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## **Cost-effectiveness of ART Restorations in Elderly Adults:**

### **A Randomized Clinical Trial**

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# **Cost-effectiveness of ART Restorations in Elderly Adults: A Randomized Clinical Trial**

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## **Abstract**

As the world population ages, the requirement for cost-effective methods of treating chronic disease conditions increases. In terms of oral health, there is a rapidly increasing number of dentate elderly with a high burden of maintenance. Population surveys indicate that older individuals are keeping their teeth for longer and are a higher caries risk group. Atraumatic Restorative Treatment (ART) could be suitable for patients in nursing homes or homebound elderly but very little research has been done on its use in adults. Objective: to compare the cost-effectiveness of Atraumatic Restorative Treatment (ART) and a conventional technique (CT) for managing caries as part of a preventive and restorative programme for older adults. Methods: In this randomised clinical trial, 82 patients with caries were randomly allocated to receive either ART or conventional restorations. Treatment costs were measured based on treatment time, materials and labour. For the ART group, the cost of care provided by a dentist was also compared to the cost of having a hygienist to provide treatment. Effectiveness was measured using survival percentage of restorations after a year. Results: Eighty-two patients received 260 restorations, 128 ART and 132 conventional restorations. 91.1% of the restorations were on one surface only. After a year, 254 restorations were assessed in 80 patients. The average cost for ART and conventional restorations was €16.86 and €28.71, and the survival rates were 90.4% and 96.9% respectively. This resulted in a cost-effectiveness ratio of 0.18 (ART) and 0.29 (CT). When the cost of a hygienist to provide ART was inserted in the analysis, the resulting ratio was 0.14. Conclusions: ART was found to be a more cost-effective alternative to treat older adults after 1 year, compared to conventional restorations, especially in out of surgery facilities and using alternative workforce such as hygienists. ART can be a useful tool to provide dental care for frail and fearful individuals who might not access dental treatment routinely.

## **Introduction**

The proportion of older people continues to grow worldwide. In Ireland, the Census 2011 recorded that 535,411 individuals or 12% of the population of 4.58 million are aged 65 years or older (CSO 2012). Recent trends indicate a clear shift in the Irish population structure from young to old as 23% of the population are between 45 and 64 and will shortly begin to inflate the ranks of the elderly. Population projections predict significant increases in the total number of older people in Ireland to over 1.1 million by 2036. Those aged 80 and over are set to rise even more dramatically to a projected 323,000 in 2036 (CSO, 2004a). This trend is mirrored throughout the world, with an estimate of a 2 billion population of those aged 60 and over by 2050 (1).

The prevalence of oral diseases increases with age. Globally, poor oral health amongst older people has been manifested in high levels of tooth loss, dental caries experience, periodontal disease, xerostomia and oral pre-cancer/cancer (2). Petersen et al (1) found that the elderly are keeping their teeth for longer and are a higher caries risk group. Recent surveys of oral health in Ireland found significant unmet need for extractions, fillings, dentures, and periodontal treatment amongst those aged 65 and over (3). This is further complicated by low dental service utilisation rates, with less than 10% of those aged 65 and over visiting the dentist in 2002 (4). McKenna et al. (5) state that the importance of dental care is often underestimated within the overall medical care for our frail elders and a more holistic approach must be encouraged. They argue that oral health must be considered within overall patient management and integrated into more wide reaching public healthcare policy as recommended by the World Health Organisation.

Research by Woods et al. (6) identified several barriers to dental care for the elderly such as: difficulty getting to the dentist caused by their reduced mobility; cost of transport to the dentist, particularly in rural areas; requiring a companion to accompany them to the dentist; difficulty obtaining suitable and timely dental appointments; being on prescribed medications (e.g. anticoagulant medication); hearing and/or speaking difficulties which hamper communication with the dentist; and fear of the dentist. Additionally, a further current barrier to dental care for the elderly in Ireland has resulted from budgetary cutbacks to the Dental Treatment Services Scheme (DTSS) following the severe downturn in the Irish economy since 2008. The exchequer funded DTSS provided routine dental care at zero monetary cost to those on low incomes and those aged 70 and over. The negative consequence of budgetary cutbacks on the oral health of the elderly requires that alternative more cost-effective

methods of treating older patients should be considered. It is important therefore, that we examine alternative targeted ‘care packages’ for older people in order to remove the barriers which discourage our elderly patients from seeking routine dental care. One such method of treating patients is Atraumatic Restorative Treatment (ART) which was pioneered in the 1980’s to treat underserved communities. The ART approach involves the excavation of cavitated carious lesions with hand instruments and restoration of the cavities with a glass-ionomer restorative material.

