ISRCTN80200202 https://doi.org/10.1186/ISRCTN80200202

Comparing two devices with visual examination to assess tooth colour

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
12/04/2019

Overall study status
Completed

Last Edited
19/07/2021

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Currently, tooth colour is often assessed by eye by dental professionals using shade guides (colour charts for teeth). From other research, it is clear that assessment of tooth shade in this way can provide acceptable results in some cases; however, this approach can be affected by other factors such as the experience level of the dental professional, the lighting conditions in the assessment room and even fatigue of the eye muscles.
Over the past decade, new technologies have been developed which may be able to help dental professionals to measure tooth colour more quickly and more accurately. The purpose of this study is to evaluate these new technologies for the assessment of tooth colour. This study aims to explore whether these methods can pick up small changes in colour, i.e. changes you might see after having a scale and polish, as well as larger changes in colour, i.e. changes you might see after using professional teeth whitening products. The technologies involved in this study are the VITA Easyshade® (colour measuring device) and the 3Shape TRIOS® Intraoral Scanner (3D scanner).

Who can participate?
Healthy adults aged between 18 to 65 years old (inclusive) will be eligible for this study. Participants need to be in good dental health, with no signs of advanced gum disease or dental decay. Participants need to have the upper and lower front teeth present with no large fillings or crowns.

What does the study involve?
The study will last for 3 weeks. Participants will be randomly divided into two groups. One group will receive teeth whitening during the course of the study and one will continue with standard care. All participants will undergo multiple assessments at each study visit (manual shade measurement, VITA EasyShade measurement and 3D Scanning). Participants in the treatment group will use the at-home tooth whitening product on a daily basis for 30 minutes between the 7-day and 21-day visits. The whitening product used in this study is Colgate MaxWhite One Professional (6% hydrogen peroxide).

What are the possible benefits and risks of participating?
Participants may experience temporary tooth sensitivity and/or gum irritation as a result of

using the whitening product - these side effects are common and normally resolve quickly on their own. Participants will be provided with training on the usage of the whitening product to minimise any problems.
Participants may find their teeth become whiter as a result of using the whitening product.
Participants who are not provided with the whitening treatment during the study will be offered the same treatment upon completion of the study.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
December 2018 to July 2019 (updated 19/07/2021, previously: June 2019)

Who is funding the study?
The University of Manchester (UK)

Who is the main contact?
The main contact is Mrs. Nicola Boothman (Trials Manager), nicola.boothman@manchester.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Nicola Boothman

Contact details
The University of Manchester
Dental Health Unit
Williams House
Manchester Science Park
Lloyd Street North
M15 6SE
Manchester
United Kingdom
SK9 7JA
+44 (0)161 226 1211
nicola.boothman@manchester.ac.uk

Type(s)
Scientific

Contact name
Prof Iain Pretty

ORCID ID
https://orcid.org/0000-0001-6298-4189

Contact details

The University of Manchester
Dental Health Unit
Williams House
Manchester Science Park
Lloyd Street North
Manchester
United Kingdom
M15 6SE
+44 (0) 161 226 1211
iain.pretty@manchester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
254177

Protocol serial number
NHS001483, IRAS 254177

Study information

Scientific Title
A clinical study to evaluate the performance of visual assessment and novel imaging methods to monitor and assess changes in tooth colour.

Acronym
Diagnostic Whitening Study

Study objectives
To compare the performance of an intra-oral 3D scanner, spectrophotometer and visual assessment for the assessment of tooth colour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2019, South Central - Berkshire B Research Ethics Committee (Whitefriars Level 3, Block B, Lewins Mead, Bristol, BS1 2NT; 0207 104 8059; nrescommittee.southcentral-berkshireb@nhs.net), ref: 19/SC/0018

Study design
Single-centre, single-blind, two-cell, parallel-group, randomised controlled study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Tooth discolouration

Interventions
Advertisements, in the form of posters, will be placed at the dental practice before the start of the study. If patients would like to participate in the study they can speak to a member of the research team. The member of the research team will provide potential participants with an information sheet with further details on the study. Potential participants interested in taking part will be provided with an appointment to return for screening and recruitment.

At the screening visit (Day 0 Visit), the participant will be asked to sign an informed consent form. The examiner will carry out a brief dental examination to assess if the participant meets the inclusion criteria; this examination involves the use of an overhead operating light and a dental mirror. The examiner will also ask about their general medical history.
Participants who are successfully recruited will be provided with a toothbrush and toothpaste for use throughout the study. Participants will have moulds (impressions) taken of their teeth to provide the fabrication of dental whitening trays. Participants will be block-randomised into two groups, one group will receive teeth whitening and the other group will continue with their normal standard of care.

