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Comparing tissue glue to suturing in gum graft surgery

Submission date	Recruitment status	[_] Prospectively registered
20/12/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/01/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/07/2022	Oral Health	

Plain English summary of protocol
Background and study aims
This study aims to compare using glue or suturing (stitches) to hold gum tissue in place during gum grafting surgery.

Who can participate?
Healthy adults aged 18-45 years who are non-smokers

What does the study involve?
Two pieces of gum will be grafted for each patient. One will be attached using suturing, the other with the glue. The size of the grafts, their healing and the patient's pain will be assessed afterwards.

What are the possible benefits and risks of participating?
Dentists commonly use suturing and glue in these procedures. Both are safe and should not cause any additional risks, other than those involved in the gum grafting procedure. All participants will receive the same treatment.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2019 to January 2020

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mohamed Aghiad Alhourani, agheadhou@hotmail.com

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MS2773

Study information

Scientific Title
Comparison between using tissue adhesive (N-butyl cyanoacrylate/octyl cyanoacrylate) and conventional sutures in free gingival graft surgery

Study objectives
We are trying to test the efficacy of a new formula of cyanoacrylate tissue adhesive (IceBerg Glue tissue adhesive), and comparing it to traditional methods in free gingival graft surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/08/2019, Damascus University Rector (Baramkeh, Damascus, Syria; +966 55 506 3806; no email), ref: 2773MS

Study design
Randomized internal-controlled trial

Primary study design

Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files for participant information sheet in Arabic

Health condition(s) or problem(s) studied
Free gingival (gum) graft treatment for absence or insufficiency of attached gingiva

Interventions
This study is a split mouth randomized clinical trial. The patient chose a piece of paper to decide which side was to be sutured and which was to be sealed with tissue adhesive and the paper was opened just before the operation.
The patient's palate was anaesthetized. Then one long piece of the free gingival graft 1-1.5 mm thickness was harvested from the palate (from the second molar to the first pre-molar), then it was divided into two equal pieces for the vestibuloplasty. The grafted area was made by a small blade to gain a depth about 10 mm and was extended along the targeted area on two sides.One piece was fixed in its bed using nylon sutures. The other one was put in its bed and the dentist held his finger on it for 5 min to encourage its initial stability. Then 4 drops of the tissue adhesive "IceBerg Glue" were applied.
Patients returned after 1 week to have the sutures removed. They were followed up at 2 weeks, 1 month, 2 months, 3 months, and 6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Shrinkage of the graft assessed using at 2 months, 3 months and 6 months. A standard sizing template of known size is placed beside the graft and digital photographs are taken. Software is used to calculate the size of the graft by comparing it with the template in the images.

Secondary outcome measures
1. Recipient site healing assessed using the modified early-wound healing index (MEHI) at 1 week, 2 weeks, 1 month and 2 months
2. Recipient site pain assessed by the patient using a 1-10 visual analogue scale at 6 h, 12 h, 24 h, 2 days, 3 days, 4 days, 5 days, 6 days and 7 days after surgery

Overall study start date
16/03/2019

Completion date
10/01/2020

Eligibility

Key inclusion criteria
1. Attached gingiva ≤1 mm
2. No systemic diseases
3. Non-smoker
4. Gingival inflammation and plaque indexes <20% at time of surgery
5. Aged 18-45 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
12

Total final enrolment
12

Key exclusion criteria
1. Systemic disease that would interfere with the healing process
2. Has undergone previous periodontal surgery
3. Poor endodontic treatment
4. Tooth mobility
5. Severe gingival pigmentation
6. Pregnant
7. Radiation-exposed
8. Alcoholic
9. Receiving diuretic treatment
10. Taking hormone alternatives
11. Immunocompromised

Date of first enrolment
06/04/2019

Date of final enrolment
10/06/2019

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Periodontology
Mazzah High Way
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
Alabaramkeh
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Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan
After finishing the follow up procedure and writing the article, I am planning to publish it (with all results, statistical analysis and some photos) in Damascus University's journal, and many other international journals.

Intention to publish date
02/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr.Mhd Aghiad Alhourani (agheadhou@hotmail.com/dr.aghiadalhourani@hotmail.com) or the Higher Education Council at Damascus University by application in person. All photos for all the participants will be available, along with all the data and the statistical analysis after Dr Alhourani has finished follow-up and collected all the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		02/01/2020	02/01/2020	No	Yes
Results article		30/06/2022	01/07/2022	Yes	No