0.05$). However, Cention was significantly better than RMGIC at 6 months ($p= 0.013$) and one year period ($p= 0.026$). Marginal integrity of the cervical abrasive lesions restored with Cention were significantly better than RMGIC at all-time intervals ($p= 0.022$). On assessment of marginal discoloration, resin modified glass ionomer restorations had significantly higher discoloration at period of 6 months ($p= 0.025$) and one year ($p= 0.018$) compared to the alkasite-based material. There was no difference between the two restorative material for the anatomic form at one month period ($p= 0.098$). However, Cention presented significantly better results at 6 month ($p= 0.003$) and 1 year period ($p= 0.008$). None of the teeth restored with either materials had secondary caries at any time intervals.

DISCUSSION

This study aimed to evaluate an alkasite-based and a resin-modified glass ionomer cement as restoration materials for non-carious cervical lesion considering the USPHS criteria. Both cements materials were compared regarding adhesion, biological, technical, and aesthetical criteria retention,

Table 1. Overview of USPHS rating criteria included in this study.

Category	Rating	Criteria
Retention	Alpha (A) Charlie (C)	Restoration is present. Restoration is partially or totally lost.
Marginal integrity	Alpha (A) Bravo (B) Charlie (D) Delta (D)	No visible gap in which the explorer will penetrate. There is visible gap, in which the explorer will penetrate or catch. The explorer penetrates the gap and dentin or base is exposed. The restoration is mobile, partially or totally fractured or lost.
Marginal discoloration	Alpha (A) Bravo (B) Charlie (D)	No discoloration. Discoloration is present but has not penetrated along the margin. Discoloration has penetrated along the margin.
Anatomic form	Alpha (A) Bravo (B) Charlie (D)	Restoration is continuous with existing anatomic form. Restoration is discontinuous with existing anatomic form, but dentin or base is not exposed. Sufficient material is lost to expose dentin or base.
Secondary caries	Alpha (A) Charlie (C)	No caries is present at the margin of the restoration. There is evidence of caries at the margin of the restoration.

Table 2. Evaluation of resin-modified glass ionomer cement and alkaside-based material regarding the USHPS criteria retention, marginal integrity and discoloration after one month, six months and one year after placement.

Criterias		One month		6 months		1 year	
		Cention	RMGIC	Cention	RMGIC	Cention	RMGIC
Retention	A	40 (100.0%)	39 (97.5%)	39 (97.5%)	32 (80.0%)	33 (82.5%)	24 (60.0%)
	C	0 (0.0%)	1 (2.5%)	1 (2.5%)	8 (20.0%)	7 (17.5%)	16 (40.0%)
Marginal Integration	A	34 (85.0%)	23 (57.5%)	33 (82.5%)	11 (27.5%)	17 (42.5%)	3 (7.5%)
	B	6 (15.0%)	16 (40.0%)	6 (15.0%)	18 (45.0%)	14 (35.0%)	20 (50.0%)
	C	0 (0.0%)	1 (2.5%)	0 (0.0%)	2 (5.0%)	2 (5.0%)	1 (2.5%)
	D	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	0 (0.0%)	0 (0.0%)
	Nil	0 (0.0%)	0 (0.0%)	1 (2.5%)	8 (20.0%)	7 (17.5%)	16 (40.0%)
Marginal Discoloration	A	40 (100.0%)	39 (97.5%)	39 (97.5%)	31 (77.5%)	32 (80.0%)	20 (50.0%)
	B	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.5%)	4 (10.0%)
	Nil	0 (0.0%)	1 (2.5%)	1 (2.5%)	8 (20.0%)	7 (17.5%)	16 (40.0%)

Table 3. Evaluation of resin-modified glass ionomer cement and alkaside-based material regarding the USHPS criteria anatomic form and secondary caries after one month, six months and one year after placement.

