The ART of GIC proximal restorations in primary teeth

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Chapter 1

Introduction
Introduction

The introduction of adhesive dental materials changed the principles of cavity preparation. At the same time, a better understanding of the caries process promoted the substitution of the mechanical design by the biological principles of cavity preparation. The concept of Minimal Intervention (MI) dentistry advocates not only saving sound tooth material before applying an adhesive technique and/or restorative material but it also includes the remineralisation of non-cavitated lesions, inducing repair instead of replacement of inadequate restorations and a careful education of the patient (1).

One of the most investigated MI approaches in the last twenty years is the Atraumatic Restorative Treatment (ART), which was developed in response to the unavailability of restorative care for populations with limited resources (2). This approach of treating cavitated carious lesions uses only hand instruments to remove the soft carious tissue and the cavity is restored with a high-viscosity glass-ionomer cement (GIC). The same material is placed in excess to seal remaining fissures using the “press-finger” technique. Simultaneously, a preventive program is implemented alongside the restorative treatment. Learning the importance of removing dental plaque and having healthy eating habits, the patient can shift from high to low caries risk, consequently reducing the indications for extractions.

Atraumatic Restorative Treatment

Developed in the 1980s to manage dental caries in underserved communities, the main goal of ART was to provide an affordable alternative for preventing decayed teeth from being extracted where the required resources for modern dental treatment such as electricity, piped water and finances were scarce (3). The efforts of implementing mobile units with mobile drilling and suction equipment, portable dental chairs and generators would be too expensive to implement and maintain, and were discarded as having been deemed not economically sustainable (4, 5).

When working in the Dental School in Dar es Salaam, Tanzania, Dr. Jo Frencken audited the dental clinics in the countryside and observed that most of the dental equipment was not functioning but that hand instruments were available. The cavities were large enough to be treated with excavators and there was no need for drilling machines. A pilot study in 28 cavities, cleaned with hand instruments and restored with polycarboxylate cement showed promising results and the method was well accepted by the patients. These results were presented in a scientific meeting of the Tanzanian Dental Association in 1986 and the ART approach was officially born (3).

Some years later, a randomized clinical trial comparing ART using GIC as the filling material with the conventional treatment using amalgam was conducted in permanent and primary teeth (6), and the favourable results of the ART approach caught the attention of many people working in under-served communities. In 1994, ART was adopted by the World Health Organization (WHO) and in 2002 by the World Dental Federation (FDI). The introduction of ART also challenged some concepts such as the need for complete
removal of affected dentin and step-wise excavation (7), and supported concepts such as the exclusive use of hand instruments (8).

Hand instrumenting is a more effective and efficient method than rotating equipment to remove caries in cavitated lesions in primary teeth and is less likely to lead to over-preparation of the dentin (9-11). Removing only the infected tissue, local anesthesia is seldom required and dental anxiety in children is reduced (12-14). In this way, ART is not only less traumatic to the patient (15) but also to the tooth structures (9, 10).

**ART procedure**

*Caries removal:* Firstly, it is important to remove food debris, which can easily be combined with brushing instructions. If the cavity opening is not large enough for the use of excavators, the enamel must be cut with dental hatchet or enamel access cutters. The infected tissue is removed with sharp excavators. At the enamel/dentin junction, the excavation is done until hard tissue is exposed to allow a good seal of the remaining lesion.

*Cavity restoration:* The restorative material for ART is a high-viscosity GIC and in most of cases. The lack of electricity implies the use of the hand-mixed version. Cavity conditioning with polyacrylic acid is performed using the liquid of the GIC diluted in water for 10-20 seconds. The cavity is then rinsed and dried using cotton pellets. Moisture isolation is achieved using cotton rolls. Proximal cavities are filled after placement of matrix bands and wedges.

*Press finger technique:* The cavity and adjacent pits and fissures are slightly overfilled and the material is pushed into the cavity with a gloved index finger covered with a layer of petroleum jelly. The finger is removed sideways to simultaneously seal the remaining fissures, the excess of the material is removed and the occlusion is checked after the initial setting (3 min). After final adjustments, another layer of petroleum jelly is applied. The patient is asked not to eat for at least one hour.