Whilst Ireland is not considered economically a less developed country, its ability and commitment to fund oral health care is severely diminished by the current financial and budgetary crisis. With increasing financial pressures on health care policy makers it is imperative that researchers provide high quality evidence in order to aid decision making. The requirement for health care programmes, policies and interventions to be economically evaluated has increased. Cost-effectiveness analyses are the most commonly used evaluation method in a health care, including dental care, to inform decision and policy makers about managerial implications of different treatment alternatives. Cost-effectiveness is defined as the analysis of the costs of alternative ways of achieving a given goal (7). Cost-effectiveness analyses have been used to appraise endodontic treatment choices, periodontal interventions and direct versus indirect restoration (8), and to evaluate cost-effectiveness of tooth replacement strategies for partially dentate elders (9). Whilst ART has been subjected to clinical evaluation in several studies (9-13) no economic evaluation of its use in older adults has been undertaken. The ART studies reviewed mostly involved treatment of children and young adults, although research by Honkala and Honkala (14) and Lo et al. (15) investigated the use of ART in older patients. Both studies involved treatment of patients living in nursing homes with survival of the restorations as the main evaluated outcome. However, in terms of the economic evaluation of ART, there has been a dearth of reported evaluations of the cost-effectiveness of the technique relative to conventional interventions.

ART has several characteristics that make it a considered alternative for treating the elderly: reported good survival rates (11, 16), patient-friendly nature and cost-effectiveness (17-19). Mickenautsch et al (19) compared the use of ART to conventional techniques using amalgam and composite and found that the annual cost of ART in a dental school in South Africa was approximately 50% of the other two options. Furthermore, because it involves only the use of hand instruments to remove the carious tissue and no rotary instruments are used, it can be performed outside dental facilities and was found to be associated with less discomfort during

dental treatment (20). Hence, it could be a suitable approach to treat homebound and hospitalized patients and those living in nursing homes.

This study aims to evaluate ART in terms of its cost effectiveness relative to a conventional technique as part of a preventive and restorative programme for older adults over a twelve-month period.

## **Material and Methods**

In a randomized controlled trial using a parallel design, patients (n = 82) were recruited in a day-care hospital and in a community centre adjacent to Cork University Dental School and Hospital. The patients from the day hospital were examined and treated there, with the use of a mobile dental unit, whereas the other patients were examined and treated in the Cork University Dental School and Hospital. The study protocol was approved by the Cork Dental School and Hospital Ethics Committee and consent was obtained from each patient prior to clinical examination.

The criteria for inclusion in the study were to be over 65 years of age, present with a dentinal carious lesion with no painful symptomatology and be able to perform usual daily activities such as tooth brushing.

Patients who presented with carious teeth with a history of pain, cavities resulting from attrition, erosion or abrasion, with no caries, and teeth that were periodontally involved (Grade III mobility) and therefore had a poor prognosis were excluded.

Patients were examined by two calibrated dentists (Kappa score= 0.88) and, with the use of a computer generated randomisation list, they were assigned to receive either ART or the Conventional Treatment (CT). The allocation sequence was concealed from the researcher treating the participants in sequentially numbered, opaque, sealed envelopes. One of the examining dentists was trained in the ART technique by the WHO Collaborating Centre and subsequently performed all the restorations. Before the restorative treatment commenced, patients received tailored oral hygiene instructions and scaling and polishing of teeth. Patients who had other restorative needs or needed extractions were referred either to the clinics in the Dental Hospital or to their own dentist to have these performed.

## **Sample size Calculation**

In order to detect a difference of 10% in restoration survival between groups, which was regarded as clinically significant, with a 5% significance level and a power of 80%, a sample size of 129 restorations per group was necessary, anticipating a 30% drop out rate.

