Title: Clinical experience of using Virtual 3D modelling for pre and intraoperative guidance during robotic-assisted partial nephrectomy

Key words: Robotics, Partial nephrectomy, 3D modelling, 3D reconstruction, Surgical planning, Patient education

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Introduction

Partial nephrectomy (PN) is the standard of care for clinically organ-confined renal tumors.[1,2,3,4]

This is a complex and demanding procedure that aims at complete tumor resection and accurate repair of injured renal structures, to achieve cancer control and functional preservation within an acceptable burden of complications. Surgical planning for PN is complex, with numerous patient and tumour characteristics having to be accounted for, especially the relationship between the tumour and renal hilar anatomy.

Historically, the appreciation of these anatomical factors has been through the examination of two-dimensional (2D) coronal, sagittal, and axial images of computed tomography (CT) datasets. By performing this function, surgeons cognitively construct a three-dimensional (3D) model that is their singular guide to simulate the patient's anatomy. Although repetition over the course of the surgeon's career lends a certain comfort and familiarity with this technique, it is unclear if this cognitive representation accurately depicts the real anatomy with all its complexities.

To overcome the limitations of 2D viewing of images, dedicated computer software has been developed to classify medical scan voxels into their anatomical components in a process known as image segmentation.[5] Once segmented, stereolithography files are generated which can be used to visualise the anatomy, interactively as a 3D model.[5]

Pioneering work showed that surgeons can benefit from virtual 3D models in the theatre, particularly with regard to improved appreciation of hilar vascular anatomy and enhanced pre-operative planning and simulation.[6]

In recent years, several studies have shown benefits of 3D modelling for pre-operative planning in RAPN. A recent prospective study showed that 3D models increased the ability for selective clamping from 13% to 57%, thus limiting the chance of long-term ischemic damage to the kidney.[7] A retrospective study showed 20% surgical decision changes with 3D models,[8] and another retrospective survey based study showed 27% increase in possible organ-sparing operations for complex cases.[9]

For intraoperative use, a prospective randomized clinical trial (n=92) demonstrated that patients whose surgical planning involved 3D models had reduced operative time, blood loss, clamp time, and length of hospital stay.[10]

This feasibility study aims at exploring the potential role, practicality and safety of 3D modelling for preoperative planning and intraoperative use during RAPN at our institution. To the best of our knowledge this is the first prospective UK-based study of this kind and was approved by the local ethics committee.

The main novel contributions of this work in addition to providing a highly detailed and interactive 3D model of the kidney tumour are as follows:

1) A novel way of colouring vessels to highlight uncertainty within the 3D model and improve safety.
2) A surgeon survey assessing the utility of the 3D models during the different phases of the operation.
3) A patient survey evaluating whether it is feasible to carry out a future randomised controlled trial of this technology.
4) A detailed discussion on the practicality and safety considerations when using 3D modelling as part of routine practice.

Materials and Methods

Twenty-four patients with a renal mass scheduled for robot-assisted PN at the Specialist Centre for Kidney Cancer at the Royal Free London NHS Foundation Trust were prospectively enrolled in the study. The study was approved by the South West Frenchay Research Ethics Committee (Ethics Number 18/SW/0238).

Imaging and 3D model generation: CT scans were performed by standard protocol for the staging of a solid renal mass, which is a contrast-enhanced CT with 1-3mm sections of the renal region with an arterial phase.

CT scans for patients in the intervention cohort were converted to deidentified 3D models prior to the patient's operation by the surgical planning company Innersight Labs.[11] 3D models were made available to surgeons pre-operatively using a web-based application, allowing for interactive rendering using a mobile phone or tablet. Buttons enabled the surgeon to render structures solid or transparent. The 3D model was also shown to the patients to better explain the procedure and highlight potential risks of the operation. Intra-operatively, a tablet was mounted on a stand next to the robotic-console to allow the surgeon to refer to the 3D model throughout the operation at any point.

