The present clinical study aims at comparingthe clinical performance of two high viscous glass ionomer based restorative materials in treatment of occluso-proximal carious lesions using Atraumatic Restorative Treatment (ART).

I. Materials

Materials utilized in the present study were:

- High viscous glass-ionomer restorative material (Fuji IX-HVGI, Table1,Figure 1)
- High viscous glass-ionomer restorative material (ChemFil Rock-HVGI, Table1,Figure 2)
- Local anesthesia (Table1)
- Haemostatic Liquid (Table1, Figure 3)
- Calcium hydroxide (Table1, Figure4).
- Dentin conditioner (Table1, Figure5).
- Vaseline (EVA cosmetics Co., Egypt, Figure6)
- Addition silicon rubber base material (putty and injection types, Table1, Figure 7 and Figure 8).
- Extra hard type IV dental stone (Table1, Figure9).
- Radiographic processing solutions (Table1, Figure 10).

Table 1 shows the materials names, manufacturers, types, composition and lot numbers.

Table 1: Materials names, manufacturers, types, composition and lot numbers

Material name/ Manufacturer	Type	Composition	Lot #
Fuji IX GP CAPSULE (GC Corporation, Tokyo, Japan)	High Viscous Glass-ionomer (HVGI)	Powder: Fluoro-alumino-silicate glass, ployacrylic acid powder. Liquid: polyacrylic acid, polybasic carboxylic acid.	12051818
ChemFil Rock (DentsplyDetreyGmbH,Konstanz, Germany)	High Viscous Glass-ionomer (HVGI)	Powder: Zinc- modified fluoro-alumino-silicate glass. Liquid: polyacrylic acid, itaconic acid.	1112001327
Mepivacaine-L (Alexandria company for pharmaceuticals, Alexandria, Egypt)	Local anesthetic/ Injection carpoule	MepivacaineHCl 36.00 mg /1.8 ml +LevonordefrinHCl 0.11664 mg/1.8 ml	2H130423
Dycal(Dentsply Caulk, USA)	Calcium hydroxide (Base/ Catalyst)	Base paste:calcium tungstate, zinc oxide, disalicylate ester of 1,3 butylene glycol Catalyst paste: calcium hydroxide, zinc oxide, titanium dioxide	120813
Dentin Conditioner (GC Corporation Tokyo, Japan)	Glass-ionomer conditioner	10% Polyacrylic acid conditioner	0712041
Experss TM STD (3 M ESPE, Switzerland, USA)	Addition silicon impression material	Vinyl Polysiloxane (Putty consistency)	N 404105
Experss TM (3 M ESPE, Switzerland, USA)	Addition silicon impression material	Vinyl Polysiloxane (Injection type)	N 346052
Fuji Rock EP (GC Corporation Tokyo, Japan)	Improved type IV dental stone	Calcium sulfate hemihydrates	0710011
Kodak CE (Kodak,Carestream Health Inc.,Rochester, New York, USA)	Radiographic Developer and Fixer solutions	Developer:sodium carbonate, Elon™, potassium bromide, and sodium sulfate and water. Fixer: acetic acid, sodium thiosulfate, platinum alum, sodium sulfite and water.	5003791
Hemostal (PrevestDenpro, Jamma, India)	Hemostatic Liquid	25% Aluminium Chloride Buffer	84035

II. Armamentarium

- Diagnostic instruments; mirrors, tweezers and explorers (Zeffiro,Florence, Italy)
- ART Excavator (small-discoid excavator, Henry Schein, New York, USA, Figure11)
- ART Hatchet (Henry Schein, New York, USA, Figure12)
- Gingival Marginal Trimmer (LM Instruments OY, LM Dental, Finland, Figure 13).
- Matrix band (KerrHawe Sycamore international wedges, KerrHawe SA,Bioggio, Switzerland, Figure14)
- Matrix holder (Contact Outward Rings, Danville, California, USA Figure 15).
- Wooden wedges (Hawe Sycamore international wedges,KerrHawe SA, Bioggio, Switzerland, Figure 16).
- ChemFilRock capsule Extruder (DentsplyDetreyGmbH,Konstanz, Germany, Figure 17)
- Fuji IX capsule Extruder (GC Corporation, Tokyo, Japan, Figure 18)
- ART Applicator/Carver (Henry Schein, New York, USA, Figure 19)
- Articulating paper (Bausch Anti-check 40 μm, Bausch articulating paper Inc, Kölin, Germany, Figure 20)
- Dental intraoral radiographic Film (D-speed, Carestream Inc., New York, USA, Figure 21).
- Community periodontal index (CPI) probe with a tip diameter of 0.05mm (CP 11.5 B probe, Hu-Friedy,Chicago, USA, Figure 22).
- Pre-modified sectionaltrays (Misr Dental, Egypt, Figure 23).
- Amalgamator (AOSU ADT, AOSU medical devicement, Zhejiang, China, Figure 24).
- Digital Camera (Nikon D40, Nikon, Tokyo, Japan) and a Macro lens (Sigma Marco Lens 105 mm, Sigma Crop, Tokyo, Japan, Figure25).

Methods

Sampling procedures

1. Patients' selection

The current study was carried out at the Faculty of Oral and Dental Medicine, Cairo University, Egypt after obtaining the approval from the local Ethics Committee.A single blindcontrolled clinical study was performed where a total of 2500 patients of both gender were screened. Fifty-two patients were included in the current study fulfilling the inclusion criteria, which were as follow:

1. Being young adult (16-20 years old) ***Virden et al, (2014)*** of both genders.
2. Being with no history of any medical disease or taking any medication that might interfere with the study (e.g medications that may cause hyposalivation).
3. Patients should have a medium-sized (bucco-ligually and mesio-distally) occluso-proximal carious lesions extending into dentin and with at least occlusal access of approximately 0.5to1.0 mm ***Kemoli and van Amerongen, (2009),***where if more than one cavity existed per patient,only the most matching carious lesion size per patientwas selected. The other lesions were treated but not included within the study design.
4. Being fully erupted and in contact with opposing and adjacent tooth.

- The exclusion criteria were as follow:
    1. Patients with abnormal occlusion, bad oral hygiene, chewing, eating and drinking habits as well as those with low salivary rate were not included in the study.
    2. Teeth with pulp involvement that had sign or symptoms of pain, pulp exposure, and/or presence of a swelling or fistula or pathological mobility were excluded from the study.

2. Patients grouping and randomization

Fifty two participants of both genders (26 females and 26 males) were included in the current study.Teeth of both groups were treated using the ART approach and were subdivided into two subgroups according to the restorative material used. For each gender, the first half of the cavities (n=13) was restored with Fuji IX HVGIRM while the other half restored using ChemFil Rock-HVGIRM (n = 13).

In order to achieve randomization in the current clinical study, each patient met the inclusion criteria and was accepted to be enrolled in the study, was asked to choose one envelope that had a number from (1- 26) written on a black paper (5×5 mm) with an indelible pin. The envelopes wereidentical, sealed and opaque (does not permit the light transmission). The number was taken as his/her code. If the chosen number was an odd one, the participant received a restorative material (I) representing ChemFil Rock HVGIRM. On the other side, those chose an even number received a restorative material (II) representing Fuji IX HVGIRM. Patients were blind to the type of restorative material used for them whereas that was not applied to the operator who did the restorations for the cavities.

Treatment procedures

The nature and objectives of the clinical trial were fully explained to the patients that were fulfilling the inclusion criteria. Informed consents were obtained from the participants. The Participant's name, address, age, medical and dental history, plus the contact information were recorded. The chief complain of the patient was recorded and managed for the enrolled participant if it was rather than the selected carious lesion in the study.

Tooth preparation procedures

Field isolation was maintained during the whole restorative procedure using cotton rolls.They were placed in the buccal and the lingual vestibules for mandibular molars and in the buccal vestibule of maxillary ones for isolation ***Tandon (2001***). Local anesthesia was only administered upon patient's request.Cavities were prepared entirely using hand instruments ***Frencken et al.(1996)*** where, an ART sharp excavator of suitable size was chosen for excavation of carious dentin (Figure 11).Caries removal followed the recommendations of ***Frencken et al. (1996)*** where the walls of the cavity were excavated at first then the cavity floor. The preparation was not intended to be extending into any adjacent intact fissures. The undermined enamel was cleaved out using ART Hatchet (Figure12). The cavity walls were planned using ART Hatchet and GMT. Then, the cavity walls and margins were checked to be free from any remaining carious dentin that may jeopardize the restoration adaptation and adhesion to tooth structure as much as possible. Freeing of the proximal contact was also checked and a haemostatic liquid was used if needed. Deep dentin layers approaching

the pulp were capped with calcium hydroxide paste, provided that no pin point exposure was encountered (Figure 4).

