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WHITE PAPER

Using data fusion to enhance surgical navigation and visualisation

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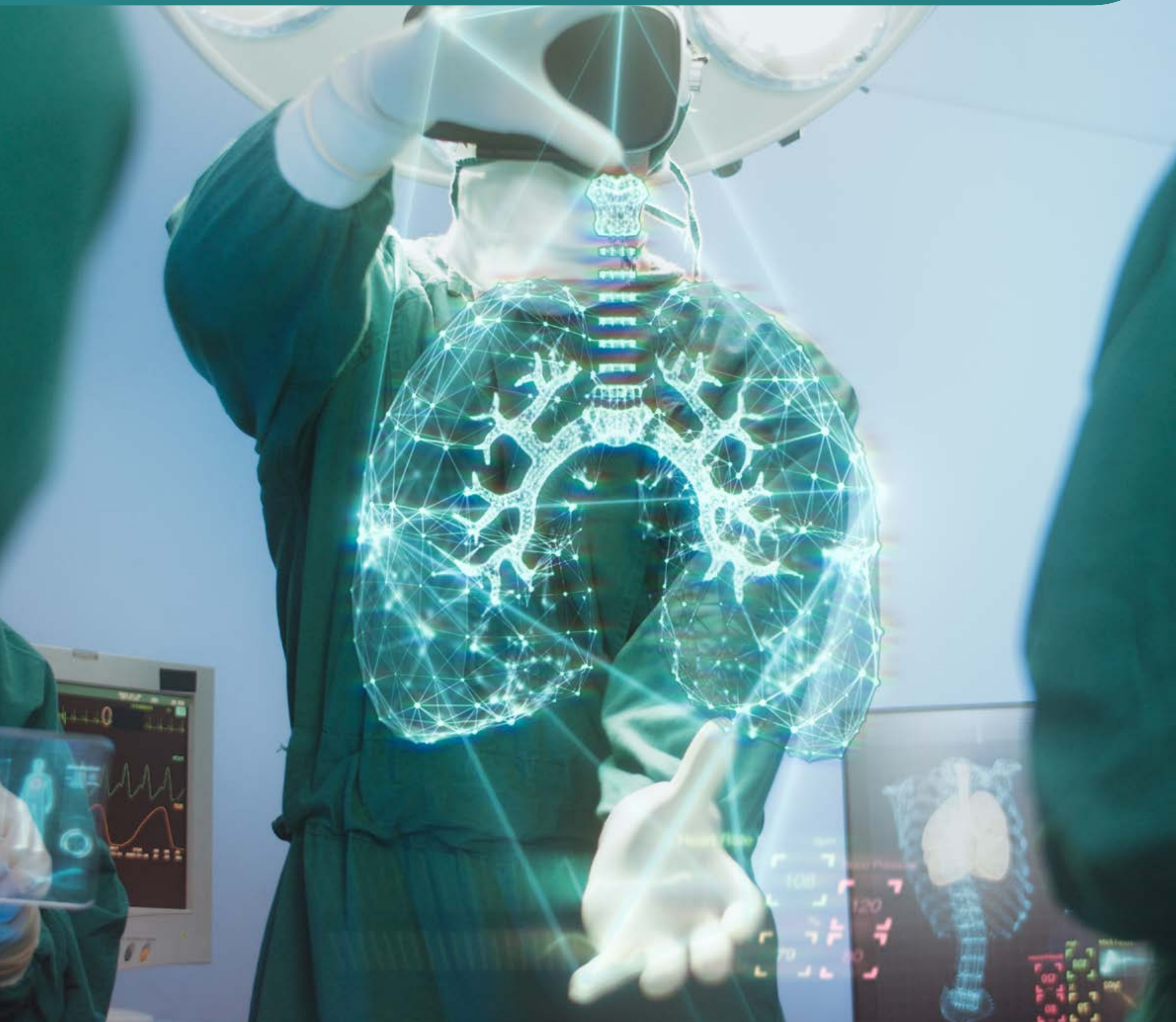

Advanced navigation and visualisation technologies facilitate challenging surgeries and enable less experienced surgeons to achieve better outcomes. Yet as these technologies become more complex, they can add time to simpler procedures and place a greater cognitive burden on the surgeon. In this white paper, we discuss the use of data fusion techniques to address this problem.

