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Treatment of tooth decay in older patients: comparison between two filling techniques

Submission date
19/08/2013

Recruitment status
No longer recruiting

Registration date
09/09/2013

Overall study status
Completed

Last Edited
14/03/2019

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The world population is ageing, and there has been an increase in life expectancy. Not only are people living longer, but they are also retaining their natural teeth into their later years. Although this is a positive development, there is a high prevalence of tooth decay among older people in several countries. Research shows that dental decay is a major public health problem in older people. Despite this, there are many barriers that make it difficult to provide dental treatment to elderly patients, such as reduced mobility, negative attitudes or fear of dental procedures, and lack of interest. It is known that poor oral health affects several aspects of an individuals life, including nutrition, speech, social contact and self-esteem. Recent research showed the impact of oral health on quality of life. It is now important to address these issues both with preventive and minimally invasive approaches, and to also attempt to find alternative dental care settings in order to facilitate attendance to dental treatment. Atraumatic restorative treatment (ART) has been shown to be useful for treating tooth decay in children and disadvantaged communities. ART is considered to be a patient-friendly approach as it does not require the use of drills or local anesthesia. There are hardly any data available for the performance of ART in elderly patients. The aims of the study are to assess the oral health status of older people, to compare the impact of ART to usual care, and to find out how cost-effective ART is.

Who can participate?
People aged 65 or above, with natural teeth, living independently.

What does the study involve?
Patients were randomly allocated to one of the treatment groups: either ART or conventional treatment. Treatment consisted of clinical examination, oral hygiene instructions (OHI), scaling to remove plaque, either ART or conventional restorations for teeth with decay, and extraction of teeth that are considered unfit for restoration. ART involved the use of hand instruments only, to remove decay. No anaesthesia was administered as the procedure is usually painless. Handpieces (drills) were not used and the cavities were filled. The conventional treatment involved the use of local anaesthesia and of fast and slow handpieces to access and remove decay, and the cavities were filled. Patients were reviewed 6 months and 1 year after treatment by a dentist not involved in the provision of treatment and who did not know which technique

had been used in placing the restoration. Two months after completion of the treatment, they were asked to answer a questionnaire to assess the impact of dental disease on quality of life.

What are the possible benefits and risks of participating?
The benefits of participating were receiving restorations of decayed teeth without any costs. There were no risks associated with the procedures investigated in this study.

Where is the study run from?
Patients for the study were recruited from those attending a Geriatric Day Care Centre at St Finbarrs Hospital and a community centre in Cork, Ireland. Patients were treated in the clinics in the University College Cork Dental School and Hospital (Ireland) or in the Geriatric Day Centre (Ireland) with the use of a mobile dental unit.

When is the study starting and how long is it expected to run for?
Patients were recruited and treated from July 2009 to December 2011.

Who is funding the study?
This study was funded by the Irish Health Research Board, Ireland.

Who is the main contact?
Dr Cristiane da Mata
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Contact information

Type(s)
Scientific

Contact name
Prof Finbarr Allen

Contact details
University College Cork Dental School and Hospital
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HRAPOR/2010/154

Study information

Scientific Title
The use of atraumatic restorative treatment in older patients: a randomised controlled clinical trial

Study objectives
The survival rates of Atraumatic Restorative Treatment (ART) restorations are similar to the ones of conventional restorations after 1 year. Both ART and a conventional restorative technique result in improvement in subjective oral health. ART and a conventional restorative technique present similar cost-effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained on the 3rd of September of 2009, from the University College Cork Clinical Research Ethics Committee. Reference number: ECM 5(4) 02/09/2008

Study design
Randomised controlled clinical trial single-blind single-centre using a parallel design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheetCristiane da Mata, email address: cristmata@yahoo.com.br, postal address: University College Cork Dental School and Hospital, Wilton Road, Cork, Ireland.

