

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

Submission date 12/05/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/07/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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

Contact name

Prof Paolo Pesce

Contact details

Largo Rosanna Benzi

Genoa

Italy

16100

+39 (0)103537421

paolo.pesce@unige.it

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Other

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. Parallely, 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 ΔE_{94} 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

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Colorimeter

Primary outcome(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

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

Largo Rosanna Benzi

Genoa

Italy

16100

Sponsor information**Organisation**

University of Genoa

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

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