		One month		6 months		1 year	
		Cention	RMGIC	Cention	RMGIC	Cention	RMGIC
Anatomic form	A	34 (85.0%)	26 (65.0%)	26 (65.0%)	10 (25.0%)	18 (45.0%)	4 (10.0%)
	B	6 (15.0%)	13 (32.5%)	13 (32.5%)	20 (50.0%)	14 (35.0%)	18 (45.0%)
	C	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.5%)	1 (2.5%)
	D	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	0 (0.0%)	1 (2.5%)
	Nil	0 (0.0%)	1 (2.5%)	1 (2.5%)	8 (20.0%)	7 (17.5%)	16 (40.0%)
Secondary caries	A	40 (100.0%)	40 (100.0%)	40 (100.0%)	40 (100.0%)	40 (100.0%)	40 (100.0%)

marginal integrity and discoloration, secondary caries and anatomic form. The null hypothesis could be rejected for all criteria at the time points 6 months and one year except for the criteria secondary caries. The null hypothesis could not be rejected for the time point 1 month regarding all criteria.

Non-carious cervical lesions are treated clinically in case of patient discomfort, e. g. dentinal hypersensitivity or aesthetical problems. Furthermore, in order to prevent possible biological complications such as plaque retention and pathological changes in the pulp,[9-11] concerns might lead to restoring these lesions using resin-composite or glass ionomer cements. It was observed, that the shrinkage of resin composites during polymerization might cause contraction stress at the restoration-tooth interface resulting in marginal failure and microleakage. Microleakage is prone to secondary caries formation, postoperative sensitivity, marginal staining and in worst cases to partial or total restoration loss.

Glass ionomer cements on the other hand bonds chemically to the tooth surface and presents a thermal expansion coefficient (11x10-6/°C) closure to tooth structure (Enamel: 11.4x10-6/°C, Dentin: 8x10-6/°C) compared to resin composite (25 to 60x10-6/°C) and therefore result in less voids or openings at the tooth restoration interface during temperature changes.[18] However, also glass ionomer cements are technique sensitive, are negatively influenced by dehydration and leach ions once exposed to water during their setting phase.

In order to overcome all the difficulties of resin composites and glass ionomer cements when used as restoration material especially in the cervical regions of teeth, a new alkasite-based dual-curing bulk-fill resin composite was introduced. This material resulted in better marginal integrity and less marginal discoloration compared to glass ionomer cement, due to the chemical composition of its liquid and powder components. The liquid is based on dimethacrylates, while the powder contains glass fillers. The methacrylate monomers cross-links combined with the self-cure initiators result in a high polymer network like density and thereby associated degree of conversion, resulting in better marginal integrity. Furthermore, it also includes patented fillers, the so-called "Isofillers", that act as shrinkage stress reliver in combination with the favorable organic/ inorganic ratio and monomer composition, resulting in less volumetric shrinkage.[19] Volumetric shrinkage on the other hand as well as the elasticity modulus influence the shrinkage stress at the restoration-tooth surface. The elasticity modulus of Cention N is low (10 GPa) and therefore lowers the stress at the restoration-tooth interface. This is also in accordance with one other study, which evaluated microleakage of Cention N using various dying methods.[20]

The superior retention of the resin-modified glass ionomer cement restorations to the tooth tissues are a result of the chemical bond. The decreased stress and less frequent void or gap formation due to thermal expansion and contraction result in a better bond.[21] A 96% 2-year retention rate of resin-modified cements was reported by Brackett *et al*. He attributed failures to the stiffness of the restorative material.[22]

As Cention N presents a low elasticity modulus this might explain the higher retention values compared to resin-modified glass cements. If compressive stresses are not exceeded by the shear stress of the restoration, no adhesive (restoration-tooth interface) and/or cohesive (within composite or tooth) failures can occur.

As Cention N is reported to have good color stability[23] and high translucency (11%) according to one study, which correlated with the findings of this study regarding anatomic form of the restorations.

The limitation of this study is the limited patient number. The results of this study should be verified in future clinical multi-center trials, with further investigation of the possible failures.

CONCLUSIONS

The alkasite-based restorative material Cention performed better in the follow-up period of six months and one year regarding retention, anatomical form, discoloration and marginal integrity compared to resin-modified glass ionomer cements when used for restoring cervical abrasion lesions. No difference could be observed in regards of the parameter of secondary caries.

CLINICAL RELEVANCE

Alkasite-based restorative materials displayed superior adhesion, technical, mechanical and aesthetical performance in a follow-up period of more than six months and up to one year and can therefore be recommended as an alternative in restoring cervical abrasive lesions compared to resin-modified glass ionomer cements.

DISCLOSURE

The authors declare that they have no conflict of interest.

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