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As surgical navigation and visualisation technologies become more advanced, they also become more complex, potentially negating the benefits they bring. As well as taking time to set up, they can increase cognitive load during surgery and may result in procedures taking longer. For instance, surgeons might be required to compare multiple real-time images with a pre-operative scan or model, without automatic registration of the images.

Here, we consider how data fusion techniques can integrate surgical data sources for more cohesive, useful navigation and visualisation support. We start by looking at Computer Assisted Surgery for orthopaedics, which introduces elements of data fusion, and the development of 'pinless' navigation. This leads us to the more challenging application of soft tissue navigation for oncology. We describe data fusion approaches currently being explored in a research capacity and obstacles to their implementation in the operating room. Finally, we outline key prospects for surgical navigation in soft tissue, highlighting the importance of surgeon interaction.

CAS in orthopaedics as a benchmark in data fusion

Use of surgical navigation and visualisation is well established for orthopaedic procedures, where it's referred to as Computer Assisted Surgery (CAS). Figure 1 shows a typical orthopaedic CAS system and its four key processes:

1. A pre-op image of the joint is taken, usually via a CT or MRI scan
2. The image is segmented to provide a 3D model of the joint. This model can be used to plan surgery and determine sizing of implant components, location of cuts, and placement of screws.
3. During surgery, optical fiducials (markers) are inserted in the bone and landmarks on the bone are picked out by the surgeon. This enables the system to perform registration (i.e. aligning the model to real-world co-ordinates).
4. The surgeon is presented with a navigation display, showing the posture of surgical instruments on the model. Traditionally, this involves a screen in the operating room, but more recently, Augmented Reality (AR) headsets have enabled overlay of the model on the surgeon's view.

These orthopaedic systems typically achieve position accuracies of 1mm and angular accuracies of 1°, with a ten-minute setup time. Similar systems are now used in spine surgery and neurosurgery too.