Restorative procedures

For each prepared cavity, an auto adjustable matrix band and a wedge were adapted (Figures14 and 16). The prepared cavity was conditioned (Figure 5) by a drop of dentin conditioner which was applied and rubbed on the floor, walls and extended to include adjacent fissures by using a microbrush for 15 seconds ***Kemoli et al, (2009)***.Thereafter, the conditioner was rinsed outwith waterfor 20 seconds and the cavity was blotted dryusing a small cotton pellet.

Afterwards, the glass ionomer capsules were mixed according to manufacturer's instructionsusing an amalgamator (Figure24). Fuji IX capsules were mixed for 10 seconds while ChemFil Rock capsules were mixed for 15 seconds. The capsules were evacuated into the cavity and the glass ionomer was pressed in its place using the press-finger technique, where a slight pressure was applied on the entire occlusal surface until the initial setting **Scholtanus and Huysmans (2007)**. After the initial setting of the material, the matrix holder, band and the wooden wedge were removed.Carving was done to the proximal part of the restoration using ART carver to give the tooth itsnormal contour and anatomy.The occlusion was checked using an articulating paper (Figure 20). The excess was removed using ART carver (Figure 19), and the surface of the restoration was coated with a layer of Vaseline.The post operative instructions were given to the patient not to eat or brush on the restored side for at least two hours after the tooth was restored. Meanwhile, each patient was instructed to do the regular oral hygiene measures confirming the use of tooth brush twice daily. Finally, restorations were inspected at every recall appointment and the

participant was also advised to contact the operator if there is any problem was anticipated.

Evaluation procedures

Digital photographs, directandindirect clinical evaluation besides radiographic examination were done at the baseline (after one week from restorative material placement) ***Shabayek et al. (2011)*** and at the follow up recalls (after threeand six months).

1- Photographic records

Digital Photographs were obtained for the proposed teeth after cavity preparation and after restoration using a digital camera Nikon D40 and a Macro lens supplied with a ring flash (Figure25).

2- Clinical evaluation

2.1 Direct clinical evaluation

Two calibrated independent examiners,who were blind to the type of the GIRMs, carried out the direct clinical evaluation.The evaluation was done using a mirror and 0.5 mm ball-end of a metal CPI probe under a good illumination using ART criteria (Figure 22).

Table 2: ART evaluation criteria used to assess proximal ART restorations (*Roeleveled et al., 2006*).

Code	Criteria
0	Present, satisfactory (correct)
1	Present, slight deficiency at cavity margin of less than 0.5 mm
2	Present, deficiency at cavity margin of 0.5 mm or more
3	Present, fracture in restoration (accepts repair and not replacement)
4	Present, overextension of proximal margin of 0.5 mm or more
5	Not present, most or all of restoration missing
6	Not present, other restorative treatment performed

2.2- Indirect clinical evaluation

An accurate impression was made using addition silicon rubber base (putty/light material, two steps technique) (Figures 7 and 8).The putty material was mixed according to manufacturer's instruction, placed in a pre-modified sectional tray (Figure 23) to accommodate only three teeth. Then the tray seated in its place with a gentle pressure using two fingers. After setting, the impression was rinsed, dried and the excess material was removed. The light body was injected into the impression as well as intoproximal and occlusal surfaces of the prepared tooth, to decrease the possibility of air bubble entrapment.Then, the tray reseated over the occlusal surface of the teeth. After setting of the impression, it

was removed, rinsed, dried and then checked for the presence of any defects.A positive replica of the restored tooth was poured using extra hard stone (type IV) (Figure 9) according to the manufacturer instructions. Plaster base was finally fabricated for such replica.

3.2-Radiographic examination

Post operative bitewing radiographic records were taken for the restorations at baseline and at the follow up recall periods. Radiographic records were used for assessment of restoration loss, marginal integrity, cervical gaps formation and presence of any residual caries ***Kemoli et al. (2010)***.

Data analysis

The clinical study findings were tabulated, statistically analyzed and interpreted. Qualitative data were described using number of cases and percentages. Restorations scored with 0 and 1 were considered as successful, whereas those with scored from 2 to 6 were considered as failures. The statistical significant difference between the restoration time variables was tested using the Kaplan Meier and long lank tests. $p < 0.05$ was considered statistically significant. Data were analyzed using SPSS for Windows (Statistical Package for Social Sciences, release 15 for MS Windows, 2006, SPSS Inc, Chicago, IL, USA).

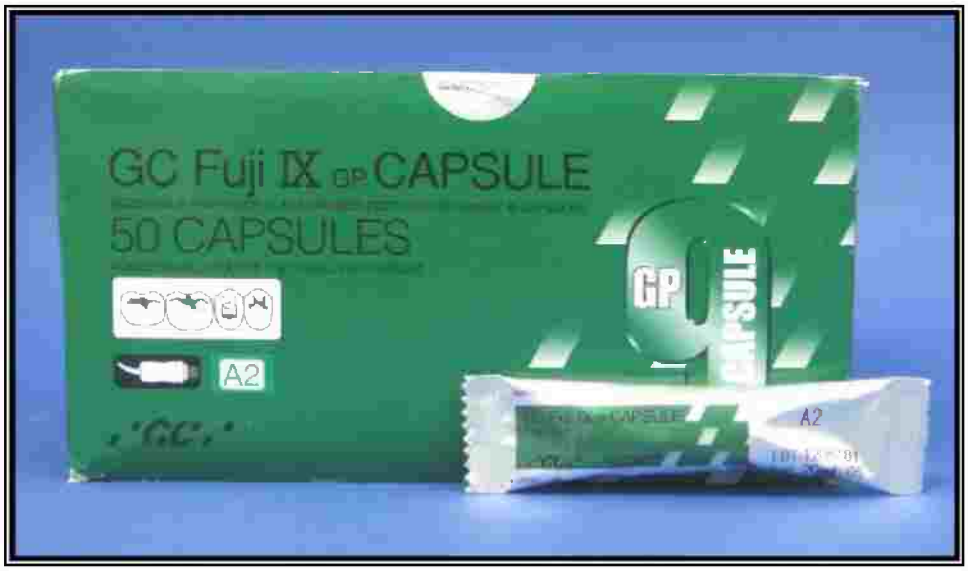

Figure 1: Fuji IX restorative material Kit

Figure 2: ChemFil Rock restorative material Kit

Figure 3: Haemostatic Liquid (Haemostal)

Figure 4: Calcium hydroxide (Dycal).

Figure 5: Dentin Conditioner

Figure 6: Vaseline

Figure 7: Addition silicon rubber base impression material (Express STD, Putty)

Figure 8: Polysiloxane rubber base impression material (Express TM, Injection type)

