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Different methods of colour evaluation between the human eye and a digital instrument

Submission date	Recruitment status	[_] Prospectively registered
12/05/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/05/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/07/2025	Oral Health	

Plain English summary of protocol
Background and study aims
The subjective nature of visually determining tooth shade is an issue for dentists. Several instruments have been used in the hope of achieving more consistent and reliable shade selection. However, the best method remains a topic of debate. The aim of this study is to investigate the accuracy of a recently introduced colorimeter and compare its ability in shade matching with human vision.

Who can participate?
Students of the University of Genoa or dental collaborators of the university

What does the study involve?
The study involves examining several composite discs and trying to match the colour of the test discs with the control discs.

What are the possible benefits and risks of participating?
The benefit is screening for eventual color blindness. No risks are expected.

Where is the study run from?
University of Genoa (Italy)

When is the study starting and how long is it expected to run for?
December 2023 to April 2024

Who is funding the study?
University of Genoa (Italy)

Who is the main contact?
Paolo Pesce, Paolo.pesce@unige.it

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
COL1

Study information

Scientific Title
Dental colour matching ability: comparison between visual determination and technology

Study objectives
To compare the accuracy of a recently introduced colorimeter in shade matching with human vision. In addition, possible variables affecting color-matching by human eye have been analysed.

Ethics approval required
Ethics approval not required

Ethics approval(s)
This study was assessed by the authors to be very low risk and as such approval by the ethics committee was not required

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Dental clinic

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Dental color matching

Interventions
18 disc-shaped composite samples with identical size and shape were produced from a composite flow system (Enamel plus HriHF, Micerium): 9 were considered control samples (UD 0-UD 6) and 9 were test samples with identical flow composite shade to the control ones. Parallelly, 70 individuals (dental students and dental field professionals) were individually instructed to sit in a dark room illuminated with D55 light and perform visual shade matching between control and test discs. An error matrix containing ΔE94 between control and test discs was generated, containing four match-clusters depending on perceptibility and acceptability thresholds. The frequency and severity of errors were examined for both the colorimeter and the test subjects, considering variables such as age, gender, experience. Folded F-test has been computed for capturing any difference in the number of matches and the Satterthwaite t-test has been used to identify differences among Optishade and visual determination.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Colorimeter

Primary outcome measure
The frequency of right matches among the test and control colours, obtained once for each participant

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/12/2023

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. Italian dental students from the 5th or 6th academic year, dentists, and dental technicians attending, working at or collaborating with the Dental School of the University of Genova from different branches and dental specializations
2. Aged 18 to 70 years

Participant type(s)
Health professional, Learner/student

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
Color blindness, according to ISO/TR 28642:2016 standard

Date of first enrolment
10/12/2023

Date of final enrolment
15/01/2024

Locations

Countries of recruitment
Italy

Study participating centre
University of Genoa
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Sponsor information

Organisation
University of Genoa

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Sponsor type
University/education

Website
http://www.unige.it/

ROR
https://ror.org/0107c5v14

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Genova

Alternative Name(s)
University of Genoa

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Publication and dissemination plan
The plan is to publish an article in a peer-reviewed journal

Intention to publish date
12/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Paolo Pesce (paolo.pesce@unige.it)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/09/2024	07/07/2025	Yes	No