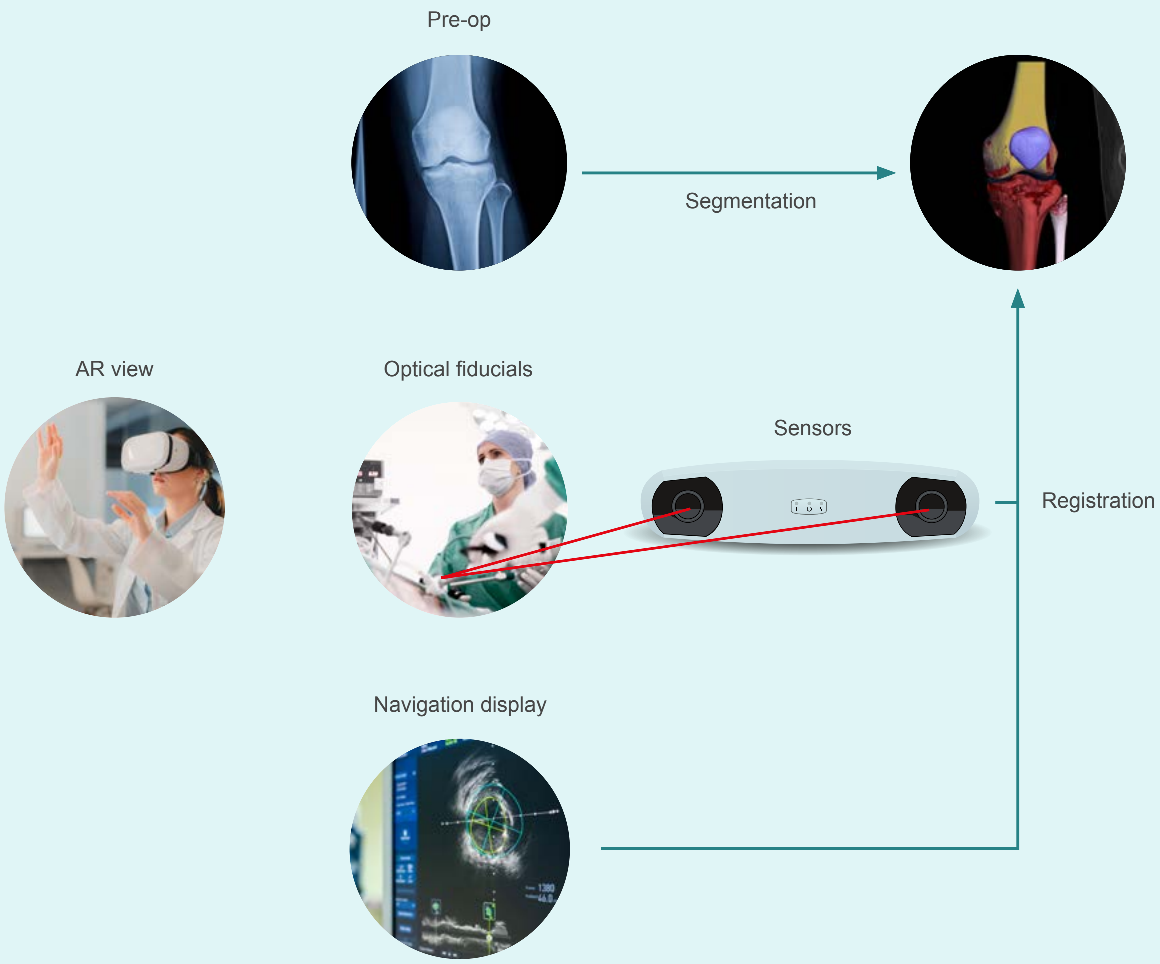


Figure 1: CAS in orthopaedics

Pinless surgery as a forerunner in data fusion

A disadvantage of standard CAS in orthopaedic surgery is the need to insert fiducials into bone. This exacerbates patient discomfort and lengthens recovery time as well as increasing risk of infection. Pinless surgery addresses this to a certain extent by deriving some positional information via other means. For example, in knee and hip surgery, hip joint location can be determined by swinging the femur through a range of angles while tracking its distal portion. However, it's hard to fully eliminate fiducials; pinless hip surgery usually requires a pin in the iliac crest.

There is potential to overcome this challenge and make the system truly pinless through the addition of sensors. Figure 2 shows a conceptual system where bone fiducials are replaced by an ultrasound imager. An algorithm extracts features from the ultrasound image and registers these to the pre-op model. The posture of the ultrasound imager itself is also tracked optically, along with the surgical instruments. This system is feasible today1. However, commercial impetus is limited because existing navigation systems for orthopaedics have a high level of acceptance among surgeons.