Figure 9: Extra hard dental stone type IV

Figure 10: Radiographic solutions

Figure 11: ART Excavator

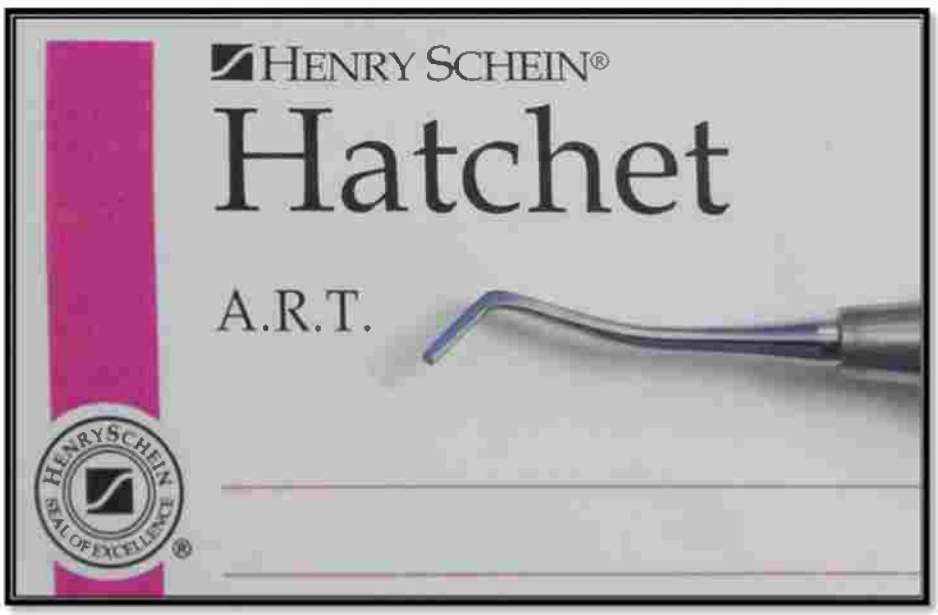

Figure 12: ART Hatchet

Figure 13: Gingival Marginal Trimmer

Figure 14: Matrix band used for proximal area restoration

Figure 15: Matrix holder used for matrix band adaptation

Figure 16: Wooden Wedges

Figure 17: ChemFil Rock RM Extruder

Figure 18: Fuji IX RM Applier IV

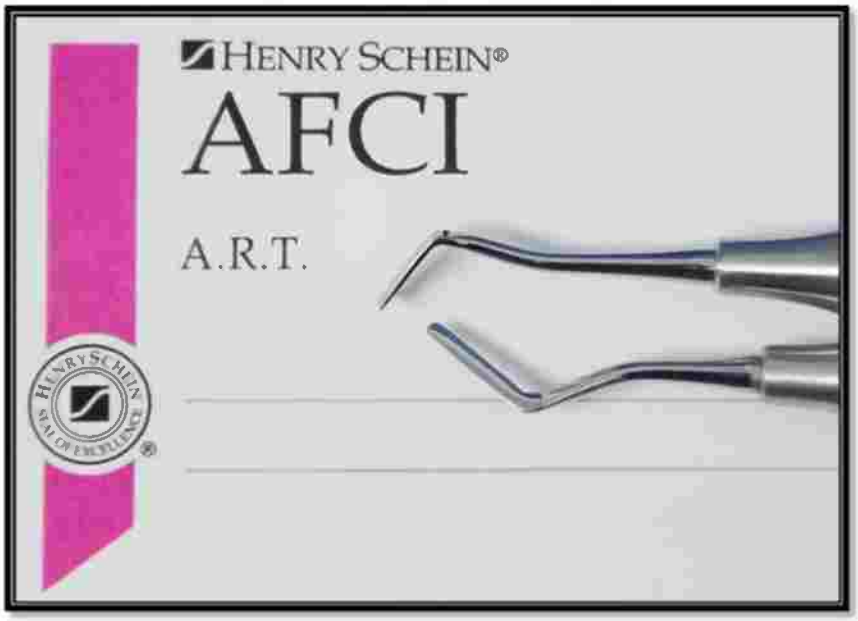

Figure 19: ART Applicator/Carver

Figure 20: Articulating paper for occlusal contact checking

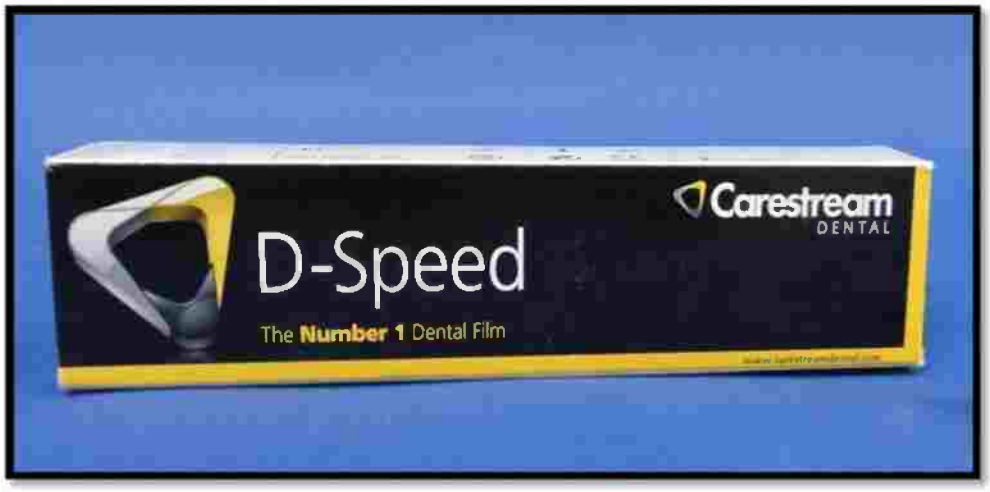

Figure 21: Intraoral radiographic films

Figure 22: Community periodontal index (CPI) probe

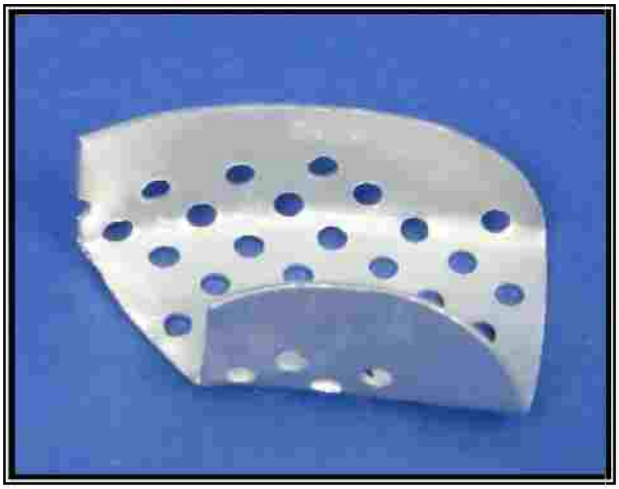

Figure 23: Pre-modified sectional tray

Figure 24: Amalgamator

Figure 25: Digital camera supplied with a macro lens and a ring flash

Fifty-two patients of both genders (26 females and 26 males) participated in this single blind clinical study. The students' age range was (16-20 years) at first examination. Participants in the current study received ART restorations and regularly evaluated at baseline, three and six months evaluation periods. Table 3 describes the number of teeth and percentage of drop out at baseline and at each evaluation period. As mentioned earlier, each restoration was evaluated by digital photographs, direct and indirect clinical evaluation through positive replicas. As no discrepancies revealed between the evaluations methods, results were presented in the same tables and figures. Evaluation was done by applying ART criteria. Radiographic records were additionally obtained for each restoration.

The single dropout case at six month evaluation period was found for male patient who received Fuji IX HVGIRM.

Table 3: Number of restorations for each HVGIRM and drop out at each evaluation period

Evaluation period	Type of restoration			Dropout
	Fuji IX HVGIRM	ChemFil Rock HVGIRM	Total	
Baseline	26	26	52	0
Three months	26	26	52	0
Six months	25	26	51	1

Values represent number of restorations at each evaluation period.

Evaluation of ART restorations

Descriptive statistics for ART evaluation codes of the two tested HVGIRMs for both genders at baseline evaluation period were represented in Tables 4 and 5 and Figure 26 showing that all restorations recorded Code 0 for both genders regardless to type of glass ionomer material.

Table 4: Evaluation of both HVGIRMs according to ART criteria at baseline for female patients

ART Code	Fuji IX HVGIRM (%) *n=13*	ChemFil Rock HVGIRM (%) *n=13*	Total (%) *n=26*
0	13 (100)	13 (100)	26 (100)

Values represent number of restorations with the corresponding ART evaluation codes together with their percentages in between brackets.

Table 5: Evaluation of both HVGIRMs according to ART criteria at baseline for male patients

ART Code	Fuji IX HVGIRM (%) *n=13*	ChemFil Rock HVGIRM (%) *n=13*	Total (%) *n=26*
0	13 (100)	13 (100)	26 (100)

Values represent number of restorations with the corresponding ART evaluation codes together with their percentages in between brackets.

At baseline evaluation, Figures (31, 36 and 44) show representative photographs and positive replicas for the ChemFil Rock HVGI restorations of both genders. While those for Fuji IX HVGI restorations were presented in Figures (41 and 47).