**Applications of ART**

Although developed for outreached rural areas in developing countries, ART is also mentioned as a treatment option in modern equipped dental practices (16, 17). Additionally, this technique can be used in special-needs patients, elderly living in nursing homes and patients with high anxiety levels (13, 18).

Occlusal cavities are, without doubt, the best indication for ART restorations using high-viscosity GIC. The results of meta-analyses show significantly higher survival rates in occlusal cavities for ART restorations made with GIC than for conventionally prepared amalgam restorations (19-22). The survival rates of occlusal-ART restorations in primary and permanent molars after three years are generally 85% or higher while for the proximal-ART restorations this percentage drops to 49% (22, 23).

ART may also be applied in anterior teeth but the appearance of GIC is not as good as that of a resin-based material and it is not be the first option for permanent teeth of patients with aesthetical requirements (17). The low wear-resistance of GIC leads to a roughening of the surface and discoloration develops in time. In cervical lesions, though,
GICs are preferred above composites as far as aesthetics is not a priority, as they present better retention (24). ART has been used to treat cervical lesions in elderly patients living in nursing homes (25, 26), and Lo et al. (25, 26) reported no difference in success rate after one year between the conventional approach using drill and resin-modified GIC (91.7%) and the ART approach with high-viscosity GIC (87%).

The performance of GIC in multiple-surface or proximal preparations is considered not good enough as a long-lasting restoration in permanent teeth, neither with the conventional nor the ART technique (27, 28). For the primary dentition, amalgam proximal restorations did not seem to survive longer than GIC with ART (29, 30). An “imperfect” ART restoration, however, might be effective in the control of progression of carious lesions and avoid extractions of primary teeth until they naturally exfoliate (31, 32).

**Shortcomings of proximal-ART restorations in primary molars**

There are many factors that may influence the success of proximal-ART restorations in primary molars. Factors such as operator, material, extent of caries removal, isolation method, post-restoration meal, size of the lesion/preparation and cooperation of the patient are related to failures in proximal-ART restorations.

**Operator effect**

Even though the application of ART seems to be easy for any dentist, an operator training course is indicated (29). In a recently published meta-analysis, the authors excluded the studies performed by operators who were not dentists, as they supposed the little experience of the non-dentists could influence the results (22). However, the literature shows that ART restorations made by dental students (33) or by dental health workers can have higher survival rates than those performed by dentists (33, 34). Individual characteristics of the operators may be always of influence. Frencken et al. (35) found an operator effect in a study comparing the ART approach using GIC with conventional amalgam restorations in spite of the fact that all the dentists had ample experience in applying the ART approach and had followed a training course on ART prior to the study.

Proximal cavities require more caution from the operator than occlusal ones in several aspects, starting with preparation and caries removal, which are both more difficult in cervical areas of proximal cavities. During restoration, contamination with saliva and blood must be avoided. Even when a rubber dam is used, the control of the saliva flow is difficult as the cervical margin lies under the contact point. The restoration technique is also more sensitive as there is an increased risk of lack of adaptation in the cervical area of the cavity and the finger-press technique is hampered by the presence of the matrix band. Another factor is the use of hand-mixed GIC, which may impose an extra variable in addition to the operator (36). When using such an operator-sensitive technique, a comprehensive training course is recommended (34). Knowledge in cariology is essential but most important is to practice the technique under supervision of an experienced operator in order to execute it properly (29).
Caries removal

Inadequate caries removal may result in insufficient sound dental structure to adhere. The adhesion of GIC to caries-affected dentin is lower than that to sound dentin (37). The insufficient caries removal may also lead to inadequate cavity sealing (38) and fracture of the restorations due to the lack of a strong dentin support. However, partial caries removal is preferable to complete caries removal in deep lesions to avoid pulp exposure (39), which often leads to immediate extraction for the primary dentition when treated under field conditions. However, partial caries removal is preferable to complete caries removal in deep lesions to avoid pulp exposure (39).