Data Collection: Clinical data collected included mass size, R.E.N.A.L nephrometry score, laterality, T stage, and patient demographics age and sex. The primary outcome measure, operative (OR) time, and secondary outcome measures, clamp time (warm ischemia time - WIT), estimated blood loss (EBL), and hospital lenght-of-stay, were collected from the operation notes.

Patients were asked to complete a short survey before the operation, after having seen the 3D model. At the end of the operation, surgeons also completed a survey. For some questions, a Likert scale in the range 1-5 (Strongly disagree, disagree, neutral, agree, strongly agree) was used.

All operations were led by 3 consultant surgeons who were beyond their learning curve, having completed 100+ of RAPN operations, and were assisted by 3 trainee surgeons. Cases were equally distributed according to the RENAL score between the 3 consultants. Surgeons were not blinded to the source CT as part of the preoperative and intraoperative planning.

Statistical analysis: The prospective surgical outcomes were compared to a retrospective control group which did not receive 3D modelling. Individual case matching was performed using R.E.N.A.L score. This single matching variable was selected with the intention to balance the variable most likely influencing operative bias. Statistical analyses were carried out utilising t-test and Fisher's exact test for continuous or categorical variables, respectively.

Results

Two of the 24 patients were excluded from the study because their operations had to be postponed due to other medical complications. The retrospective cohort was selected from patients having undergone RAPN at our center within the last 12 months. Overall, 12 (55%) were cT1a and 10 (45%) cT1b tumours. No postoperative complications were noted and all patients had negative surgical margins. Two patients (R.E.N.A.L. score 11A and 10P) underwent conversion to radical nephrectomy due to risk of positive margins during resection. Clinical characteristics, patient demographics and surgical outcomes are shown in Table 1. Results from the surgeon survey and patient survey are shown in Table 2 and Table 3, respectively.

Table 1. Clinical characteristics, patient demographics and surgical outcomes.

Variable	RAPN with 3D (n=22, prospective)	RAPN without 3D (n=22, retrospective)	P
Age, years, mean (SD)	56.6 (11.1)	56 (11.7)	0.875
Sex, *n* (%)			
Male	15 (68.2)	16 (72.7)	1
Female	7 (31.8)	6 (27.3)	
BMI, kg/m^2 median, mean (SD)	28, 29 (4)	28.5, 36.1 (20.4)	0.105
R.E.N.A.L. score, median (IQR)	8 (6-9)	8 (6-9)	1

Clinical tumour size, mm, median (IQR)	35.5 (28.5-45)	37.5 (24.3-45)	0.704
Operative time, min, mean (SD)	158.6 (35)	153.4 (38.8)	0.677
Console time, min, mean (SD)	126.8 (36.7)	120.5 (46.4)	0.673
WIT, min, mean (SD)	17.3 (6.3)	17.8 (7.2)	0.724
EBL, mL, median (IQR)	125 (50-237.5)	100 (100-200)	0.993
Hospital LOS, days, median (IQR)	2 (2-3)	2 (2-2)	0.362
Conversion to radical, n (%)	2 (9.1)	4 (18.2)	0.664

Table 2. Surgeon survey results (n=22).

Surgeon survey question	**Likert score (1-5), median (IQR)**
Did you find the 3D model useful for pre-operative planning?	5 (5-5)
Do you believe that the 3D model helped to reduce clamp time?	4 (3.75-4)
Did the 3D model improve the patient's understanding of the procedure?	5 (4-5)
For pre-op planning, which of the following did you use the 3D model for?	**Number of answers yes (max n=22)**
Assisting with surgical approach i.e transperitoneal vs retroperitoneal	7 (31%)
Clarification of vascular anatomy	22 (100%)
Assessing feasibility of selective clamping	13 (59%)
Not needed	0 (0%)
Any other item?	“Planning shape of dissection plane”, “Extent of hilar involvement”.
During the operation, which of the following did you use the 3D model for?	**Number of answers yes (max n=22)**
Renal hilum dissection	21 (95%)
Identifying feeding arteries for clamping	20 (91%)
Assessing feasibility of tumour enucleation vs partial nephrectomy	14 (64%)
Clarification of the tumour margins	12 (55%)
Assisting with excision and suture planning	9 (41%)
Not needed	0 (0%)

Any other item?	None

Table 3. Patient survey results (n=22).

