

What do patients think about rhomboid flap scars?

Submission date 05/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The rhomboid flap is a popular reconstructive technique for skin defects. However, no study to date has explored the patient's perceptions of this technique. The aim is to try to answer that question.

Who can participate?

An adult who has undergone rhomboid flap surgery at UPMC Hamot, Erie, PA (USA)

What does the study involve?

Patients complete an outcome questionnaire to record their views about appearance and satisfaction of the scar at one year after the procedure.

What are the possible benefits and risks of participating?

The data will help guide future patients about anticipated scars. No risk of participating. The participation is voluntary.

Where is the study run from?

University of Pittsburgh (USA)

When is the study starting and how long is it expected to run for?

April 2021 to August 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

Public

Contact name

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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

Assessment of rhomboid flap scars: a patient-reported outcome study. A case series

Study objectives

Patients believe that the rhomboid flap scars are well-matched with their skin and are satisfied with the scars.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/04/2021, University of Pittsburgh Institutional Review Board (Human Research Protection Office, 3500 Fifth Avenue, Main Office, Suite 106, Pittsburgh, PA 15213, USA; +1 412 383-1480, askirb@pitt.edu), ref: STUDY21030045

Study design

Retrospective observational case series

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Rhomboid scar quality

Interventions

The researchers studied 100 consecutive rhomboid flaps performed in 73 patients by a single surgeon. After at least 1 year from flap completion, a validated published Patient Scar Assessment Questionnaire (PSAQ) by Durani et al was completed for each of the 100 flaps.

Intervention Type

Procedure/Surgery

Primary outcome measure

Appearance and satisfaction scores of rhomboid scar quality measured using a questionnaire at least one year post procedure

Secondary outcome measures

Demographic information: age, gender, size of scar measured using patient records at least one year post procedure

Overall study start date

02/02/2021

Completion date

01/09/2021

Eligibility

Key inclusion criteria

All consecutive patients 18 years and older who underwent reconstruction of a cutaneous defect using a rhomboid flap between 01/09/2019 and 31/01/2020 by the primary author

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Total final enrolment

73

Key exclusion criteria

1. Rhomboid flap performed in patients aged under 18 years
2. Patients with incomplete data
3. Deceased patients
4. Individuals with non-rhomboid flap method of reconstruction

Date of first enrolment

01/05/2021

Date of final enrolment

21/08/2021

Locations

Countries of recruitment

United States of America

Study participating centre

UPMC Hamot

201 State Street

Erie

United States of America

16507

Sponsor information

Organisation

UPMC Hamot

Sponsor details

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+1 (0)8148776000

bianchilm@upmc.edu

Sponsor type

Hospital/treatment centre

Website

<https://www.upmc.com/locations/hospitals/hamot>

ROR

<https://ror.org/038fqcc39>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in the Annals of Medicine and Surgery

Intention to publish date

01/01/2022

Individual participant data (IPD) sharing plan

Raw data will not be made available due to privacy.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/02/2022	06/01/2023	Yes	No