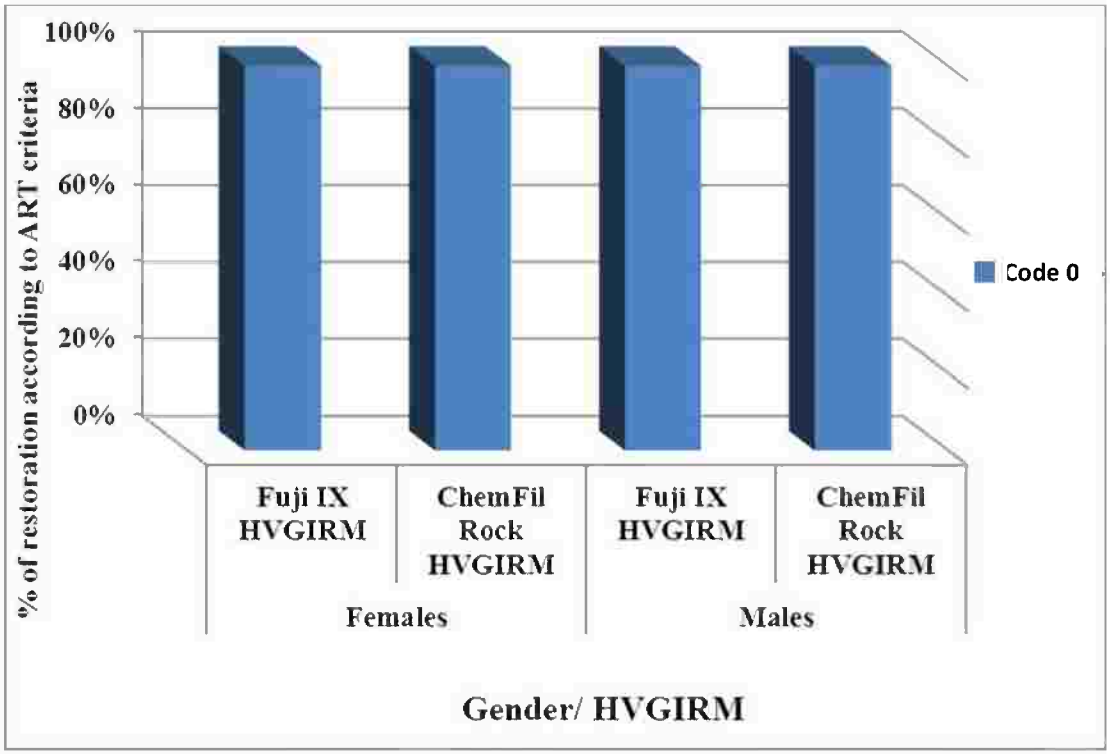

Figure 26: Evaluation of both HVGIRMs according to ART criteria at baseline for female and male patients.

At three months evaluation period, all restorations were considered successful with code 0 regardless to the HVGIRM type or the gender. Descriptive statistics for ART evaluation codes of the two tested HVGIRMs for both genders at the three months evaluation period was presented in Table 6, 7 and Figure 28.

Table 6: Evaluation of both HVGIRMs according to ART criteria at three months evaluation period for female patients

ART Code	Fuji IX HVGIRM (%) *n=13*	ChemFil Rock HVGIRM (%) *n=13*	Total (%) *n=26*
0	13 (100)	13 (100)	26 (100)

Values represent number of restorations with the corresponding ART evaluation codes together with their percentages in between brackets.

Table 7: Evaluation of both HVGIRMs according to ART criteria at three months evaluation period for male patients

ART Code	Fuji IX HVGIRM (%) *n=13*	ChemFil Rock HVGIRM (%) *n=13*	Total (%) *n=26*
0	13 (100)	13 (100)	26 (100)

Values represent number of restorations with the corresponding ART evaluation codes together with their percentages in between brackets.

At three months evaluation, Figures (32, 37 and 45) show representative photographs and positive replicas for the ChemFil Rock HVGI restorations of both genders. While those for Fuji IX HVGI restorations were presented in Figures (42 and 48).

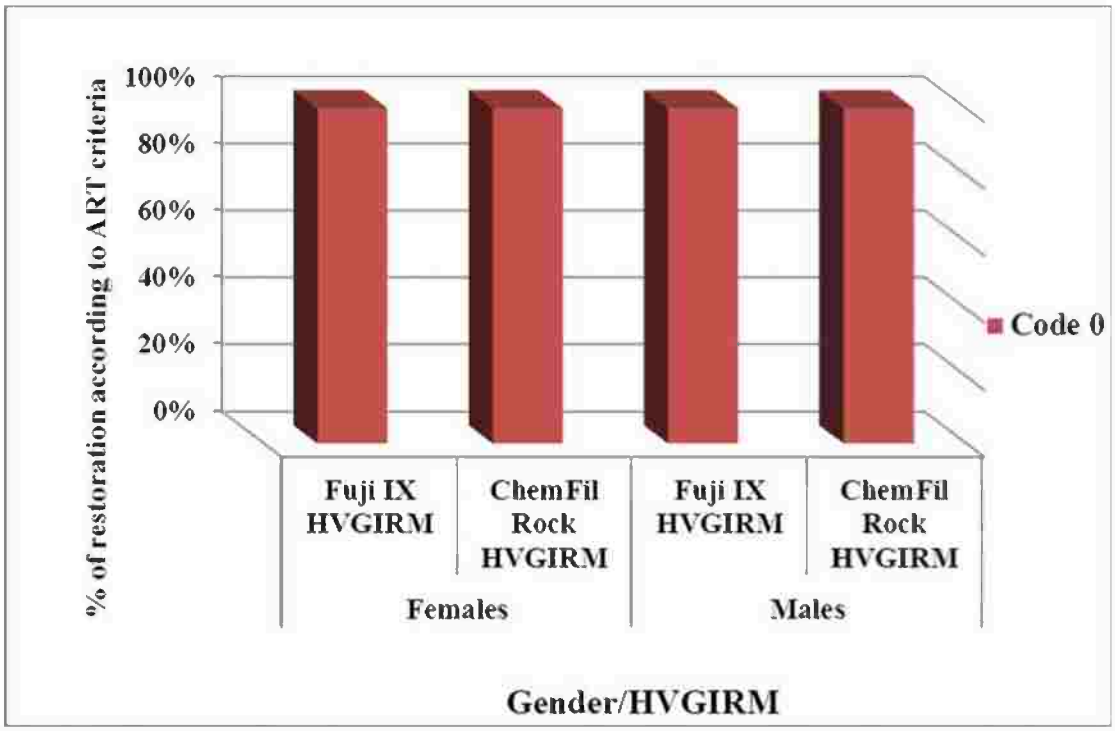

Figure 27: Evaluation of both HVGIRMs according to ART criteria at three months for female and male patients.

Descriptive statistics for ART evaluation codes of the two tested HVGIRMs for both genders at the six months evaluation period were represented in Table 8, 9 and Figure 29. For female patients, both Fuji IX and ChemFil Rock restorations recorded Code 0. While considering male patients, a single dropout case was recorded for Fuji IX restoration. Besides, twelve Fuji IX restorations and twelve ChemFil Rock restorations showed Code 0. Whereas, only one ChemFil Rock restoration scored slight deficiency at cavity margin that assigned to Code 2.

Table 8: Evaluation of both HVGIRMs according to ART criteria at six months evaluation period for female patients

ART Code	Fuji IX HVGIRM (%) *n=13*	ChemFil Rock HVGIRM (%) *n=13*	Total (%) *n=26*
0	13 (100)	13 (100)	26 (100)

Values represent number of restorations with the corresponding ART evaluation codes together with their percentages in between brackets.

Table 9: Evaluation of both HVGIRMs according to ART criteria at six months evaluation period for male patients

ART Code	Fuji IX HVGIRM (%) *n=12*	ChemFil Rock HVGIRM (%) *n=13*	Total (%) *n=25*
0	12 (100)	12 (92.3)	24 (96)
1	0 (0)	0 (0)	0 (0)
2*	0 (0)	1 (7.69)	1 (4)

*Code indicates a failure in the restoration that needs repair. Values represent number of restorations with the corresponding ART evaluation codes together with their percentages in between brackets.

At six months evaluation, Figures (33, 38 and 46) show representative photographs and positive replicas for the ChemFil Rock HVGI restorations of both genders with code 0. The only ChemFil Rock HVGI restorations that recorded code 2 was presented in Figure 50. While representative photographs and positive replicas of both genders for Fuji IX HVGI restorations were presented in Figures (43 and 49).

