Augmented reality to guide selective clamping and tumour dissection during robotassisted partial nephrectomy: a preliminary experience

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- 2 assisted partial nephrectomy: a preliminary experience

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**Keywords:** renal cancer; robotic partial nephrectomy; 3D model; augmented reality; selective clamping.

## 1 Abbreviations

2 RAPN: robot assisted partial nephrectomy

3 PSM: positive surgical margin

4 RCC: renal cell carcinoma

5 2D: 2 dimensional

6 3D: 3 dimensional

7 AR: augmented reality

8 CT: computed tomography

9 PC: personal computer

10 SD: Standard Deviation

11 IQR: interquartile range

## 1 **ABSTRACT**

- 2 **Introduction:** to explore the feasibility of augmented reality (AR) to guide arterial clamping
- during robot-assisted partial nephrectomy (RAPN).
- 4 Patients and Methods: 15 consecutive patients with T1 renal mass underwent RAPN
- 5 guided by AR. The 3D virtual model derived by computed tomography was superimposed
- 6 on the actual view provided by the Da Vinci video stream thought AR technology.
- 7 Preoperative plan of arterial clamping based on 2D conventional imaging, on 3D model
- 8 and the effective intraoperative surgical approach guided by AR were compared using the
- 9 McNeamar test.
- 10 **Results:** The plan of arterial clamping based on 2D preoperative imaging was recorded as
- follows: no clamping in 3 (20%), clamping of the main artery in 10 (66.7%) and selective
- clamping in 1 (6.7%) and super-selective clamping in 1 (6.7%) cases. After revision of the
- 3D model, the plan of clamping was modified as follows: no clamping in 1 (6.7%),
- clamping of the main artery in 2 (13.3%), selective clamping in 8 (53.3%) and super-
- selective clamping in 4 (26.7%) cases (p=0.03). The effective intraoperative clamping
- approach guided by AR-guidance was performed as planned in 13 (86.7%) patients.
- 17 **Conclusion:** AR for 3D guided renal surgery is useful to increase the adoption of selective
- 18 clamping during RAPN.

## Introduction

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Robot-assisted partial nephrectomy PN (RAPN) has been increasingly adopted in the treatment of T1 renal masses and lead to improve intraoperative and perioperative outcomes<sup>1-3</sup>. The preserved health renal parenchyma nearby the tumour is one of the most important predictors of long-term renal function<sup>4</sup>, while strong evidences concerning the ischemic damage to renal function are still lacking<sup>5</sup>. Nevertheless, to maximize the functional advantage of PN, different clamping approaches have been proposed<sup>6-8</sup>. Selective or super-selective clamping ideally induce ischemia targeted to the renal area nearby the tumour, however it could result in longer operative time due to the need of dissection of segmental arterial branches with higher risk of vascular damage. Thus, conventional 2-dimensional (2D) cross-sectional images are unable to identify the exact intrarenal vascular anatomy and to predict the real tumour blood supply from segmental branches<sup>9</sup>. Recently, some authors reported that 3-dimensional (3D) models elaborated from conventional 2D imaging<sup>9,10</sup> can be used as additional tools to improve the understanding of the size, location, depth of a renal mass and vascular anatomy before PN<sup>11</sup>. The high-fidelity 3D reconstruction of renal vasculature allows the surgeon to be more confident with selective or super-selective clamping <sup>12</sup> and to change the preoperative plan based on 2D imaging toward a more selective clamping approach<sup>9,13</sup>. An additional step towards the precise medicine and imaging-guided surgery is the adoption of augmented reality (AR) in different surgical interventions 14-20. During PN, the AR technology can facilitate a rapid and accurate anatomic identification of the renal vasculature. In this case-series we evaluate the intraoperative application of AR to identify the main anatomical structures and to guide the surgical dissection and the level of the arterial clamping during RAPN.

