Understanding the Science Behind Interim Therapeutic Restorations

NNOHA Annual Meeting 2017

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Goals & Learning Objectives

- Review World Health Organization’s approach to managing caries in underdeveloped regions (ART)
- ...explain to colleagues and patients how Atraumatic Restorative Treatment (ART) differs from conventional techniques
- Translate World Health Organization’s caries management and restorative techniques to modern dental settings (ART & ITR)
- ...describe the clinical appearance and behavioral characteristics of hardening glass ionomer cements at gel stage, initial set, and maturation
- ...list at least two indications & two contraindications for placing Interim Therapeutic Restorations using WHO’s Atraumatic Restorative Treatment technique
Conflict of Interest & Bias Disclosure

- Presenter received research funding from and directed Department of “New Technologies” GC Corporation 1992-2001

- VOCO Dental has provided funding support for this presentation

- Presenter voluntarily evaluates donated dental products for various dental manufacturers
Evidence-based Clinical Treatment Decisions

- Quality of evidence (Randomized Clinical Trial)
- Bias & Randomization (risk-assessment filter)
- Prospective Study Design & Statistical Treatment of Data
- Repeatability
- Meta analysis pooling outcomes from related trials

Global and regional restorative-based approaches to caries management have been *ad hoc*

For more than a quarter of a century World Health Organization has conducted field-studies evaluating restorative materials and techniques where conventional dental treatment was impractical or impossible.

**Opinion:** Ethical oversight committees, failure to acknowledge gaps in care, and Standard of Care misconceptions all share the responsibility for U.S. failing to keep up with even the least developed nations addressing childhood caries.
Early childhood caries (ECC); Severe ECC (S-ECC)

ECC = caries prior to 71 months; S-ECC = any smooth surface lesion @ 3 yrs

Classifying Childhood Caries:

Early Childhood Caries & Severe Early Childhood Caries (20% 2-5 year olds)
Early Childhood Caries & Severe Early Childhood Caries

- Caries is a biofilm-induced acid demineralization of the enamel/dentin modulated by saliva
- ECC is the presence of 1 or more [caries lesion], missing or filled surface prior to 5th year
- Up to the age of 3, any sign of smooth surface caries
- From ages 3-5, one or more [caries lesion] in maxillary anteriors ......or
- DMF > age of the child (up to age 6) constitutes S-ECC

taken from American Academy Pediatric Dentistry: Definition Early Childhood Caries
How did we get HERE & where do we go NOW?

Using the science behind ITRs to address a caries epidemic
Defining *Interim Therapeutic Restoration (ITR)* & Sedative filling

- **ADA Glossary of terms:** A sedative filling is a *restoration intended to relieve pain*
- **Current Dental Terminology  CDT 2015**
  - **D2940** “Protective restoration, not to be used as a base or liner under a restoration."
  - **D2941** “Interim Therapeutic Restoration (ITR), primary dentition”

- **American Academy Pediatric Dentistry (AAPD 2004-2013 Policy Statement ITR):** a provisional technique to *restore & prevent the progression of dental caries* in young patients, uncooperative patients with special health care needs, and [when] traditional dental restorations are not feasible. *ITR may be used for caries control in children with multiple carious lesions* prior to definitive restoration
- **Academy of Operative Dentistry, American College of Prosthodontics, American Academy of Endodontics**………no definition yet
- **Indian Health Service (www.ihs.gov)** “Mighty Mouth Fillings” IHS/ECC Collaboration “an interim therapeutic restoration (ITR) is placed on teeth to prevent the progression of caries“
Tooth Decay (Caries) is a *bacteria-mediated* process resulting in subsurface demineralization, cavitation of tooth surface and advancing destruction toward the pulp.

