Towards Image Guided Laparoscopic Liver Surgery, Defining the System Requirement

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Abstract. The first stage in the development of a surgical image guidance system should be the identification of the desired clinical outcomes. This paper identifies a set of desired clinical outcomes for a laparoscopic image guided liver surgery system. Working backwards from these a set of design goals and system parameters are identified. Knowledge of the important system parameters will allow system development to proceed in a controlled manner towards a system with maximal clinical benefit. After setting the system design goals and system parameters an image guidance system is proposed and details of development progress to date are given.

1 Introduction

Image guided surgery allows the surgeon to refer to preoperative images (from MRI, CT, or PET) of the patient in an intuitive manner during surgery. Such a system should allow the surgeon to make better decisions during surgery, leading to improved clinical outcomes. Another perceived advantage of such a system is improved communication within the surgical team as the surgeon can better explain the surgical approach in the context of the pre-operative images.

The idea of image guided liver surgery is not new, indeed for open surgery there are FDA approved image guidance systems commercially available, [10]. This paper is concerned with the design and development of an image guidance system for laparoscopic liver surgery. In theory image guidance for laparoscopic surgery should enable even greater gains in clinical outcomes, by combining the reduced post operative pain and shorter hospital stay that can be achieved with laparoscopic surgery with enhanced visualisation through image guidance. Laparoscopic image guidance systems have been proposed by several groups, [2, 11] are recent examples, while [7] provides a recent review of current technology. To date however, no such system has progressed beyond the research stage and into development. It seems likely though, given the quantity and quality of research, and the likely financial viability of an image guided laparoscopic system that these systems will move from research into development, and through to commercial availability with a few years. The development and assessment of such systems will require a framework, in the context of surgical innovation [6], that

will allow their performance to be properly assessed. This paper is an attempt to work backwards from clinical goals to arrive at a set of technical requirements.

The development of medical devices, new procedures, or pharmaceuticals is ultimately measured by clinical outcomes, for example quality adjusted life years. However, full assessment of clinical outcomes requires extended, randomised, clinical trials, due to many potentially confounding factors. For an image guidance system undergoing development it is not feasible to test potential improvements using randomised trials measuring clinical outcomes. However by working out what measurable system parameters are most likely to impact the clinical outcomes it should be possible to assess the impact of a system change within a development time frame.

The above approach is in line with the approach put forward by [6] for surgical innovation. The proposed innovation, in this case image guidance, progresses through five stages, idea, development, exploration, assessment, and long term study. The measurement techniques used to assess the performance at each stage are necessarily different, with randomised trials only being feasible from the assessment stage onwards. In reality, given the intuitive appeal of image guided surgery, recruitment of patients for a randomised trial at this stage will be very difficult, meaning that many institutions are likely to adopt image guidance systems before the completion of the assessment stage. It is likely that proper assessment will not be possible. It is therefore of critical importance to get the measures used in the initial stages correct. Given that the desired clinical outcomes are defined by surgeons, whilst the systems are developed by scientists and engineers, there is great potential for the clinical needs and the technical possibilities to be lost in translation. With this paper we hope to inform a discussion to better determine the system requirements. The paper begins with a discussion of the clinical needs.

2 Clinical Needs

The aims of a laparoscopic image guidance system are twofold. The first aim is to improve the outcomes for patients who are already eligible for laparoscopic liver resection. The second aim is to enable patients who would currently only be eligible for open resection to be considered for laparoscopic resection. The measured clinical outcomes for each group will be subtly different.

Table 1 gives a set of clinical outcomes for liver resection. For patients already eligible for laparoscopic liver resection, an effective image guidance system should improve some of the clinical outcomes summarised in table 1, without having any adverse effects. If the image guidance system is effective it should show an improvement in the oncological outcomes (the first 4 items in table 1). It is possible also that the system could lead to improvements in the post operative liver function. The system would not be expected to affect the remaining outcomes, but these should be monitored anyway. In the case of patients who would not otherwise have been eligible for laparoscopic resection, the effects should be measurable as a reduction in post operative pain and hospital stay with no neg-

Clinical Outcomes	Measure
Positive Resection Margins	% of Patients
Local Recurrence	% of Patients
Survival	Years (avg.)
Post operative liver Function	-
Conversion to Open Surgery	% of Patients
Serious Adverse Effects (ICH-GCP)	% of Patients
Cosmetic Appearance	-
Post Operative Pain	Visual Analogue Scale
Length of hospital stay	Days
Quality of Life	-

Table 1. The key clinical performance measures. An effective laparoscopic image guidance system should have a net positive effect on these.

ative impact on the oncological or functional measures. In all cases measurement of these outcomes would require a randomised trial and a significant number of patients.