# Patients and methods

- 2 Study design, participants and sample size
- 3 We prospectively enrolled 15 consecutive patients with clinical diagnoses of T1 renal
- 4 mass, scheduled for RAPN at our institution between December 2018 and June 2019. One
- 5 single experienced robotic surgeon performed all the RAPN cases. Participants signed a
- 6 written informed consent document. The study was approved by our Institutional Ethics
- 7 Committee (IRB approval 3386/2018). The surgical complexity of the renal masses was
- 8 scored according to PADUA<sup>21</sup> and R.E.N.A.L.<sup>22</sup> score based on conventional imaging.
- 9 Then, PADUA and R.E.N.A.L. scores for each lesion were re-assessed in a separate
- section, using the 3D virtual model. The preoperative surgical plan to define the level of
- arterial clamping (namely, no clamping, non-selective, selective [first branch] or super-
- selective [second or tertiary branch] clamping) was recorded by surgeon basing on the 2D
- conventional imaging and re-assessed after reviewing the 3D virtual model before surgery.

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- 16 3D modeling
- 17 To obviate bias due to inaccurate 2D preoperative imaging, before surgery all patients
- underwent high quality chest and abdominal contrast-enhanced computed tomography
- 19 (CT) at our institution (slice thickness: 1.25 ÷ 2.5 mm, step interval: 0.8 ÷ 2.0 mm) using
- angiography protocol. Intravenous non-ionic contrast material (lomeprol 350 mg/mL,
- 21 Iomeron; Bracco Imaging srl, Milan, Italy) was injected at a flow rate of 3mL/s. The time
- delay to scanning was determined on the basis of the typical time to the renal arterial (25-
- 23 30s), parenchymal (80–100s), and delayed (5–10min) phases. All 3D virtual model
- 24 reconstructions based on preoperative high-quality CT scans, were carried out by the
- 25 Laboratory of Bioengineering of DIMES Department at the University of Bologna.

- 1 Multiple imaging series with different contrast levels were used for the selective
- 2 identification of each anatomical structure of interest (healthy parenchyma, tumour lesion,
- 3 arterial tree, renal veins, collecting system) in the image segmentation process.
- 4 Segmentation, i.e. the labelling of each structure of interest in each CT slice was achieved
- 5 using D2P<sup>TM</sup> software ('DICOM to PRINT'; 3D Systems Inc., Rock Hill, SC), a modular
- 6 software package designed to convert DICOM patient's medical images into 3D digital
- 7 models, and CE-certified for the purpose of preoperative surgical planning<sup>13</sup>.
- 8 Manual refinement of the overall obtained automatic/semi-automatic segmentation output
- 9 was carried out in 2 to 4 hours. The segmented anatomical structures arising from the
- multiple imaging series were then combined into one file using alignment of common
- 11 regions, such as the healthy renal parenchyma that was segmented in all the series
- 12 (Figure 1).
- 13 D2P<sup>TM</sup> was also used to obtain the 3D virtual models by converting the segmented
- 14 structures to 3D triangulated surface mesh file (STL), using mesh creation methods of D2P
- 15 (contour or gridbase).
- 16 For each case the surgeon viewed the 3D virtual model before the operation on a
- dedicated personal computer (PC) in the operating room.

19 AR technique

- 20 An ad-hoc hardware and software set-up (Figure 2) have been implemented in order to
- 21 develop an AR technique to guide robotic surgery. The surgical DaVinci video stream has
- been sent to a frame grabber (USB3HD, Startech, London, Ontario, Canada) connected to
- 23 an AR-dedicated PC (equipped with an Intel i7 CPU, 8 GB RAM and NVIDIA GeForce
- 24 840M video card), as previously described for prostatic surgery<sup>23</sup>. Thus, the received
- 25 DaVinci video stream and a 3D view of the 3D virtual model (MeshMixer, Autodesk Inc,
- 26 San Rafael, CA, US) have been overlapped in real-time (vMIX, StudioCoast Pty Ltd,

- Robina, Queensland, Australia). To this end, a biomedical engineer employed a 6 degrees
- of freedom (3D) mouse (SpaceMouse, 3D Connexion, Munich, Germany) for manipulating
- 3 the 3D virtual model in order to achieve, in agreement with the surgeon, the best alignment
- 4 with the Da Vinci video stream. The resulting AR video stream constituted of the 3D virtual
- 5 model aligned and superimposed on the actual anatomical view provided by the Da Vinci
- 6 video stream (AR-3D video stream) was then sent, in real-time, to a second monitor for
- 7 quality control and, at the same time, imported inside the robotic console by TilePro.

