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Efficacy of gingival retraction and hemostasis of Merocel strip

Submission date 05/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/10/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/10/2024	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at how well a new material called Merocel works for dental procedures. Dentists need to record the edge of the gums accurately when making dental impressions for crowns. Traditionally, they use cords to push the gums back, but this can be tricky and sometimes harmful. Merocel strips are a new, gentler option that might work better.

Who can participate?
- Healthy adults over 18 years old.
- People who need crowns on their front teeth.
- Those with a gum depth of 1-2 mm.
- People with thick gums.

What does the study involve?
The study involves 23 participants with 122 teeth needing crowns. Participants are divided into two groups to test gum retraction and bleeding control. Each group uses either traditional cords or Merocel strips. The study is double-blinded, meaning neither the participants nor the researchers know who is using which method.

What are the possible benefits and risks of participating?
- Benefits: Participants will receive full coverage crowns for their front teeth.
- Risks: There is a risk that the crown might not fit perfectly.

Where is the study run from?
The study is conducted at Damascus University in Syria.

When is the study starting and how long is it expected to run for?
April 2022 to July 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr. Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy

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
Nil known

Study information

Scientific Title
Efficacy of gingival retraction and hemostasis of Merocel strip compared with conventional retraction cord: a randomized controlled trial

Study objectives
The null hypothesis is that the Merocel strip will not outperform the conventional cord in retracting the gingiva and achieving adequate hemostasis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/04/2022, The Biomedical Research Ethics Committee (Mezzeh highway, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: N1493

Study design
Randomized double-blinded split-mouth active-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Training facility/simulation

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dental caries

Interventions
The sample consisted of 122 abutments, including incisors, canines, and premolars in 23 participants, which was randomly divided into two groups:
• Group A: Gingival retraction was evaluated in 44 abutments of 8 participants.
• Group B: Hemostatic efficacy was assessed in 78 abutments of 15 patients.

Each group was further divided into two equal sub-groups using the split-mouth technique:
• Sub-group I (ACIKRC): Size 000 aluminum chloride-impregnated knitted retraction cord (SURE-CORD®, Sure-endo, Gyeonggi-do, South Korea) was applied.
• Sub-group II (MS): Merocel strips (Epistaxis Nasal Dressings, Eon Meditech, Gujarat, India) were applied.

Randomization and blinding
It was a double-blinded trial where participants and outcome assessors were masked to group allocation. Randomization was performed by applying a simple randomization method, which is flipping a coin.

Efficacy of gingival retraction
The finish line was initially prepared above the gingival margin and then placed 0.5 mm below the gingival margin to minimize damage to the periodontium. A conical bur with a non-cutting tip (Dentsply, Maillefer, Ballaigues, Switzerland) was utilized to protect the sulcular epithelium from damage and to provide an identical finish line thickness. The two-stage impression technique was considered utilizing condensation silicone (Zetaplus, Zhermack, Badia Polesine, Italy) before the gingival retraction. After achieving adequate isolation, retraction cords were applied using a single-cord technique. The final impression was taken utilizing condensation silicone in two stages. A virtual model of recorded impressions was created using a scanner

(AutoScan-DS-EX Pro, SHINING 3D Tech Co., Ltd., Hong Kong, China). Virtual gypsum models were designed utilizing the exocad software (DentalCAD® 3.1 Rijeka, exocad, Hesse, Germany), and then a single gypsum model was created by matching models before and after gingival retraction. A longitudinal section was determined of the prepared abutment from the incisal edge or the occlusal surface to the gingival margin parallel to the longitudinal axis. The following measurements were considered at the following points for each abutment: midbuccal, mesiobuccal, distobuccal, midpalatal, mesiopalatal, and distopalatal. The angle of the gingival sulcus opening, which formed between the abutment surface and the inner surface of the gingival sulcus, was measured before and after gingival retraction by two blinded outcome assessors (ICC > 0.8). The difference between the two angles was calculated to determine the horizontal retraction.

Hemostatic efficacy
The finish line was initially prepared above the gingival margin and then placed 0.5 mm below the gingival margin to minimize damage to the periodontium utilizing a conical bur with a non-cutting tip. The bleeding was assessed before (t0) and after (t1) ginigival retraction according to Weir and Williams study by two blinded outcome assessors (ICC > 0.8) as follows:
Score 0 = No bleeding.
Score 1 = Bleeding controlled within one minute.
Score 2 = Bleeding not controlled within one minute.
After achieving adequate isolation, retraction cords were applied using a single-cord technique, and then the two-step impression technique was considered utilizing condensation silicone. In the first step, a heavy-body impression was made. The gingival retractor cords were removed after moistening the gingival sulcus with water to avoid damaging the sulcular epithelium, dislodging the blood clot, and causing bleeding. The hemostatic efficacy was evaluated according to Weir and Williams's abovementioned study. In the second step, a light-body impression was made.

Intervention Type
Other

Primary outcome measure
1. The angle of the gingival sulcus opening, which formed between the abutment surface and the inner surface of the gingival sulcus, was measured before (t0) and after (t1) gingival retraction. The difference between the two angles was calculated to determine the horizontal retraction
2. The bleeding was assessed before (t0) and after (t1) gingival retraction according to Weir and Williams study

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
04/04/2022

Completion date
28/07/2024

Eligibility

Key inclusion criteria

1. Healthy participants
2. Participants older than 18 years
3. Anterior teeth indicated for full coverage crowns
4. The gingival sulcus depth is 1-2 mm
5. The gingival biotype is thick

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
23

Total final enrolment
23

Key exclusion criteria
1. Participants with systemic diseases that impact oral health, including cardiovascular and hematologic disorders, diabetes, and hyperthyroidism
2. Pregnant participants
3. Participants with periodontal diseases
4. Participants are allergic to the materials used
5. Abutments with abnormal size and position

Date of first enrolment
09/05/2024

Date of final enrolment
24/07/2024

Locations

Countries of recruitment
Syria

Study participating centre
Faculty of Dentistry, Damascus University
Mazzeh highway

Damascus
Syria
Nill

Sponsor information

Organisation
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ROR
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Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

Syria

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			08/10/2024	No	No