## **Restorative Procedure**

The ART approach consisted of opening of the cavity with an enamel hatchet, removal of soft carious tissue with excavators, conditioning of the cavity with polyacrylic acid for 20 seconds, washing and drying with cotton pellets and restoration with a high-strength glass-ionomer cement (GC Fuji IX). Moisture control was achieved with the use of cotton wool rolls and saliva ejector. The chair-side assistant hand-mixed the glass-ionomer according to manufacturers' instructions. Excess material was removed with a carver after checking the occlusion and the restoration was coated with petroleum jelly. In the case of proximal cavities, plastic bands and wooden wedges were used when necessary.

The conventional treatment procedure consisted of local anaesthesia when necessary, use of rotary instruments for access, rotary and hand instruments for removal of all carious tissue, conditioning of the cavity with a polyacrylic acid for 20 seconds, washing and drying with cotton pellets and a resin-modified glass-ionomer (GC Fuji II LC) to restore it. Isolation was achieved using cotton wool rolls and saliva ejector and matrix bands and wooden wedges were used in proximal cavities if necessary. The material was light-cured for 20 seconds and the restoration was polished with soflec discs after checking the occlusion. The final restoration was then coated with G-coat plus according to manufacturers' instructions.

## **Estimation of cost-effectiveness**

The average cost per restoration was estimated for both ART and conventional treatment. The effectiveness or outcome was measured in terms of the survival percentage of restorations after a one year period.

### **1. Estimates of cost of the Programme**

The direct costs of treating patients with ART or CT included the capital costs such as equipment and instruments, materials and overheads, and the costs of time and labour.

In order to estimate costs for treating patients with either ART or CT technique, the procedure for placement of restorations was timed using a stopwatch. The stopwatch was

started when the patient had his mouth open and the dentist was about to start the restorative intervention and stopped when the chair was brought back to a neutral position and the patient allowed to rinse their mouth if desired. It could be estimated so, the average time to place an ART or a conventional restoration.

The cost of restorations was calculated then taking into account:

1. Capital cost: Fixed cost of equipment and instruments such as the cost of autoclave, examination kits (ART and CT) and mobile dental unit and hand-pieces (CT).

Assumptions of analysis:

- a. The life-span of an instrument is approximately 3 years or 1,095 days (constant depreciation rate) (21).
- b. Programme designed to treat homebound, hospitalized patients, and those living in nursing homes, so indirect costs such as electricity and dental chair were excluded.

The total cost of each instrument was divided by 1095 (days) and then by the number of restorations completed per day by a professional working 7 hours per day for both ART and CT. The result was an estimate of the average cost per restoration.

2. Materials cost or cost of expendable supplies such as gloves, masks, saliva ejectors, articulating paper and restorative materials. Their accumulated costs were estimated per restoration.
3. Labour costs included salaries of personnel such as a dentist and a dental nurse per day using maximum of the Irish Health Service Executive salary scale. The labour cost per day was divided by the number of restorations placed per day for each intervention. In the case of ART, the cost of labour of a dentist was compared to the cost of employing a dental hygienist to perform the restorations, assuming equal efficiency.
4. Total Cost = Capital Cost + Material cost + Labour Cost.

#### b) Effectiveness of the programme

Restorations were assessed after a year by a calibrated examiner who was not involved in the placement of restorations and did not know which treatment had been provided for each case. The ART criteria (Table 1) was used to evaluate the restorations as in previous studies (22-26).

**Table 1- ART Criteria**

<b>Code</b>	<b>Criteria</b>
0	Present, in good condition
1	Present, slight marginal defect ( $\leq$ 0.5 mm), no repair is needed
2	Present, slight wear ( $\leq$ 0.5 mm), no repair is needed.
3	Present, gross marginal defect, repair is needed.
4	Present, gross wear, repair is needed.
5	Not present, restoration partly or completely missing
6	Not present, restoration replaced by another restoration.
7	Tooth is missing
8	Restoration not assessed, patient is not present
C	Caries present

Codes 0, 1 and 2 were considered success and 3, 4, 5, 6, 7 and C, failure. Where a patient was lost to follow up at the 1 year review, they were excluded from the analysis. However, if it was known that the restoration had failed at 6 months review, it was assumed to be a failure at 1 year and included in analysis.

The cost-effectiveness ratio was generated by dividing the average cost per restoration by the percentage survival after one year. All statistical analyses were performed in SAS® (Version 9.2), after being hand-checked by the principal investigator.