Advanced caries = pulpitis

Reversible pulpitis = *sensitivity to cold or sweets* (short duration discomfort)

*Lingering pain upon exposure to heat or spontaneous pain at night* = irreversible pulpitis

*Percussion tenderness* suggests dental abscess (dead, infected tissue)

*Sharp pain* when chewing suggests either a cracked tooth or dental abscess
Sedative filling: management of reversible pulpitis

- insults associated with microleakage, recurrent or continuing caries, high-speed cutting & other thermal insults

Zinc oxide & eugenol

Berman MH JADA 1959 p97
Protective Restoration VS Interim Therapeutic Restoration

D2940 vs D2941

- Direct placement restorative material to protect tooth and/or tissue form. This procedure may be used to relieve pain, promote healing, or prevent further deterioration. Not to be used for endodontic access closure or as a base or liner under restoration.

- Placement of an adhesive restorative material following caries debridement by hand or other method for the management of early childhood caries. Not considered a definitive restoration.
Controlling acute caries using ‘sedative fillings’ (D2940)
Caries debridement completed
Chlorhexidine solution applied for 1 minute
GIC Sedative Fillings (Pulp Protective Restorations)
Sedative Fillings in deciduous teeth are termed……..
ITRs reduce levels of cariogenic bacteria in the oral cavity; hand-instrument excavation, debridement
GIC restorations
Highly viscous GICs bond to caries debrided enamel and dentin
Policy on Interim Therapeutic Restorations (ITR)

Purpose
The American Academy of Pediatric Dentistry (AAPD) recognizes that unique clinical circumstances can result in challenges in restorative care for infants, children, adolescents, and persons with special health care needs. When circumstances do not permit traditional cavity preparation and/or placement of traditional dental restorations or when caries control is necessary prior to placement of definitive restorations, interim therapeutic restorations (ITR) may be beneficial and are best utilized as part of comprehensive care in the dental home. This policy will differentiate ITR from traumatic/alternative techniques (ART) and describe the circumstances for its use.

Methods
This updated policy is based upon a review of current dental literature. Database searches were performed using key words dental caries, cavity, primary teeth, deciduous teeth, traumatic restorative treatment, interim therapeutic restoration, and glass ionomer. Search limits used were humans, children 0-12 years, clinical trial, comparative study, controlled clinical trial, meta-analysis, multicenter study, randomized controlled trial, systematic review, and validation studies.

Background
Traumatic/alternative restorative technique (ART) has been endorsed by the World Health Organization as a means of restoring and preventing cavities in populations with little access to traditional dental care. In many countries, practitioners provide treatment in non-traditional settings that restrict restorative care to placement of or=ment.

Because circumstances do not allow for follow-up care, ART mistakenly has been interpreted as a definitive restoration. ITR utilizes similar technique but has different therapeutic goals. Interim therapeutic restorations more accurately describe the procedure used in contemporary dental practice in the U.S. ITR may be used to restore and prevent cavities in young patients, uncooperative patients, or patients with special health care needs when traditional cavity preparation and/or placement of traditional dental restorations are not feasible and need to be postponed. Additionally, ITR may be used for step-wise excavation in children with multiple open carious lesions prior to definitive restoration of the teeth, in erupting molars when isolation conditions are not optimal for a definitive restoration, or in patients with active lesions prior to treatment performed under general anesthesia. The use of ITR has been shown to reduce the levels of cariogenic oral bacteria (e.g., Mutans Streptococci, lactobacilli) in the oral cavity immediately following its placement. However, this level may return to pretreatment counts over a period of six months after ITR placement if no other treatment is provided.

The ITR procedure involves removal of caries using hand or rotary instruments with caution not to expose the pulp. Leakage of the restoration can be minimized with maximum care removal from the periphery of the lesion. Following preparation, the tooth is restored with an adhesive restorative material such as glass ionomer or resin-modified glass ionomer cement. ITR has the greatest success when applied to single surface or small two surface restorations. Inadequate cavity preparation with subsequent lack of retention and insufficient bulk can lead to failure. Follow-up care with topical fluoride and oral hygiene instruction may improve the treatment outcome in high caries-risk dental populations, especially when glass ionomers (which have fluoride releasing and recharging properties) are used.

Policy statement
The AAPD recognizes ITR as a beneficial provisional technique in contemporary pediatric restorative dentistry. ITR may be used to restore and prevent the progression of dental caries in young patients, uncooperative patients, patients with special health care needs, and situations in which traditional cavity preparation and/or placement of traditional dental restorations are not feasible. ITR may be used for caries control in children with multiple cavities lesions prior to definitive restoration of the teeth.

