

DESIGN AND EVALUATION OF IMAGE GUIDANCE SYSTEMS FOR RARP

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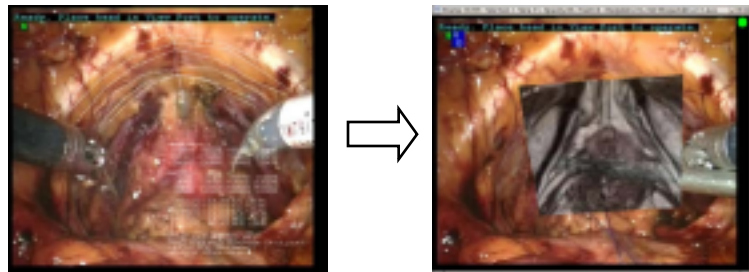
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Introduction: There is a strong appetite amongst laparoscopic surgeons for image guidance during the procedure. It seems intuitively obvious that providing the surgeon with additional information on the location of unseen anatomy can only improve patient outcomes. This is not necessarily the case however. If the system gives information that is not relevant to the procedure it becomes a distraction. Similarly, if the system has large alignment errors the information may be dangerously wrong. One danger is that image guidance systems can be developed on an ad-hoc basis based not on targeted clinical goals but on the technical expertise and research goals of the scientists and engineers involved. Such a system may or may not benefit the patient. However, there is a real danger, as discussed by [1], that such systems will be introduced into surgical practice without proper assessment. We present our minimalist image guidance system for robot assisted radical prostatectomy together with a design and evaluation framework built upwards from the desired clinical outcomes.

Methods: Our system allows the surgeon to refer to pre-operative MRI images of the patient aligned to the visible anatomy. The MRI is aligned manually to the intra-operative scene as shown in Figure 1. The surgeon is able to intuitively match anatomy shown in the MRI to its intra-operative location.

Results: We have measured the system accuracy and so far tested the system during 11 clinical cases. Despite having a very low accuracy (around 2cm) the system has scored highly when rated by the surgeons. Table 1 lists the desired clinical outcomes and the design goals.

Conclusion: We present a simple image guidance system and a framework to evaluate its performance. The framework will also be used to evaluate the performance of comparable systems. Despite its limitations our current system has been very well received clinically and been used to inform intra-operative decision making. This indicates that careful thought must be given to the real surgical needs before the development of more complex systems.



Align

Overlay MRI

Figure: The patient's MRI is aligned to the surgical scene using a wireframe image of the visible inner surface of the pubic arch (left). The process takes less than 30 seconds. Once aligned the patients MRI can be shown to the surgeon overlaid on the surgical scene (right).

Table 1: The design and development process begins with the identification of desired clinical outcomes. These inform a list of system design goals, which are linked to underlying system parameters. Correlations between the system parameters and how well the design goals are met are used to control the design and development process.

| System Parameters | Design Goals | Clinical Outcomes |
|-----------------------|---------------------------------|----------------------------|
| Accuracy | Show Tumour location | Positive margin rate |
| Update rate | Show Bladder/Prostate Interface | Biochemical PSA Recurrence |
| Visualisation design | Show Extent of Prostate Capsule | Urinary Continence |
| User interface design | Show rectum | Erectile Function |
| | Show Neuro- Vascular Bundles | Damage to rectum |
| | Aid Pre-Op. Planning | Conversion to open |

[1] McCulloch, P et al. "No surgical innovation without evaluation: the IDEAL recommendations." *Lancet* 2009;374 (9695):1105-1112.