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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

**Contact name**
Prof Paolo Pesce

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# Additional identifiers

**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

**Primary study design**
Observational

**Study design**
Observational cross-sectional study

**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.

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

### 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
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# 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 |