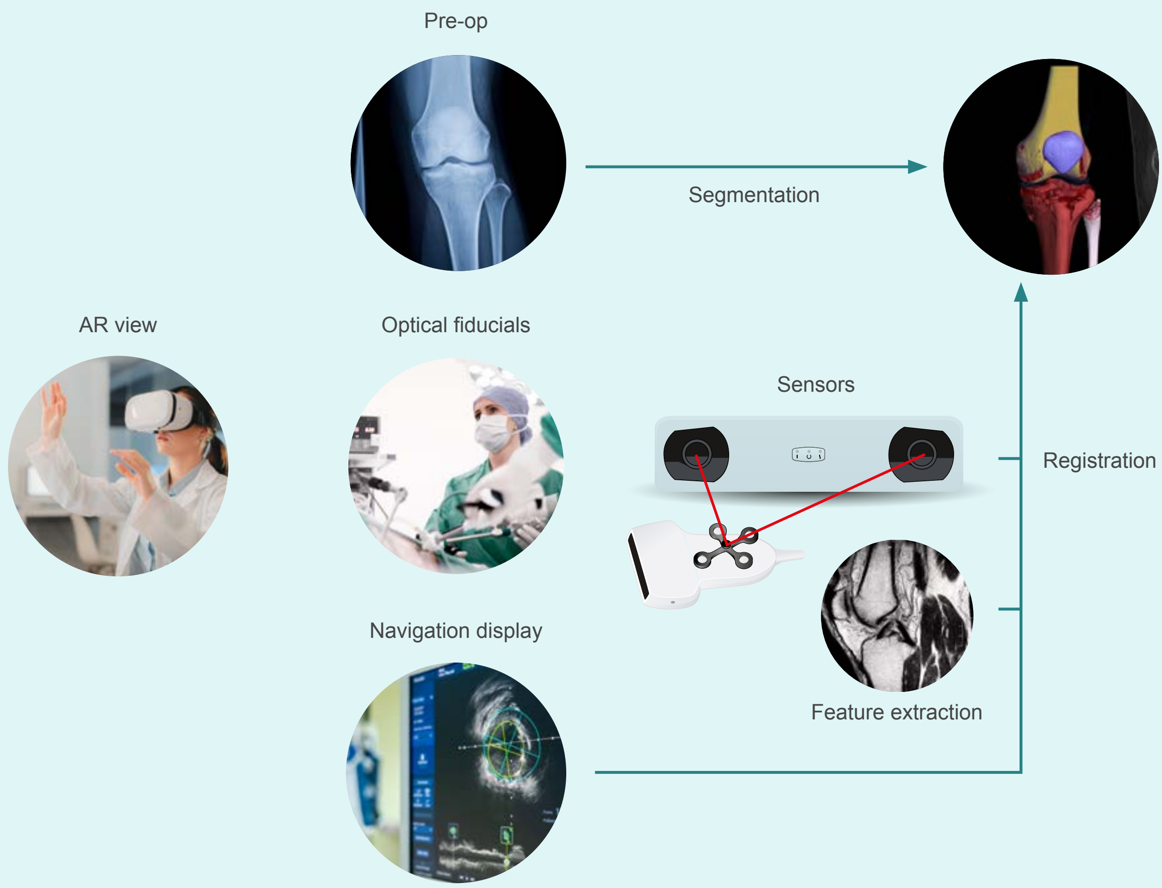


Figure 2: Pinless navigation enabled by ultrasound imaging

Ultrasound imaging is widely used for navigation in other surgical procedures, but it's important to note that its use requires the attendance of an additional clinician. Positioning an ultrasound scanner to yield a clear image so features can be recognised by an algorithm requires human expertise. Despite the advent of more capable algorithms, some tasks are performed more effectively by people; we'll come back to this later.

Soft tissue navigation for oncology

Soft tissue surgical navigation in oncology presents significant challenges. Tumours must be located and neatly excised without leaving cancerous cells in the margins or removing too much healthy tissue. Avoiding critical structures such as blood vessels and nerves is also essential. A complicating factor with soft tissue is that it readily deforms, and it is also modified during the surgery. This deformation makes real-time registration much more challenging than in the hard tissue surgeries described above.

Figure 3 shows an idealised navigation system for surgical oncology, with an endoscope located relative to the target organ. It's performed using a surgical robot, so surgical instruments are automatically located relative to the main sensor (the endoscope).

A stereo endoscope can determine the 3D shape of tissue surface as well as identifying surface features. In this idealised example, it allows registration with a pre-op model as well as determining any deformation of the tissue surface relative to the model. A simulation (e.g. using Finite Element Analysis) determines deformation of the organ's internal structures. This allows the model to be overlaid on the endoscope view in a realistic way.