Patient survey question	Likert score (1-5), median (IQR)
Do you think that the use of the 3D model led to you having a better understanding of your procedure ?	5 (4-5)
	Number of answers yes (max n=22)
Would you agree to take part in a future randomised controlled trial?	22 (100%)

3D model use cases for surgical planning: 3D models were found to be most useful for cases with multiple feeding arteries and/or complex hilar tumours. Two such examples are shown in Figure 1. In other cases the 3D model helped in deciding whether a partial nephrectomy was feasible or whether instead a radical nephrectomy should be pursued to avoid otherwise likely complications, see Figure 2. The 3D model was also useful for planning and performing selective clamping, see Figure 3. For intermediate complexity tumours, further from the hilum, the 3D models were useful for managing vascular control and excision/suture planning, see Figure 4. For lower complexity tumours with standard vasculature of one main feeding artery and vein, the 3D model added little additional information to the surgeon. However reconfirmation of the anatomy and tumour position found intra-operatively against the 3D model, and tumour depth findings from ultrasound against the 3D model, was still reassuring to the surgeon and of benefit, see Figure 5.

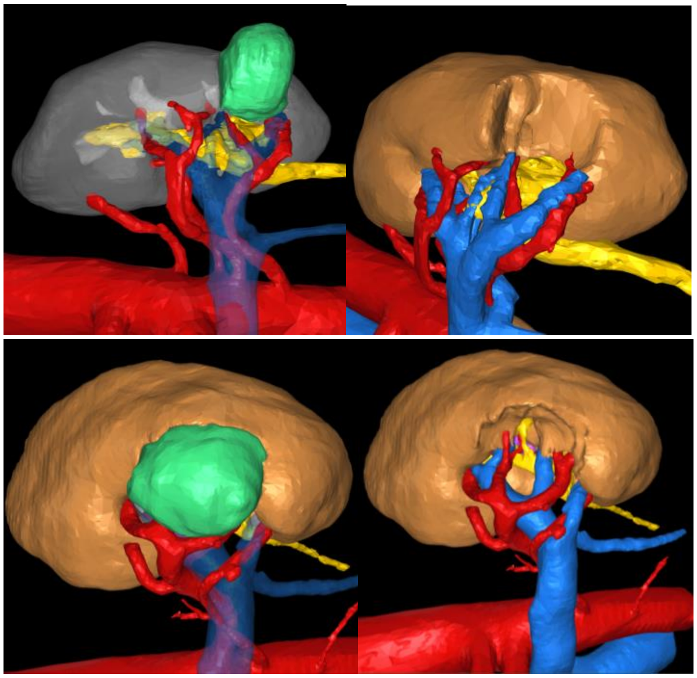

Figure 1: (Top) Hilar tumour with four feeding arteries. (Top Left) The vein is turned transparent so the four arteries can be seen clearly with respect to the main vein and clamped to control bleeding. (Right)

The tumour is removed from the 3D model to show the tumour bed and the “V” shaped vessels beneath, which could then be identified intraoperatively to aid with the enucleation of the tumour. (Bottom) Hilar tumour with two feeding arteries. (Bottom Left) View to aid in hilum dissection and vascular control (clamping) of both arteries. (Bottom Right) The tumour is removed to show the tumour bed and tertiary arteries feeding the tumour that can be clipped and secondary arteries that are to be preserved.