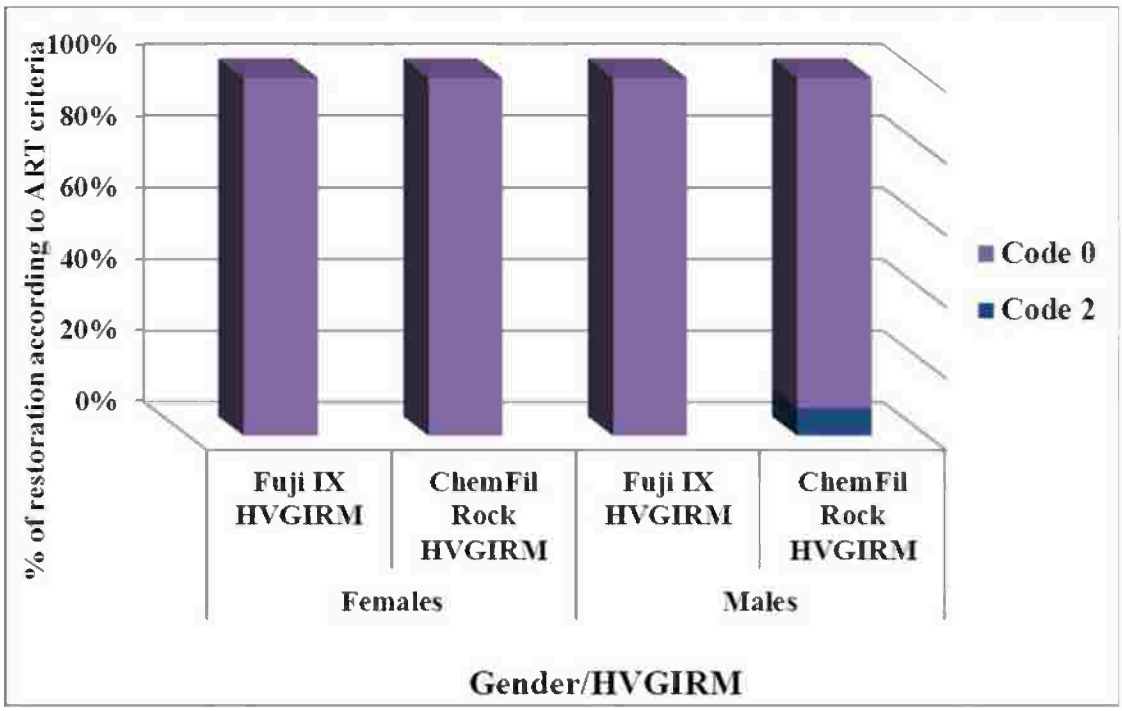

Figure 28: Evaluation of both HVGIRMs according to ART criteria at six months for female and male patients

For radiographic evaluation, all restorations scored 0 were with good margin integrity, and did not show any presence of cervical gaps or residual caries. The representative radiographic records were presented in Figures (51 and 52). The failed restoration of six month evaluation for the ChemFil Rock case showed also no difference in its radiographic evaluation than those scored 0.

The results of survival analysis based on the ART evaluation codes (Table 10) showed that the two materials have comparable survival rates over the 6 months analysis. No significant difference was found between the survival estimates of the two materials at six months periods using Log rank test (P>0.05).

Table 10: Survival estimates according to Kaplan-Meier test for both HVGIRMs according to ART criteria.

	HVGIR **Material**					
	Fuji IX HVGI			ChemFil Rock HVGI		
	Survival Distribution Function Estimate	**SDF Lower 95.00% Confidence Limit**	**SDF Upper 95.00% Confidence Limit**	**Survival Distribution Function Estimate**	**SDF Lower 95.00% Confidence Limit**	**SDF Upper 95.00% Confidence Limit**
Three months	1.00	--	--	1.00	--	--
Six months	1.00	--	--	0.9855	0.9016	0.9979

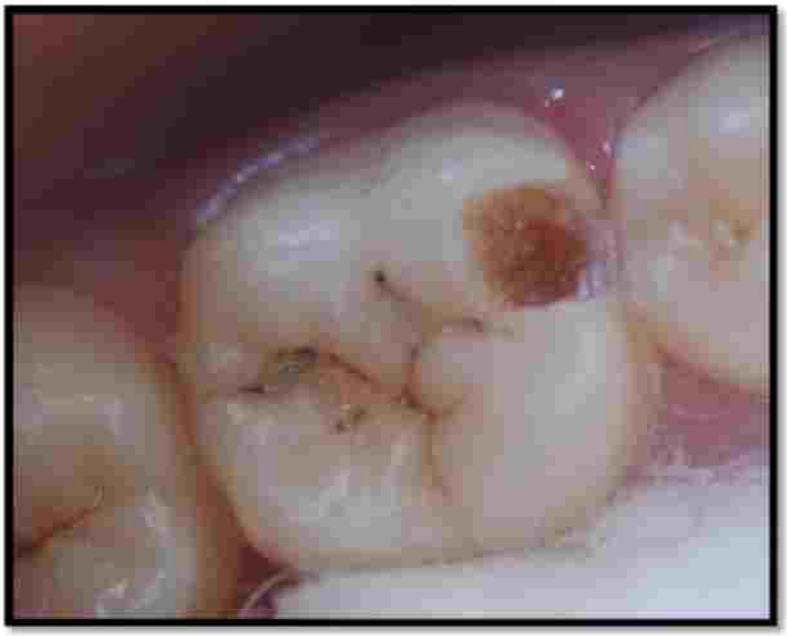

Figure 29: A representative photograph of a cavity preparation using ART approach

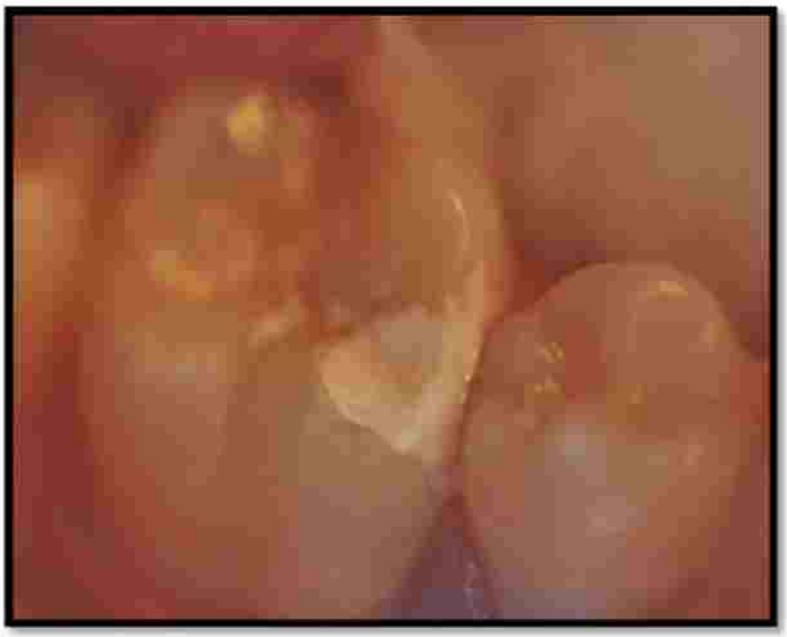

Figure 30: A representative photograph of a cavity restored with ChemFil Rock HVGIRM

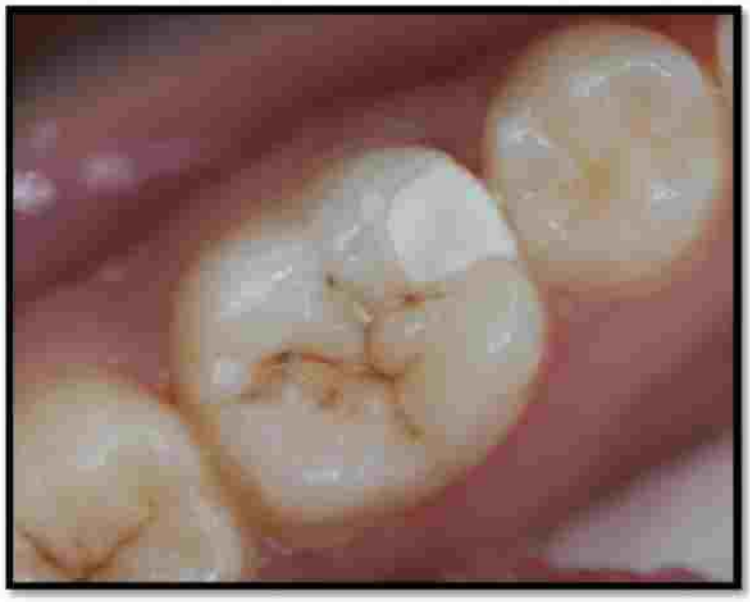

Figure 31: A representative photograph of a cavity restored with ChemFil Rock HVGIRM at baseline evaluation