In addition to the clinical factors outlined in table 1 the image guidance system may have other important effects. For example the ability for the lead surgeon to refer to the pre-operative images during surgery should act as a useful training guide for the assistant surgeons, resulting in improved surgical training. Measurement of this outcome may be difficult.

Measurement of the clinical outcomes can be used to determine objectively whether a given image guidance system is having a beneficial effect. The clinical outcomes on their own do not however give any insight into the design requirements of an image guidance system. The task now is to convert the target clinical outcomes into a list of design requirements for the system. This is the point at which communication between the clinical and technical teams is paramount, so that a system can be developed that addresses the root causes of the clinical outcomes. In the next section we attempt to list a set of design requirements based on our experience of laparoscopic liver surgery.

3 System Design Goals

The first four clinical outcomes in table 1 are direct functions of clearing all the tumour tissue. For the image guidance system to be useful in this regard the system must show the surgeon where the tumour/s are relative to the visible anatomy of the patient. The estimated position will have an error measured in millimetres. Similarly the system will only be able to show tumours that are visible in the pre-operative imaging, so there will be a size threshold on the tumours, also in millimetres. The value of the acceptable error depends on the margin that the surgeon is planning to leave around the tumour. Typically this may be 1 to 2 cm, but may vary depending on where the tumour is, which in turn influences the eligibility of a given patient for laparoscopic surgery. Therefore the surgeon must have a clear understanding of the planned margin size and the

system accuracy. It is up to the system developer to communicate the accuracy in a meaningful way.

There are numerous factors affecting post operative liver function, and it is difficult to make a strong case that the image guidance system could improve this outcome. Factors that could influence this outcome are the volume remaining liver, its blood supply and venous drainage and the integrity of the bile duct. Being able to present the surgeon with a map of the liver vessels could therefore help improve this outcome. In this case the system may not need not be highly accurate. Errors in the region of 10mm may be acceptable, as the aim is primarily to understand the blood supply to the intact liver regions.

Conversion to open procedure may occur when the surgeon cannot be confident of removing all the tumour using laparoscopic resection. This has been addressed by the tumour display. Another reason for conversion to an open procedure is unintended damage to blood or biliary vessels. To avoid these the image guidance system would need to show these vessels. Putting figures on the accuracy required here is more straightforward. Small vessels (below about 3.5mm [5]) can be cut and sealed using a harmonic scalpel. Vessels larger than these need to cut more carefully and sealed with staples or similar. To be useful for this purpose the guidance system should be accurate to within 3mm.

Patients are deemed ineligible for laparoscopic surgery for two main reasons. Firstly it may not be physically possible to reach the tumour using inflexible laparoscopic tools. Secondly the tumour may be very close to blood vessels reducing the surgeon's confidence in being able to remove the tumour without causing significant damage. In the second case an image guidance system able to accurately display blood vessels and tumours may enable laparoscopic resection. Patients with a tumours inaccessible to laparoscopic tools may benefit if the image guidance system enabled improved pre-operative planning and the testing of alternative surgical approaches. Patient specific planning is a key outcome of the European PASSPORT project. The resection planes and port locations required could also be included in the image guidance system. Table 2 summarises the derived design goals.

Design Goal	Measure
Show Tumour Location	Accuracy (5 mm) and resolution (5 mm)
Show Blood Vessels	Accuracy (3 mm) and resolution (3 mm)
Show Bile Ducts	Accuracy (3 mm) and resolution (3 mm)
Show planned resection planes	Accuracy (3 mm)
Enable preoperative simulation	

Table 2. The design goals. To improve the outcomes shown in table 1 the system should meet some or all of the goals shown here.