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- 9 Surgical technique
- 10 RAPN was performed using the DaVinci® Xi™ Surgical System (Intuitive Surgical Inc.,
- 11 Sunnyvale, CA, USA) in a four-arm configuration with the integrated Firefly™
- 12 fluorescence-imaging mode, as previously described<sup>3</sup>.
- During intervention, the exact identification of tumor's localization and the dissection of the
- renal hilum was guided by the AR-3D video stream, with the 3D virtual model manually
- oriented through the AR-dedicated PC by the assistant engineer. In case of a selective
- arterial clamping plan, 10 mg indocyanine green was injected after one or more segmental
- 17 vessels were clamped to assess if adequate ischemia of the tumour was achieved. If the
- 18 ischaemic area was not adequate, a non-selective clamp was then performed. After
- 19 tumour resection, early unclamping was always performed between inner renorrhaphy and
- 20 outer renorrhaphy, using the sliding clip technique as previously described<sup>24</sup>.

- 22 Statistical analyses
- 23 Mean and standard deviation were reported for continuous variables. Frequencies and
- 24 proportions were reported for categorical variables. Correlations between PADUA<sup>21</sup> and
- 25 R.E.N.A.L.<sup>22</sup> scores evaluated with and without the 3D model were calculated using the
- 26 Pearson correlation coefficient. Preoperative plan of arterial clamping based on 2D

- 1 conventional imaging, on 3D model and the effective intraoperative surgical approach to
- 2 the renal hilum guided by the 3D-AR video were compared using the McNeamar test. A p-
- 3 value of <0.05 was considered significant. All statistical tests were performed using SPSS

4 23.0 for Windows.

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## <u>Results</u>

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2 Overall, 9 (60%) and 6 (40%) tumours were clinical T1a and T1b stage, respectively 3 (Supplementary Table 1). After revision of the 3D virtual model reconstructions, PADUA 4 and R.E.N.A.L. scores were reassessed in 9 (60%) and 8 (53%) cases, respectively (all p≤0.04; Supplementary Table 2). The plan of arterial clamping based on 2D preoperative 5 6 imaging was recorded as follows: no clamping in 3 (20%), clamping of the main artery in 7 10 (66.7%) and selective clamping in 1 (6.7%) and super-selective clamping in 1 (6.7%) 8 cases. After revision of the 3D model, the plan of arterial clamping was modified as 9 follows: no clamping in 1 (6.7%), clamping of the main artery in 2 (13.3%), selective 10 clamping in 8 (53.3%) and super-selective clamping in 4 (26.7%) cases (Table 1; p=0.03). The intraoperative management of renal hilum was performed with clampless, non-11 12 selective, selective and super-selective approach in 2 (3.3%), (20%), 7 (46.7%) and 3 (20) patients, respectively. The effective intraoperative clamping approach guided by AR-13 guidance was performed as planned in 13 (86.7%) patients (Table 2). Median (IQR) warm 14 15 ischemia time (considering on clamp approach) was 9 (6-12) minutes. Mean± SD 16 estimated blood loss was 140± 190ml. No positive surgical margins were observed and 1 (6.7%) major (Clavien≥3) postoperative complication was observed. 17