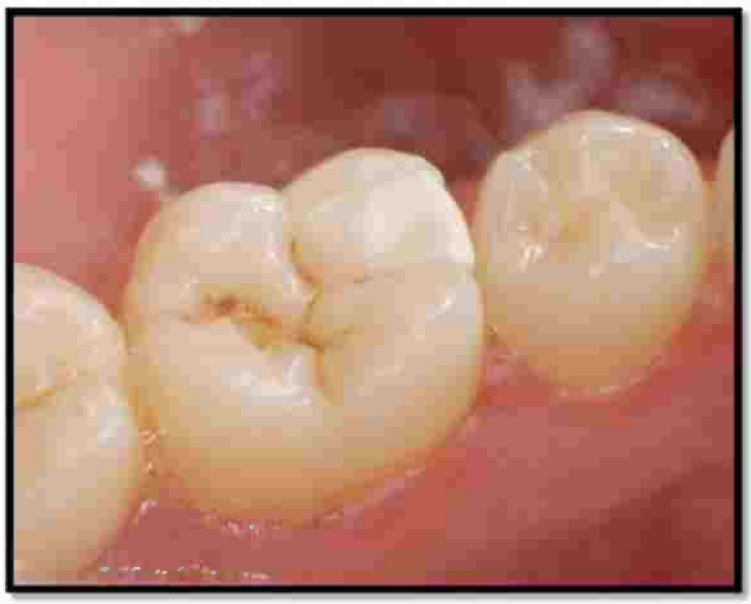

Figure 32: A representative photograph of a cavity restored with ChemFil Rock HVGIRM at three months evaluation

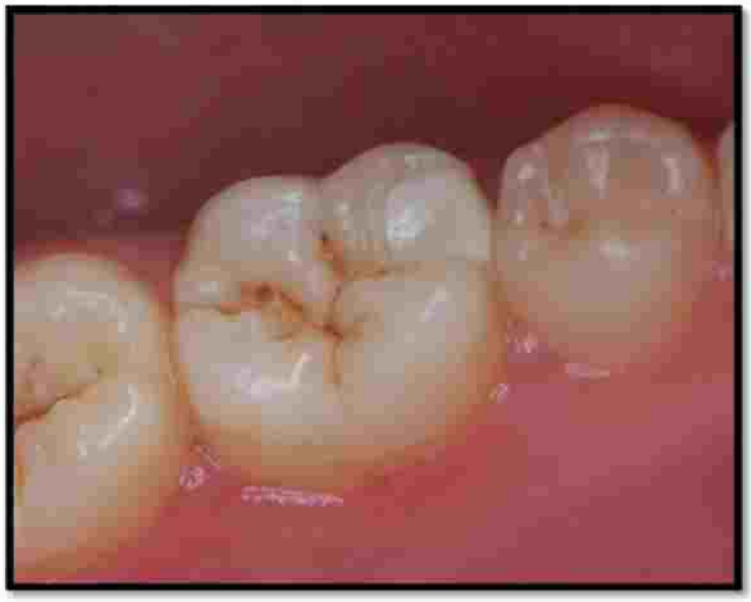

Figure 33: A representative photograph of a cavity restored with ChemFil Rock HVGIRM at six months evaluation

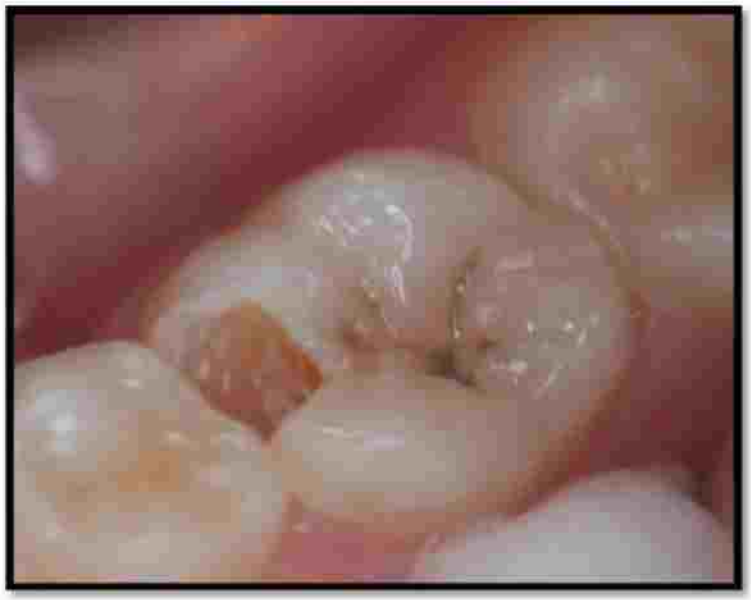

Figure 34: A representative photograph of cavity preparation using ART approach

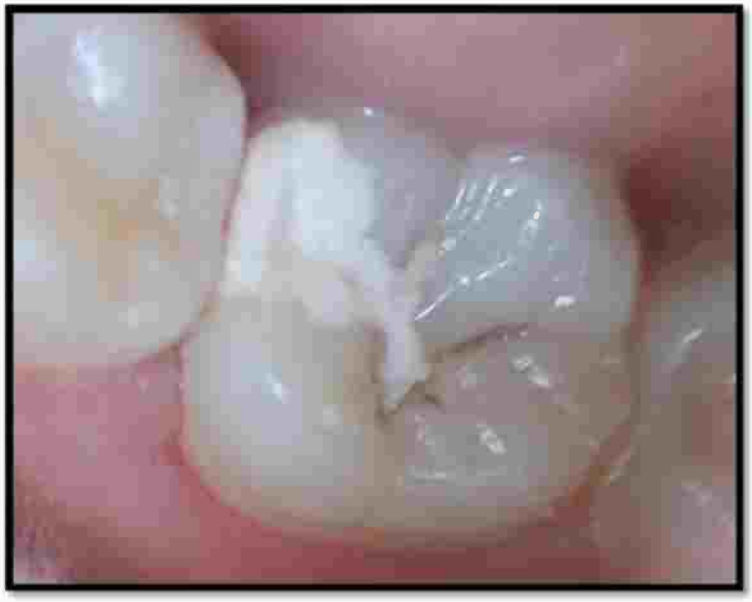

Figure 35: A representative photograph of a cavity restored with ChemFil Rock HVGIRM

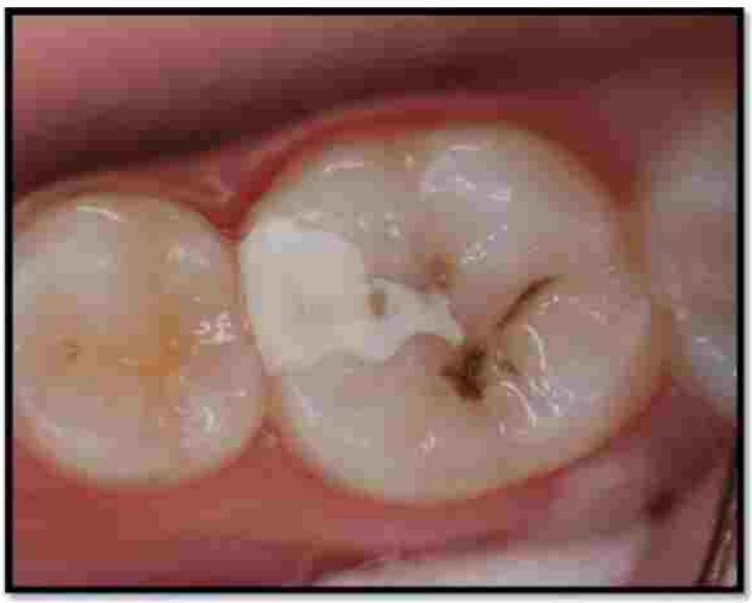

Figure 36: A representative photograph of a cavity restored with ChemFil Rock HVGIRM at baseline evaluation

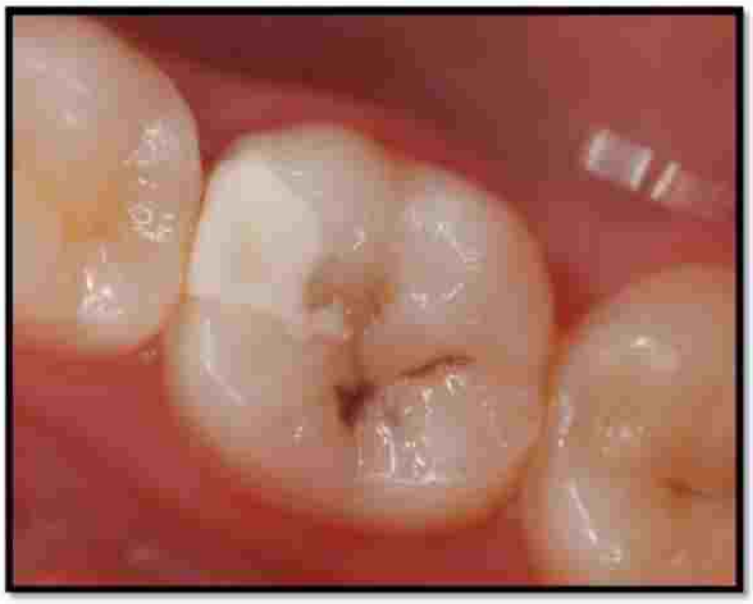

Figure 37: A representative photograph of a cavity restored with ChemFil Rock HVGIRM at three months evaluation

