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Effectiveness of Modified Class IV Atraumatic Restorative Treatment – One Year Clinical Follow-Up

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Short Communication

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ABSTRACT

Objectives: To investigate the effectiveness of modified ART class IV restorations in a one-year follow-up interventional study with historical control.

Materials and Methods: In 69 adults one modified class IV ART restoration per subject was placed at a public dental ward in Gambia in 2012 by one community oral health worker. Historical controls were 12-months data collected in 2005 in 61 patients with original ART class IV anatomical structure rebuilding restorations. One independent examiner evaluated the restorations according to ART evaluation criteria (secondary outcome parameter). Primary outcome parameter was the annual failure rate.

Results: Modified class IV ART performed significantly better compared to historical controls in short-term 12 months follow-up ($p < 0.001$). The annual failure rate in modified class IV ART was 19.2% and was 83.6% in historical controls.

Conclusions: One-year performance was close to multiple-surface ART restorations in permanent teeth using high-viscosity glass ionomer cements.

Clinical Relevance: Class IV cavities might be treated with modified ART technique in dentally underserved areas.

INTRODUCTION

Atraumatic Restorative Treatment (ART) has become an evidence-based treatment in class I caries cavities for countries with developing dental infrastructure ^[1]. Though epidemiological data also demonstrate restorative treatment needs in anterior teeth in several African countries ^[2], scientific evidence for ART in this application appeared so far unrewarding ^[3]. Consequently, many carious teeth remain untreated or are scheduled for extraction. In deciduous teeth, class III and IV ART presented 86% failures due to partial or complete loss already within the first year ^[4], and longitudinal data in the permanent dentition are rare. Survival rates of 71% after three years ^[5], and of 68% after six years ^[3] in the same study cohort were reported from Brazil.

Basically, ART appears to be an interesting treatment approach as it combines a manual cavity preparation technique with the use of a glass-ionomer cement as an adhesive and fluoride releasing restoration material. Biomechanical stress, however, is above-average in class IV restorations when intending to reconstruct the incisal edge with glass-ionomer cement resulting in reported high rates of restoration fractures or loss ^[6]. It was therefore the aim to evaluate the clinical effectiveness of a modified ART class IV restoration technique in a clinical study.

MATERIALS AND METHODS

This was a one-year follow-up interventional study with historical control. We assumed the null hypothesis that there was no statistically significant difference in the effectiveness of modified versus original class IV ART restorations after one year of clinical performance.

Study Population and Setting

In 69 adult patients scheduled for ART, one modified class IV ART restoration per subject was placed at the public dental ward at Kindergarten Wattenscheid in Brikama-Kabafita, West Coast Region of The Republic of The Gambia in 2012. Inclusion criteria for participation were the presence of at least one incisor with class IV cavity extending into dentine, and an informed consent. Exclusion criteria were teeth with symptomatic irreversible pulpitis, reversible pulpitis, or pulp necrosis, or symptomatic or asymptomatic apical periodontitis, and acute and chronic apical abscess (according to the terms of endodontic pulpal and apical diagnosis published by the American Association of Endodontics (AAE) in 2008). The treatment was performed by one community oral health worker (O.B) who was trained in ART in 2001^[7], thus offering continuous practical ART experience for over ten years.

Intervention

Patients were treated by the standing operator. The area around the carious tooth to be treated was protected from saliva with cotton rolls. In the upper jaw, cotton rolls were placed in the vestibular fold. In the lower jaw, cotton rolls were placed additionally sublingually. Usually, the cotton rolls were placed two-ply, and the upper rolls were replaced during the ART procedure by the chairside assistant on demand. Rubber dam was not used. Occasionally, a dental hatchet was used for initial cavity access. Carious tissue was removed with an excavator until a sound probing was obtained. Unsupported enamel was cracked with a dental hatchet. Restorations were performed using a mechanically improved glass-ionomer cement for ART (Ionofil® Molar, VOCO, Cuxhaven, Germany). The cement was prepared by a chair side assistant according to the manufacturer's instructions. Isolation from a proximate tooth or from an antagonist was ensured by placing plastic strips. The modified class IV ART restoration was inserted into the cavity using a spatula.

