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Survival of multiple-surface ART restorations using a zinc-reinforced glass-ionomer restorative after 2 years: A randomized triple-blind clinical trial

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ABSTRACT

Objective. To investigate the effectiveness of a new zinc-reinforced glass-ionomer in comparison to a common high-viscous glass-ionomer cement (HVGIC) used in multiple-surface ART-prepared cavities. The hypothesis tested was that the cumulative survival percentage of the new HVGIC is higher than that of the common HVGIC over 2 years.

Methods. A randomized triple-blind parallel group clinical trial was used. A total of 218 participants, average age 15.4 years (SD = 0.2), with an occluso-proximal carious lesion in a permanent (pre-) molar were included. Restorations using test (ChemFil Rock) and control (Fuji IX GP) restoratives were placed according to the ART method by four calibrated operators. Restorations were evaluated after one week (baseline), and at 6-, 12-, 18- and 24 months from replicas and coloured photographs according to the ART restoration assessment criteria by two independent evaluators. Restoration survival curves were estimated using the Kaplan–Meier method and difference between dependent and independent variables tested with a Wald (chi-square) test.

Results. There was a statistically significant difference in cumulative survival percentages between the two types of restorations at 2 years ($P = 0.02$). A higher percentage of multiple-surface restorations of Fuji IX GP (95.4%) than ChemFil Rock (85.3%) survived. Gender ($P = 0.64$), operator ($P = 0.56$) and cavity size ($P = 0.81$) had no effect on the survival of the type of restoration observed. Type of tooth ($P = 0.004$) and type of jaw ($P = 0.05$) showed an effect. Severe wear was the major reason for restoration failure (ChemFil Rock = 7; Fuji IX GP = 1).

Significance. ChemFil Rock appears not to be a viable alternative to Fuji IX GP in restoring ART multiple-surface cavities in permanent posterior teeth.

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1. Introduction

Reviews have concluded that the Atraumatic Restorative Treatment (ART) method is indicated for treating cavitated dentine carious lesions in single-surface cavities in both primary and permanent posterior teeth [1–3]. For multiple-surface carious lesions, although systematic reviews have not shown a significant difference in the survival percentage of ART restorations using powder-liquid mixed high-viscosity glass-ionomer cement (HVGIC) and comparable amalgam and resin composite restorations in primary teeth, adopting the ART method or the traditional methods, should be considered cautiously for this type of cavity. All three restorative treatments have produced relatively low survival percentages [4,5]. However, few studies have used the ART method to treat multiple-surface carious lesions in permanent posterior teeth [6].

The quality of a restoration over time is dependent on a number of factors, which are operator, patient and material related [7]. HVGICs have been used for the last 20 years and have improved since their introduction. Laboratory studies show that capsulated HVGICs provide higher survival percentages than their powder-liquid versions [8,9]. But, despite these possible improvements, the fracture toughness of HVGICs remains a weak aspect of this material. In order to produce quality multiple-surface ART/HVGIC restorations in permanent and primary posterior teeth, the fracture toughness of the HVGIC needs, therefore, to be improved.

Some years ago, a zinc-reinforced capsulated HVGIC was introduced that, in laboratory studies, showed higher fracture toughness values than conventional HVGICs [10,11]. Such HVGIC might be a suitable restorative for improving the survival of multiple-surface ART restorations in both permanent and primary posterior teeth. As a review of the literature did not reveal any studies that had investigated this zinc-reinforced HVGIC clinically, it was decided to conduct a clinical trial to investigate its effectiveness.

The hypothesis tested was that the survival of multiple-surface ART zinc-reinforced HVGIC restorations in permanent posterior teeth was significantly higher than that of comparable restorations with conventional HVGIC after 2 years.