## **Results**

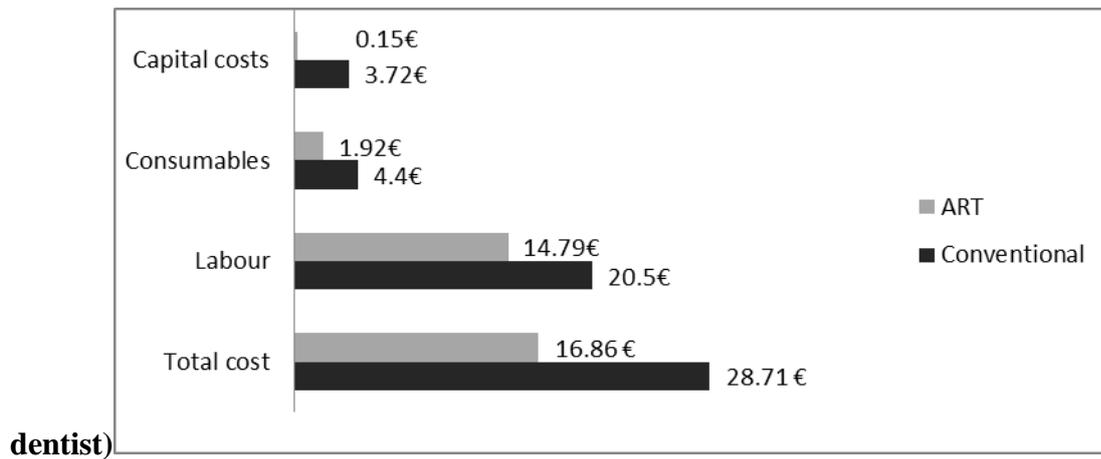
The trial profile is shown in Figure 2. Eighty-two patients participated in the trial, 40 males and 42 females, ranging in age from 65-88 years, with a mean age of 73 years (SD 6.7). In total, 260 restorations were placed, 128 ART (44 patients) and 132 conventional restorations (38 patients), with an average of 2.9 and 3.4 restorations per patient, respectively. The

majority of restorations (91.1%) were on one surface only. In the ART group, 50.8% were Class V restorations against 45.4% in the Conventional group and they were mainly root caries. The average time of procedures was 13 minutes for ART and 18 for conventional restorations. It was estimated then that 32 restorations could be performed using the ART technique per day and 23 conventional restorations.

**Costs**

The total average cost per restoration is broken down in Figure 1. The capital cost involved instruments, autoclave (ART and CT), mobile dental unit and hand-pieces (CT). The consumables included restorative materials, disposables such as masks, gloves and cotton rolls.

**Figure 1- Average cost per restoration (both interventions undertaken by**



dentist). Table 2 shows the comparative average cost per restoration when ART is undertaken by a dentist or dental hygienist.

**Table 2- Average cost per restoration (ART undertaken by dentist or hygienist)**

Average restoration cost	ART (dentist)	Conventional
	16.86€	28.71€
	ART (hygienist)	
	12.76€	

## Effectiveness

### Survival of restorations

After 12 months, 80 patients and 254 fillings could be assessed. 90.4% (113/125) ART restorations were considered successful compared to 96.9% (125/129) conventional. The reasons for failure were mostly restoration partly or completely missing, in both groups.

### *Cost-effectiveness*

After obtaining average costs per restoration and survival rates after 1 year, cost-effectiveness ratios were generated. The figures below (Table 3) represent the cost per unit of effectiveness for each restorative approach.

Table 3- Cost-effectiveness ratios

ART (dentist)	0.18
ART (hygienist)	0.14
Conventional	0.29

### **Discussion:**

This was the first RCT comparing the use of ART and a conventional treatment in older patients and has the largest sample size when compared to previous studies on ART in the elderly. In total, 260 restorations were placed in 82 elderly, with a median age of 73. All patients were community-dwelling adults, differently from the Finnish (14) and the Chinese studies (15) which treated residential and nursing home residents. The majority of restorations (91,1%) were one-surface only , and although a great number of cavities were on the root surface, other surfaces were treated including occlusal and proximal surfaces.

After one year, only 2 patients were lost to follow up and this is considered a low drop-out rate especially when treating senior adults. This can be explained by a slightly younger and healthier profile of the participants, compared to previous studies which had larger drop-out rates when treating homebound or nursing home residents (14, 15).

