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Intraoperative detection of c-section scar dehiscence with a light source

Submission date	Recruitment status	[X] Prospectively registered
05/09/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/09/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/11/2024	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
As a result of the rising caesarean rate, uterine scar dehiscence (niche) is getting more prevalent. Depending on the imaging techniques and definitions, it has a prevalence of 19-84%. Many of these patients have a desire for a subsequent pregnancy. In women with a niche, a higher risk of uterus rupture is found during the subsequent pregnancy if the remaining uterus wall is thin (<3mm). Consequently, surgically is recommended to repair the niche before the next pregnancy. The surgery is performed minimally invasive with a conventional laparoscopy or a robot-assisted laparoscopy with for example the DaVinci® robot. For safer surgery and faster scar detection, the Scar-Light-System (SLS) was invented. It is an intra-uterine manipulator with an integrated, scalable light source. In planned future development, the SLS will also be equipped with image processing. The goal is to perform a diaphanoscopy through the defect zone under ambient surgery light conditions for the localisation of the niche, stabilization of the uterus, and to acquire data for developing image processing algorithms.

Who can participate?
Female patients aged between 18 and 50 years old with uterine scar dehiscence (niche) who need a laparoscopic repair (remaining uterine wall <3mm)

What does the study involve?
Patients meeting the inclusion criteria who agree to participate in the clinical investigation must sign the study-specific informed consent form prior to surgery.

The expected duration for light application is 10–30 minutes until the niche is detected. Patients will be recruited from the gynecological outpatient clinic at the Department of Gynecology, University Hospital Zurich. During gynecological consultations, the indication for laparoscopic niche repair will be established. All patients participating in the study will be informed about the risks and benefits of the laparoscopic isthmocele repair, as well as the specific risks, benefits, and mechanisms associated with the SLS manipulator.

Following the surgery, patients will typically stay in the hospital for one or two nights, with a follow-up visit scheduled six weeks postoperatively.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
January 2022 to October 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Cornelia Betschart, cornelia.betschart@usz.ch

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SLS20240901

Study information

Scientific Title
Pilot project of an intra-uterine manipulator with integrated, scalable light source with image processing system for correction of uterine scar dehiscence (niche)

Acronym
SCAR-LIGHT-SYSTEM

Study objectives
The niche/defect zone in the c-section scar can be localized by diaphanoscopy through the scar tissue under ambient surgery light condition. The manipulator further allows the stabilization of the uterus. The SLS acquires data for developing image processing algorithms.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted, Ethics committee of the Canton Zurich (Stampfenbachstrasse 191, Postfach, Zürich, 8091, Switzerland; +41 43 2597970; info.kek@kek.zh.ch)

Study design
Pilot proof-of-concept study

Primary study design
Interventional

Study type(s)
Diagnostic, Safety

Health condition(s) or problem(s) studied
Women with a isthmocele (c-section scar dehiscence)

Interventions
Due to the increasing rates of caesarean sections, there is a growing prevalence of uterine scar dehiscence (niche) and subsequent niche repair. Women with a niche and a thinner remaining uterine wall (<3 mm) face a higher risk of uterine rupture during subsequent pregnancies, prompting a recommendation for surgical niche repair before the next pregnancy. This surgery is minimally invasive and can be performed via conventional laparoscopy or robot-assisted laparoscopy, such as with the DaVinci® robot.

For enhanced safety and more efficient scar detection during surgery, the Scar-Light System (SLS), model v1.0, was developed. The SLS is an intrauterine manipulator equipped with an integrated, scalable light source and an image processing system. It is designed to perform diaphanoscopy through the defect zone under ambient surgical lighting to localize the niche and stabilize the uterus. The device is manufactured by Fachhochschule Nordwestschweiz, Hochschule für Life Sciences, Institut für Medizintechnik und Medizininformatik, Muttenz, Switzerland. It is not yet CE-marked and does not have a registered UDI. Patients meeting the inclusion criteria who agree to participate in the clinical investigation must sign the study-specific informed consent form prior to surgery.