- young, uncooperative, special care patients, ECC
- differentiate ITRs from ART restorations
- contemporize ART with follow up, dental home
- similar techniques, different therapeutic goals
- reductions in oral levels of Mutans Streptococci, lactobacilli (6 month benefit)
An atraumatic restorative treatment (ART) technique: evaluation after one year.
Frencken JE, Songpaisan Y, Phantumanvanit P, Pilot T.

Extraction is the most common dental treatment in rural and suburban areas in less-industrialized countries, restorative care is rarely provided.

Atraumatic Restorative Treatment (ART) technique, follows the concept of minimal intervention, does not require electrically driven equipment. Hand excavation of carious lesions using glass-ionomer cement as a filling material and a sealant.

Longevity of fillings and sealants placed using the technique in rural Thailand:
- caries was treated using the ART technique in one village
- population in a second village received restorative care (amalgam fillings)
- third village was the control

79% of single surface ART fillings, 55% of ART fillings of greater than one surface in deciduous teeth were judged successful after 1 year.

ART filling success in the permanent dentition was 93%. Retention rate for sealants was 78%.

Children were pleased at having received treatment by this technique and showed little fear.
Atraumatic Restorative Treatment: World Health Organization
UNMC Student Project: 1996-1999

@ 2.5 yrs

@ 6 yrs

@ 1 yr

@ 1 yr

@ 3 yrs, repaired
Prior to ITR Policy, AAPD’s Alternative Restorative Treatment (ART)

-Differentiate “Alternative” vs “Atraumatic”

-Planned follow up including topical fluorides & OHI
How much tooth preparation is sufficient?
D1352 Preventive resin restoration:

- classification high-risk for caries
- active caries, removed by the dentist
- composite restoration placed
- all susceptible ‘adjacent’ pits & fissures simultaneously sealed
Airborne particle abrasion selectively removes carious enamel and dentin without rotary instruments.

Non-rotary tooth preparation

Finger-pressed GIC restoration shown at 33 months in service
Fill/seal restorations “press-finger” placed @ 8 years (#31) and at 2 years (#30)
Glass ionomer sealants differ from resin sealants in loss pattern characteristics.
GIC Sealants: Zone of protection

- Effects of a glass-ionomer cement on the remineralization of occlusal caries – an in situ study
- Human 3rd molars, (2) 30 day evaluations, sealed with Delton or Fuji IX.
- Protection/remineralization zone
  125 μm
Learning A.R.T. Technique:
Manual dexterity, clinical knowledge, GIC properties/behaviors, occlusion & tooth form

- assessing the oral environment, pulp status (periodontium), caries

- identifying & accessing the lesion, spoon excavation "ringing sound"

- cleaning the cavosurface margin, conditioning/rinsing

- preparing the GIC mix, isolation

- placing & contouring the GIC, functional generation of occlusion

- maintaining hydration, applying surface protection
#1 ITR Contraindication: necrosis with fistula

Periodontal Assessment:
- fistula
- granuloma
- tooth mobility

Evaluate pulp vitality using clinical signs of necrosis......as well as radiographic assessment when possible
Summary of Clinical Steps

- assess intraoral conditions, classify caries risk, consider ITRs when caries lesions are accessible, likely to worsen before dentist visit

- assess periodontal conditions & pulp status, inform patient caries removal is frequently completed without local anesthetic

- begin with large spoon at cavosurface margin, work toward the center of the lesion

- cease excavating pulpally when the patient expresses discomfort

- establish a smooth, clean cavosurface margin, apply cavity conditioner for 15 sec.