In general it is not possible to objectively measure whether the system achieves these design goals during a specific procedure. How well the system achieves each goal is a function of underlying system features. The most obvi-

ous of these is the "accuracy", but there are other equally important factors, such as the resolution of the pre-operative images, and the type of visualisation used. The underlying system parameters can be controlled and/or measured. A meaningful development process will measure system parameters in a meaningful way and attempt to correlate the parameter values with how well the system achieves its design goals and ultimately the clinical outcomes. In the next section the system parameters that will influence the design goals are introduced.

4 Quantifying the System Performance

The first design goal in table 2 is to show the tumour location within a given accuracy and resolution. At this point it is necessary to define the meaning of the term "accuracy", which depends on the "registration" process.

4.1 Registration and Accuracy

In its simplest form image guided surgery could take the form of having the pre-operative images displayed on a separate console, (or a separate window on the laparoscopic video screen) with no attempt made to align the pre-operative images to the intra-operative scene. A prominent example of such a system is the daVinci TilePro [12] system. In this case the error cannot be defined. However, such systems are still likely to have benefit as the surgeon may be able mentally locate intra-operative features within the pre-operative images.

In general though, when clinicians and scientists talk about image guided surgery they usually imply a "registration" process, wherein the pre-operative images are aligned so that they closely match the position of the patient in theatre. A practical example of this is the Pathfinder system [10]. Here the surface of the liver is used as a matching feature. The surface of the liver is first segmented from the pre-operative image. The surface of the patient's liver in theatre is then found using either a laser range finder or tracked pointer. The two surfaces can then be "registered" to align the pre-operative image with the patient. By tracking the surgical tools it is then possible to show their position on the pre-operative images whilst the surgeon manoeuvres them within the patient. In the current implementation the registration is rigid, so that the pre-operative image cannot deform to match the intra-operative liver shape. As the surgeon interacts with and moves the liver the errors can become very large. The surgeon can mentally correct for some of this distortion and the system has progressed to full clinical trials. The use of finite element models to account for the non-rigid deformation encountered during liver surgery is under active development [1].

When dealing with laparoscopic procedures the registration process can be slightly simplified. It is not necessary to know the location of the liver relative to an absolute frame of reference within the operating theatre, only the position and pose relative to the lens of the laparoscope. The bulk of the work in this area uses the laparoscope images themselves to estimate this, [7, 3, 8]. Similarly

to the open case, there is substantial work towards using deformable models to account for soft tissue deformation [9].

The registration errors should be measured relative to the laparoscope lens. An absolute error (in millimetres) can be estimated by comparing the position of a given point in the model with its position measured by an independent tracking system. For a typical 2 dimensional display, however, the absolute error is of little interest. The absolute error should be projected onto the screen. The registration errors are usually anisotropic, and through intelligent design the projected errors can be significantly less than the absolute errors.

It is important to ensure that the error measurement accounts for all sources of error. For a given image guidance system these may include; errors (distortion) in the pre-operative image; errors in the processing of the pre-operative image due to low tissue contrast; physical changes in the patient between pre-operative imaging and surgery; errors in the estimate of the liver surface from the laparoscope; errors in the deformation model of the liver. It is almost certain that the accuracy of a given system will vary depending on the visible anatomy and the position and pose of the laparoscope.

Clearly the accuracy of the registration process is key to an image guidance system as described. However the goal of the system is not accuracy, the system must communicate the position of points of interest to the surgeon in a clear way. This means that not only must the visualisation method be well thought out, but that it must be controlled for in the development and assessment of the system. The Data, Visualisation processing and View (DVV) taxonomy introduced by [4] provides a useful way to define the visualisation of the of the pre-operative images. Data consists of the pre-operative images. Visualisation processing defines how they are processed from raw images to information that can be intuitively communicated to the surgeon, including but not limited to the registration process described above. Finally the view stage defines how the images are presented. As pointed out by [4], deciding what data to present to the surgeon and how and when to do it are defining, but often overlooked, features of an image guidance system. Similarly the way the surgeon interacts with the system must be well thought out and controlled.