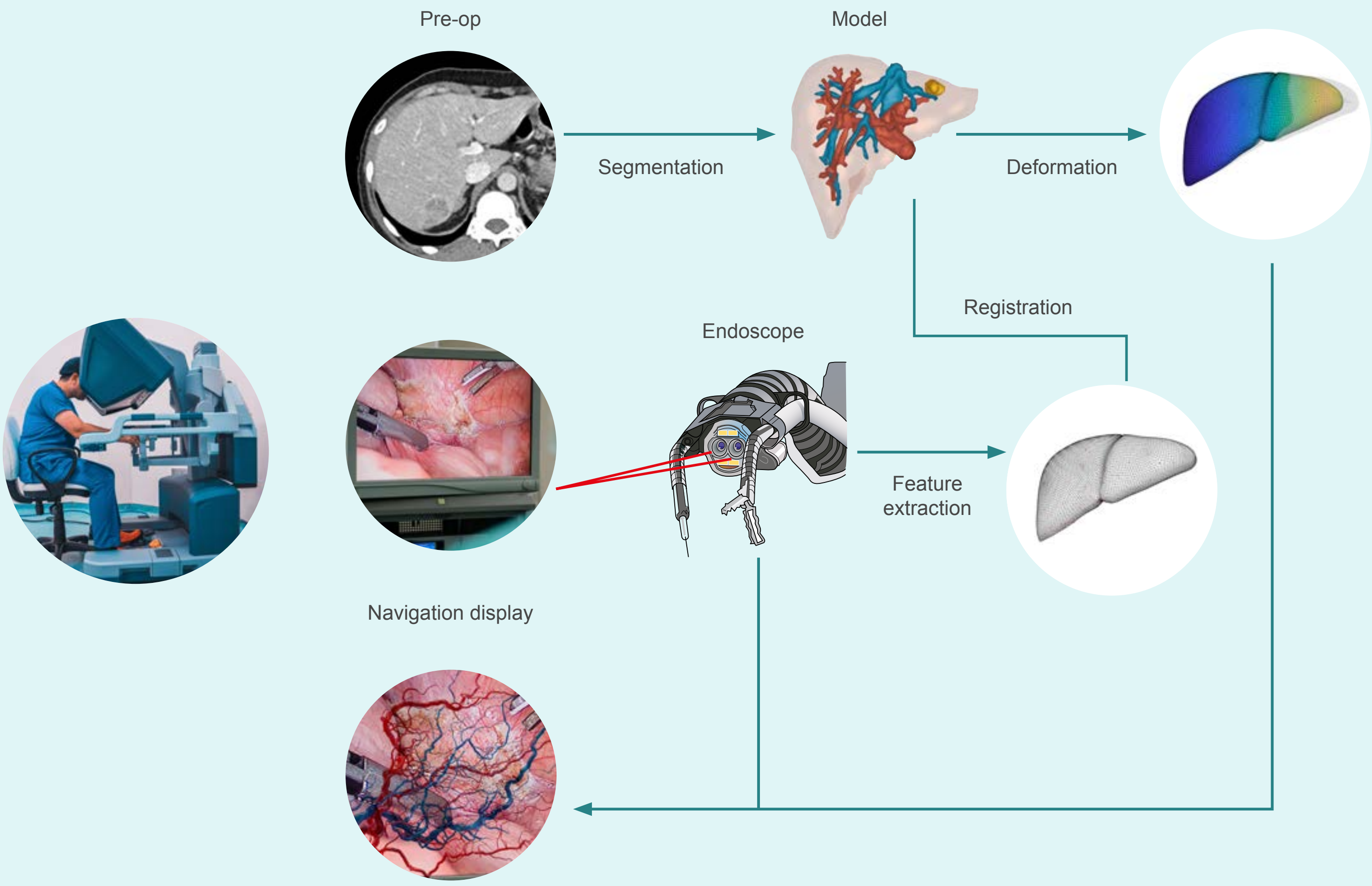
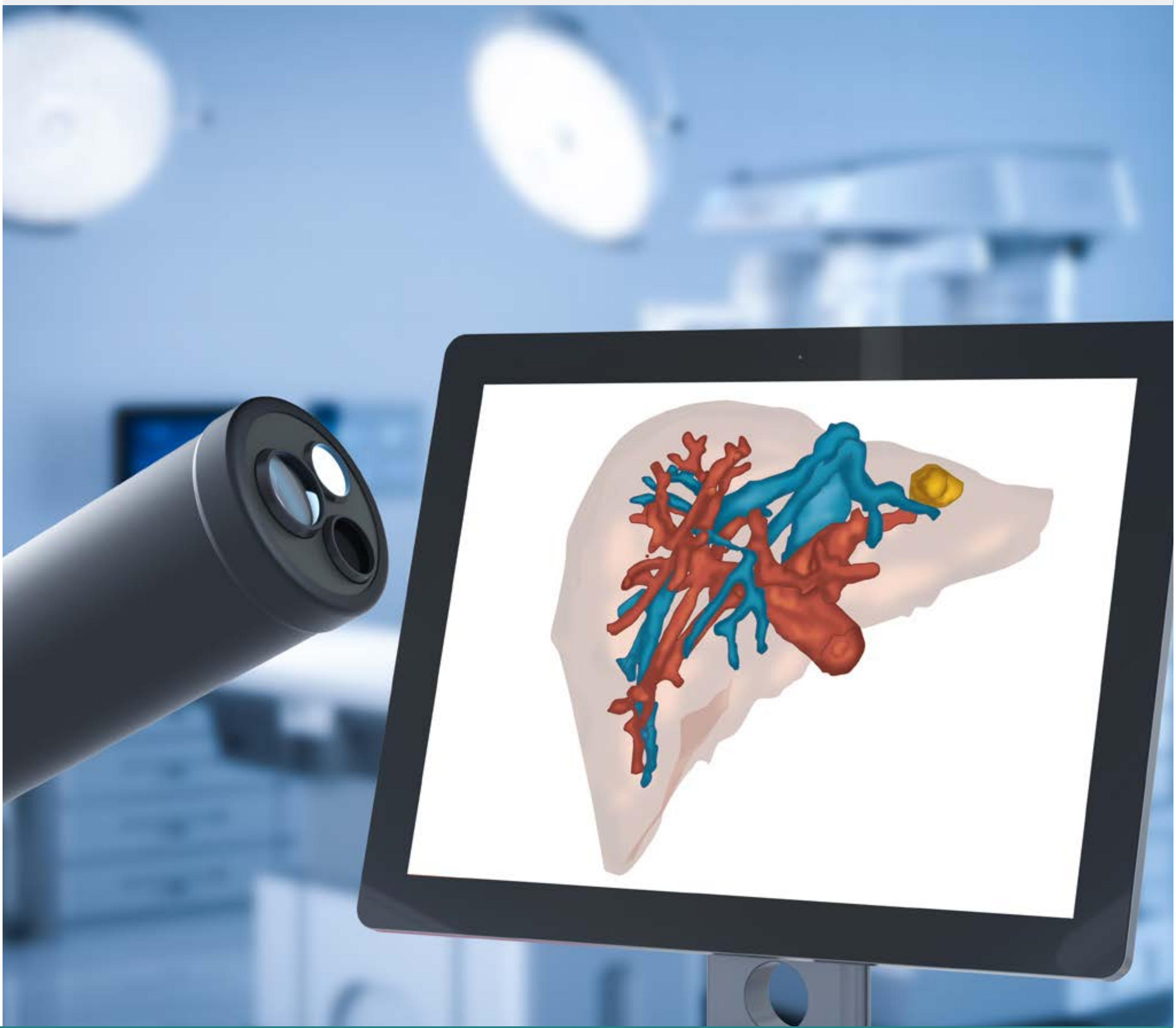