- rinse, blot cavity preparation dry, control saliva and prepare GIC mix

- deliver GIC mix to the deepest areas first then overfill and use pressed-finger placement

- functionally shape the occlusal (bite) and carve/contour immediately after gel stage

- confirm occlusion, polish & apply surface protection to extend clinical service life
Caries Arrest Treatment

- Topical fluoride, Fluoride Varnish
- Silverdiamine fluoride
- Silverdiamine fluoride with potassium iodide
Silverdiamine fluoride (SDF)

Two minute application, 30-40% solution, pH = 9.0 rinsed for 30 seconds


Knight GM, et al Inability to form s mutans biofilm on SFD/KI treated dentin, Quint Int. 2009: 40(2) 155-61
Silverdiamine fluoride (38% applied for 1 min) followed by 15% potassium iodide for 30 sec
Staining may be reversed by gentle polishing with tincture of iodine (weak iodine solution).
Partial removal of carious dentine: a multicenter randomized controlled trial and 18-month follow-up results.

Maltz M¹, Jardim JJ, Mestrinho HD, Yamaguti PM, Podestá K, Moura MS, de Paula LM.

Abstract

AIM:
The aim of this study was to evaluate the effectiveness of partial removal of carious dentine and restoration in a single session (PDR) and stepwise excavation (SW), both of which are treatments for deep carious lesions, in Public Health Services in Brazil.

METHODS:

INCLUSION CRITERIA:
patients ≥6 years old, permanent molars with deep caries lesions (having a radiolucency halfway or more into dentine) and pulp vitality but absence of spontaneous pain, positive percussion test, and periapical alterations. The subjects received either PDR (test group) or SW (control group). The radiological and clinical exams were performed after a mean time of 18 months.

OUTCOMES:
success was defined as pulp sensitivity to cold test and absence of periapical alterations.

RESULTS:
Of the 299 treatments performed, 146 were SW and 153 were PDR; 122 were amalgam restorations and 168 resin-composite restorations. There were no differences between the groups regarding the baseline characteristics (i.e. age, gender and family income). After 18 months, 212 evaluations were performed, which indicated 99 and 86% success rates in the PDR and SW groups, respectively (p = 0.016). Reasons for failure were: PDR - 1 pulpitis; SW - 8 pulpitis; 1 osteitis; 4 necrosis; 1 endodontic treatment. None of the baseline variables were significantly associated with the outcomes.

CONCLUSION:
The retention of carious dentine does not interfere in pulp vitality. Data from this 18-month study suggest that the procedure of reopening the cavity to remove the residual infected dentine is not necessary.

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Abstract
The objective of this paper is to review recent research and developments with respect to the atraumatic restorative treatment (ART) approach and to outline future areas of research and development. Areas identified as requiring further investigation include the evaluation of: ART restorations for longer than 3 years duration using recognised evaluation criteria, multi-surface ART restorations, ART restorations in primary teeth and ART sealants. In addition, the possibility and potential dangers of caries remaining after cavity cleaning with hand instruments must be investigated and the findings balanced against the known damage to sound tooth tissue caused by more routine cavity preparation techniques. New bioactive restorative materials which offer the possibility of healing dentinal caries lesions should be developed and evaluated. Finally, behavioural and educational aspects of the ART approach should be investigated.
Restorative dentistry is based on the assumption that bacterial infection of demineralized dentine should prompt operative intervention. One of the concepts of practical dentistry is to create a favourable environment for caries arrest with minimal operative intervention. The progress of remaining primary caries is key to any discussion of this concept. This discussion is important for the atraumatic restorative treatment (ART) approach, since the removal of all carious dentine is sometimes difficult using hand instruments only. In this paper the results of possible measures to guard against the effects of residual carious and its consequences are reviewed, in order to obtain an impression of the justification for (in)complete excavation of occlusal dentinal caries. Three types of measure are considered: isolating the caries process from the oral environment, excavating the carious dentine, and using a cariostatic filling material. Each of these measures contributes to the arrest of the caries process. However, none of these measures can arrest this process by itself. A combination of all three seems necessary. It is concluded that although residual caries does not seem to be the criterion for rerestoration, one has to strive for as complete caries removal as possible. If this cannot be fulfilled the sealing capacities of the filling material seem to be more important than its cariostatic properties.
Is ART really atraumatic?
van Amerongen WE¹, Rahimtoola S.