Table 3 unites the system parameters, the design goals, and the clinical outcomes in a single table, attempting to show how the different measure interact and how they are measured and controlled throughout the development stages identified by [6].

5 A Proposed Image Guidance System

Having developed a framework to enable the systematic development of an image guided laparoscopic liver resection system, it is now possible to put forward a possible system. The proposed system is under active development within our laboratory.

Figure 1 shows a schematic flow chart of the proposed system. Recently developed novel algorithms [3, 13] are used to warp the pre-operative model to

System Parameters	Design Goals	Clinical Outcomes
Measures		
→Accuracy	→Tumour location	→Pos. resection margins
—→Preop. image resolution	→Blood vessels	→Local reccurence
—→Preop. image distortion	→Bilary system	→Conversion to open
—→Preop. image contrast	→Planned resection plane	→Survival
—→Elapsed Time	→Pre-Op. Planning	→Liver Function
—→Surface error		→Conversion to open
—→Model Errors		→Serious adv. effects
→Update rate		→Comsmetic appearance
→Visualisation design [4]		→Post-Op. Pain
→User interface design		→Length of hospital stay
		→Quality of life
		→Improved Training
Measurement Methods		
Direct measurement and laboratory experiment	Observation of system in use and user questionnaire	Analysis of trial results
Development Stage [6]		
1 Idea, 2a Development	2a Development, 2b Exploration	2b Exploration, 3 Assessment, 4 Long-term Study

Table 3. The parameters in the left most column define the image guided liver surgery system, and will change during system development. The success of failure of the system, however, will be judged by the outcomes in the right hand column. A key requirement for an effective development process is to link the system parameters with the outcomes. This can be done by the careful assignment of system design goals in the centre column.

the visible laparoscope image during and initial alignment. During surgery only rigid alignment is performed.

Work has begun on quantifying the performance of some of the individual components shown in Figure 1. The structure from motion algorithm [3] has been successfully used to reconstruct the liver surface from a laparoscopic video sequence, though the accuracy has not been fully quantified. The optical tracking collar and improved tracking algorithm will allow tracking of the laparoscope tip to within 1.6 mm. Integration of the fast finite element solver [13] with the surface tracking is ongoing.

6 Discussion and Conclusion

Working backwards from the desired clinical outcome, a target accuracy of 3 mm has been identified. Most of the component technologies for a practical image guided laparoscopic liver surgery system are available. Development work on bringing together the system components to form a working image guidance system is now under way. Through out development, by measuring and recording the system parameters and testing their effect on the design goals, it should be

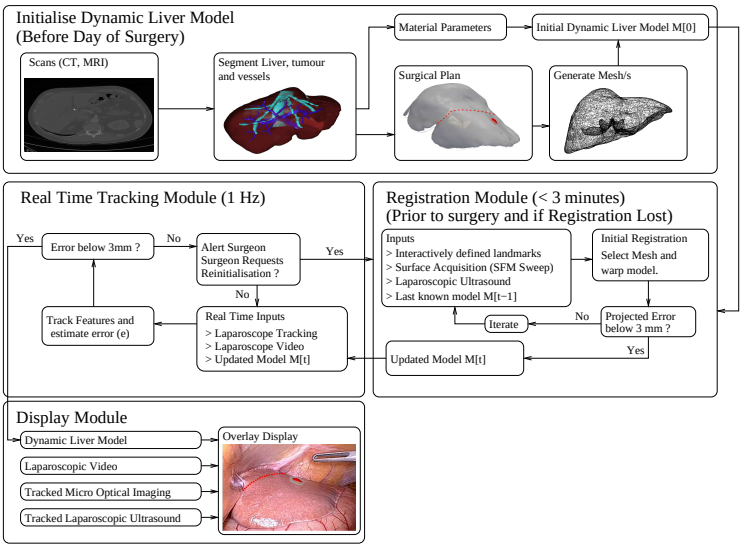

Fig. 1. Flow chart of a proposed image guidance system. The pre-operative liver model is registered and warped to the visible liver surface using recently developed algorithms [3, 13]. After this stage the position of the laparoscope lens is tracked, and the model rigidly aligned with the laparoscope lens.

possible to develop a system that has a positive and demonstrable effect on the clinical outcomes.

