Intra-operative pelvic vessel and bone acquisition, towards ultrasound registration for surgical navigation

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Primary objective: - To develop an automatic segmentation algorithm using artificial intelligence for real-time intra-operative pelvic vessel segmentationSecondary objectives: - Post-operative evaluating the accuracy of different registration...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49933

Source
ToetsingOnline

Brief title
Vessel- and bone-based Ultrasound Registration

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
Pelvic-abdominal cancer

Health condition

Chirurgische ingrepen: laparotomie en robot geassisteerd lymfeklierdissectie

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Registration, Surgical navigation, Ultrasound, Vessel segmentation

Outcome measures

Primary outcome

The number and quality of ultrasound sweeps for automatic segmentation of the

vessels.

Secondary outcome

Localization of clinical targets with an electromagnetically tracked pointer to

compute a target registration error.

Study description

Background summary

Image-guided navigation surgery allows for full utilization of pre-operative imaging during surgery and has the potential of reducing both irradical resections and morbidity. To use navigation, a registration procedure is required to correlate pre-operative imaging with the patient*s position on the operating room (OR). Currently, registration is done by Cone-Beam CT (CBCT) scanning on the OR prior to navigation surgery. However, the main limitation of the CBCT method is that it cannot compensate for per-operative changes such as bed rotation, retractor placement and tissue displacement due to the surgery. Alternatively, by using intra-operative tracked ultrasound and vessel-based patient registration, changing conditions during surgery can better be dealt with. This improved patient registration method could lead to an increased navigation accuracy and improved clinical usability and outcomes.

The main difference between CBCT and proposed ultrasound registration is that CBCT is based on bones, while the ultrasound is based on vessels. Bones can be very easily imaged on the CBCT and therefore used for bone-bone registration with pre-operative CT-scans. However, vessels are more difficult to acquire,

especially with ultrasound, and an automatic registration process with pre-operative imaging is needed for efficient clinical usability. For this, the vessels need to be extracted from the tracked ultrasound images to create a 3D representation that can be registered. Therefore, an algorithm needs to be developed that can automatically segment the pelvic vessels from ultrasound images.

Study objective

Primary objective:
- To develop an automatic segmentation algorithm using artificial intelligence for real-time intra-operative pelvic vessel segmentation

Secondary objectives:
- Post-operative evaluating the accuracy of different registration methods, such as 3D model or centerline registration
- The usability of the tracked ultrasound setup (SUS-score)

Study design

A single center observational feasibility study.

Study burden and risks

No additional burden or risks are expected apart from to the extended surgery time, approximately 10 minutes, for the included patients. Ultrasound imaging takes place in the same way that conventional intra-operative ultrasound is acquired (for example during liver surgeries), using the same standardized sterile cover or sterilized ultrasound transducer. The electromagnetic tracking system (NDI Aurora) including the tracked pointer is the same system as applied during conventional abdominal navigated surgeries at the NKI-AvL and multiple navigation studies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- >= 18 years old
- Scheduled for laparotomy (first 30 patients) or robotic assisted pelvic lymph node dissection (second 20 patients)
- A pre-operative abdominal CT scan is available
- Patient provides written informed consent

Exclusion criteria

- Metal implants in the pelvic area which could influence the 3D modelling or tracking accuracy
- Patients with a pacemaker or defibrillator
- Patient received pelvic-abdominal treatment, e.g. surgery or radiotherapy, between the pre-operative CT scan and surgery, which might altered the patient*s anatomy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Image-guided navigation setup
Registration:	No

Ethics review

Approved WMO

Date:	02-11-2021
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	17-07-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05637346
CCMO	NL78660.031.21