Abstract
Atraumatic restorative treatment (ART) is an approach to the management of carious lesions that uses only hand instruments to remove carious tissue and to restore the tooth involved. The name ART implies that the approach is atraumatic to both the patient and the tooth. This study set out to evaluate whether ART is atraumatic in terms of both patient discomfort and tooth tissue conservation. Three hundred and fifty-nine patients were divided in two groups: one group was treated with hand instruments and the other with rotary equipment. Each patient received two restorations: one using amalgam and one using glass ionomer as the restorative material, placed without the use of anaesthesia. Less discomfort was reported with the ART approach compared to conventional restorations made using rotary instruments and amalgam. Moreover, preparations with hand instruments were smaller than those produced with rotary instruments. Reported discomfort was associated with the size of the preparation, although the influence of the operator on both criteria was considerable. A patient effect was also observed since patients who reported discomfort during the first treatment were more likely to report discomfort after the second treatment. In conclusion, the choice of the term "ART" as an atraumatic procedure is defensible.
The comparative radiopacity of Fuji IX-GP, an intermediate restorative material.

DuBois DJ¹, Reichl RB, Hondrum SO.

Abstract
The radiopacity of intermediate restorative materials should be sufficient to enable the clinician to distinguish the material from normal and decalcified tooth structure. The purpose of this study was to determine the relative radiopacities of intermediate restorative materials, including a newly introduced high-viscosity, self-cured, condensable glass ionomer material. Radiographs were made of six intermediate restorative materials: two reinforced zinc oxide-eugenol materials (IRM and Zinroc), a conventional glass ionomer material (Ketac-fil), a synthetic resin material (Cavit), a eugenol-free zinc oxide material (Tempit), and a new, general-purpose, condensable glass ionomer material (Fuji IX-GP). Optical density was measured using a densitometer. The optical density of dentin and enamel were used for radiographic comparison. Statistical analysis revealed significant differences among materials: Cavit = IRM = Tempit > Zinroc = Fuji IX-GP > Ketac-fil = enamel > dentin (where > indicates a statistical difference at p < or = 0.05). Although not as radiopaque as some other intermediate materials tested, the radiopacity of Fuji IX-GP appears sufficient to aid diagnosis.
Success of an alternative for interim management of irreversible pulpitis.
McDougual RA¹, Delano EO, Caplan D, Sigurdsson A, Trope M.

Abstract

BACKGROUND:
Extraction and endodontic therapy are treatment options for irreversible pulpitis. Extraction often is chosen for financial reasons. The authors conducted a study to investigate an alternative interim therapy.

METHODS:
The authors recruited patients (N = 73) with irreversible pulpitis and whose teeth were restorable but who opted for extraction owing to financial reasons. After undergoing pulpotomy, the teeth were restored by random assignment with one of two intermediate restorative materials: Caulk IRM (Dentsply Caulk, Milford, Del.) (Group I, n = 38) or an IRM base with glass ionomer core (Fuji IX GP, GC America, Alsip, Ill.) (Group II, n = 35). The authors monitored the teeth over six and 12 months for pain, integrity of restoration and radiographic periapical status by densitometric analysis.

RESULTS:
By six months, 10 percent of subjects remaining in the study (Group I, n = 27; Group II, n = 25) reported pain; by 12 months, 22 percent (Group I, n = 22; Group II, n = 18) reported pain. A two-tailed Fisher exact test showed no significant difference (P > or = .05) between groups at either time interval. No apical radiographic change was noted in 49 percent of teeth at six months (Group I, n = 18; Group II, n = 19) and 42 percent at 12 months (Group I, n = 16; Group II, n = 15). Chi² analysis demonstrated no significant differences (P > or = .05) between groups. Seven of 22 restorations in Group I and four of 18 in Group II required repair at 12 months with no statistical difference (chi² analysis, P > or = .05).

CONCLUSIONS:
The interim treatment of eugenol pulpotomy using either restorative material reliably prevented pain for six months. For longer periods, both restorations may require repair.

CLINICAL IMPLICATIONS:
This option should preserve the integrity of the arch and extend the use of the tooth while the patient finds the means to finance complete endodontic treatment.
Atraumatic perspectives of ART: psychological and physiological aspects of treatment with and without rotary instruments.