# **Discussion**

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Several points of our study are remarkable. First, in our study we observed a significant 3 difference between preoperative planning based on 2D conventional imaging and the reassessment of surgical planning after revision of the 3D model resulting in a higher rate (80% vs. 13.4%) of selective and super-selective arterial clamping (p=0.03). Accordingly, Bianchi et al<sup>13</sup>. reported that the rate of intraoperative selective clamping was significantly higher in patients referred to partial nephrectomy with the use of 3D virtual models compared to individuals scheduled for preoperative planning based on conventional 2D imaging (57.1% vs. 13.3%; p = 0.01). Moreover, we found no significant differences between the preoperative plan of arterial clamping based on 3D virtual model and the effective intraoperative approach to the renal hilum guided by AR (p=0.4). Thus, the effective intraoperative management of renal hilum guided by AR-guidance was performed as preoperatively planned in 86.7% of patients. In 1 case the super-selective plan of clamping was change into a clampless approach due to exophytic pattern of the renal mass and in 1 patient the selective clamping planned based on 3D model was changed through non-selective clamping due to high fibrotic tissue at renal hilum with increased risk of vascular damage. Our results are consistent with those reported by Porpiglia et al. 12. Second, AR technology allows a fast and real-time overlapping of the 3D models inside the robotic console, thus it can guide surgeons during arterial clamping and dissection without the need of temporarily stop the intervention to review the 3D model on a separate device. Third, after revision of the 3D virtual reconstruction, PADUA<sup>21</sup> and R.E.N.A.L.<sup>22</sup> scores were reassessed in 9 (60%) and 8 (53%) cases, respectively (all p≤0.04) due to the better comprehension of tumour's anatomy, as previously reported<sup>25</sup>. Fourth, the 3D virtual renal models with AR implementation were found to be feasible to represent the intraoperative vascular anatomy (Supplementary Video). Finally, our 3D-planned RAPN proved to be safe, with no case of PSM. Moreover, 2 (13.3%) minor (Clavien 1-2) and only 1 (6,7%)

- 1 major (Clavien ≥3) postoperative complication were observed: urinary linkage managed by
- 2 ureteral stenting. In this case, the 3D model revealed suspected collecting system
- 3 involvement not detected by CT scan.
- 4 Our study is not avoid from limitations. First, the restricted number of patients included
- 5 limits our results. Second, despite the 3D-AR model is feasible to reproduce renal
- 6 anatomy, some variability between the model and the intraoperative findings should be
- 7 related to the lack in precisely defining consistence of tissues, to the patient's position on
- 8 the surgical table and to the surgical manipulation of tissues and organs. Third, the lack of
- 9 a control group of patients submitted to RAPN without the use of AR, did not allow to
- assess the real impact of this technology in modifying the surgical approach. Finally, the
- major limitations of AR-assisted surgery consist of possible registration inaccuracy,
- translating into a poor navigation precision and the need of manual external adjustments of
- the 3D model on the surgical field<sup>13</sup>. The size and shape of the kidney during a PN also
- 14 vary both because of the surgeon's manipulation of the organ and the dissection of
- 15 tissues<sup>26</sup>. Indeed, the 3D virtual model displayed in AR is manually moved and adjusted on
- the surgical field by an assistant nearby the surgical console with a dedicated computer
- and software for AR, with a potential impact on reducing the precision of the tracking and
- lengthening the surgical time. Thus, further efforts to improve the automatic registration of
- the virtual content (3D model) to the surgical view are expected by the future improvement
- 20 of artificial intelligence technology.

# 1 Conclusion

- 2 The use of AR for 3D guided renal surgery could be useful to improve the intraoperative
- 3 knowledge of renal anatomy and the surgical outcomes of RAPN with higher adoption of
- 4 selective and super-selective clamping approach.

# **Clinical practice points**

- 3D models can be used as additional preoperative tools to improve the understanding of the size, location, depth of a renal mass and vascular anatomy before robot assisted partial nephrectomy (RAPN).
- During RAPN, the augmented reality (AR) technology with overlapping of 3D models inside the robotic console, can facilitate a fast and accurate anatomic identification of the renal vasculature and tumour's anatomy in real time manner
- The 3D-guided approach with AR during RAPN allows surgeon to perform selective and super-selective clamping in higher proportion of cases compared to conventional planning based on 2D imaging.
- The effective intraoperative management of renal hilum guided by ARguidance was performed as preoperatively planned in 86.7% of patients.
- 3D models were more accurate than 2D standard imaging to evaluate the surgical complexity of renal masses according to nephrometry score's
- The use of AR for 3D guided renal surgery is useful to improve the intraoperative knowledge of renal anatomy with higher adoption of selective and super-selective clamping approach and safe surgical outcomes.

- 1 Acknowledgements
- 2 None



# 1 <u>Disclosure of potential conflicts of interest</u>

- 2 The project was supported by a Technology Research Grant by Intuitive Surgical for the
- 3 development of augmented reality technology in robotic surgery.