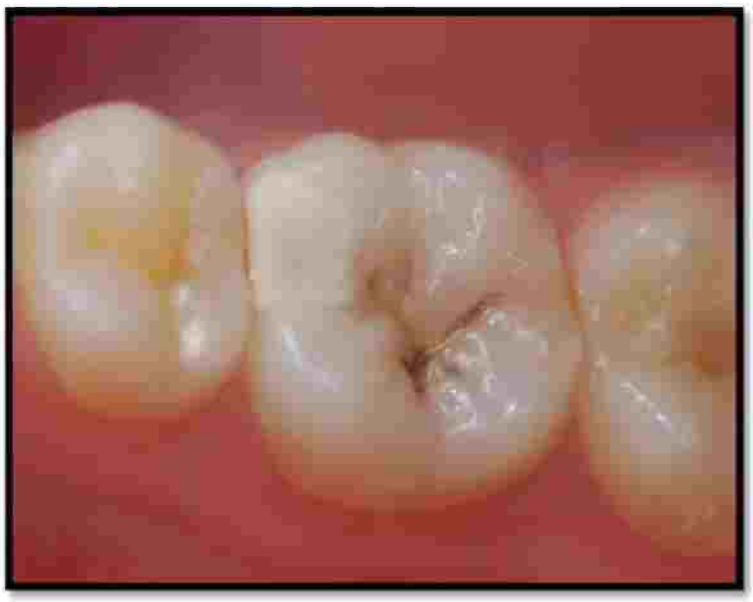

Figure 38: A representative photograph of a cavity restored with ChemFil Rock HVGIRM at six months evaluation

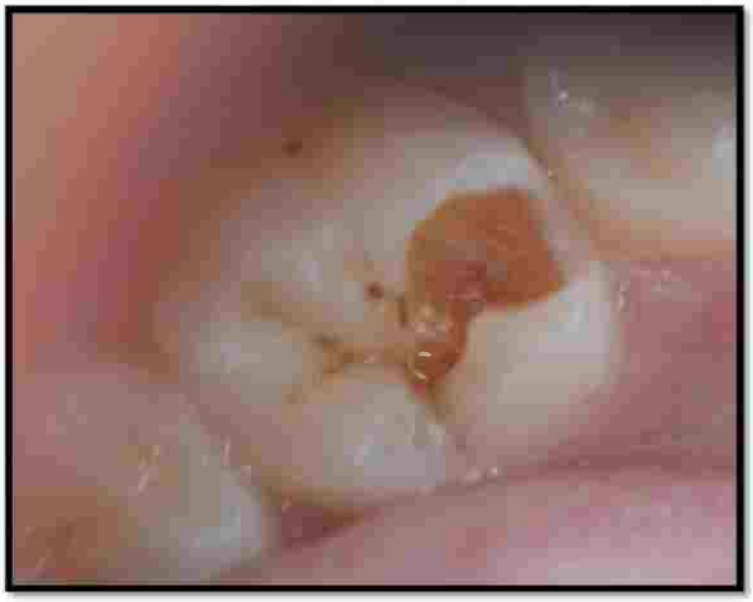

Figure 39: A representative photograph of cavity preparation using ART approach

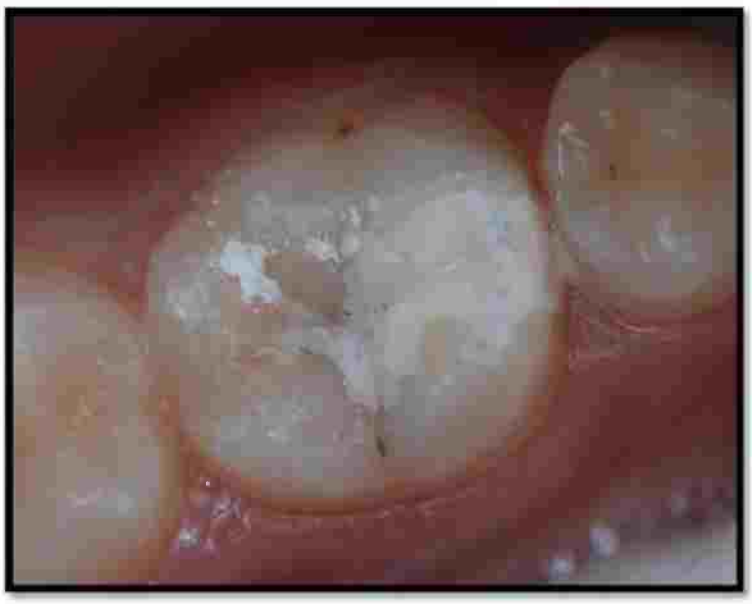

Figure 40: A representative photograph of a cavity restored with Fuji IX HVGIRM

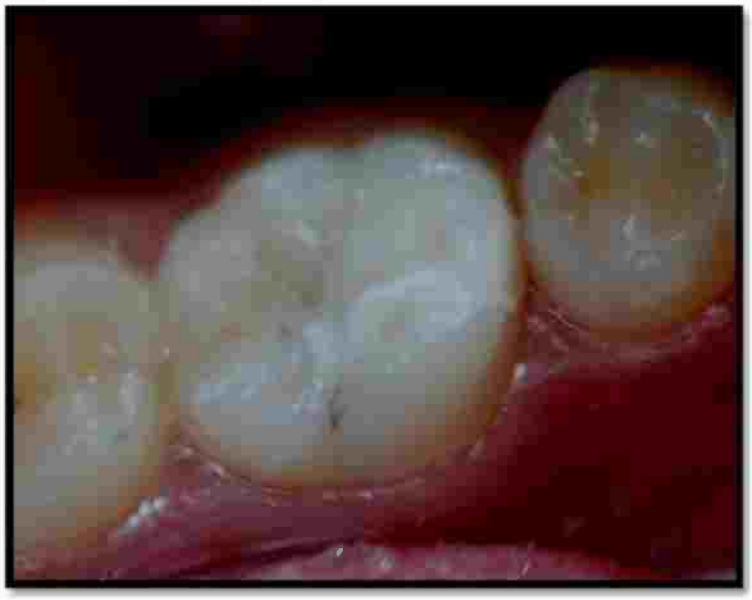

Figure 41: A representative photograph of a cavity restored with Fuji IX HVGIRM at baseline evaluation

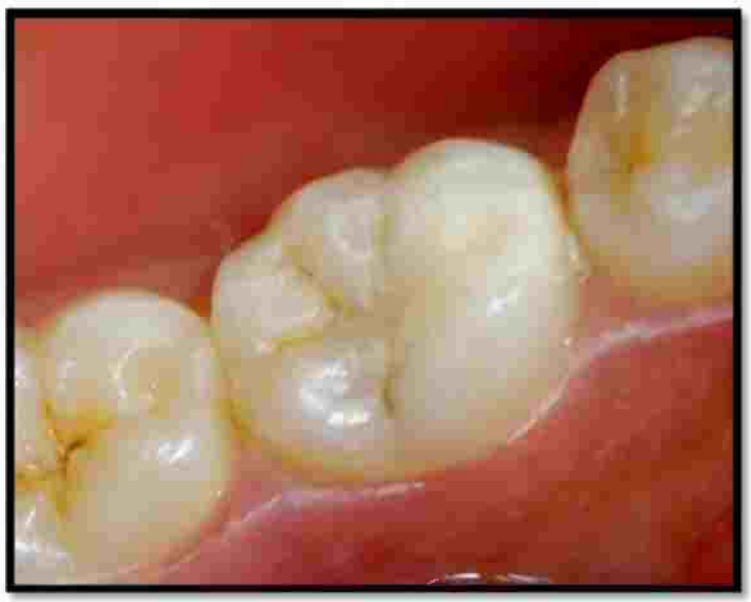

Figure 42: A representative photograph of a cavity restored with Fuji IX HVGIRM at three months evaluation

