Computer-assisted intraoperative 3D-navigation for liver surgery: a prospective randomized-controlled pilot study

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Background: Liver surgery is the standard of care for primary and many secondary liver tumors. Due to variability and complexity in liver anatomy preoperative imaging is necessary to determine resectability and for planning the surgical strategy. In the last few years, computer-assisted resection planning has been introduced in liver surgery. Aim of this trial was the evaluation of computer-assisted three-dimensional (3D)-navigation for liver surgery.

Methods: This study was a prospective randomized-controlled pilot trial and patients were randomized in navigated or non-navigated group. Primary end point was the quotient of intraoperative resected volume and planned resection volume. Secondary end points included operation time, resection margin and postoperative complications. 3D reconstructions were performed with MeVis Distant Services (MeVis AG, Bremen, Germany). The navigation system CAS-One Liver (CAScination AG, Bern, Switzerland) was used for intraoperative computer-assisted 3D-navigation.

Results: The data of 16 patients with 20 liver tumors were used in this analysis. Of these, 8 liver tumors were resected with the utilization of intraoperative navigation. Two postoperative complications were classified grade IIIa or higher. There was no difference in duration of operation (189 *vs.* 180 min, P=0.970), rate of postoperative complications (n=1 *vs.* n=1, P=0.696) and length of hospital stay (9 *vs.* 7 days, P=0.368) between the two groups. Minimal resection margin (0.15 *vs.* 0.40 cm, P=0.384) and quotient of planned to intraoperative resection volume (0.94 *vs.* 1.11, P=0.305) were also similar.

Conclusions: Intraoperative navigation is a technology that can be safely used during liver resection. Surgical accuracy is not yet superior to the current standard of intraoperative orientation. Further technological advances with suitable deformation algorithms and augmented reality systems will enable a further improvement of the technical feasibility.

Keywords: Liver surgery; three-dimensional liver reconstruction (3D liver reconstruction); 3D navigation; liver tumors; surgical planning

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Introduction

Today, liver surgery is the standard of care for primary and many secondary malignant liver tumors (1). Complete tumor removal often remains the best treatment option and can offer the chance of cure for the patients (2). However, the anatomy of the liver with its high variability in major blood vessels is very complex. To plan the appropriate surgical strategy and to determine the technical and functional resectability, preoperative imaging modalities such as magnetic resonance imaging (MRI) or computed tomography (CT) scan are necessary.

Usually, sonography—and during open surgery also palpation—are used to identify liver tumors intraoperatively. Furthermore, intraoperative ultrasound helps to identify critical structures in proximity to the tumor during the operation, as harming or rather sealing major blood vessels and/or biliary structures lead to severe complications after surgery. Therefore, computer-assisted resection planning was introduced in liver surgery to improve the identification of the position of the tumor to surrounding major vessels (3). Based on a two-dimensional (2D) MRI or CT scan, a three-dimensional (3D) reconstruction of the liver can be performed. Major vessels and the corresponding parenchyma volume can be highlighted. Furthermore, the planned resection volume can be calculated to avoid postoperative liver failure or small for size syndrome (4). Intraoperative navigation systems have been established in neurosurgery and spine surgery, which consequently led to the development of a soft tissue navigation system for liver surgery. There are different approaches to improve intraoperative orientation in liver surgery. The application of indocyanine green (ICG) with either positive or negative staining supports surgeons during tumor resection (5-7), yet this technology is not based on a preoperative 3D reconstruction of the patient's anatomy. Thus, only allowing indirect feedback to the surgeon. The currently used soft tissue navigation system is based on 3D reconstructions and is intraoperatively registered and aligned with the actual organ (8). In the literature, evidence for the use of this type navigated liver surgery is scarce and there are only few case series regarding navigation systems in liver surgery so far. These previous studies on the used soft tissue navigation system describe the first implementation of the system, the definition of use cases and focus on registration methods and accuracy (8-12).

Aim of this study was to evaluate the feasibility and safety of computer-assisted 3D-navigation for liver resection in a prospective randomized-controlled pilot study. We present this article in accordance with the CONSORT reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-5489/rc).

Methods

Study eligibility

Patients scheduled for elective primary laparoscopic or open liver resections were eligible, while re-operations were excluded from the study due to the increased probability of conversion in the laparoscopic group and the potentially impaired anatomical orientation. All tumor entities were eligible for this study, and patients were allowed to have one to a maximum of four primary or secondary malignant tumors with no extrahepatic disease. Since intrahepatic navigation was considered less helpful in anatomical resections, only non-anatomic liver resections of segments 2–6 were included. Tumors in segments 7 and 8 were excluded from the study as large manipulation of the liver distracts the accuracy of the intraoperative navigation. Surgery was always performed by one of two experienced hepatobiliary surgeons (HL and SH). Both surgeons have had experience with the navigation system and the system was available in the department prior to the study.

Study design

This study was a single-center randomized-controlled pilot


Highlight box

Key findings
- Intraoperative navigation is a technology that can be safely used during liver resection.

What is known and what is new?
- Soft tissue navigation systems have been developed for liver surgery.
- Previous analyses have shown feasibility of soft tissue navigation in liver tumor ablation.
- This is the first prospective randomized trial on soft tissue 3D navigation in liver surgery.

What is the implication, and what should change now?
- Surgical accuracy is not yet superior to the current standard of intraoperative orientation.
- Further technological advances with suitable deformation algorithms and augmented reality systems will enable a further improvement of the technical feasibility. Report here about implications and actions needed.
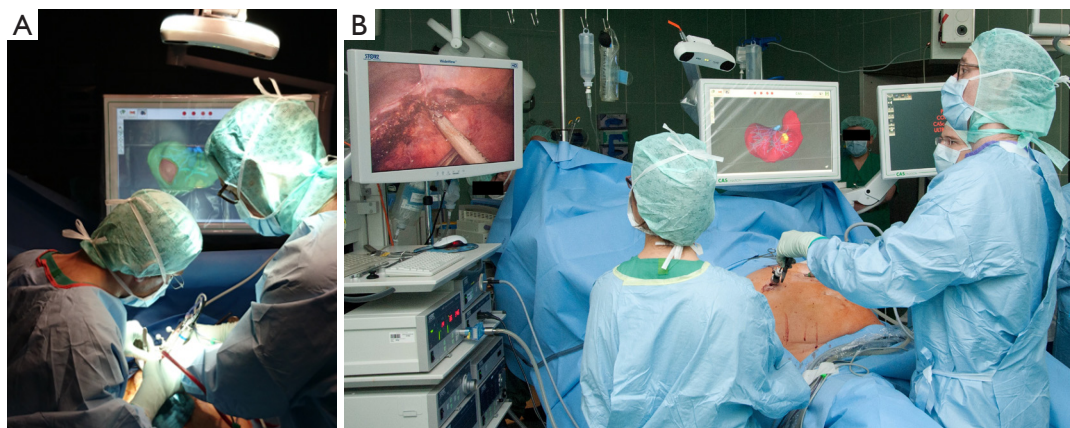
Figure 1 Technical setup of the navigation system during open (A) and laparoscopic (B) liver resection.
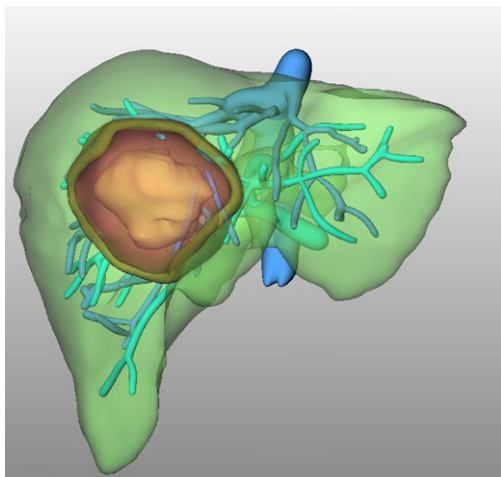
Figure 2 A snapshot of the preoperative resection planning of a colorectal liver metastasis in segment 5 (green: liver parenchyma; yellow: metastases; brown: planned resection volume).

trial. It was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was reviewed and approved by the local ethics committee (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz, ethics board No. 837.477.15). Written informed consent was obtained from all individual participants before inclusion into the study.

After patient stratification for laparoscopic and open technique, liver resections were randomized to either the navigated or non-navigated group using a closed envelope system. Consequently, a patient with more than one liver tumor could have been randomized to a non-navigated resection of one, and a navigated resection of another lesion (*Figure 1*).

Technical aspects

The preoperative CT or MRI-scans were segmented to result in a 3D data set. The 3D-reconstructions were performed by MeVis Distant Services (MeVis AG, Bremen, Germany) (*Figure 2*). The resection volume was also planned by the external provider with safety margins based on the tumor volume with voxel-based calculation of 10mm to all sides. The navigation system CAS-One Liver (CAScination AG, Bern, Switzerland) (8) was used for intraoperative computer-assisted 3D-navigation. The System works with optical tracking of three markers placed on the surgical instrument. A defined distance to the tip of the instrument then allows the synchronization with the preoperative 3D reconstruction of the liver.

For this study, parenchyma dissection was always performed by a Cavitron Ultrasound Surgical Aspirator (CUSA), on which the markers were placed (*Figure 3*). The intraoperative synchronization of 3D CT-reconstruction was performed with so-called 4-point landmark registration on the liver surface for calibration in both laparoscopic and open cases. The registration process is conducted by choosing 4-point on the surface of the liver. Registration was performed for each tumor in cases with multiple lesions. Virtual and real CUSA are then aligned and registered by the infrared camera. The calibration is then checked for accuracy bevor proceeding. Misregistration sometimes occurs and can then be easily repeated.

The surgeon was able to use the real-time 2D-image (laparoscopy) as well as the reconstructions of the preoperative imaging for intrahepatic orientation. While the CUSA was visible on the 2D-screen, the virtual CUSA was projected in real-time into the 3D-reconstruction as well.
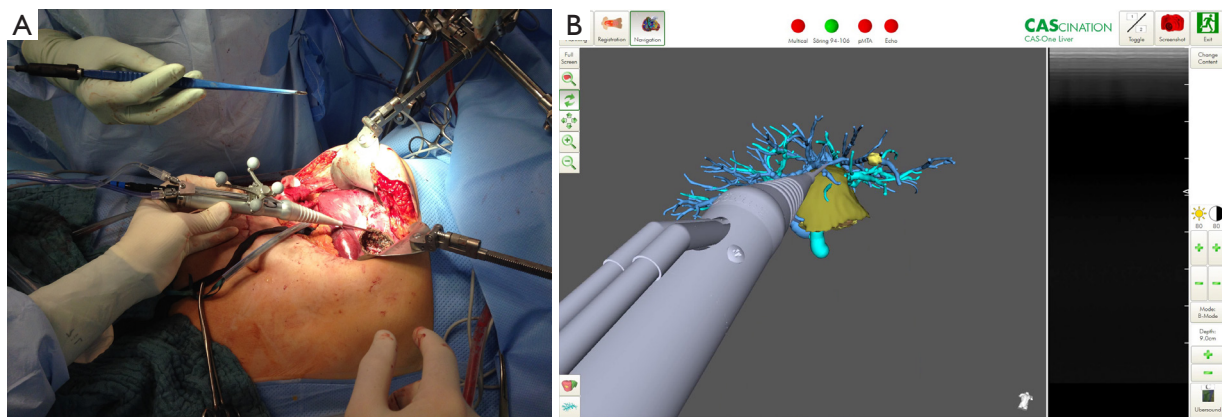
Figure 3 Close up view of the CUSA system: real (A) and virtual (B). CUSA, Cavitron Ultrasound Surgical Aspirator.

During open resection, additional intraoperative orientation was possible using the screen with the 3D-reconstruction with the projected CUSA.

Intraoperative volumetry of the resected tissue was performed by measuring the water displacement in a calibrated vessel by the specimen according to Archimedes' principle.

Study endpoints

The primary end point was the ratio of the planned and real resection volumes. The resection volumes and the calculated quotient were chosen as a surrogate for the accuracy of staying with a preoperative plan as intraoperative navigation should allow the surgical team to have better intraoperative orientation. The surgical team was blinded for the preoperative volumetric estimations. Secondary end points included the operation time, extent of resection margin (in cm) and postoperative morbidity.

The postoperative surgical complications were graded according to the Dindo-Clavien classification, with only grade $\geq$ III being included (13). The size of the resection margin was identified from the final pathology results. Patients' characteristics, as well as intraoperative data, and postoperative outcome were analyzed. We also assessed the surgeons personal rating and the accuracy of the intraoperative navigation as well as the accuracy of preoperative reconstruction on a non-validated 5-point-Likert scale.

Statistical analysis

Since this was a pilot study, and solid clinical data on navigated liver resection were not available when this study was designed, we did not perform a proper sample size calculation, but decided to include 20 resections into this study.

Categorical variables were presented as numbers and percentages, whereas continuous variables were expressed as median/range. Continuous variables were compared by Mann-Whitney U test and categorical variables were compared by χ^2 test. P values <0.05 were considered significant. SPSS version 26 (IBM Corporation, Armonk, NY, USA) was used for statistical analysis.

Results

We included 18 patients in this study, of which two dropped out due to a change in the treatment plan after randomization. Of these, four patients had two colorectal liver metastases each. Consequently, 20 liver resections in 16 patients were included into this analysis. Patients' characteristics and intraoperative data are summarized in *Table 1*. The most common indication for liver resection were colorectal liver metastases (CRLMs), followed by hepatocellular carcinoma. Laparoscopic resections were performed in 40% (8/20) of the resections. Ten resections were randomized into the navigated group, but two patients crossed over to the non-navigated group due to technical errors. Thus, 8 liver tumors were resected with the utilization of intraoperative navigation (*Figure 4*).

In the entire study cohort, we did not observe any intraoperative complications. The median duration of surgery was 185 (range, 103–288) min. Postoperative complications $\geq$ °III occurred in two patients (one wound infection requiring vacuum therapy and one bowel

Table 1 Patients' and operative characteristics

Characteristics	Value
Total number of patients	16
Age (years)	70 [55–80]
Cirrhosis	1 (6.25)
Gender (male/female)	12/4
Tumor entity	
CRLM	11 (68.75)
HCC	3 (18.75)
CCC	1 (6.25)
FNH	1 (6.25)
Laparoscopic/open	8 (40.00)/12 (60.00)
Length of hospital stay (days)	8 [6–40]
Dindo-Clavien	
Grade IIIa	1 (6.25)
Grade IIIb	0 (0.00)
Grade IVa	1 (6.25)
Grade IVb	0 (0.00)
Grade V	0 (0.00)
Total number of liver tumors	20
Type of operation	
Segment 2	1 (5.00)
Segment 3	9 (45.00)
Segment 4	6 (30.00)
Segment 5	2 (10.00)
Segment 4/5	2 (10.00)
Navigated/not navigated	8 (40.00)/12 (60.00)
Minimal resection margin (cm)	0.15 [0.1–1.0]
Planned resection volume MeVis (mL)	33 [14–199]
Intraoperative resection volume (mL)	35.5 [9–221]

Data are presented as median [range] or n (%) or n. CRLM, colorectal liver metastases; HCC, hepatocellular carcinoma; CCC, cholangiocellular carcinoma; FNH, focal nodular hyperplasia.

perforation). The median postoperative hospital stay was 8 (range, 6–40) days and the 90-day mortality was 0%. In the entire study cohort, the mean planned resection volume was 61.5 (range, 14–199) mL and the mean intraoperative resection volume was 66.9 (range, 9–221) mL (P=0.799). The overall ratio of planned to real resection volume was 1.26. The median minimal resection margin was 0.15 cm and R0-resection was achieved in 100% of the cases.

Regarding the analysis of navigated and non-navigated resections the ratio of the planned and intraoperative resection volumes of did not differ (0.94 vs. 1.11, P=0.305). Furthermore, we did not find any differences between both groups regarding duration of surgery, morbidity nor length of hospital stay. Furthermore, we did not observe differences regarding the minimal resection margins nor R0 resections (Table 2).

Subgroup analysis of laparoscopic and open resections did not reveal any differences between these subgroups regarding general and intraoperative parameters (Table 3).
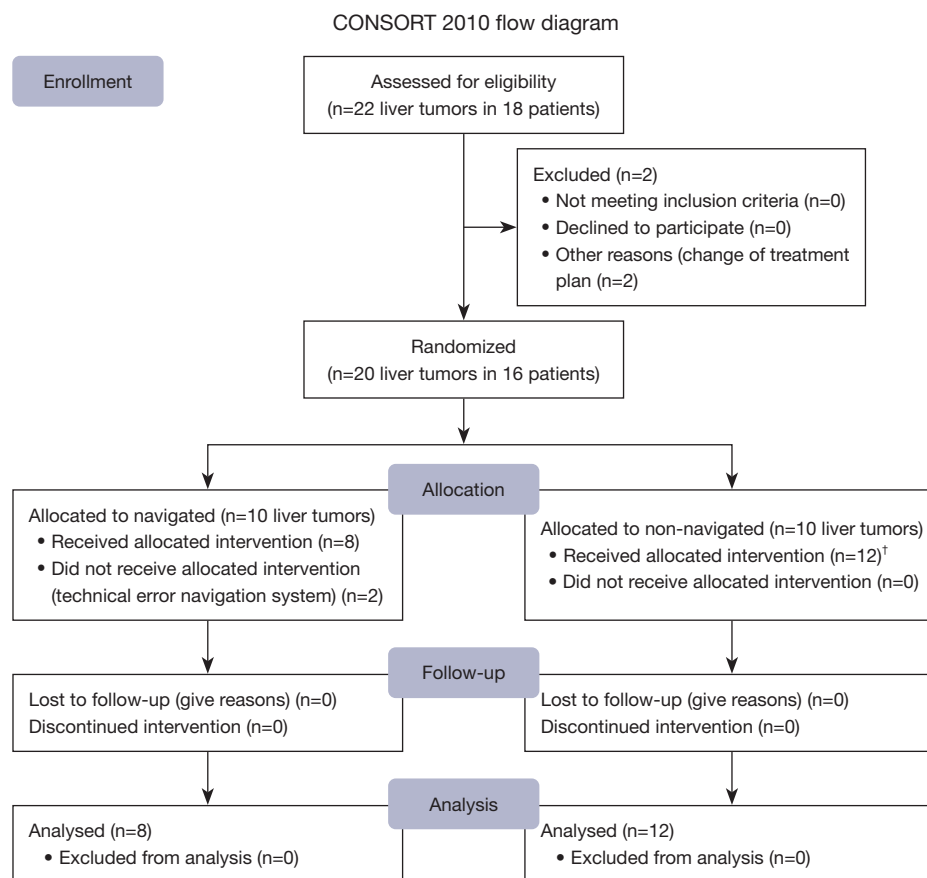
Immediate non-validated surgeons rating of the soft tissue navigation revealed that it was a "nice amendment" in 7 out of 8 cases. In one case, the navigation was categorized as not useful due to repeated registration errors. The accuracy of the preoperative 3D-reconstruction was rated high in all cases (n=8), while the accuracy of the soft tissue navigation was rated good (n=3), medium (n=4) and poor in 1 case.

Discussion

Minimal-invasive approaches are increasingly used in liver surgery adopted. One of the major drawback of minimal-invasive liver surgery compared to open surgery is the lack of tactile orientation. Intraoperative soft tissue navigation might overcome this disadvantage since ideally the tip of the dissection device is continuously tracked by the system and projected in the 3D-reconstruction. Consequently, a predefined safety margin may be achieved and critical situations avoided by this technique. However, solid data on the feasibility and safety of this technology are lacking for liver surgery. Intraoperative navigation should allow the surgical team to have better intraoperative orientation that can thus stay closer to a preoperative surgical plan. Therefore, resection volume was chosen as primary endpoint as a surrogate parameter.

In this study, we did not observe significant morbidity, and the primary and secondary endpoints did not differ between navigated and non-navigated resections. The current study confirms the feasibility of the intraoperative soft tissue navigation.

Banz et al. (10) postulated a time delay of 5–10 min, which would be clearly acceptable for a beneficial technology. In our study, however, the duration of surgery did not differ between navigated and non-navigated

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CONSORT 2010 flow diagram

Enrollment

Assessed for eligibility
(n=22 liver tumors in 18 patients)

Excluded (n=2)
• Not meeting inclusion criteria (n=0)
• Declined to participate (n=0)
• Other reasons (change of treatment plan (n=2)

Randomized
(n=20 liver tumors in 16 patients)

Allocation

Allocated to navigated (n=10 liver tumors)
• Received allocated intervention (n=8)
• Did not receive allocated intervention (technical error navigation system) (n=2)

Allocated to non-navigated (n=10 liver tumors)
• Received allocated intervention (n=12)[†]
• Did not receive allocated intervention (n=0)

Follow-up

Lost to follow-up (give reasons) (n=0)
Discontinued intervention (n=0)

Lost to follow-up (give reasons) (n=0)
Discontinued intervention (n=0)

Analysis

Analysed (n=8)
• Excluded from analysis (n=0)

Analysed (n=12)
• Excluded from analysis (n=0)

Figure 4 CONSORT flow diagram. [†], two from navigated group crossed to non-navigated group.

Table 2 Results of primary and secondary end points

Parameters	Navigated (n=8)	Non-navigated (n=12)	P value
Ratio of planned and intraoperative resection volume, median [range]	0.94 [0.44–2.10]	1.11 [0.29–3.00]	0.305
Duration of operation (min), median [range]	190 [103–267]	185 [103–288]	0.970
Postoperative complications, n	1	1	0.696
Length of hospital stay (days), median [range]	9 [7–13]	7 [6–40]	0.368
Minimal resection margin (mm), median [range]	15 [1–70]	4 [1–10]	0.384
R0 resection, n	8	12	–

resections in our study. The lack of differences in operative times may be real, but may also be due to the sample size of our study cohort, as the extent and techniques of liver resections varied widely from patient to patient.

We did not observe differences in morbidity or postoperative length of stay. Considering the potential beneficial impact of 3D-navigation on the surgical planning and intraoperative orientation, an increase in morbidity would have been a major surprise to us, and indeed we did not experience postoperative complications in minor liver resections.

The intraoperative 3D-navigation did not impact on the surgical plan in the current setup. This may be due to the fact, that the resections were minor liver resections in anterior segments due to technical reasons of the navigation system, as these resections are considered "laparoscopic

Table 3 Subgroup analysis of laparoscopic and open resections

Parameters	Laparoscopic (n=8)	Open (n=12)	P value
Planned resection volume (mL), median	40.0	25.5	0.068
Intraoperative resection volume (mL), median	32.5	39.0	0.361
Ratio of planned and intraoperative resection volume, median	1.11	0.93	0.361
Minimal resection margin (mm), median	2.0	1.5	1.000
Postoperative complications, n			0.530
Grade 0	6	5	
Grade I	0	0	
Grade II	1	2	
Grade IIIa	0	1	
Grade IIIb	0	0	
Grade IVa	0	1	

segments" according to IWATE criteria (14).

This was a pilot study with a technology that is Food and Drug Administration (FDA)- and European Conformity (CE)-approved. We were able to show, that the technology can be safely performed in open and laparoscopic cases, yet the additional value in a controlled setting with two highly experienced hepato-pancreato-biliary (HPB) surgeons was limited. The intraoperative soft tissue navigation during open and laparoscopic liver resection in its current form, however, has limitations which is the reason, why the technology has not been established as a standard procedure, yet (15). Thus, the costs of the navigation system may not be amortised by advantages in its everyday clinical use at the moment. Impact of soft tissue navigation systems on learning curves and educational values especially with an increased use of robotic technologies are part of future investigations. Especially, since the robotic consoles enable a multimodal display during liver surgery (16). Since the calibration of the CUSA is mainly performed on the liver surface, the projection into the 3D-reconstructions best works on the liver surface and in the anterior parts of the resection. In our experience, the accuracy of the projection in the 3D-reconstructions decreases deeper in the liver parenchyma, mainly due to the elasticity of the liver and the movements during parenchymal transection which can currently not be resembled by soft tissue navigation systems. Later research tried to support the soft tissue navigation by the placement of fiducials in a preclinical porcine model, yet the placement around the tumor in healthy tissue can be hazardous as well (17).

A promising technology seems to be real-time-virtual sonography, which aligns CT datasets and intraoperative sonography (18). Maybe a combination of technologies will enable innovative advances in the future.

The challenge will be to develop navigation systems that are able to measure the deformation and movement of the liver and to adapt the preoperative 3D-dataset to the intraoperative situation. This highly challenging task may be accomplished by including artificial intelligence algorithms to predict the intraparenchymal movements and also further improving computing capabilities to enable real-time calculation of liver deformation algorithms in the future. Such an improvement may offer great benefits for the intraoperative orientation during laparoscopic and robotic liver surgery and might then allow fusion of the real-time data with the preoperative imaging.

Conclusions

Intraoperative navigation is a technology that can be safely used during liver resection. In its current form, the use is limited. Further technological advances with suitable deformation algorithms and augmented reality systems may enable a further improvement of the technical feasibility.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-5489/rc

Trial Protocol: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-5489/tp

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-5489/dss

Peer Review File: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-5489/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-5489/coif). SW is the co-founder of CAScination AG Bern, the manufacturer of the device under investigation. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was reviewed and approved by the local ethics committee (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz, Ethics board No. 837.477.15). Written informed consent was obtained from all individual participants before inclusion into the study.

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