2. Materials and methods

2.1. Sample size calculation

Very few studies are available regarding multiple-surface ART restorations in permanent posterior teeth. A significance level of 0.05, with a power of 80%, was chosen for this study. In addition the findings from the 10-year study by Zenata et al. [12], which showed a 3-year survival percentage of 79 for multiple-surface ART permanent posterior restorations using hand-mixed HVGIC, were extrapolated. With these factors and the expected 14% higher survival percentage (93%) obtained from using the zinc-reinforced HVGIC, the required sample size per group was calculated at 92 multiple-surface carious lesions per treatment group. Allowing for a dropout of participants of 15%, the sample size was 106 per group for the 3-year period (PS Power and Sample Size Calculations Software, version 3.0.11 for MS Windows, William D. Dupont and Walton D. Vanderbilt, USA).

2.2. Study setup and ethical considerations

A randomized prospective parallel, triple-blind (patients, evaluators and statistician), controlled clinical study design was used. The study protocol was approved by the ethical committee at the Ministry of Health and Population, Government Health Insurance in Egypt (RHD-IRB0000687-13Oct2014-EM02) and registered in the International Standard Randomised Controlled Trials Number (ISRCTN13550429). The study was fully explained, in verbal and written form, to the school authorities and to the participants and their parents. Once the subject and his/her parent agreed, the parent was requested to fill in a consent form. Only participants whose parent had filled in and signed the form were allowed to participate in the study.

Based on in- and exclusion criteria (Table 1), participants from 24 local governmental preparatory schools (12 boys' and 12 girls' schools only) in low- to moderate-socioeconomic regions, in Giza governorate, Cairo, Egypt were eventually included in the study. These schools had nearby dental clinics, which meant that the clinics could be used for treating the study participants. Four dentists screened all the participants in the second and third preparatory school year at the school compound. Participants who met the inclusion criteria were invited to participate in the study (Fig. 1). Data were recorded for each participant regarding age, gender, grade, school name, phone number of both parents, detailed home address, tooth type/location, DMFS count, and plaque and gingivitis score according to the Simplified Oral Hygiene Index (S-OHI) [13]. Cavitated teeth that scored 2.2, 2.3 or 2.4 according to the Si/Sta classification [14] were included in the study. Figs. 2 and 3 show representative photographs of the included prepared cavities with different sizes before and after restoration with Fuji IX GP and ChemFil Rock restorations. After the study participants had been selected, non-study participants who required treatment were referred to the regular school dental clinic.

2.3. Blinding of patients and randomization of the restoratives

The HVGIC restorative materials used in the study were Fuji IX GP (GC Corporation Tokyo, Japan) (Batch no: 12051818) [Powder: Fluoro-alumino-silicate glass, ployacrylic acid powder. Liquid: polyacrylic acid, polybasic carboxylic acid.] and ChemFil Rock (Dentsply DeTrey GmbH, Konstanz, Germany) (Batch no: 1112001327) [Powder: Zinc-modified fluoro-alumino-silicate glass. Liquid: polyacrylic acid, itaconic acid]. The two tested HVGICs were supplied in two different capsules, which made masking them impossible. Both HVGICs were in shade A3.

A total of 218 participants for both treatment groups were selected for treatment by four operators and almost equally divided according to operator. A computer software program randomized the two types of restoration per operator. After that, each restoration/operator group was separated into two halves (female and male participants) for obtaining a nearly equal number of both types of restorations per gender. Then,

Table 1 – Inclusion and exclusion criteria for patients enrolled in the present study.

Inclusion criteria
• Healthy patients without any history of any medical condition that could interfere with the study protocol or affect clinical results. • Good oral hygiene (Simplified Oral Hygiene Index (S-OHI ≤ 0.5%). Caries status (DMFS < 12). • Patients without adverse oral habits that could affect the study results. • Presence of natural antagonist which is not restored. • Presence of at least one tooth with a cavitated dentine carious lesions including at least occlusal-proximal (multiple) surface in first or second permanent premolars/molars situated in any side of the jaw. • Presence of adjacent tooth to the cavity and being fully erupted, normally positioned (not tilted or rotated) and having natural (not restored) contact. • Occluso-proximal carious lesions with size (Site/Stage 2.2, 2.3 and 2.4). • Absence of apparent enamel crack or fracture. • No pulp involvement or symptoms of pulpitis or apical periodontitis.
Exclusion criteria
Teeth without antagonists or with a prosthetic antagonist. Occlusal-proximal carious lesions limited to enamel layer. Deciduous teeth Patients who suffer from abnormal oral habits with excessive occlusal function or parafunction, such as pencil chewing or bruxism Patients declaring daily consumption of citric juices.