Health condition(s) or problem(s) studied
Dental caries

Interventions
The Atraumatic Restorative Treatment was compared to a conventional restorative technique to treat carious lesions in older patients, according to the protocol below:
1. Atraumatic Restorative Treatment (ART)
The Atraumatic Restorative Treatment involved the use of hand instruments only, such as enamel hatchets to create access to the caries lesion (occlusal cavities without access) and excavators to remove the very soft, demineralized dentin. Removal of tissue was stopped when some resistance on excavation was felt. The cavity was then washed with water spray and dried

with cotton pellets. Moisture isolation was achieved with the use of saliva ejectors and cotton wool rolls. A dentin conditioner was then used for 20 seconds, namely polyacrylic acid. The acid was washed away with a water spray and cotton pellets used again to dry the cavity but not desicate it. A high-strength glass-ionomer cement (GIC) GC Fuji IX was hand-mixed by a chair side assistant according to manufacturers instructions. The material was placed into the cavity using a flat plastic instrument and the press-finger technique was used. In the case of proximal cavities, plastic bands and wooden wedges were used when necessary. The restoration was coated with a petroleum jelly. On occlusal restorations, a press-finger technique was used. Occlusion was checked and any excess removed with the use of a carver instrument, before the re-application of a petroleum jelly.

2. Conventional Treatment
The conventional treatment involved the use of local anaesthesia when judged necessary, access to the carious lesion created with a fast-handpiece and removal of all carious tissue with a slow hand-piece. The cavity was then washed with water spray and dried with cotton pellets. Moisture isolation was achieved with the use of saliva ejectors and cotton wool rolls. A dentin conditioner was then used for 20 seconds, namely polyacrylic acid. The acid was washed away with a water spray and cotton pellets used again to dry the cavity but not desicate it. A resin-modified glass-ionomer GC Fuji II LC was hand mixed by the chair side assistant according to manufacturers instructions and inserted into the cavity with a flat plastic instrument. The material was light-cured for 20 seconds. In case of deep cavities, a layering technique was used and in proximal cavities, plastic bands and wooden wedges were used when necessary. Occlusion was then checked and any excesses removed with the use of soflex discs. G-coat plus varnish was then applied with the use of a brush and light-cured for 20 seconds.

The duration of recruitment and intervention phase was from July 2009 to December 2011. Follow up from December 2009 to December 2012.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Survival of restorations after 1 year, assessed by a calibrated examiner who had not been involved in the placement of restorations, using codes and criteria similar to ART criteria.

Secondary outcome measures
1. Cost-effectiveness of ART compared to a conventional technique. Costs were calculated based on time to place the restorations and labour and materials costs. Effectiveness was measured in terms of survival of restorations after 1 year.
2. Impact of treatment on quality of life measured using the Oral Health Impact Profile (OHIP-14) administered before and after treatment.

Overall study start date
01/07/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Be either male or female aged 65 years or older
2. Present with some natural dentition
3. Present carious lesions 1mm or more in depth, as marked with a periodontal probe, without pulpal involvement and painful symptomathology
4. Agree to be seen again for review appointments in the period of a year
5. Have self-care ability for normal basic activities including tooth-brushing
6. Sufficient cognitive ability to understand consent procedures and be able to complete a questionnaire.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100 patients/266 restorations

Total final enrolment
99

Key exclusion criteria
1. Teeth presenting cavities caused by abrasion, erosion or attrition with no caries present
2. Teeth that were likely to be extracted for periodontal reasons or for construction of new prostheses
. Patients who were too ill to attend the appointments

Date of first enrolment
01/07/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Ireland

Study participating centre

University College Cork Dental School and Hospital
Cork
Ireland
na

Sponsor information

Organisation
Irish Health Research Board (Ireland)

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Irish Health Research Board (Ireland) Grant number: HRAPOR/2010/154

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	2-year results	01/04/2015		Yes	No
Results article	5-year results	01/04/2019	14/03/2019	Yes	No