Isolation method

The isolation from blood and/or saliva contamination is a fundamental step for a good adaptation and sealing of the restoration. In a study in the rainforest in Suriname, van Gemert-Schriks et al. (40) showed that in more than 30% of the restorations made by experienced dentists there was blood or saliva contamination. However, no difference in success rate was found between the groups with and without contamination. Carvalho et al. (41) did not find any improvement on the survival rate using either a rubber dam or cotton rolls as isolation methods for proximal-ART restoration in primary teeth. Kemoli et al. (42), however, observed that the use of a rubber dam resulted in a statistically significant higher survival rate, but it is questionable whether this difference is clinically relevant. With a survival rate of 30% after two years in a sample of 804 patients, the significant difference found for the rubber dam group might be not clinically relevant to justify the use of a rubber dam in ART restorations.

Size of the cavity

The size and position of the cavity will influence the access of excavators to the cavity as well as the direct or indirect view of the operator. Kemoli et al. (43) observed that the one-year survival rate of proximal-ART restorations was significantly better for the cavities with mean dimensions between 2 and 3 mm, when compared to smaller or larger sizes. In the smaller cavities it might be more difficult to accomplish an adequate caries removal and material adaptation. On the other hand, the larger ones may have suffered a pulpal injury effect or failed because of bulk fracture of the cement (43).

Post – restoration meal

After placing the restoration, all patients are instructed not to eat for at least one hour but in practice some of them eat already a few minutes after the restoration is placed, hereby loading the incompletely set cement. Kemoli et al. (44) documented the type and consistency of the next meal taken by the children who received proximal-ART restorations. The type and consistency of food were classified as hard, soft or mixture. The children who had a "hard" consistency meal after the placement of the restoration showed a significantly higher failure rate at baseline and also two years later.
Cooperation of the patient

During the treatment, the cooperation of the patient is important and may influence the success of the final restoration, regardless of the technique. Studies show that the acceptance of the ART in child- and adult-populations is high, and is attributed to the absence of anesthesia and drilling, which increases comfort for the patient (15, 45). Although ART may be more acceptable than conventional treatment, the low survival rates for ART restorations in proximal cavities may lead to higher frequency of dental treatment and to eventual pain experience, in case caries progression occurs in the tooth with a failed restoration.

Material

The main failures of proximal-ART restorations are their partial and total loss, which are frequently attributed to the GIC (40, 46-48). The mechanical properties and, in particular, the poor fracture resistance of the GIC have led to the conclusion that a stronger and more durable material would be beneficial to the success rate of the proximal-ART restorations (46, 47, 49). However, there is no evidence that materials such as glass carbomer cement, resin composite and amalgam used in field conditions will perform better than GIC in proximal-ART restorations (50, 46, 47, 49, 50).

The high-viscosity of the material and the use of hand instruments instead of burs challenge the insertion of the GIC in the deepest site of the cavity. Two studies showed that more than two-thirds of the restorations had a cervical gap on bite-wing radiographs (51, 52). Another study (38) showed that most of the restorations with a cervical gap at baseline ended up having secondary caries adjacent to them.

All these limitations of the proximal-ART restorations cannot individually explain the high failure rate of these restorations. A combination of these variables is most likely a better explanation and for each operator a different combination can be found. ART is not the ideal method for proximal cavities; however, no other alternative and accessible restorative treatment has yet shown better results in field studies. The need for restoring these cavities is, most of the times, essential to allow removal of dental plaque and, in this way, control the caries increment. In this thesis the focus is on the material of choice for ART, the glass-ionomer cements, its properties and possible modifications.

Glass-ionomer cements

GICs were developed in the 1970s by combining the benefits of two existing materials: polycarboxylate cement and silicate cement (53). The main advantages of the GICs are the chemical bonding to the enamel and dentin allowing a proper seal of the cavity and the sustained release of fluoride. Other advantages of the conventional GICs are their biocompatibility with dental structures, an insignificant shrinkage during the setting reaction, a linear coefficient of thermal expansion similar to tooth structures and a low thermal conductivity. Disadvantages of the GICs include a long setting reaction, a low wear resistance and a relatively low compressive and tensile strength, in particular during the first 24 hours. These characteristics exclude the GICs as the first choice of restorative material for multi-surface restorations, such as the proximal ones (54).
GICs are available in hand-mixed and encapsulated systems. As with any material presented in a powder and liquid form, the powder/liquid ratio determines the properties of the GIC. By encapsulating the material, the operator variability is reduced as the powder/liquid proportion is pre-determined by the manufacturer and the mixing is mechanically driven (36). The GIC is subsequently injected in the cavity allowing a better adaptation. The composition of the powder is generally based on fluor alumino-silicate glass, sodium and silica. The liquid is composed of weak organic acids with a high molecular weight, usually an aqueous solution of polyacrylic acid, maleic acid and itaconic acid (55). These acids may also be incorporated into the powder in a freeze-dried form. The chemical setting reaction starts in the presence of water, when after dissociation of the acids, the hydrogen ions attack the glass particles releasing calcium, strontium, aluminium, sodium and fluoride. This acid-base reaction results in a poly-acid salts matrix. The poly-acids are responsible for the adherence to dental structures under wet conditions (56).