Timing the procedures provided some grounds for costing the restorations, although no difference in terms of cavity size and type of restoration was taken into account for this analysis. The mean time of 13 minutes for placing an ART restoration is comparable to previous studies done in children (27-29) but in most of them it was not clear what was being timed. They reported time for placing an ART restoration ranging from 10.5 to 15.6 minutes. Longer cavity preparation time for the ART approach compared to conventional rotary instrumentation has been found by Yip et al (30). This might be true especially when treating large cavities, although in this study excavation was not timed separately, and the total mean time for placing ART was smaller than that for conventional restorations. This can be explained by the fact that local anaesthesia was used most of the times in the conventional approach and restorations were polished immediately after completion, what did not happen in the ART group, resulting in longer total restorative time for the conventional method. Another factor in favour of the ART approach would be the possibility of performing multiple restorations, in different quadrants, in the same visit, as local anaesthesia is not needed. This could make the technique more efficient.

In the present study, only one dentist trained in the ART technique provided the restorations, but it was assumed that a hygienist could produce the same output. Other studies have shown no difference in restoration placement time between properly trained operators (31).

After obtaining the average time for placing a restoration using ART or the conventional approach, the number of restorations that could be performed in 1 day was calculated. This was 23 for the conventional and 32 for the ART technique. It is important to highlight that this was done in order to calculate costs but, in a real life situation, where time for cleaning and preparing the surgery before patients, and the usual time spent with explaining the procedure and giving oral hygiene instructions to the patient would not allow that number of restorations to be accomplished in one day.

The cost of dental treatment can vary enormously from country to country. The costs described here referred to the costs of dental materials, equipment and labour in the Republic of Ireland.

Labour costs represented the greatest component of the total cost, approximately 87% in ART and 72% in conventional restorations. This finding is in agreement with previous studies on micro costing of restorations (21, 32), although Putthasri et al (21) found ART a more time-consuming technique, consequently being more labour intensive. In developed countries,

workforce can be quite costly and the fact that ART is an easy procedure to perform is a great advantage of the technique. It means that other members of the dental team could be easily trained to perform ART restorations. Dental therapists are being utilized in several countries such as the Netherlands, Australia and New Zealand, usually to treat children (33). In Ireland, there are no dental therapists, but hygienists have had their scope of practice amplified and are now administering anaesthesia and placing temporary restorations. These professionals could be trained to provide ART restorations making dental treatment to the elderly viable and improving access to care.

The survival of ART restorations (90.4%) was high and comparable to the ones undertaken according to the conventional approach (96.9%) and in both groups survival was higher than that encountered by previous ART studies with senior patients. The fact that restorations were carried out in a clinical setting in this study, with chair-side assistance and good moisture control could have resulted in higher survival rates for both techniques. The reasons for failure in both groups were restoration partly or completely missing, similar to what was found by Lo et al in the Chinese study, although they reported the presence of recurrent caries in 3 patients after 1 year, whereas no caries was found around restorations in this trial.

Evidence from previous children's studies indicate that, patients experienced less discomfort with the use of hand instruments and without local anaesthesia or hand-pieces being used (34, 35). This finding is corroborated in our study as patients treated with ART expressed satisfaction with both the absence of drilling and more importantly the absence of pain. These are additional intangible benefits of ART, and although not measured in this study, they provide further justification for the implementation of this less invasive technique in older adults.

The cost-effectiveness of ART was substantially higher than that of the conventional treatment. This means that to generate one unit of effectiveness would cost less using ART. The cost-effectiveness became even greater when the labour of a hygienist was inserted in the analysis. A study by Puttharsi et al (21) found ART to be more cost-effective than a conventional treatment using amalgam, but this difference was not significant, given that ART was considered a labour intensive approach. They calculated restoration cost using the labour of a dentist and alternatively, of a dental nurse. The possibility of using less costly professionals to perform ART restorations was discussed, as it is a simple enough technique to be learned and applied. This could improve the cost-effectiveness of the technique even more, as demonstrated by the present study.

In conclusion, the cost-effectiveness of ART compared to a conventional restorative technique seems to be satisfactory after 1 year and this could assist policy makers in allocating resources in the dental field in times of financial constraints, improving older patients' access to dental care. Longer follow-up periods would be of great benefit in order to confirm the comparable survival of ART to conventional techniques.

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## CONSORT 2010 Flow Diagram