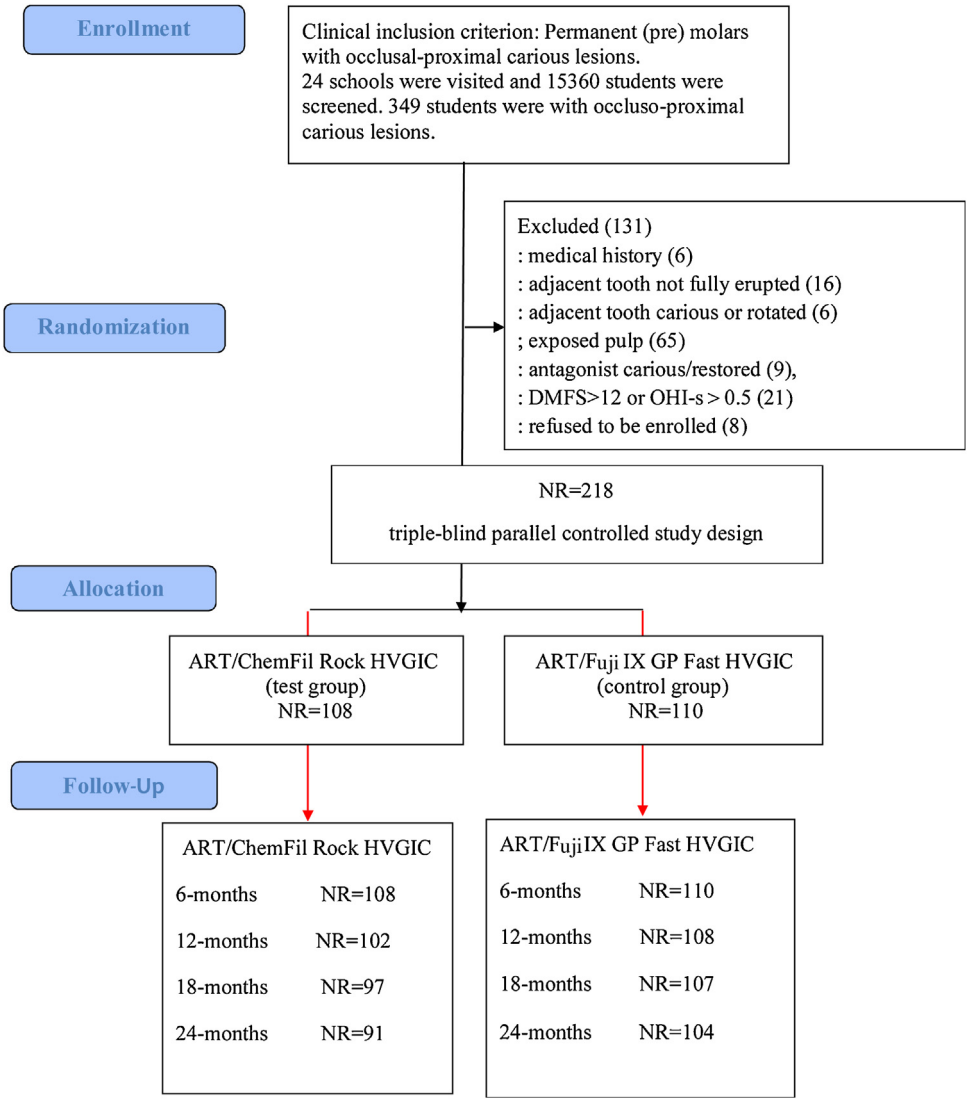

Fig. 1 – Consort study flowchart on the basis of the ART caries assessment criteria. NR: number of restorations.

Fig. 2 – The included three cavity sizes before and after restoration with Fuji IX; A & B represent size 2.2, C & D represent size 2.3 and E & F represent size 2.4.