Adhesion is a result of an ion exchange between the GIC and some dental structures, which is mainly represented by the reaction of the carboxyl group from the acid with the calcium ions from the tooth (chelation). After two- to four-minutes, the initial setting is finished and the material loses its glossy appearance. This is an indication that most of the carboxyl groups have reacted with the powder particles. In this initial stage, the material is very sensitive to water sorption and the uptake of water will result in weakening of the surface. The second stage lasts 24 to 48 hours and is a slower continuation of the acid-base reaction, involving the release of calcium and aluminium cations within the matrix. During this stage the material is very susceptible to dehydration. The water evaporation in this stage would lower the mechanical properties of the material. To reduce this water sensitivity it is imperative to protect the GIC surface during its setting reaction.

In the search for improved mechanical properties of the GIC, the conventional GIC has been modified. The so-called metal-modified GIC contains amalgam alloy, silver, stainless steel or even gold particles fused to (Cermets, such as Ketac Silver, 3M Espe) or mixed with (Miracle Mix, GC Europe) the glass particles (57, 58). Although supposed to perform better than conventional GIC, the literature does not always support these “additions” (59). Another significant modification was the addition of metacrylate groups, giving rise to the resin-modified GIC (60). This modification allowed a better working- and setting-time as these materials are based on a dual-cure setting reaction (61). The resin-modified GIC is frequently used as a liner in combination with a resin composite or amalgam restoration. However, the addition of a hydrophilic monomer (HEMA) has a negative effect on biocompatibility.

Glass ionomers have a relatively low cost compared to resin composites, and they are technically less sensitive. These characteristics make them an accessible material to the world population. Associating the low cost with the adhesive auto-setting reaction and the potential effect of inducing remineralisation, the GIC became the material of choice for use in the ART (59). Moreover, conventional GICs contain fewer components that can cause allergic reactions when compared to resin composites or resin-modified GIC (62).
High-viscosity glass-ionomer cements

The restorations made with ART are intended to be long lasting and the restorative material of choice should be able to withstand masticatory forces (63). Specially developed for the ART technique, the high-viscosity GICs are the ideal material for clinical conditions when optimal saliva isolation cannot be achieved (64-66). To increase the concentration of glass in the matrix, the size of the glass particles was reduced, allowing some degree of packability and improving mechanical properties (59). On the other hand, the higher powder/liquid ratio raised the viscosity of the GIC, reducing wettability. This less-fluid consistency may have a negative effect in the adaptation, bonding and the retention of the restoration.

Mechanical properties

Better mechanical properties of the high-viscosity GIC improved the ART restoration survival rate (20) but its fracture strength and early-wear rates remained unsatisfactory compared to amalgam and resin composite materials (27). The setting reaction is shortened because of the higher powder concentration but it is still a long-term reaction, which makes it a sensitive material in particular during the first 24 hours, a period in which the material is prone to dissolution (65). This might result in lower strength of the surface and as a consequence, in low early wear resistance and flexural strength. To avoid the consequences of water sensitivity during the setting reaction, it is recommended to protect the GIC’s surface. Petroleum jelly is the most used coat but copal cavity varnish, light-cured bonding resins, cocoa butter or even nail varnish can also be used (67-70).

The brittleness of the material and the fact that it is prone to dehydration and erosion must be considered when performing mechanical tests. The bond strength tests for GICs, for example, cannot always express the interface bond strength as they frequently report cohesive failures within the material, limiting the results to the material strength (71-74).