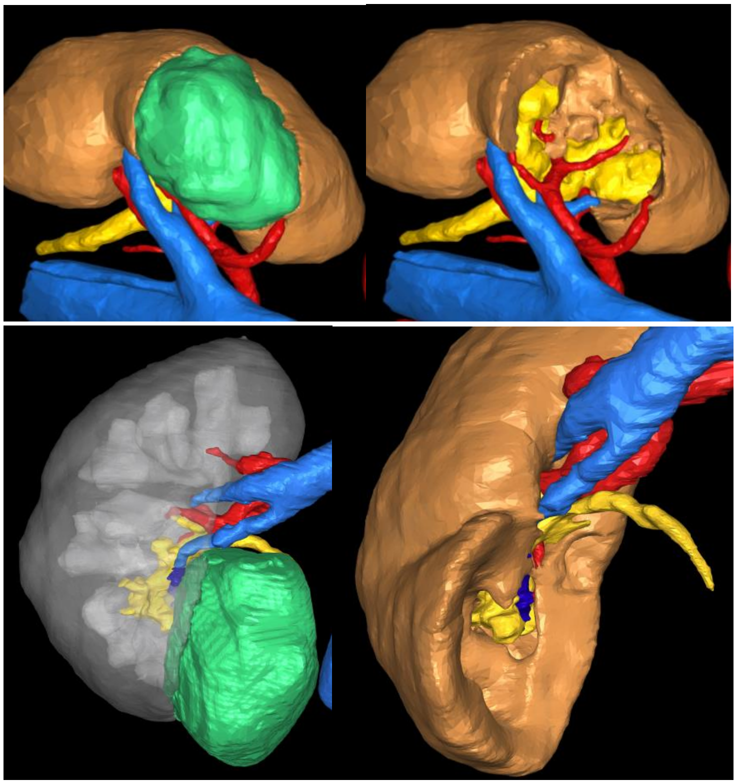

Figure 2: (Top) Large hilar tumour with involvement of the main arteries and large sections of the collecting system. Due to the high complexity, possibility of tumour invasion into the sinus fat, high chance of postoperative complication and a healthy second kidney a radical nephrectomy was carried out instead. (Bottom) Large lower mass. From inspecting the 3D model one can see how the tumour is pushing into the collecting system. Because of the high risk of damaging the collecting system beyond repair during tumour excision, a radical nephrectomy was carried out instead.

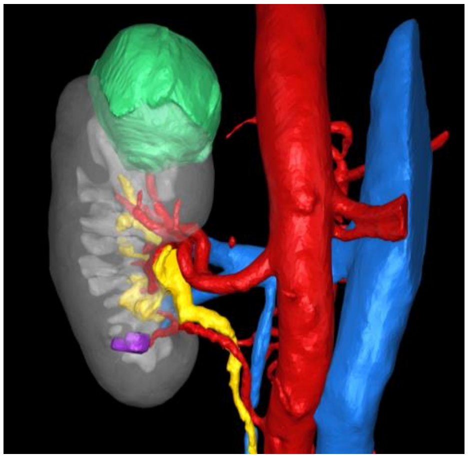

Figure 3: Posterior view of left kidney, with two feeding arteries. Selective clamping was performed, leaving the lower artery unclamped to limit ischemia.

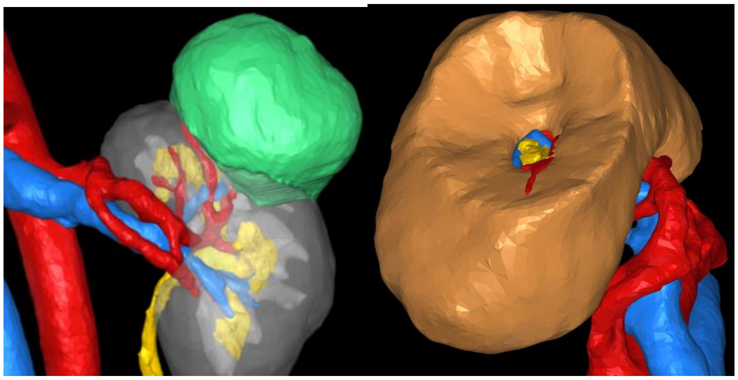

Figure 4: Intermediate complexity tumour with some limited amount of collecting system involvement. The 3D model aided with assessing the depth and amount of collecting system involvement (left), as well as suture planning (right).