Fig. 3 – The included three cavity sizes before and after restoration with ChemFil Rock; A & B represent size 2.2, C & D represent size 2.3 and E & F represent size 2.4.

identical opaque sealed envelopes, containing randomized numbers assigned to each operator, were prepared so that half of the envelopes had round pink stickers for female participants and the other half had blue ones for male participants. Each eligible participant was asked to choose one envelope, based on his/her gender. The chosen number was used as the participant's identity code and was taken by a third person, who had the code distribution, to inform the operator of which HVGIC restorative should be used for that particular case. In this way, randomization of the two restoratives over the prepared cavities was achieved and each cavity was restored with its selected restorative material.

2.4. *Operator training and ART cavity preparation and restorative procedures*

Before the study began, operators underwent theoretical (lectures) and practical training in the ART restoration method to ensure standardization of the clinical procedures. During 10 training sessions (one/three weeks), under close supervision of the first author (EM), who had been trained by an experienced ART operator (JEF), and with the assistance of the second (HE) and third author (LE), trained by the first author, a total of 30 occlusal-proximal restorations were performed by each operator using the ART method.

From March 2012 to May 2014, on school days, ART treatments were performed as recommended by Frencken et al. [15]. Local anaesthesia (Mepivacaine-L, Alexandria Company for pharmaceuticals, Alexandria, Egypt) was administered only on participant demand during clinical procedures. After cotton roll isolation, cavities were prepared using hand instruments only. The ART Cavity Opener (Henry Schein, NY, USA) and the ART Enamel Hatchet (Henry Schein, NY, USA) were used to gain access to the carious dentine cavity (if needed). Soft carious dentine was excavated by small and medium-sized ART excavators (Henry Schein, NY, USA). After removal

of the soft, decomposed dentine and having broken away weak undermined enamel, the cavity was contoured and smoothed with the enamel hatchet and a gingival margin trimmer (LM Instrument OY, LM Dental, Finland). The cavity was wiped with water-soaked cotton pellets, dried using dry cotton pellets and cautiously inspected for the presence of soft dentine, which was then removed.

For the prepared cavities receiving Fuji IX GP, the manufacturer-supplied dentine conditioner (10% Polyacrylic acid conditioner) (GC Corporation Tokyo, Japan) was applied to the floor and the walls of the prepared cavity with a microbrush (Microbrush, São Paulo, Brazil) for 10 s. The conditioner was rinsed out using a cotton pellet soaked in water till no remnant of the conditioner was visible (about 10 s). Then, the cavity was blotted using dry cotton pellets (5 s). A prefabricated matrix band (KerrHawe SA, Bioggio, Switzerland) and a wedge (KerrHawe SA, Bioggio, Switzerland) were inserted. ChemFil Rock was applied without conditioner. For both types of HVGIC, capsules were mixed using amalgamator according to the manufacturer's instruction. Numbers of capsules applied depended on the cavity size.

The selected HVGIC was placed first into the prepared cavity corners and under thick unsupported enamel. Thereafter, it was inserted into the entire cavity and in the adjacent fissures, with care taken not to cover the cusps. Finally, the material was held under pressure by the index finger coated with a thin layer of petroleum jelly for 10–15 s [15]. Excess HVGIC was removed with a large excavator and ART contouring instrument (Henry Schein, NY, USA) and left to harden for 25–30 s for both HVGICs. The wooden wedge and matrix band were then removed. The restoration margins were burnished using the backside of the excavator, and the occlusal and proximal contours were carved. Occlusion was checked using an articulating paper (Hanel, Coltène/Whaledent GmbH Germany). In case of any occlusal adjustment, the surface of the restoration was recoated with another layer of petroleum jelly. Participants were instructed neither to eat nor to brush the restored side of the mouth for at least two hours, and to brush the teeth twice daily with a fluoride-containing toothpaste every day thereafter. Participants were also advised to contact the operator if they had any complaint or experienced pain.