Adhesion to dental structures

The adhesion of GIC to hard dental tissues appears to be mainly of a chemical nature (3). In addition to this chemical bonding, a mechanical interlocking of the cement in dentinal tubules is reported (73, 75). The chemical adhesion is formed through ionic and polar attractions between hydroxyapatite and polycarboxylate radicals in a way that the latter displace the phosphate and calcium ions from the former, maintaining the electrical neutrality (76) and promoting the chemical bond. This interaction layer is also considered to be beneficial in reducing the hydrolytic degradation of the bonding interface and consequently, enhancing the restoration longevity (77).

The bond strength may be influenced by two factors: the morphology of the adherent and the surface treatment. The presence of contaminant agents can interfere in the surface energy and therefore, reduce the wettability (78). In this way, the dentin pretreatment with polyacrylic acid is indicated to increase the bond efficiency of the GIC. The acid produces a superficial cleaning and a partial demineralisation, which creates micro-
porosities and enhances the possibility of chemical and micromechanical interaction with the hydroxyapatite (73, 76).

The polyacrylic acid used in the pre-treatment is a weak acid with high molecular weight. The high molecular weight gives a high viscous consistency to this acid, which hinders its penetration into the dentinal tubules, and is not harmful to the pulp structures. This is one of the characteristics that classifies the GIC as a biocompatible material. The chemical adhesion itself also improves the biocompatibility of this material. During the setting reaction of the GIC, when polycarboxylate radicals meet calcium ions from the tooth structures, there is a salt deposition at the dentin-GIC interface. This deposition may help promoting a good sealing and preventing bacterial invasion at the interface between tooth and restoration (79).

**Fluoride release**

The long term and continuous fluoride release is considered to be one of the greatest assets of the GIC. The highest release occurs in the first hours after placement and is due to the slow setting reaction of the material, when a large amount of ionically active elements is released (80). Because of the possibility of recharging fluoride from the environment, the fluoride release may continue thereafter. Although studies show that the fluoride release from GIC is low and clinically insignificant (81-83), others found a preventive effect including hypermineralisation of the adjacent dentin (84, 85) and remineralisation of incipient enamel lesions (86).

**Indications and limitations of GIC**

The GICs have a wide variety of applications. They can be used as fissure sealant, cavity liner, bonding agent, endodontic sealer, restorative material, and luting cement for prosthetics and orthodontics.

In field situations, GICs are certainly the material of choice for fissure sealing. The retention rate of fissure sealants made in a dental practice setting is showed to be higher for resin-based materials (87, 88) but under field conditions, GIC performs better or similarly to resin-based materials (89, 90). The best indication for GIC sealants is during tooth eruption, when the tooth cannot be satisfactorily isolated by the use of a rubber dam. The advantage of GIC sealants is that the material may remain in the bottom of the fissure for a long time, even when the sealant is partially broken or appears to be completely lost (91, 92). Studies investigating the caries preventive effect of resin-based and GIC sealants are inconclusive as to whether one is better than the other (20, 88, 89, 93-95).

As restorative material, GICs are particularly used in paediatric dentistry. Occlusal restorations in the primary dentition made with high-viscosity GICs show lower failure rates than the ones made with amalgam (19-22). Also in proximal restorations, the high-viscosity GICs show a good survival up to three years when made under optimal clinical conditions, in permanent (27, 28) and primary teeth (63, 96). In the primary dentition, Marks et al. (96) reported 92% survival after 12 months using a hand-mixed material, while Rutar et al. (63) observed 93% survival after two years using an encapsulated one; both studies were conducted in proximal cavities under optimal clinical conditions. On the other hand, the
The GICs used as a liner and luting agent are generally the resin-modified ones. The liners are used in combination with an amalgam or resin composite restoration with the aim of protecting the pulp against acids used for etching prior to the application of a resin-bonding agent, or against the thermal conduction of amalgam restorations. Because of its biocompatibility, conventional GIC can be used in deep carious lesions as a protection layer for the pulp tissues. A GIC liner can also be applied in the so-called "open sandwich" technique (97). The "open sandwich" technique is recommended in circumstances where the cervical area of the cavity is difficult to isolate from the exudation of gingival crevicular fluid or blood. In these cases, the use of an adhesive and fluoride releasing material in the cervical area, such as the GIC, is indicated to prevent secondary caries formation (98). However, on the long term, a liner of GIC may have a negative effect on the fracture resistance of the composite restoration (99).