Figure 3: An idealised system for surgical navigation of soft tissue in oncology

While this is an attractive prospect, there are many challenges to achieving it in practice. Some organs, notably the liver, have very few surface features. What's more, most of the time, only a small portion of an organ's surface will be visible to the endoscope, making it difficult to fully specify boundary conditions for deformation simulation. Another issue is the inability of standard simulation methods to provide sufficient accuracy while running in real-time. It's also difficult to provide accurate tissue properties for simulation, and it's very difficult to adapt a simulation to account for tissue removed during surgery. A good review of image guided navigation for liver surgery is provided by Schneider et al[3]. The report suggests that accuracies of 10mm are typical (i.e. 10x less than that seen in orthopaedics).

The emergence of segmented models for endoscopic procedures

At present, soft tissue navigation may involve a pre-op MRI or CT scan but usually lacks a 3D model as well. However, this is changing with companies like **Innersight** developing segmented models that can be viewed alongside the endoscopic view during surgery[4].



Data fusion in soft tissue navigation

Many data fusion approaches have been explored in clinical research. They typically combine endoscope imagery with one of the technologies listed in Figure 4, and often involve deformation simulation.

Technology	Advantages	Disadvantages	Established applications
Optical	Accurate 6DOF tracking of instruments.	Fiducials take up space near the surgical port and require line-of-sight.	Tool tracking in laparoscopic surgery.
Electromagnetic	Accurate 5DOF/6DOF tracking of markers added to instruments or tissue.	Limited compatibility with metal instruments.	Large-scale tracking of flexible 'scopes (bronchoscopes, colonoscopes, etc.).
Fluorescence imaging	Enhances contrast of surface features.	Only images surface features.	See our white paper Transforming oncology surgery with label-free technologies: sagentiainnovation.com/insights/transforming-oncology-surgery-with-label-free-technologies/5 for more information on this and other spectroscopic methods.
Ultrasound	Low cost, readily available. Feature extraction is possible in real-time.	Requires intimate contact and fluid-filled organs, e.g. it can be challenging to use in lungs. Imaging head needs to be positioned close to the surgical site and typically provides only a 2D section (for real-time imaging).	Real-time tracking of heart and adjacent structures.
X-ray (Fluoroscopy, CT, CBCT)	High resolution, good contrast at tissue-air interfaces and bone.	Health risks associated with X-ray dose, particularly for surgical staff.	Brain surgery, dentistry, placement of tools in arteries, targeting of radiation therapy.
MRI	Detailed 3D images.	Very expensive. Usually an enclosed system, making surgical access difficult. Metal instruments distort the image.	Brain surgery.