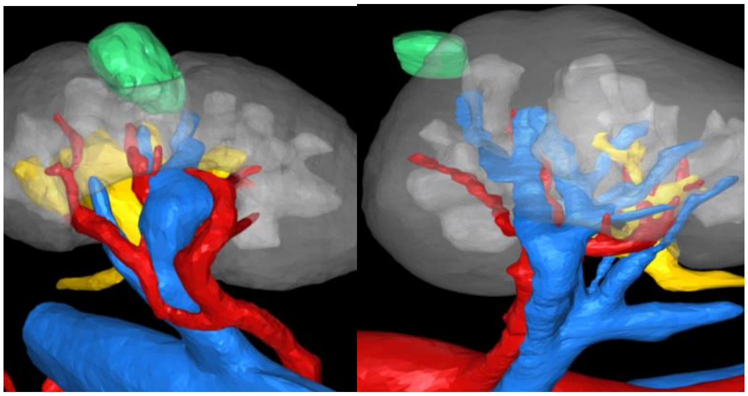

Figure 5: Smaller and lower complexity tumours. (Left) The 3D model was still useful for reconfirming intraoperative ultrasound findings that showed a dip in tumour, towards the right in the image, which helped to plan the excision. (Right) Small proximal and exophytic tumour and with single feeding artery. For this simpler case the 3D model was not needed but it did reconfirm the intraoperative findings.

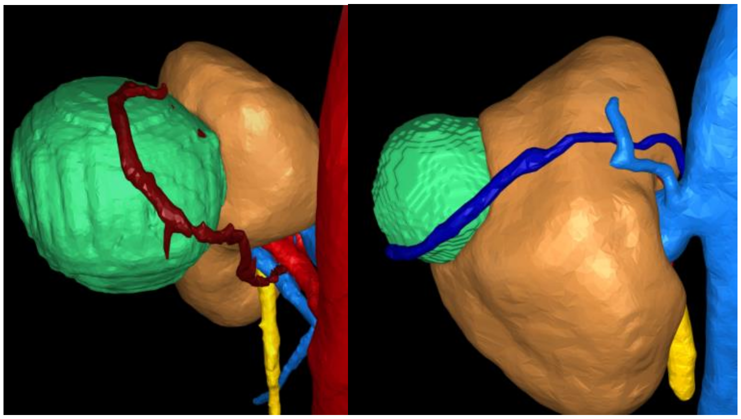

Figure 6: Thin vessels that start off near complex artery/vein crossing points are difficult to identify as being arteries, veins or other structures/vessels present in the perirenal fat, and therefore have a higher uncertainty associated with their labelling. To communicate this information to the surgeon in the 3D model a dark red and dark blue colour was used for uncertain arteries (Right) or veins (Left), respectively.

Discussion

The present feasibility study showed that 3D models of the renal anatomy can have a wide range of use cases in aiding with pre and intraoperative planning for robotic assisted partial nephrectomy. We also found that patients responded positively to their 3D models as it allowed them to better understand the operation and possible difficulties.

From the surgeon survey carried out (Table 2), surgeons agreed (Likert score 4) in 14/22 and strongly agreed (Likert score 5) in 1/22 cases that the 3D model helped to reduce clamp time. We acknowledge that this was not formally shown in the results section due to the small sample size of this feasibility study, however we feel that it was strongly suggested that the 3D model helped with the understanding prior to clamping of the exact depth of the tumour and the shape of the defect. This allowed the surgeon to precisely plan the excision of the tumour and renorrhaphy, which in turn would reduce the time planning this part of the procedure whilst on clamp. This is very well illustrated in Figure 1 which shows the nature of the defect and how one should plan the closure of the defect pre clamp.