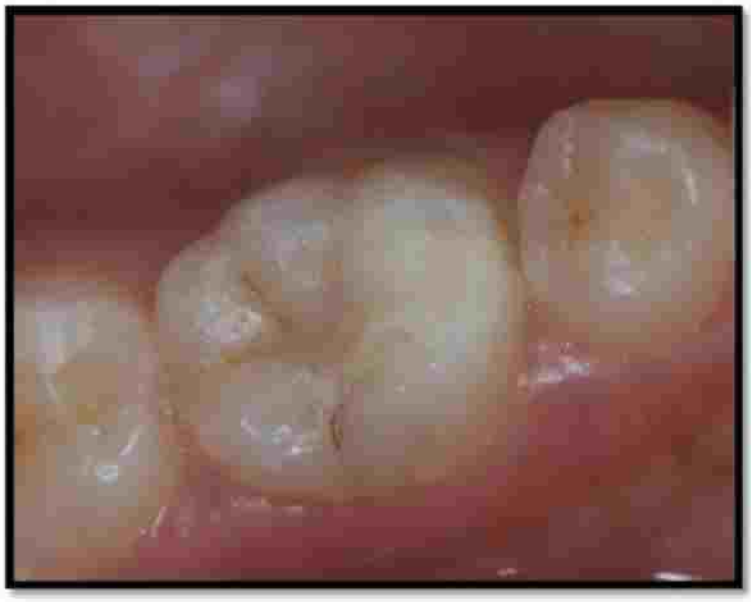

Figure 43: A representative photograph of a cavity restored with Fuji IX HVGIRM at six months evaluation

Figure 44: A representative positive replica of a cavity restored with ChemFil Rock HVGIRM at baseline evaluation

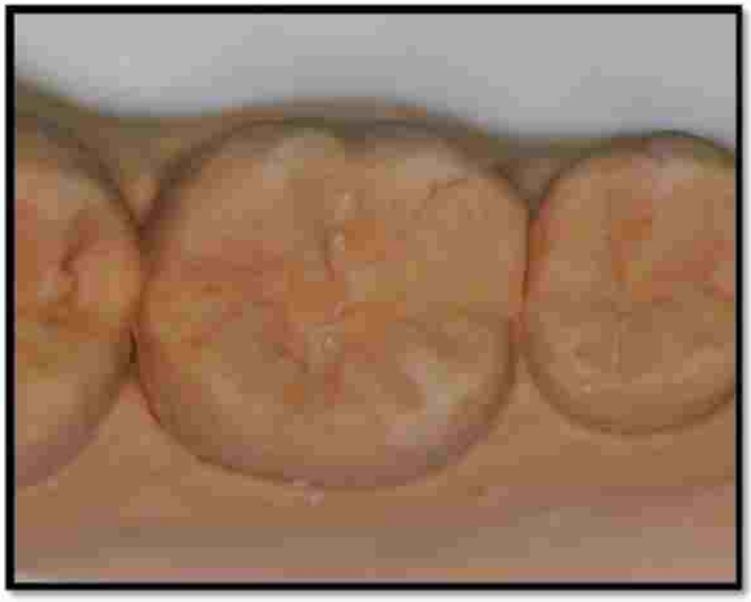

Figure 45: A representative positive replica of a cavity restored with ChemFil Rock HVGIRM at three months evaluation

Figure 46: A representative positive replica of a cavity restored with ChemFil Rock HVGIRM at six months evaluation

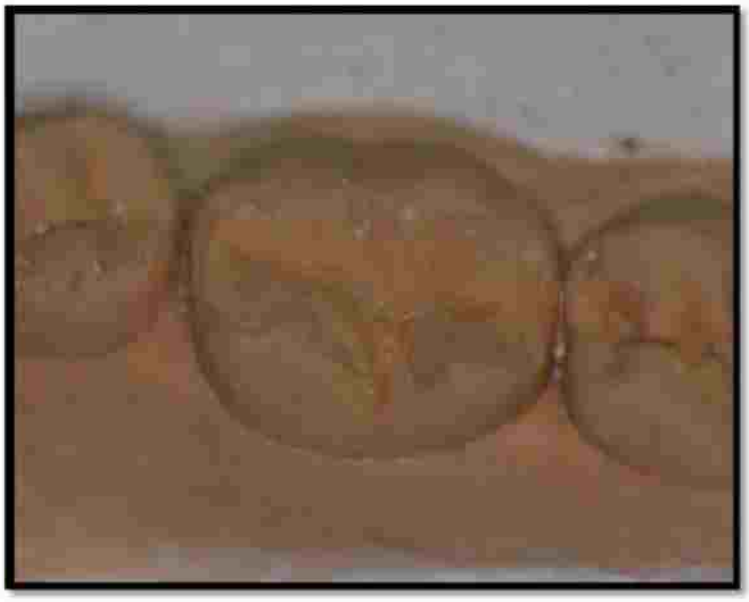

Figure 47: A representative positive replica of a cavity restored with Fuji IX HVGIRM at baseline evaluation

Figure 48: A representative positive replica of a cavity restored with Fuji IX HVGIRM at three months evaluation

Figure 49: A representative positive replica of a cavity restored with Fuji IX HVGIRM at six months evaluation

Figure 50: A representative positive replica of a failed ChemFil Rock HVGI restoration at six months evaluation

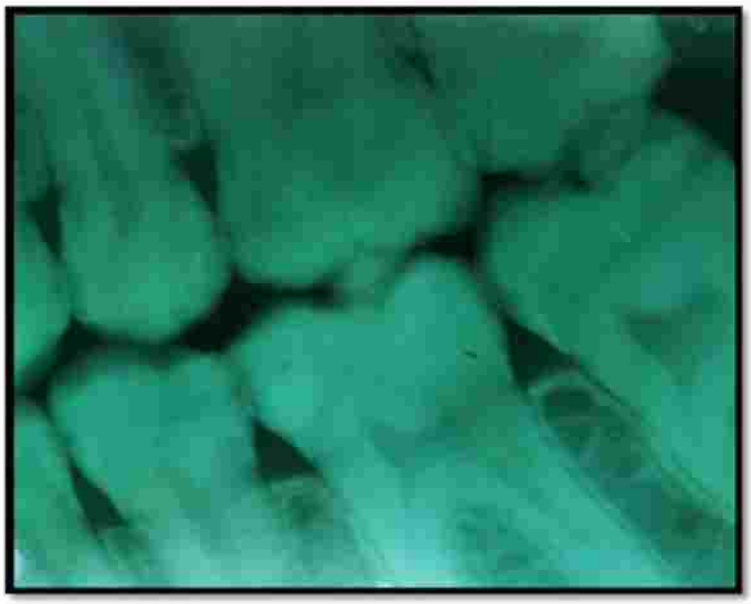

Figure 51: A representative radiographic record of a cavity restored with ChemFil Rock HVGIRM at six months evaluation

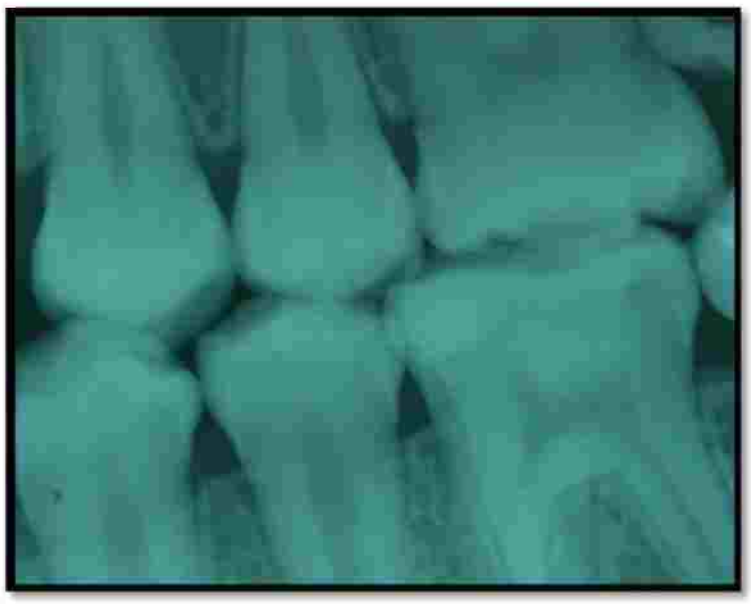

Figure 52: A representative radiographic record of a cavity restored with Fuji IX HVGIRM at six months evaluation