Figure 4: High-level summary of surgical navigation technologies

There are also some notable examples of commercial systems which employ data fusion:

- **BrainLab's** mobile X-ray systems are fused with optically tracked instruments[6] to enable precision placement of instruments in spine surgery and minimise X-ray dose
- **J&J Ethicon's** *MONARCH™* platform[7] navigates branched lung and kidney structures by combining analysis of the endoscopic view with magnetic tracking and mechanical indexing, all registered to the pre-op image. The system also allows the use of endoscopic ultrasound or external CBCT to confirm the location of a lesion relative to the working tip.
- **Abbott's** *Ensite*™ Cardiac Mapping System[8] combines magnetic and electrical impedance tracking to capture the geometry of the inner surface of the heart. Magnetic tracking provides a rigid frame of reference, while electrical impedance tracking is based on conduction to a set of electrodes attached to the patient. This provides a reference frame that moves with the patient and with the beating heart.

BrainLab's system is an extension of established methods in orthopaedics, exploiting the fact that the spine has rigid components and is essentially immobile during surgery. **Ethicon's** *MONARCH™* navigates soft tissue using 'landmarks' inherent to the branched structure of the lung and kidney. **Abbott's** *Ensite*™ system is the most sophisticated of the three examples listed here, dealing with real-time motion of deformable tissue. Various other cardiac systems also use real-time imaging (often by ultrasound) to enable beating heart surgery.

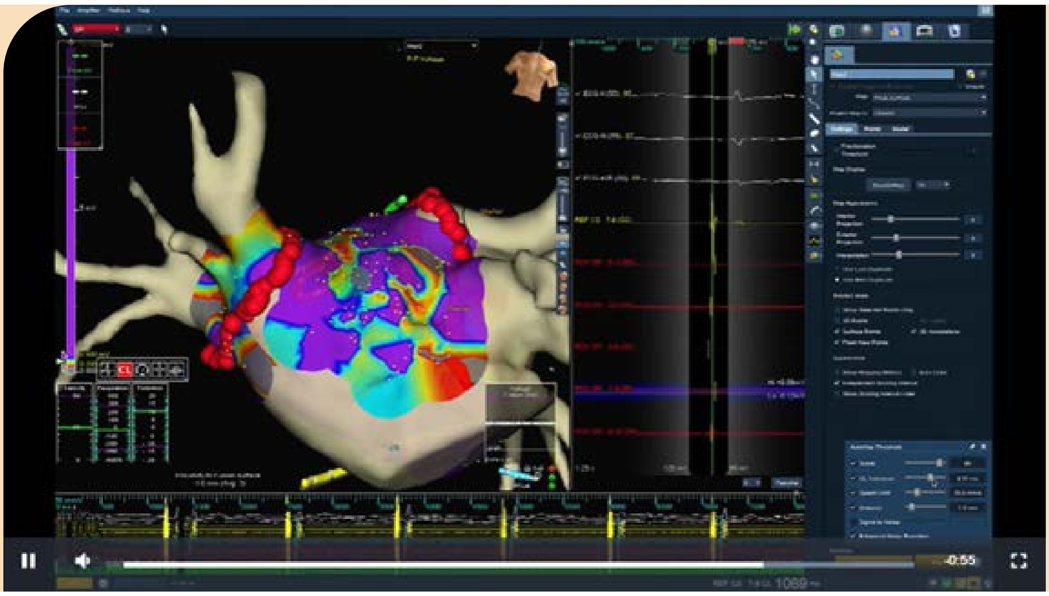


Figure 5: Screenshot from Abbott's Ensite™ Cardiac Mapping system – a leading example of data fusion used to navigate a deformable (moving) organ.[8]

Each of these three systems cleverly exploits its respective navigation constraints to provide precise and robust solutions. However, while many approaches for general soft tissue navigation have been tested, none have achieved the necessary level of maturity for development as a mainstream product. Limiting factors include setup time, interruptions to surgical workflow, and additional staff requirements. Lack of robustness is also a problem, with issues such as sensor drop-out, occasional lack of features, and algorithm errors.