The development and diffusion of the ART approach has stimulated dentistry manufacturers to expand the number of GICs indicated for ART. Although several brands are available, most of the long-term follow-up studies use the most well known materials; the ones presenting better mechanical properties in laboratory experiments and also the most expensive ones (44, 48, 100, 101). It is of interest to study new and less established GIC brands in laboratory and clinical studies and verify if they may be applicable to proximal cavities made in isolated and rural areas of developing countries. In these areas where often no other option of restorative dental treatment is available, the costs of the materials and the high-caries activity of the population must be considered when choosing both restorative approach and material.

Aim and outline of the thesis

The laboratory and clinical studies in this thesis evaluated the influence of GICs indicated for ART on the longevity of Class II or proximal-ART restorations. We explored different brands, a new nano-filled resin coating and a new insertion technique to improve material adaptation, aiming to increase the longevity of this type of restorations.

Many brands of high-viscosity GIC have been developed and marketed for the use with ART, but only few of them have been tested in clinical trials (8, 46, 47, 49, 50). In order to choose the materials to be tested in a clinical trial, the physical-mechanical properties of GICs indicated for ART were investigated (chapter 2). A laboratory study evaluated the wear resistance, knoop hardness, flexural and compressive strength of six GICs indicated for ART. From this study, three GICs were selected for a clinical trial based on their composition, price and mechanical properties. The effect of GIC brand on the survival rate
Introduction

of proximal-ART restorations in primary molars is described in chapter 3. This study was conducted in Itatiba (in the southeast of Brazil) and considered not only the survival of the restorations but also the survival of the tooth.

During the evaluation period of this clinical study, we observed a high failure rate of the restorations and an alternative method to improve the survival rate of proximal-ART restorations was desired. Searching for a better marginal adaptation of ART restorations, we performed a laboratory study using a flowable GIC as a liner (two-layer insertion technique). Chapter 4 describes the material adaptation and the microleakage of this new insertion technique.

Because of the promising laboratory findings, the two-layer technique was clinically applied in the cavities that resulted from a complete loss of the restoration from the previous trial (described in chapter 2). As inserting the GIC in two layers with two different consistencies is a laborious procedure, we investigated the operator effect on the survival rate of proximal-ART restorations using this two-layer technique in primary molars (chapter 5).

We speculated that the good results of the flowable layer as liner could be also originated from an improved bond strength of the flowable GIC to tooth structures. This could result from its better adaptation and a higher concentration of polyacrylic acid available. Chapter 6 describes the results of a microtensile bond strength test of this flowable glass-ionomer cement layer bonding to sound and caries-affected dentin of primary teeth.

To confirm the validity of our results in the previous bond strength test, we evaluated different micro-mechanical bond strength tests for the assessment of the adhesion of GIC to the dentin. We submitted different GIC-based materials to microtensile and microshear bond strength tests in order to assess their ranking as well as their failure pattern (chapter 7).

Concluding from the previous study that microshear bond strength tests seemed to better represent the clinical behaviour of brittle materials such as the GIC, we investigated the microshear bond strength of flowable GIC to sound and caries-affected dentin (chapter 8).

To evaluate the mechanical properties and stress distribution of the two-layered GIC, a three-point-bending test was performed and a Finite Element Analysis was used to interpret the results. This study is described in chapter 9.

To draw a preliminary conclusion as to whether the two-layer technique compared favourably to the conventional insertion technique of GIC in proximal-ART restorations, it was necessary to compare it with a conventional one-layer technique. The 18-month results of a randomised controlled clinical trial are described in chapter 10.

As most of the drawbacks of the GICs are related to their low mechanical properties in the first hours and the highest failure rates of ART restorations are reported in the first six months, improving the early mechanical properties of the material may help in improving restoration survival. We used a nano-filled resin (G-Coat Plus) to protect the surface of a GIC (chapter 11). It is assumed that such a layer protects the GIC during its slow- and long-setting period. This chapter investigates the flexural strength and the early wear resistance of a high-viscosity GIC coated and uncoated with a nano-filler-containing fluid resin.
References