The SLS manipulator comprises two main components: a light rod and an adjustment piece. The light rod extends from the intrauterine illuminating tip to the external handle, and the maximum length of the tip is fixed to prevent rupture or tearing of the uterus. The adjustment piece has a

conical design at its proximal end, which helps secure the device to the cervix, stabilizing it and preventing gas escape from the uterus. The intrauterine fiber optic tip of the SLS shines through the niche, and the defect site is detected as a halo sign under laparoscopic view.

Preclinical safety testing of the SLS included in-vitro experiments on excised uteri at the Institute of Pathology, University Hospital Zurich (USZ), and assessments of biological, mechanical, and electrical safety. The device has a 12-hour battery life, is reusable (autoclave-compatible), features adjustable light intensity, and is constructed from rigid materials for the stabilization and isolation of parauterine tissue, with a maximum temperature increase of less than 4°C in the surrounding tissue. The tip of the device is made of polymethyl methacrylate (PMMA) and is translucent to allow light emission, while the conical adjustment piece stabilizes the manipulator and prevents gas escape.

The expected duration for light application is 10–30 minutes until the niche is detected. Patients will be recruited from the gynecological outpatient clinic at the Department of Gynecology, University Hospital Zurich. During gynecological consultations, the indication for laparoscopic niche repair will be established. All patients participating in the study will be informed about the risks and benefits of the laparoscopic isthmocele repair, as well as the specific risks, benefits, and mechanisms associated with the SLS manipulator.

Following the surgery, patients will typically stay in the hospital for one or two nights, with a follow-up visit scheduled six weeks postoperatively.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
Scar-light-system

Primary outcome(s)
Measured at the time of the procedure:
1. Light detection through the niche (yes/no)
2. Light intensity intraabdominal. The SI unit of light intensity is lumen by steradian (lm/sr) measured as candela (cd) (1 cd = 1 lm/sr)
3. Light intensity through the niche in comparison to the surrounding intraabdominal light intensity (measured in %)

Key secondary outcome(s))
Measured at the time of the procedure, unless noted otherwise:
1. Time for installation of the SLS (min)
2. Surgery time from the start of laparoscopy to detection of the niche (min)
3. Surgery time from detection of the niche to excision (min)
4. Surgery time from excision to the closure of the niche (3-layered suture) - complete surgery time (min)
5. Blood loss during surgery (ml)
6. Thickness of the niche tissue intraoperatively compared with the preoperatively measured sonographic thickness of the residual myometrium over the niche (mm)
7. Perioperative and postoperative complications (Clavien-Dindo classification) at time of

operation and 6 weeks follow up
8. Subjective characteristics such as surgeon satisfaction and difficulty of the procedure measured using a Likert scale after the procedure
9. Safety outcomes measured using patient records

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Female patients with uterine scar dehiscence (niche) who need a laparoscopic repair (remaining uterine wall <3mm)
2. Signed general consent/informed consent
3. Patients ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Key exclusion criteria
1. Missing signed general consent/informed consent
2. Contraindications to general anaesthesia
3. Not knowledgeable in the German language

Date of first enrolment
01/02/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Zurich
Department of Gynecology, Frauenklinikstrasse 10
Zürich
Switzerland
8091

Sponsor information

Organisation
Innosuisse – Swiss Innovation Agency

ROR
https://ror.org/05a2bhn71

Funder(s)

Funder type
Other

Funder Name
Investigator initiatd and funded

Funder Name
Innosuisse - Schweizerische Agentur für Innovationsförderung

Alternative Name(s)
Innosuisse - Swiss Innovation Agency, Innosuisse - Agence suisse pour l’encouragement de l’ innovation, Innosuisse - Agenzia svizzera per la promozione dell’innovazione, Swiss Innovation Agency, Innosuisse, Innosuisse

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Original raw data of the study will be shared with the thesis at the Zurich Open Repository and Archive: https://www.zora.uzh.ch/.

IPD sharing plan summary

Stored in publicly available repository