7 Acknowledgements

This work was funded by EU FP7 project PASSPORT under Grant No. 223894.

References

1. Cash, D.M., Miga, M.I., Sinha, T.K., Galloway, R.L., Chapman, W.C.: Compensating for intraoperative soft-tissue deformations using incomplete surface data and finite elements. IEEE Transactions on Medical Imaging 24(11), 1479–1491 (Nov 2005)
2. Cohen, D., Mayer, E., Chen, D., Anstee, A., Vale, J., Yang, G.Z., Darzi, A., Edwards, P.J.: Augmented reality image guidance in minimally invasive prostatectomy. In: Prostate Cancer Imaging'10. pp. 101–110 (2010)
3. Hu, M., Penney, G., Edwards, P., Figl, M., Hawkes, D.: 3d reconstruction of internal organ surfaces for minimal invasive surgery. In: Ayache, N., Ourselin, S., Maeder, A. (eds.) Medical Image Computing and Computer Aided Interventions. LNCS, vol. 4791, pp. 68–77. Springer (2007)

4. Kersten-Oertel, M., Jannin, P., Collins, D.: Dvv: A taxonomy for mixed reality visualization in image guided surgery. In: MIAR. LNCS, vol. 6326, pp. 334–343 (2010)
5. Landman, J., Kerbl, K., Rehman, J., Andreoni, C. et al: Evaluation of a vessel sealing system, bipolar electrosurgery, harmonic scalpel, titanium clips, endoscopic gastrointestinal anastomosis vascular staples and sutures for arterial and venous ligation in a porcine model. J Urol 169(2), 697–700 (Feb 2003), http://dx.doi.org/10.1097/01.ju.0000045160.87700.32
6. McCulloch, P., Altman, D.G., Campbell, W.B. et al: No surgical innovation without evaluation: the ideal recommendations. Lancet 374(9695), 1105–1112 (Sep 2009), http://dx.doi.org/10.1016/S0140-6736(09)61116-8
7. Mirota, D.J., Ishii, M., Hager, G.D.: Vision-based navigation in image-guided interventions. Annu Rev Biomed Eng 13, 297–319 (Aug 2011), http://dx.doi.org/10.1146/annurev-bioeng-071910-124757
8. Mountney, P., Stoyanov, D., Davison, A., Yang, G.Z.: Simultaneous stereoscope localization and soft-tissue mapping for minimal invasive surgery. In: Medical Image Computing and Computer Assisted Intervention. LNCS, vol. 4190, pp. 347–354. Springer (2006), http://pubs.doc.ic.ac.uk/stereoscope-tissue-surgery/
9. Pratt, P., Stoyanov, D., Visentini-Scarzanella, M., Yang, G.Z.: Dynamic guidance for robotic surgery using image-constrained biomechanical models. In: Jiang, T., Navab, N., Pluim, J.P., Viergever, M.A. (eds.) Medical Image Computing and Computer-Assisted Intervention. LNCS, vol. 6361, pp. 77–85. Springer (2010)
10. Stefansic, J.D., Bass, W.A., Hartmann, S.L., Beasley, R.A., Sinha, T.K., Cash, D.M., Herline, A.J., Galloway, R.L.: Design and implementation of a pc-based image-guided surgical system. Comput Methods Programs Biomed 69(3), 211–224 (Nov 2002)
11. Su, L., Vagvolgyi, B.P., Agarwal, R., Reiley, C.E., Taylor, R.H., Hager, G.D.: Augmented reality during robot-assisted laparoscopic partial nephrectomy: Toward real-time 3d-ct to stereoscopic video registration. Urology 73, 896–900 (2009)
12. Tan, G.Y., , Goel, R.K., Kaouk, J.H., Tewari, A.K.: Technological advances in robotic-assisted laparoscopic surgery. Urologic Clinics of North America 36(2), 237–249 (2009)
13. Taylor, Z.A., Cheng, M., Ourselin, S.: High-speed nonlinear finite element analysis for surgical simulation using graphics processing units. IEEE Transactions on Medical Imaging 27(5), 650–663 (2008)