2.5. *Evaluation of restorations*

Using intra-oral photographic mirrors, digital clinical photographs of the occlusal and approximal surfaces were taken from the occlusal, buccal/lingual and proximal sites using a digital camera Nikon D40 (Nikon, Tokyo, Japan) and a Macro lens (Sigma Macro Lens 105 mm F2.8, Sigma Corp, Tokyo, Japan) supplied with a ring flash. The photographs were taken preoperatively, after cavity preparation and postoperatively at baseline (one week post-restorative) and at each of the four follow-up time points (6-, 12-, 18- and 24 months).

Additional to the digital clinical photographs, replicas of all restorations were made at baseline and at each of the follow-up points using a silicon rubber base (putty/light material, two steps technique). A sectional tray was cut short and modified to cover three teeth only: the treated tooth, a mesial tooth and a tooth distal to the restored one. Express™ STD putty material (3MESPE, St. Paul, USA) was mixed according to the manufacturer's instructions, placed in the sectional tray and positioned on the area of interest under steady pressure applied by two fingers. After the impression material had set, the tray was removed from the mouth. The impression was rinsed, dried and checked. Excess putty material that extended into the buccal and/or lingual vestibules was cut away with a sharp knife. Express light body paste (3MESPE, St. Paul, USA) was injected onto the occlusal surface of the adapted putty impression, with minimal air bubble entrapment. Then, the tray was replaced over the occlusal surfaces of the teeth. After the paste had set, the tray was removed from the mouth, rinsed, dried and inspected under illumination for the presence of any defect. A type IV extra hard stone (Fuji Rock EP, GC Corporation Tokyo, Japan) was poured into the impression to produce a replica of the restored tooth. A plaster base was fabricated for situating the set stone replica.

Follow-up appointments for assessing the restorations at the school compound were arranged with scheduled participants via telephone. In case the research team failed to contact a participant by phone or to meet him/her at school because of absenteeism, a home visit was made and a clinical photograph and mouth impression were taken by either one or two members of the research team. The participants who could not be contacted were considered dropouts.

Restorations were evaluated at baseline and at 6-, 12-, 18- and 24 months. Baseline evaluations were carried out one week after completion of the restorations [16]. This was done so that any faulty restoration (those with initial persistent pain or unbearable hypersensitivity or improper occlusal contacts) could be discarded. The evaluation was performed using the ART restoration criteria (codes 0–9) [17] and the FDI restoration criteria (marginal adaptation B.6 and occlusal contour and wear B.7) [16]. The evaluation process was carried out on replicas. In case of doubt, digital photographs were consulted independently by two experienced evaluators (EM and HE), who did not take part in the clinical procedures, as recommended by Hickel et al. [16], and who were blinded to the restorative used per case. Differences in assessment scores were discussed and a final score was reached by consensus.

2.6. *Statistical analyses*

The independent variables were gender, operator (four dentists), type of tooth (premolar and molar), type of jaw (maxilla and mandible) and cavity size (large, medium and small) while the dependent variable was type of restoration (ART/cavities restored with ChemFil Rock and ART/cavities restored with Fuji IX GP). ART restoration criteria codes 0 and 1 indicate a successful restoration, while codes 2–8 and a dentine carious lesion indicate a defective restoration. Four longitudinal series of evaluation codes were incomplete, and imputation was performed. Using the flip of a coin, the score on the left and right side of the missing score was chosen alternately to complete a series. Survival estimates were calculated on the basis of the scores obtained from using the ART restoration criteria. The FDI scores were used to distinguish between marginal failure because of fracture of the restoration and because of its severe wear.

Table 2 – Distribution of multiple-surface restorations using test (ChemFil Rock) and control (Fuji IX GP) restoratives over the independent variables at start of the trial.

	ChemFil Rock	Fuji IX GP
Cavity size		
Small (2.2)	4	2
Medium (2.3)	20	23
Large (2.4)	84	85
Type of tooth		
Premolar	14	28
Molar	94	82
Type of jaw		
Maxilla	43	57
Mandible	65	53

The analyses were performed by a statistician using SAS 9.2 software (Cary, NC, USA). The symbol (number) for the test and control restorative was only disclosed after the analyses had been completed. The survival curves were estimated using the Kaplan–Meier method. A Proportional Hazard model was used to test the difference in type of restoration and the effect of the independent variables with a Wald (chi-square) test. Statistical significance was set at $P = 0.05$.