As it was shown previously, original ART class IV anatomical structure rebuilding restorations (with detailed reconstruction of the incisal edge) often fractured or were lost due to mechanical stress. Modified class IV ART restorations in this study were therefore performed. By this restoration technique, the cavity was (i) sealed to stop further caries progression. The cavity was (ii) capped to protect the vital dentin-pulp-complex from external stimuli. The modified class IV ART was aimed at conserving the carious incisor for prospective functional use and for prolonging tooth preservation rather than at anatomical reconstruction of the tooth form for cosmetic reasons.

The enamel-glass ionomer cement interface was aligned by bending a plastic strip for approximately one minute. By biting on the plastic strip, a potential antagonist surface profile was formed. Excess material was removed with a carver. Finally, the restoration was coated with a varnish (Final Varnish, VOCO, and Cuxhaven, Germany) to protect from saliva during the setting process.

Follow-up

One independent, calibrated examiner (O.D) evaluated the restorations after 12 months to avoid medium-term or long-term functional influences on the deterioration of restorations. Using a WHO PCI periodontometer (DB 767 R, Aesculap A.G, Tuttlingen, Germany) and a plane front surface mirror (D.A 026 R, Aesculap A.G, Tuttlingen, Germany) the restorations were assessed according to the ART evaluation criteria (secondary outcome parameter)^[8]. As primary outcome parameter the annual failure rate was defined (**Table 1**). Cohen's kappa calibration results revealed an inter-rater (master (R. A.J) vs examiner) reliability of 0.82.

Table 1. Evaluation criteria and distribution of modified and original (historical control) class IV ART according to evaluation criteria after 12 months^[8].

Code	Criteria	Rating	Modified class IV ART (n (%))	Original class IV ART (historical control) (n (%))
0	Present, satisfactory	success	31 (44.9)	10 (16.4)
1	Present, slight deficiency at cavity margin < 0.5 mm ^a	success	11 (15.9)	0
2	Present, deficiency at cavity margin of 0.5 mm or more ^a	failure	2 (2.9)	20 (32.8)
3	Present, fracture in restoration	failure	2 (2.9)	3 (4.9)
4	Present, fracture in tooth	failure	0	0
5	Present, overextension of approximal margin of 0.5 mm or more ^a	failure	0	8 (13.1)
6	Not present, most or all of restoration missing	failure	5 (7.2)	20 (32.8)
7	Not present, other restorative treatment performed	failure	0	0
8	Not present, tooth is not present (exfoliated)	failure	1 (1.4)	0
9	Unable to diagnose		17 (24.6)	-

^aas assessed using the 0.5-mm ball-end of a WHO PCI periodontometer

Historical Control

Original ART class IV anatomical structure rebuilding restorations follow-up data as historical control were obtained from an

earlier study we performed in rural Gambia in 2005 in 61 patients [6]. For original ART class IV restorations, the same restoration material was used.

Statistical Analysis

Contingency tables were used to compare the modified class IV ART restorations with the original ART class IV anatomical structure rebuilding restorations of the historical control. Statistical significance was computed according to Pearson with SPSS 22 (IBM, Armonk, NY, USA). Statistical significance was set with $p < 0.05$.

Ethics

Ethical approval was obtained from Witten/Herdecke University institutional review board (No. 76/2011) and from the Gambian Department of State for Health, Social Welfare and Women Affairs (Banjul, The Gambia).