It's often suggested that AI could help mitigate these problems, providing a more flexible approach to feature extraction or faster simulation of tissue deformation. However, AI is also in its infancy. Large surgical companies are still establishing the infrastructure to capture surgical data; leveraging that data to train AI algorithms will require further effort and investment. The regulatory approach to AI is still evolving too. At present, FDA-approved AI products mainly relate to the interpretation of radiology images and other medical diagnostics[9].

Prospects for data fusion in surgical navigation

Our work in surgical navigation suggests three key approaches are likely to deliver benefits in the short-term.

1. Highlighting critical structures in endoscopic views

Optical markers are increasingly used to highlight critical structures during surgery. They have the advantage of addressing a significant need and being relatively simple to integrate into existing surgical systems. An image overlay can often be achieved directly (optically) rather than requiring software for registration and feature extraction. Our white paper Smart Surgery: a new era in surgical technology (sagentiainnovation.com/insights/smart-surgery-a-new-era-in-surgical-technology/)[10] identifies advances and trends in this space.

2. Enhancing workflows using 3D vision and AR

Wider use of high-resolution stereo endoscopes means many surgeons now benefit from a 3D view. The software for live reconstruction of 3D geometry from stereo views is also well established. Going forward, AR headsets for open surgery may include stereo cameras and/or depth-sensing cameras. While this may not be sufficient for challenging applications such as tracking deformable tissue, there are many opportunities to enhance surgical workflows. For instance, the BrainLab system mentioned above enhances metrology through the measurement of joint angles, automated registration, and pedicle screw placement. It's also possible to track surgical tools relative to the endoscope in multiport soft tissue surgery. This can enable AR simulations in training tools or, ultimately, automated tool control.

Ultrasound also stands out as a key enabler, providing visibility of sub-surface structures in real-time at a modest cost. It is relatively straightforward to integrate ultrasound imagery into a 3D/AR view. While the images can be noisy and difficult to interpret, real-time algorithms to clean them up and identify features are close to being product ready.

3. Leveraging surgeon interaction to increase robustness

Surgeons have a wealth of skills that are difficult to automate, and they also want to be in control of the procedures they undertake. So, while automating certain aspects of surgery is beneficial, it makes sense for surgeons to interact directly with the more challenging aspects of navigation.

For instance, when aligning sensor data with a pre-op image there will be several possibilities, and registration algorithms often encounter 'local minima'. Yet a surgeon presented with multiple registration options can easily select the best option based on their awareness of the geometry. Similarly, a surgeon can assist with feature identification, manually selecting features from an image or from a small number of candidates. This echoes the registration process regularly used in orthopaedics where the surgeon uses a digitiser tool to register anatomical landmarks. However, it involves much less effort as two or three features are selected rather than 20 or 30.

In a data fusion system, each modality generates data with a different level of confidence. Theoretically, confidence levels should influence how each modality contributes to the fused output. But this is complicated by the fact that the navigation system may not be aware of which aspect of the output holds the greatest importance. If such uncertainties were communicated to the surgeon, their feedback could improve the weighting of the inputs. For example, when making an incision near a blood vessel, the surgeon could choose to reduce uncertainty in the direction at right angles to a blood vessel at the expense of uncertainty in the direction along the blood vessel to maintain an accurate distance from it.

Finally, although tissue simulations often lack accuracy, they can provide directional guidance to aid surgeons' decision making. Take radiofrequency ablation, where simulation can predict the spread of heat near a blood vessel. The rate or extent of spread may be difficult to simulate accurately, but the way the heated region is deformed by the blood vessel can be indicated.

Conclusions

As technology develops, intra-operative data processing will lead to improved visualisation, navigation, and procedural guidance. This will empower less experienced surgeons to adopt and perform standard procedures while enabling accomplished surgeons to extend their capabilities and perform surgeries more efficiently. The impetus for development will be a combination of new functionality, simpler setup, and reduced burden on the surgeon, both physical and cognitive. We expect short-term priorities to include simpler visualisation of multiple data streams and more streamlined integration of existing sensor technologies.

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