3. Results

The study CONSORT diagram is presented in Fig. 1. A total of 218 participants (109 girls and 109 boys), with a mean age of 15.4 years (SD = 0.2) ranging from 14.8 to 15.8 years, met the inclusion criteria and had the consent form signed. The mean D_3MFS score was 7.1 (SD = 1.57) and mean S-OHI score was 0.15 (SD = 0.18). The distribution of the restorations using the two types of HVGIC restoratives by cavity size, type of tooth and type of jaw is shown in Table 2. The group of small restorations was added to the medium group because of an insufficient number. Only three local anaesthesia injections had to be administrated.

The cumulative survival percentages and standard error of the ChemFil Rock (test) and Fuji IX GP (control) restorations by time point are presented in Table 3. A statistically significant difference in cumulative survival percentages was found between the two types of restoration at 2 years ($P = 0.02$). A higher percentage of multiple-surface restorations of Fuji IX GP (95.4%) than of ChemFil Rock (85.3%) survived. There was no effect of gender ($P = 0.64$), operator ($P = 0.56$) or cavity size ($P = 0.81$) on the type of restoration observed. Type of tooth ($P = 0.004$) and type of jaw ($P = 0.05$) showed an effect. Because of a possible interaction between type of tooth and type of jaw, a new variable was created for the four combinations. Analyses showed a statistically significant effect ($P = 0.003$) among type of tooth and type of jaw. Contrasts showed more defective restorations in maxillary premolars than in those of the other three combinations. The 2-year survival estimates for the 4 groups are: premolars of the maxilla (73.1%), premolars of the mandible (93.3%), molars of the maxilla (91.6%) and molars of the mandible (93.9%).

Table 4 – Reasons for multiple-surface restoration failure by type of restorative used.

ART evaluation codes showing failure	ChemFil Rock	Fuji IX GP
2 (marginal defect)	3	1
2 (severe wear[a])	7	1
3 (fracture in restoration)	1	0
4 (fracture in tooth)	1	0
5 (overextension approximal)	0	0
6 (part or full restoration missing)	0	2
Secondary carious lesion	3	1

ART = Atraumatic Restorative Treatment.
[a] Based on the FDI assessment criteria.

A total of 20 (15 ChemFil Rock and 5 Fuji IX GP) multiple-surface restorations failed. The reasons for failure are presented in Table 4. Presence of secondary carious lesions was scored in four (three test and one control) restorations. Evaluation code 2 was scored most; 10 times for the test and 2 times for the control restorative. Severe wear was observed in seven ChemFil Rock and in one Fuji IX GP multiple-surface restorations.

4. Discussion

4.1. *Research methodology*

Every effort was taken to contact the study participants, which resulted in a low number of dropouts and, consequently, in keeping the power of the study high. The fact that restoration assessment was performed from clinical photographs

Table 3 – Survival percentages (Surv) and standard error (SE) of ART multiple-surface restoration of ChemFil Rock (test) and of Fuji IX GP (control) by time interval.

Time interval (year)	ART/ChemFil Rock					ART/Fuji IX GP				
	N_{entry}	$N_{failcum}$	$N_{censcum}$	Surv	SE	N_{entry}	$N_{failcum}$	$N_{censcum}$	Surv	SE
0.0–0.5	108	2	4	98.1	1.3	110	1	1	99.1	0.9
0.5–1.0	102	4	7	96.2	1.8	108	1	2	99.1	0.9
1.0–1.5	97	10	7	90.2	2.9	107	4	2	96.3	1.8
1.5–2.0	91	15	–	85.3	3.5	104	5	–	95.4	2.0

N_{entry} = number of restorations at start of the study.
$N_{failcum}$ = cumulative number of failures.
$N_{censcum}$ = cumulative number of censored data.
ART = Atraumatic Restorative Treatment.

and replicas made the evaluation process straightforward and potentially very reliable. In this way, restorations from participants that were contacted at home could be performed in the same way as restorations from participants that were contacted at school. Assessing restorations from clinical photographs and replicas has the further advantage of enabling the restoration conditions at various evaluation points to be assessed in sufficient time and order, in contrast to a visual clinical examination, which leaves no record other than a code on a record form. The fact that evaluators were able to discuss any difference of opinion with the restoration images at hand is another advantage. An adverse effect may be that producing a replica is a time-consuming procedure; on the other hand, it increases the chance of achieving a more objective assessment than through the use of a visual clinical examination only [18].