RESULTS

Fifty-two of 69 patients with modified class IV ART restorations were followed-up after a mean observation period of 53 weeks (lost to follow-up: 24.6% (code 9 evaluation)). At the beginning of the survey, patients were 25.9 years old on average. There were no statistical differences in age ($p = 0.4$) and gender ($p = 0.1$) between the groups with modified and original ART. Modified class IV ART restorations were primarily placed mesially ($n=49$ (71.0%); distally $n=20$ (29.0%)) in tooth 11 ($n=26$ (37.7%)), followed by teeth 21 and 22 ($n=17$ each (24.6% each)), and tooth 12 ($n=9$ (13.0%)). Original class IV ART restorations were primarily placed mesially ($n=41$ (67.2%); distally $n=20$ (32.8%)) in teeth 11 and 21 ($n=20$ each (32.8%)), followed by teeth 12 and 22 ($n=6$ each (9.8% each)), tooth 13 ($n=4$ (6.6%)), teeth 23 and 33 ($n=2$ (3.3%)), and tooth 43 ($n=1$ (1.6%)). Distribution of the ART codes of both groups is presented in **Table 1**. The annual failure rate in modified class IV ART was 19.2%; the annual failure rate in original class IV ART (historical control) was 83.6%. According to success/failure rating, modified class IV ART restoration performed statistically significantly better as compared to original class IV ART restorations in short-term 12 months follow-up ($p < 0.001$) (**Table 2**).

Table 2. Cross table of success and failure ratings of modified and original (historical control) class IV ART according to evaluation criteria after 12 months [8].

Group	Success	Failure	
Modified class IV ART	42	10	52
Original class IV ART (historical control)	10	51	61
	52	61	

DISCUSSION

This study shows that atraumatic restorative treatment might be performed in anterior teeth, when a modified restoration technique is adopted. With these modifications modified class IV ART restorations performed significantly better in short-term evaluation than the traditional approach of reconstructing the cement edge with glass-ionomer cement. Modified class IV ART primarily aims to seal the cavity, thus stopping further caries progression. Based on these results, we rejected the null hypothesis.

To our knowledge, this is the first report on modified class IV ART. By modification of the restoration technique only, an improvement of the annual failure rate of 64% was measured. The results are encouraging to introduce ART in anterior teeth. This could be a strength of our study. However, our results did not achieve survival rates comparable to traditional cavity class I ART [4]. On the other hand, the 12 months success rate of modified class IV ART in our study was 80.8%. In comparison, a recent meta-analysis on multiple-surface ART restorations using high-viscosity glass ionomer cements in permanent posterior teeth was calculated with a mean of 86% after one year [9]. In this respect, it appears to be worth to critically review all practicable treatment options to further improve ART incisor restoration effectiveness. The use of dentine conditioner or resin-modified glass-ionomer cements should be considered and evaluated. Resin-modified glass-ionomer cements already showed good clinical outcomes when adopted in multi-surface ART restorations [10]. In areas without substantial infrastructure, light curing composites seem to be impracticable but chemically activated anterior resin composite restorations might be used.

Critically, the rate of patients lost to follow-up in our study with 24.6% after 12 months demonstrate the difficulties of retrieval of patients in rural Africa. The rate of patients lost to follow-up in a field study in Zimbabwe was 33% after one year [8]. The considerably different infrastructural conditions in under-developed countries must be taken into account when making comparisons with clinically controlled trial-conditions in industrial countries.

In conclusion, modified class IV ART made restorative dental care in anterior teeth available in a West African region. One-year performance was close to multiple-surface ART restorations in permanent posterior teeth using high-viscosity glass ionomers. Longitudinal clinical studies with greater populations are required to substantiate these results.

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The authors had the following contributions to this manuscript: R.A.J was principal investigator and writing the manuscript;

O.D carried out the follow-up and data processing; L.M was responsible for quality control and co-writing the manuscript; P.G was responsible for historical control; S.Z was supervising the clinical study and co-writing the manuscript.

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CONFLICTS OF INTEREST

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ETHICAL STANDARD

Ethical approval was obtained from Witten/Herdecke University institutional review board (No. 76/2011) and from the Gambian Department of State for Health, Social Welfare and Women's Affairs (Banjul, The Gambia). All persons participating in this study gave their informed consent after oral and written information that was given in English and/or local language by a translator prior to their inclusion in the study. This study has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

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