Schriks MC, van Amerongen WE.

Abstract

Atraumatic Restorative Treatment, ART, is a method of minimal caries intervention that uses only hand instruments. The aim of the present study was to explore a possible difference between the extent of discomfort experienced during dental treatment according to the ART approach and a method using rotary instruments. The study was performed in Indonesia. A total of 403 children were randomly divided in two groups. In each child, one class II restoration in a deciduous molar was made. One group received treatment using rotary instruments (750 r.p.m.). The other group was treated according to the ART approach. Glass ionomer cement was used for restoration in both groups. Discomfort scores were determined using both physiological measurements (heart rate) and behavioral observations (Venham) on specific moments during the treatment. Venham scores showed a marked difference between the two groups at most time points. Heart rate measurements were different at deep excavation. Also, a clear relation between Venham scores and heart rate measurements could be found at all time points. Confounding could be shown for operating dentist, gender of the patient and initial anxiety, not for age. No effect modification could be shown. It can be concluded that children treated according to the ART approach using hand instruments alone experience less discomfort than those treated using rotary instruments.

Comment in

• Atraumatic restorative techniques could reduce discomfort in children receiving dental treatment. [Evid Based Dent. 2005]

Restorative Outcomes of a Minimally Invasive Restorative Approach Based on Atraumatic Restorative Treatment to Manage Early Childhood Caries: A Randomised Controlled Trial. Arrow P1.

Abstract
A pragmatic randomised controlled trial comparing a minimally invasive approach based on atraumatic restorative treatment (ART) procedures (test) was tested against the standard-care approach (control) to treat early childhood caries (ECC) in a primary-care setting in Perth, W.A., Australia. Parent/child dyads with ECC were allocated to the test or control group using stratified block randomisation. Children were examined at baseline and follow-up by two calibrated examiners blinded to group allocation status. Dental therapists trained in ART provided treatment to the test group and dentists treated the control group. Restoration quality was evaluated at follow-up using the ART criteria. Data were analysed on an intention-to-treat basis; test of proportions, Wilcoxon rank test and logistic regression, controlling for clustering of teeth, were used. Two hundred and fifty-four children were randomised (test = 127 and control = 127). There was no statistically significant difference in age, sex and baseline caries experience between the test and control groups. At follow-up (mean interval 11.4 months, SD 3.1), 220 children were examined (test = 115 and control = 105) and 597 teeth (test = 417 and control = 180) were evaluated for restoration quality, of which 16.8% (test) and 6.7% (control) were judged to have failed (required replacement; p < 0.01). Intention-to-treat, multiple logistic regression found multisurface restorations (OR = 10.4) had significantly higher odds of failure, while referral for specialist paediatric care had significantly lower odds of restoration failure (OR = 0.2). The ART-based approach enabled more children and teeth to be treated, and multisurface restoration and treatment in a primary-care setting had higher odds of restoration failure.
Abstract

PURPOSE:
To directly compare the survival rates of three incomplete caries removal techniques that differed in the amount of caries removal and the base material used.

METHODS:
Ninety-six primary molars with asymptomatic deep caries or reversible pulpitis were randomly assigned to three groups: (1) indirect pulp treatment (IPT); (2) minimal caries removal with both resin-modified glass ionomer base material and luting cement (MCRB/L); and (3) minimal caries removal with only resin-modified glass ionomer luting cement (MCRL). The treatments were followed clinically and radiographically for two years.

RESULTS:
The two-year survival probabilities in the IPT, MCRB/L, and MCRL groups were 0.90 (95 percent confidence interval [CI] equals 0.73 to 0.97), 0.93 (95 percent CI equals 0.76 to 0.98), and 0.77 (95 percent CI equals 0.58 to 0.89), respectively. There was no significant difference in the two-year survival probabilities of the three studied groups (generalized Wilcoxon P=.07).

CONCLUSIONS:
Following two years, neither the amount of caries removal nor the base material affected the success of incomplete caries removal treatment. However, minimal caries removal with MCRB/L presented the highest survival rate among the tested groups and resulted in no incidence of pulp exposure.