The present randomised study was carried out triple-blind. The participant him/herself selected the restorative; the evaluators did not know which restorative was used as both were of the same colour shade; and the statistician performed the analyses without knowing the test or the control group. Only the operators knew the restorative they would need to apply as they are bound by law to follow treatment protocol and to use the restorative according to the manufacturer's instructions. Blinding of the operators, in restoration/sealant effectiveness studies that use materials that are distinguishable or require custom cavity preparations, should no longer be considered a requisite for conducting high-level trials. Ensuring the safety of the patients takes priority over a requisite for conducting scientific dental studies of this nature.

4.2. *Main findings*

The hypothesis was rejected. The new ART/zinc-reinforced HVGIC multiple-surface restorations survived for a significantly shorter time than the control group, which used the conventional HVGIC, after 2 years. The 2-year survival percentages of both test (85.3%) and control (95.4%) groups were higher than the weighted mean survival percentage of ART/HVGIC multiple-surface restorations (78.2%) in permanent posterior teeth obtained from a meta-analysis [6]. The meta-analysis included only studies that had used hand-mixed ART restorations, which is likely to be the main reason for the apparent difference in results. The outcome shows that the use of encapsulated HVGIC in ART-produced cavities may result in higher quality ART restorations than using a hand-mixed HVGIC. This finding is supported by laboratory studies [8,9]. However, a recent study that used hand-mixed Fuji IX in ART restorations also revealed a high survival percentage (94.8%) [19].

The survival percentages of the test group (ChemFil Rock restored cavities) in the present study were lower than those of conventionally prepared cavities that were restored with an encapsulated coated HVGIC (Equia System), placed in a private practice environment, after 2 years (94%) [20] and 4 years (90%) [21] and (93.4%) [22]. Compared to these three studies, the survival percentage of the control group (Fuji IX GP restored cavities) in the present study was in line with the result after 2 years [20] and probably also with the 4-year results of the two other studies but not their survival percentages after 2 years. The latter result shows that, with careful selection of cavities and restoration by well-trained operators, the multiple-surface ART conventional HVGIC restorations in posterior permanent teeth reveal similar survival percentages after 2 years to those obtained through comparable rotary-produced encapsulated HVGIC restorations that also used a coat.

The main reason for the failure of the zinc-reinforced HVGIC was severe wear. Compared to the Equia System in a laboratory study, ChemFil Rock exhibited lower Vickers Hardness values, which may indicate loss of surface properties [10]. In another laboratory study, ChemFil Rock exhibited a higher mean surface roughness value and a lower level of microhardness than the Equia System and Fuji IX GP materials [11]. A lower microhardness (VHN) score was also reported for ChemFil Rock than for Fuji IX GP Fast and Ketac-Molar Aplicap [23]. These laboratory results may indicate easy loss of surface properties of the zinc-reinforced HVGIC.

In both materials, fracture toughness was considered the weakest aspect of HVGIC, nevertheless, this was not frequently recorded in the present study as a reason for failure. As mentioned earlier, this might be due to the use of encapsulated HVGIC.

Secondary dentine carious lesion development after 2 years was low. This might be expected considering the inclusion criterion that the participants' S-OHI scores should be less than 0.5. However, this may not be the only explanation, as in ART/HVGIC restoration studies that included subjects with different levels of hygiene, the annual restoration failure rate due to secondary dentine carious lesion development was 0.5% over the first 5 years [24]. This outcome is extremely low and is comparable to results reported for resin composite [25].

5. Conclusion

ChemFil Rock appears not to be a viable alternative to Fuji IX GP in restoring ART multiple-surface cavities in permanent posterior teeth.

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