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Effectiveness of chemical disinfection on biofilm of relined dentures

Submission date
20/08/2014

Recruitment status
No longer recruiting

Registration date
29/09/2014

Overall study status
Completed

Last Edited
29/09/2014

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hard direct autopolymerizing reliners (a type of material used to make dentures) are often used to re-establish the fit and improve the stability and retention of complete dentures. One of the main problems in use of acrylic resins is that there are chances that microorganisms (germs) can attach themselves on it due to its rough surface. Therefore, an effective method of cleaning dentures is necessary as these germs can cause infection. Dentures can be cleaned mechanically, chemically, or by a combination of the two. Mechanical procedures include brushing with soap or an abrasive paste and water and are the most used method among elderly patients. The use of chemical cleansers is usually associated with mechanical methods. They have not been seen to consistently reduce the accumulation of germs. Surface roughness is an important factor. A rough surface may contain a number of irregularities that serve as starting points for attachment and provide a place where microorganisms are protected from mechanical forces. During clinical use, the surface roughness of the denture can be modified by continued use of cleansing procedures. Previous studies have reported the effect of surface roughness and accumulation of germs (biofilm formation) on acrylic resin after continuous exposure to chemical disinfection agents. However, no clinical study has compared the effects of these agents in reducing biofilm formation when associated with brushing on chairside hard reline material. The aim of this study was to evaluate the effect of disinfection with sodium perborate or chlorhexidine combined with brushing on the removal of biofilm on relined dentures.

Who can participate?
Patients, aged 50-75, whose dentures need relining.

What does the study involve?
All patients underwent reline and polish of the denture. A biological sample was taken from the denture after 48 hours to check the initial level of microorganisms present. The patients were randomly divided into three groups based on the cleaning method used: the control group brushed with coconut soap and a soft toothbrush; the perborate group brushed and disinfected with warmed sodium perborate solution for 5 minutes once a day for 6 months; and the chlorhexidine group brushed and disinfected with 2% chlorhexidine digluconate for 5 minutes once a day for 6 months. The subjects were told to brush their dentures three times a day. Biofilm formation was analysed and compared in the three groups.

What are the possible benefits and risks of participating?
The material used to reline the dentures is internationally recognized as one of the most suitable for this procedure. In addition, patients will have their dentures again fitted to the support tissues. The advantages are comfort and preservation of tissues and surrounding bone. Moreover, the disinfection solutions and toothbrushes were provided to all patients during the 6 months follow-up. There were no risks to the patients.

Where is the study run from?
School of Dentistry of Araraquara, São Paulo State University (UNESP) (Brazil).

When is the study starting and how long is it expected to run for?
March 2011 to March 2012 with 6 months follow up

Who is funding the study?
1. São Paulo Research Foundation (FAPESP), Brazil
2. Coordination for the Improvement of Higher Level or Education Personnel (CAPES), Brazil

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U1111-1160-1207

Study information

Scientific Title

Effectiveness of chemical disinfection on biofilm of relined dentures: a randomized clinical trial

Study objectives
The aim of this randomized clinical study was to evaluate the effect of disinfection with sodium perborate or chlorhexidine combined with brushing on the removal of biofilm on relined dentures during different time intervals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Araraquara Dental School, UNESP Univ. Estadual Paulista (number 60 /2009). UTN: U1111-1160-1207

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Maxillary denture relining

Interventions
The patients were randomly divided into three groups (n = 15); allocation was concealed with the use of the BioStat program. The dentures were cleansed according to three methods: CG (control group) brushing with coconut soap and soft toothbrush; PG (perborate group) brushing according to previous methods and disinfection with warmed sodium perborate solution (Corega Tabs GlaxoSmithKline Brasil Ltda, Rio de Janeiro RJ, Brazil) for 5 minutes, according manufacturers instructions once a day for 6 months; and ChxG (chlorhexidine group) brushing according to CG and disinfection with 2% chlorhexidine digluconate (Arte &Ciência, Farmácia de Manipulação, Araraquara SP, Brazil) for 5 minutes once a day for 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Microbial growth for each type of denture 48 hours after the reline procedure. Swabs were collected 48 hours after the reline procedure (day 0) and at the follow-up time intervals of 7, 15, 30, 90, and 180 days.
2. The surface roughness (Ra-μm) of each denture as measured using a profilometer with a resolution of 0.01 μm, an interval (cut-off length) of 0.8 mm, a transverse length of 2.4 mm, a stylus speed of 0.5 mm s-1, and a diamond stylus tip radius of 5 μm. One operator recorded all measurements, taken immediately after the relining and after 7, 15, 30, 90, and 180 days of treatment.

Secondary outcome measures
N/A

Overall study start date
10/03/2011

Completion date
10/03/2012

Eligibility

Key inclusion criteria
1. Age between 50 to 75 years
2. Have attended the School of Dentistry of Araraquara/UNESP
3. Healthy with good manual dexterity whose maxillary dentures required relining

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
45

Key exclusion criteria
Presence of oral or systemic diseases

Date of first enrolment
10/03/2011

Date of final enrolment
10/03/2012

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Humaitá, 1680 - Centro
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Sponsor information

Organisation
São Paulo State University (UNESP) (Brazil)

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Sponsor type
University/education

ROR
https://ror.org/00987cb86

Funder(s)

Funder type
Other

Funder Name
FAPESP São Paulo Research Foundation (Grant 2010/009167) (Brazil)

Funder Name
CAPES Coordination for the Improvement of Higher Level or Education Personnel (Brazil)

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