The baseline examinations (Day 0 Visit) will occur directly after a participant has been screened and recruited. The examiner will use each of the devices described below to measure the colour of participants' teeth. The day 0 Visit will take approximately 30 minutes.
1. Visual. This involves using a tooth shade guide, similar to a colour chart for teeth, which will be compared to the colour of the participants' teeth. One shade will be selected for the participant’ s upper and lower anterior teeth (incisor and canine teeth, 12 teeth in total per participant).
2. Digital. This involves using a colour-measuring device (VITA EasyShade spectrophotometer). This device is placed on the front surfaces of the teeth and produces a white light, similar to a camera flash, which is reflected by the teeth and analysed by the device to generate a score. Three measurements will be collected for the participant’s upper and lower anterior teeth (12 teeth in total per participant).
3. Scanner. The scanner (TRIOS 3 Scanner) captures multiple two-dimensional pictures of teeth using white light before joining them together to produce a three-dimensional scan. One full mouth scan will be acquired.

Participants will return in 7 days for the next study visit (Day 7 Visit). The examiner will complete the relevant visit form. The participant will then receive a scale and polish to remove extrinsic surface stain from the teeth. The examiner will then carry out the three colour assessments as described above: visual, digital and scanner. The Day 7 visit will take approximately 45 minutes. If the participant is allocated to the treatment group the examiner will provide them with the whitening trays and ensure the fit of the trays is appropriate. The examiner will go through the instructions on how to use the gel whitening product and the participant will carry out the first treatment under the examiner’s supervision. The participant will be given a 1-week supply of the whitening product.

Participants will return in 3 days for the next visit (Day 10 Visit). The examiner will complete the relevant visit form. The examiner will then carry out the three colour assessments described above: visual, digital and scanner. The Day 10 visit will take approximately 20 minutes.

Participants will return in 4 days for the next visit (Day 14 Visit). The examiner will complete the relevant visit form. The examiner will then carry out the three colour assessments described

above: visual, digital and scanner. Participants in the treatment group will be given an additional week's supply of whitening product. The Day 14 visit will take approximately 20 minutes.

Participants will return in 7 days for the final visit (Final Study Visit – Day 21). The examiner will complete the relevant visit form. The examiner will then carry out the three colour assessments described above: visual, digital and scanner. Participants will be provided with the agreed compensation for their participation. The Day 21 visit will take approximately 30 minutes.

The participants in the control group who did not receive teeth whitening during the course of the study will be offered teeth whitening upon study completion. The examiner will provide them with the whitening trays and ensure the fit of the trays is appropriate. The examiner will go through the instructions on how to use the whitening product and the participant will carry out the first treatment under the examiner's supervision. The participant will be given a 2-week supply of the whitening product.

The efficacy of the whitening product does not form any part of the intended outcomes of this study. The whitening product has been demonstrated to induce changes in tooth shade in a previous study (Mohan et al., 2007), for this reason, it is being employed in this research to provide incremental changes as a test for the diagnostic methods.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Tooth shade according to the Vita Extended Bleached Guide assessed by visual comparison with the tooth shade guide, digital spectrophotometer (VITA EasyShade) and scanner (TRIOS 3 Scanner) at baseline, day 7, day 10, day 14 and day 21. Inter-method agreement will be assessed via weighted kappa calculations of absolute values and deltas in tooth shade over the study visits.

Key secondary outcome(s))
Whiteness on the WIO whiteness index assessed by visual comparison with the tooth shade guide, digital spectrophotometer (VITA EasyShade) and scanner (TRIOS 3 Scanner) at baseline, day 7, day 10, day 14 and day 21.

Completion date
12/07/2019

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years inclusive
2. In good general health, as determined by site investigator
3. Willing to give informed consent, medical history and to comply with the full study protocol
4. Present at screening with a tooth shade score ≥15 as measured by the Vita Extended BleachedGuide 3D Master on at least one anterior tooth
5. All maxillary and mandibular anterior teeth present without crowns or large restorations

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to attend all 5 visits
2. Experiencing acute dental pain and/or infection
3. Soft tissue abnormalities
4. Advanced periodontal disease (purulent exudate, tooth mobility and/or extensive alveolar bone loss)
5. Five or more carious lesions requiring immediate restorative treatment
6. Fixed orthodontic bands
7. Cavitated carious lesions on the anterior teeth requiring immediate restorative treatment
8. Pregnant women or women who are actively breastfeeding
9. Employees of the University of Manchester, Windsor Dental Practice or manufacturing company of the employed study equipment (VITA Zahnfabrik or 3Shape A/S)
10. Known or suspected intolerance or hypersensitivity to any study materials or any of their stated ingredients
11. Have participated in any other oral care study or panel test within the last 3 months

Date of first enrolment
15/04/2019

Date of final enrolment
06/05/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Windsor Dental
Denhill House
Denhill Road
Hulme

Manchester
United Kingdom
M15 5NR

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
University of Manchester

Alternative Name(s)
The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes