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Prospective study on image-guided navigation surgery for pelvic malignancies

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Background and objectives: Surgery of advanced tumors and lymph nodes in the pelvis can be challenging due to the narrow pelvic space and vital surrounding structures. This study explores the application of a novel electromagnetic navigation system to guide pelvic surgery.

Methods: This was a prospective study on surgery for malignancies in the pelvis. Preoperatively obtained imaging was used to create a patient-specific three-dimensional (3D) roadmap. In the operating room, the 3D roadmap was registered to an intraoperative computed tomography scan. A tracked pointer was used during surgery for guidance. Primary endpoint was safety and feasibility, secondary endpoints were accuracy and usability.

Results: Twenty-eight colorectal, four liposarcomas, and one gynecological patient were included. There were no safety issues. Navigation was feasible in 31 patients. The mean target registration errors of 4.0 and 6.3 mm were achieved for straight and French position, respectively. In seven of seven patients with a locally advanced rectal tumor and in seven of eight patients with recurrences, negative margins were achieved. Thirty-three of 36 target lymph nodes were successfully removed. Surgeons using the system indicated faster localization of the tumor and improved decisiveness.

Conclusion: This novel surgical navigation system was safe and feasible during pelvic surgery and can facilitate its users.

KEYWORDS
electromagnetic tracking, locally advanced rectal cancer, pelvic recurrences, surgical navigation

1 | INTRODUCTION

Pelvic surgery can be challenging due to the narrow pelvic space and the presence of surrounding organs, nerve bundles, and blood vessels. High-resolution anatomical imaging, such as computed tomography (CT) and magnetic resonance imaging (MRI), plays an important role in staging and assessment of operability of pelvic malignancies. Surgeons use available imaging preoperatively to plan the procedure but rarely during the actual surgical procedure.

Surgeons prepare for surgery by evaluating available imaging and creating a three-dimensional (3D) surgical roadmap in their minds. It is difficult to correlate this imaginary 3D map to the actual surgical procedure. Navigation technology can link preoperative anatomical information to the actual anatomical information of the patient during surgery. This is a daily clinical routine in a variety of fields, such as neurosurgery and facial surgery, cochlear implantation, and orthopedic

Nijkamp and Kuhlmann are co-first authors.

FIGURE 1 Specifically designed mattress in which the TTFG can be embedded. The back of the patient is positioned 12 cm above the TTFG to overcome the measurement gap. TTFG, tabletop field generator [Color figure can be viewed at wileyonlinelibrary.com]

oncology.[1-5] These have in common that the target area is relatively rigid due to surrounding bony structures. Part of the pelvic structures, such as pelvic muscles, sacral nerves, ureters, and iliac vessels are also reasonably rigid with respect to the pelvic bony structures. This is also the case for locally advanced primary or recurrent rectal and retroperitoneal tumors, and for lateral pathologic lymph nodes along the large vessels. The use of navigation systems might improve anatomical insight during surgery for these indications.[6]

For complete lateral lymph node dissection or removal of the single malignant nodes,[7] navigation technology could be helpful in localizing the suspect lymph nodes and decreasing operating time, minimizing the extent of dissection of the pelvic sidewall, and preventing damage to vital surrounding structures.[8,9] Similar advantages can be seen in recurrences of retroperitoneal sarcomas, which are usually not as prominent as the primary tumors and are hidden in changed anatomical locations due to previous extensive surgery.

The aim of this prospective study was to evaluate the safety and feasibility of a novel electromagnetic (EM) surgical navigation system during pelvic surgery. The usability and potential added value for future clinical application were investigated using questionnaires. The technique of this system, the improvements which were made, and the clinical results are described.

2 | MATERIALS AND METHODS

2.1 | Patients and setting

This was a prospective feasibility study of patients with pelvic malignancies conducted at The Netherlands Cancer Institute. Patients of 18 years and older, who were scheduled for open pelvic surgery were eligible. Patients had to have at least one rigid tumor target, for example pathologic lymph nodes, a locally advanced primary tumor or pelvic recurrence. Rigidity was assessed based on tumor location and extent of local invasion. In case of doubt, all available diagnostic imaging information (CT, MR, and PET) was registered based on bony anatomy and tumor displacements between scans were visually evaluated to be less than 5 mm. Patients were excluded for navigation if there was a contraindication for intravenous contrast, or if they had metal pelvic implants negatively influencing the quality of preoperative pelvic imaging. The trial protocol was approved by the institutional review board in May 2014, and informed consent was obtained of all patients. The study was

conducted in accordance with the Helsinki Declaration of 1983. The trial is registered at www.trialregister.nl under number NTR 7184.

2.2 | Navigation system

For navigation during surgery, a tracking system is needed to link the preoperative anatomical data to the patient setup and surgical tools in the operation room (OR). The used tracking system is an NDI Aurora V2 electromagnetic system (Northern Digital Inc, Waterloo, Ontario, Canada) . The system uses a tabletop field generator (TTFG) to generate an oval EM field of $42 \times 60 \times 60$ cm in which patient trackers can be localized with an accuracy of 1 mm and 1 degree.[10,11] No tracking information can be provided in the first 12 cm from the field generator. Therefore, a specific mattress was designed such that the patients back is 12 cm above the TTFG (Figure 1).

In the in-house developed navigation software (Figure 2), available imaging (CT, PET, or MRI) was loaded and automatically registered based on bony anatomy. Imaging was visualized in three orthogonal views and segmentation of the most important structures (blood vessels, ureters, and tumor) were shown as a 3D model.

To assess the patient's position during surgery, three patient trackers (Philips Traxtal/Percunav, Philips, Best, The Netherlands) with EM sensors were used. Two EM sensors were embedded in each tracker, which were taped to the skin of the patient surrounding the surgical target, at the level of bony surface landmarks such as the iliac crest or lumbosacral vertebra. The patient trackers had to be imaged on one of the loaded CT scans to assess the tracker positions with respect to the segmented structures. To enable navigation, the positions of the trackers were measured with the tracking system and linked to the positions as derived from the CT scan. An EM-tracked sterile pointer (NDI) was used to navigate through the anatomy of the patient. As soon as the pointer entered the EM field, the actual location and orientation of the pointer was with respect to the 3D model was visualized on a computer screen (Figure 2). An example video on what is seen by the surgeon during navigation is shown in Supporting Information 1.

2.3 | Initial workflow without intraoperative imaging

Patients underwent a diagnostic CT scan ($0.8 \times 0.8 \times 1.0$ mm voxels) 1 day before surgery. At the scanner, the three patient trackers were
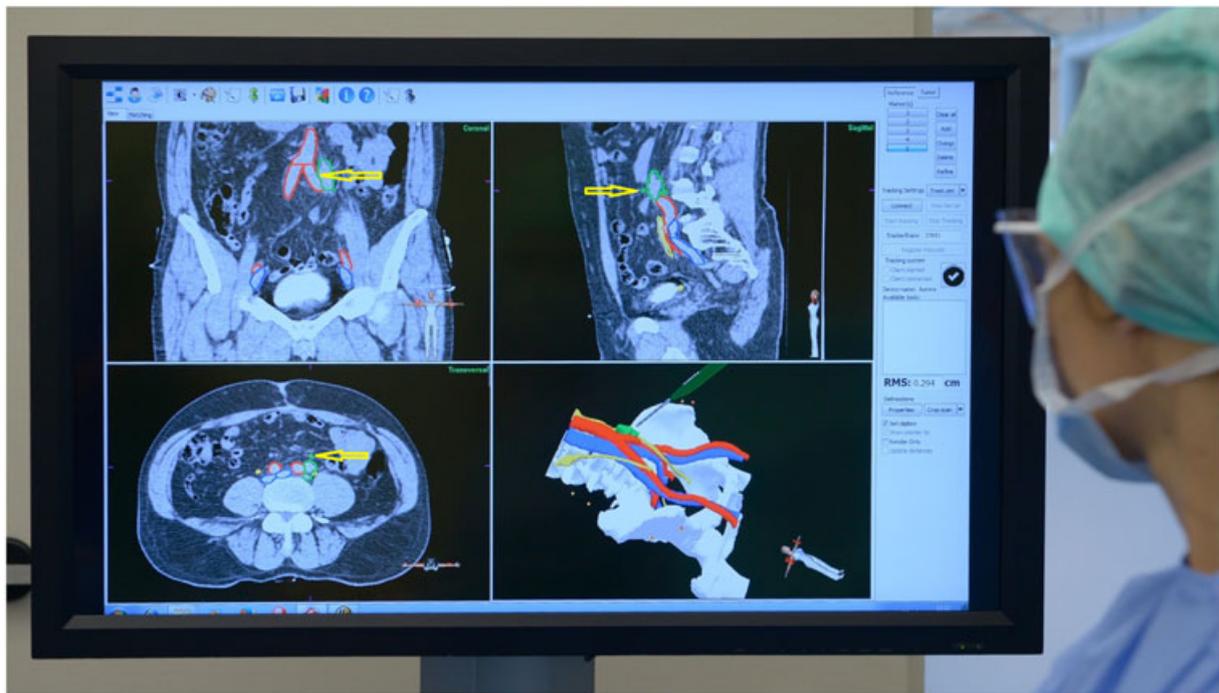
FIGURE 2   Picture of the surgical navigation user interface as it was provided to the surgeons. The planning CT scan is shown in the 3 orthogonal views, including the segmentations. In the lower-right corner a 3D render of the segmentations is shown. The slice of the CT scans in the orthogonal views is automatically selected based on the location of the surgical pointer (highlighted with the yellow arrows. A digital 3D render of the pointer is also shown in the 3D render. In this case a lymph node at the left iliac communal artery was the target (lime color). 3D, three-dimensional; CT, computed tomography [Color figure can be viewed at wileyonlinelibrary.com]

placed on the skin of the patient. One on the back in the lumbar curvature, and two on the left and right anterior superior iliac spine (Figure 3). The outlines of the trackers were marked using a semipermanent skin marker. Two supine intravenous contrast-enhanced CT scans were acquired, one in the arterial phase and one after 5 minutes for the ureters.

In-house developed segmentation software was used to outline the pelvic bones, arteries, veins, and ureters on the contrast-enhanced CT scans. The pelvic bones were segmented automatically using a threshold method to only outline the dense material in the scan. The arteries were segmented using a region growing algorithm on the arterial phase scan. All other structures were segmented manually. For tumor and pathologic lymph node segmentation, all present preoperative imaging information (PET and MR) were rigidly registered to the bony anatomy of the arterial phase CT scan. In case of doubt, a radiologist was consulted. All segmentations were evaluated before surgery by the responsible surgeon. Finally, the positions of the six EM trackers were automatically determined on the CT scan.

In the OR, the patient trackers were reapplied using the marked outlines. The patient was positioned in the desired surgical setup under anesthesia. From the start of surgery, the surgeon was able to use the pointer to assess the position of the surgical plane with respect to anatomical structures.

2.4 | Workflow with intraoperative imaging

In December 2015, a C-arm cone-beam CT (CBCT) system (Philips Allura FD20 XperCT; Philips) became available in the OR (axial field of view of $25 \times 25 \times 20$ cm, isotropic voxels of 0.66 mm). With the CBCT, the position of the patient trackers with respect to the 3D model could be assessed in the OR just before surgery. This was assumed to be much more accurate compared with the initial workflow. To confine the patient trackers within the smaller field of view of the CBCT, two trackers were positioned on the back of the patient in the lumbar curvature left and right of the spine, and the third tracker was placed at the pubic bone (Figure 2). The CBCT was acquired after surgical positioning. The CBCT was registered to the preoperative CT based on the bony anatomy and the patient tracker positions were automatically derived from the CBCT.

2.5 | Study endpoints and statistical analysis

The primary endpoints of this study were safety and feasibility. The number of procedures in which the system failed, the number of adverse events caused by the use of the system, and the amount of extra time needed to use the system were evaluated.

The secondary endpoints were the accuracy and usability of the system. The accuracy was evaluated in three ways. First, the

FIGURE 3 Top: Patient tracker positions in the initial workflow, with trackers on the left anterior iliac spine (left), the lumbar curvature (middle), and right anterior iliac spine (right); Bottom: Patient trackers in the workflow with intraoperative imaging, with two trackers in the lumbar curvature (left) and one at the pubic bone (right) [Color figure can be viewed at wileyonlinelibrary.com]

registration error of the patient trackers was evaluated by calculating the residual distances between the tracker positions as derived from the (CB)CT scan to the tracked positions after registration (tracker registration error). The tracker registration error was summarized per patient by quadratic calculating the average residual distance over the six residual distances (taking the root of the mean of the squares of the six distances). This accuracy is indicative for how reproducible the trackers can be applied to the skin of the patient. Second, the accuracy of the navigation system was tested by localizing easily recognizable abdominal landmarks during surgery. The surgeons were asked to point at the aorta and common iliac artery bifurcations while being blinded from the navigation system. The actual distance of the pointer tip to the bifurcations within the navigation system was assessed as the target registration error. Third, the surgeon was asked to localize the ureters using the navigation system. If needed for the operation, the ureter position was confirmed by opening the retroperitoneal space. If this was not part of the operation, the surgeons visually assessed if the location was correct within a range of 5 mm.

The usability of the navigation system was assessed retrospectively using a questionnaire. The questionnaire contained the Dutch translation of the System Usability Scale (SUS).[12] The SUS questionnaire returns a score ranging from 0 (*highly unusable*) to 100 (*highly usable*) of which a mean SUS score above 70 was considered having a high chance on acceptance by users.[13] Surgeons were also asked to compare the conventional setting to the innovative setting on effectiveness (survival, complications, and resection margins), efficiency (total surgery time and duration of tumor localization), and decisiveness on a 5-point Likert scale (1 to 5). A score above three is a score in favor of the innovative setting.

The surgical results from pathological evaluation were also reported. For lymph nodes, the percentage of removed predefined target nodes was evaluated. For the primary tumors and local recurrences the resection margins were evaluated.

As this study was concerning novel developing technology, no formal inclusion target or power calculation was performed. The accuracy measurements were compared between patients operated with and without intraoperative imaging using a nonpaired t test. This was also done for the accuracy of straight vs French position during surgery. Outcomes were analyzed with SPSS (IBM Corp, Armonk, NY).

3 | RESULTS

Between May 2014 and December 2016, 33 patients were included. Twenty-eight patients had a colorectal tumor, four a sarcoma, and one a gynecological tumor (Table 1).

3.1 | Safety and feasibility

In 31 patients (94%) the navigation system could be used during surgery. One patient developed a transient ischemic attack during the night before surgery. Surgery for this patient was delayed by 5 months and the patient was excluded from further analysis. For a second patient, navigation could not be used as the positioning in the OR resulted in having the trackers outside the field of view of the tracking system.

The time needed to segment the target volumes and normal structures were highly dependent on the experience of the observer and the complexity of the case and took between 1 and 3 hours. In the OR, application of the trackers and positioning of the patient added approximately 10 minutes to the total procedure time. For the use of intraoperative imaging, additional time was needed to position the scanner, perform a prerotation to assess possible collisions and for the acquisition itself. Initially, this process added 10 to 20 minutes

TABLE 1 Efficacy for tumor targeting

	Number of patients	Number of patients with tumor-free resection margins
Locally advanced primaryrectal tumors		
cT3N0 MRF+	1	1*
cT3N2 MRF+	4	4
cT4N1 MRF+	2	2
Recurrent tumor location (primary tumor)		
S2/S3 (sigmoid)	2	2
Between external and internal iliac artery (rectum)	1	1
Between external and internal iliac artery (liposarcoma)	4	4
Anterior side of pubic bone (vulva)	1	0
Lymph nodes	Number of nodes	Number of nodes found
Para-aortic	4	4
Common iliac artery	10	10
Internal iliac artery	4	4
External iliac artery	9	9
Obturator	7	4
Presacral	1	1
Adductor muscle/ obturator nerve	1	1

Abbreviation: MRF+, the distance between the tumor and mesorectal fascia (<1 mm).

*In one patient, the resection margin was less than 1 mm, but no ink on tumor.

of OR time, but towards the end of the study, scans were consistently performed within 8 minutes.

In one patient with a gynecological tumor in the initial workflow, inaccuracy of the navigation system (over 1 cm tracker registration error) was caused by a difference in leg position between the planning CT (straight legs) and the OR setup (French position). This setup difference highly affected the position and shape of the iliopsoas muscles and made it impossible to localize a lymph node in between the iliopsoas muscles. After manual calibration of the navigation system, the lymph node was successfully localized. In none of the other cases, adverse events were identified which could be attributed to the use of the navigation system.

3.2 | Accuracy of the system

Before the use of intraoperative imaging (n = 16), an average tracker registration error of 8.5 mm for straight setup and 9.8 mm for French positioning was found (Table 2). With intraoperative imaging (n = 17) the tracker registration error significantly improved to 4 mm (P = 0.02) for both setups.

Before the use of intraoperative imaging, an average target registration error of 8.8 mm for the straight setup, and 13.7 mm for French positioning (P = 0.12) was observed. With intraoperative

TABLE 2 Tracker registration error and the target registration errors of the bifurcations of the aorta and common iliac arteries for the different surgical setups and the use of the intraoperative imaging

	Number of patients	Tracker registration error (range, mm)	Target registration error (range, mm)
Straight setup			
No CBCT	4	8.5 (3.1-12.5)	8.8 (5.2-16.6)
With CBCT	7	3.6 (2.8-4.8)	4.0 (1.0-6.3)
P value		0.02	0.057
French position			
No CBCT	12	9.8 (3.3-16.8)	13.7 (1.1-26.3)
With CBCT	10	3.8 (0.2-7.7)	6.3 (0.1-12.0)
P value		0.02	0.005

imaging, the localization of internal targets improved to 4.0 mm for straight setup (P = 0.057) and 6.3 mm for French positioning (P = 0.005).

The ureters were localized at the position where it crossed the common iliac artery using the navigation system. They were localized successfully in all applicable patients (n = 23) within 5 minutes.

3.3 | Pathological evaluation

Navigation was used in seven cases to localize the borders of a locally advanced primary rectal tumor. Based on preoperative MR imaging the mesorectal fascia was threatened in all these patients. In none of the specimen tumor was found at the border, however, in one case the margin was less than 1 mm (Table 1).

Navigation was used in eight cases for localization of a local recurrence. The primary tumors of the recurrences are listed in Table 1, and examples are shown in Figures 4 and 5. In all patients, except the patient with a vulva tumor recurrence, resection margins were negative at pathology. The vulva tumor recurrence was invading the pubic bone, and despite the removal of part of the pubic bone, there was still a positive resection margin. This patient was treated with adjuvant radiotherapy.

In 20 patients a total of 36 pathologic lymph nodes were identified on the preoperative CT. The lymph nodes were mainly localized in the iliac and obturator region (Table 1). All nodes were removed by lymph node picking, no lymph node dissections were performed. Based on pathology and follow-up imaging, 33 of the 36 lymph nodes were successfully removed. The three missed lymph nodes were located in the obturator region of three different patients. In all three cases, the indication for lymph node removal was determined before neoadjuvant chemoradiotherapy (CRT). The planning CT acquired the day before surgery showed these lymph nodes were regressed to a size of less than 3, 3, and 5 mm.

3.4 | Usability of the navigation system

Thirteen individual surgeons were actively involved in the surgery of these 33 patients, of which 12 completed the questionnaire. Two of
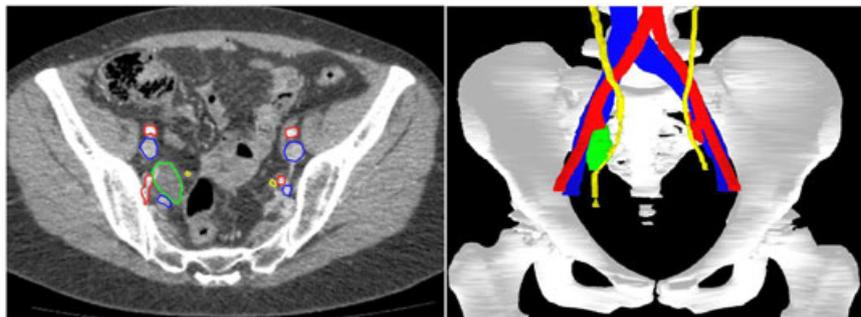
FIGURE 4 Clinical case of a recurrent liposarcoma at the right internal iliac artery and vein. On the left a CT slice is shown with the tumor (green), ureters (yellow), arteries (red), and veins (blue) highlighted. On the right image a 3D render of the anatomy of the patient is shown. 3D, three-dimensional; CT, computed tomography [Color figure can be viewed at wileyonlinelibrary.com]

these surgeons (KFDK and TJMR) were actively involved in the design and implementation of the system.

The SUS scores ranged from 57.5 to 95.0 with a mean score of 74, indicating a high chance on acceptance by the end users (Supporting Information 2). The majority of the item scores (8 of 10) indicate a promising usability. Only for the need of technical support and the integration of the system (item 4 and 5) moderate scores were given.

The questions comparing the conventional setting to an innovative setting revealed a mean score of 3.7 ± 0.5, a preference for the innovative setting (Supporting Information 3). Especially, the duration to find the tumor and decisiveness were scored higher for the innovative setting.

4 | DISCUSSION

In this prospective study, a novel EM-based navigation system was applied during 33 pelvic cancer resections. The navigation system worked in the majority of patients with a single failure where a substantially changed position during surgery as compared with preoperative imaging occurred. Adverse events related to the navigation were not observed. During the study, several improvements have been made of which the introduction of intraoperative CBCT to determine the position of the patient trackers was the most significant. Atallah et al[6] performed a pilot study using an optical tracking system during transanal minimally invasive surgery for total

mesorectal excision (TAMIS-TME). In this pilot study, reporting on three patients, an accuracy of 2 to 5 mm was reached, and an improved insight in selection of the actual anatomical planes for dissection was described. An intraoperative CT or MRI was performed on which an array of fiducial markers was placed on the lower abdomen of the patient. A tracked pointer was subsequently used to calibrate the navigation system pointing at each individual marker, resulting in a navigation accuracy of 3.2, 3.6, and 4.0 mm for the respective patients. In the current study, similar navigation accuracy (tracker registration error) was only achieved after adopting intraoperative CBCT. As was illustrated by the gynecological patient case, it is clear that imaging in the OR is needed for accurate navigation. Especially imaging in a CT or MR scanner with straight legs while performing surgery in French position affected the accuracy. With intraoperative CBCT the tracker and target registration error were comparable between French position and straight setup (Table 2). It is important to note that registration of trackers on the skin of the patient is generally more accurate than the actual navigation accuracy on internal targets. This was also illustrated by the larger target registration errors compared with the tracker registration error (Table 2). The study of Atallah et al does not provide accuracy of navigation on internal targets. The reduced target registration error could also be influenced by the reluctance of the surgeons to position the pointer against the artery.

Promising results were achieved on the primary endpoints safety and feasibility. The two cases with a technical failure (positioning error
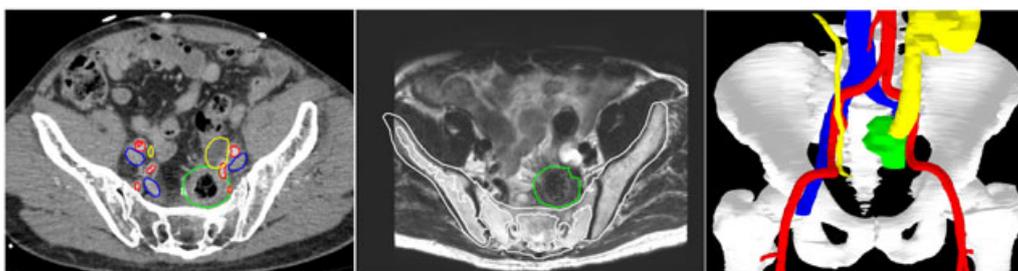

FIGURE 5 Clinical case of a recurrent sigmoid tumor at the presacral space, with involvement of the left ureter resulting in hydronephrosis. On the left a CT slice is shown with the tumor (green), ureters (yellow), arteries (red), and veins (blue) highlighted. Middle image is a T2 axial MR image. On the right image a 3D render of the anatomy of the patient is shown. 3D, three-dimensional; CT, computed tomography [Color figure can be viewed at wileyonlinelibrary.com]

and the gynecological patient) occurred at the beginning of the study. The safety and feasibility were improved by adding intraoperative imaging and better training of the staff. The additional time for the setup in the OR was limited and decreases over time to 20 minutes. In the TAMIS-TME study, 47 minutes were needed for setup.[6] The main difference between these studies is that with CBCT the scanner is moved to the patient and the patient is scanned in surgical position, whereas with CT/MRI the patient setup needs to be adapted to fit the scanner and the patient possibly needs to be moved to the scanner.

This study included a wide variety of pelvic tumor targets. For surgery of recurrences in the pelvic area, positive resection margins occur in 10% to 60% of cases.[14-16] In the current study, only one out of eight recurrence cases resulted in a positive resection margin. Further data is needed to assess the beneficial value of navigation in the setting of local recurrences. The primary rectal tumors included in this study were all T3 or T4 MRF+. At pathology, all cases were evaluated as no ink on the tumor. These results are positive compared with the literature, where approximately 15% to 30% positive resection margins are reported in these challenging cases.[17,18]

Of the 36 lymph node targets, which were all located outside the mesorectum, 33 were successfully removed. The three missed lymph node targets were all located at the obturator region, and their size was decreased to 3, 3, and 5 mm due to neoadjuvant CRT. This is probably revealing the minimal size needed to target and localize lymph nodes using this navigation system. It is questionable if lymph nodes, which decrease to a size of less than 5 mm after CRT need to be removed. The literature on targeting single extramesorectal lymph nodes during pelvic surgery is scarce. With 17 of 20 patients successfully operated on node picking with the navigation system appears feasible, but long-term oncological outcomes have to be awaited.

For technical innovations in surgery, the usability of a system is a very critical factor for clinical adoption. A mean SUS score of 74 indicates a high chance on acceptance by the end users. The high variety indicates different opinions between surgeons. The main advantage was indicated in the duration to find the tumor and the improved decisiveness when using navigation. It is also clear that two factors which need improvement: the need for technical support and the integration of the system in the clinical workflow. In the study, two dedicated technical assistants are involved in the patient setup and the imaging in the OR. During surgery, one technical assistant remains present to monitor performance and for troubleshooting. Further effort is focused on simplification of navigation software, evaluation of different viewing modes, and exploring the use of a footswitch to change program settings. We believe that these changes will make it possible to operate the navigation system without additional staff during surgery.

This study represents the first cohort of patients operated on using novel navigation imaging. Limitations include the navigation setup and software, which was changed and improved several times during the study. This has been recognized in the IDEAL stages of innovation.[19] This was a single-institution study, where the developers of the navigation system were highly involved. It is not clear whether the system usability and feasibility hold when transferred to other hospitals. Furthermore, only patients who underwent open surgery were included. Some benefits of the navigation system may be more pronounced in laparoscopic surgery. Therefore, a laparoscopic probe has been developed and tested since the end of the study.

5 | CONCLUSIONS

In conclusion, a novel surgical navigation system for guidance during procedures on relatively rigid malignancies in the pelvic area was presented. The system has shown to be safe and feasible. To achieve an acceptable accuracy of 5 mm, intraoperative imaging was needed. Including the intraoperative imaging, additional OR preparation time was less than 20 minutes. Surgeons involved in the study are enthusiastic and indicated faster localization of the tumor and the improved decisiveness as main advantages. The surgical results of the patients included in the study were promising, and further randomized studies are initiated to evaluate clinical benefit.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.