Several studies have already investigated the use of 3D models for pre and intraoperative planning of RAPN. Porpiglia et al. focused on the current use of 3D models in urology highlighting how this technology is perceived as a useful tool for surgical planning, training, education, and patient counseling.[12] Studies were conducted to compare pre-operative planning using 3D and CT only, and both showed an improved understanding of the anatomy when using 3D.[8,13] Further, 3D models have been used for nephrectomy scoring, with preliminary results indicating that these could improve the prediction of complications compared to nephrometry scoring using CT.[14]

Multiple research groups have previously used 3D models intraoperatively via the da Vinci™ console using the TilePro™ function (Intuitive Surgical, Sunnyvale, USA), or using Google Cardboard virtual reality headset.[6, 15,16] We found that displaying the 3D model on a tablet assembled on a stand next to the robotic console, allowed the surgeon to refer to the 3D model when needed without restricting the intraoperative view.

It is also important to consider the practicality of using 3D models routinely in clinical practice. We only used arterial enhanced CT scans to generate the 3D models so applicability to other scanning modalities, such as MRI or CTs without arterial phase, remains to be tested.

Giving surgeons access to the 3D model through a secure website meant the 3D model was readily accessible by surgeons on a portable platform, such as their mobile phone, irrespective of operating system (iOS/Android), at any time and could be viewed whenever convenient, without having to install any specialised software. One practical limitation was that during the study a 3D model could only be requested from a dedicated computer with a full PACS installation. This meant that clinicians often had to go to a different floor to find such a dedicated computer to carry out the 3D model request which caused some inconvenience. Further integration with the PACS system is required to allow for seamless 3D model requests from any computer within the hospital.

Safety considerations when using 3D models: Using the 3D models for surgical planning was found to be safe, primarily because the surgeon is always in full control and can choose how and when to use the additional information of the 3D model within the complex surgical planning decision making process. Preoperatively, the 3D model is only used alongside the CT scan, intraoperatively the 3D model is used alongside the intraoperative findings from the endoscopic camera feed and ultrasound probe. Therefore even if the 3D model were to be inaccurate, then these inaccuracies would be found using other available information, and thus the potential for patient harm is reduced by this inherent redundancy in visual systems. This is somewhat supported by our surgical outcomes data that showed no significant difference between the 3D and non-3D group which is not surprising for such a small cohort. The accuracy of the 3D model depends on the quality and resolution of the input CT scan, and the experience of the engineer and clinician reviewing the 3D model during the validation step. 3D model inaccuracies can occur. For example, if it is difficult to see a small vessel in the preoperative CT scan due to relatively low image resolution (partial volume effect), or poor contrast uptake, then this vessel may not feature in the 3D model. We introduced a novel way of adding uncertainty information to the 3D model by colouring vessels that have a higher chance of being labelled incorrectly with a darker colour, as shown in Figure 6. In all of the 22 cases carried out during this study we found that the 3D model matched the anatomy found intraoperatively.

Limitations: Two limitations of the study need to be disclosed: being a feasibility study, a major limitation is the small size of the cohort and consecutive and non-randomised nature, which exposes it to risks of cohort and selection biases.

Future directions: Three-dimensional modelling seems to be most effective for highly complex tumours such as tumours with R.E.N.A.L >= 9 or T2a tumours which are starting to be attempted robotically. Further, a recent analysis of the ROSULA (RObotic SUrgery for LArge) renal mass consortium dataset showed that RAPN over radical nephrectomy for T2a renal masses can be safe whilst retaining the functional benefits associated with partial nephrectomy.[17] We hypothesize that for these challenging cases there is a strong potential for 3D modelling to improve surgical outcomes such as operative time, warm ischemia time, blood loss, and to reduce the number of complications and conversions to radical nephrectomy. A large multicenter randomised controlled trial investigating the use of 3D modelling for partial nephrectomy is required to confirm this hypothesis.

Conclusions

Three-dimensional modelling for surgical planning of RAPN was found to be safe. The main uses of 3D model technology for RAPN include assisting with identification and control of vasculature, approach to the renal masses and excision planning. To properly assess whether this technology improves surgical outcomes a larger randomised clinical study is needed.

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Ethical approval: This research was approved by the South West - Frenchay Research Ethics Committee (Ethics Number 18/SW/0238).

Informed consent: Signed informed consent was obtained from the patients enrolled in this study and for their anonymized information to be published.

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