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# 1 Research involving Human Participants and/or Animals

- 2 All procedures performed in studies involving human participants were in accordance with
- 3 the ethical standards of the institutional research committee (Comitato Etico di Area Vasta
- 4 Emilia Centro, Policlinico Sant'Orsola-Malpighi, Bologna, Prot. N. 323) and with the 1964
- 5 Helsinki declaration and its later amendments or comparable ethical standards.

## 1 Figure legend

- 2 Figure 1. Example of the process to obtain the 3D virtual anatomical model using
- 3 D2P<sup>TM</sup> software (3D Systems) starting from patient CT scan (a), by the segmentation of
- 4 the renal regions of interest (b) to the final 3D renal model (c).
- 5 **Figure 2**. A schematic diagram of the hardware and software required to implement the
- 6 intra-operative use of AR to guide robotic surgery. The hardware components belonging to
- 7 the Da Vinci robot and the AR-dedicated devices are grouped in dashed line frames,
- 8 respectively. Moreover, in the "AR-dedicated devices" frame, the hardware part of the set-
- 9 up has been separated from the software running on the "AR-dedicated PC".

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**Table 1.** Intended level of arterial clamping planned basing on conventional 2D imaging and on 3D model and evaluation of the effective intraoperative approach with AR assisted surgery compared with the intended clamping approach based on 3D model (McNeamar test).

	Pre-surgical	Pre-surgical plan	X	Pre-surgical plan	Intraoperative	
	plan based on	based on 3D model	P	based on 3D model	approach with	Р
	2D imaging	.0	value		augmented reality	value
Level of clamping, n (%)		Pre				
No clamping	3 (20)	1 (6.7)	0.03	1 (6.7)	2 (13.3)	0.4
Main artery	10 (66.7)	2 (13.3)		2 (13.3)	3 (20)	
Selective (1 <sup>st</sup> segmental branch)	1 (6.7)	8 (53.3)		8 (53.3)	7 (46.7)	
Super-selective (2 <sup>nd</sup> -3 <sup>rd</sup> segmental branch)	1 (6.7)	4 (26.7)		4 (26.7)	3 (20)	

Table 2. Intraoperative, peri-operative and pathological characteristics

	Overall
WIT (min), n (%)	
0	2 (13.3)
1-19	13 (86.7)
≥20	0 (0)
WIT (min)	C.
Median (IQR)	9 (6-12)
Intraoperative clamping approach as planned, n (%)	.0
No	2 (13.3)
Yes	13 (86.7)
Intraoperative use of ICG, n (%)	
No	5 (33.3)
Yes	10 (66.7)
Operative time, min	
Median (IQR)	135 (113-177)
Time of resection, min	
Mean ± SD	9 ± 7
Time of renal suturing, min	40.0
Mean ± SD	12 ± 9
EBL, ml	
Mean ± SD	140± 190
Intraoperative complications, n (%)	
No	13 (86.7)
Yes	2 (13.3)

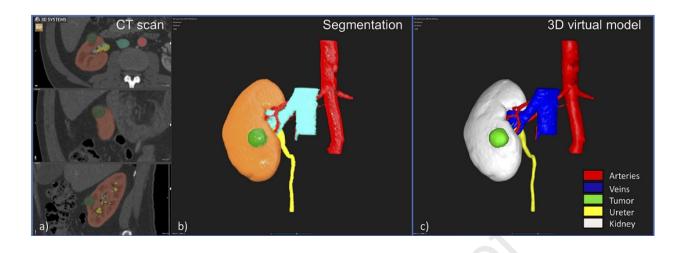
Conversion to open RN, n (%)	
No	15 (100)
Yes	0 (0)
Post-op complications grade, n (%)	
No complications	12 (80)
Clavien 1-2	2 (13.3)
Clavien ≥3	1 (6.7)
Positive Surgical Margins, n (%)	
No	15 (100)
Yes	0 (0)
Length of stay, days	5 (4-6)
Median (IQR)	3 (4 0)
Pathological lesion diameter, cm	3.6 ± 2.0
Mean ± SD	3.6 ± 2.0
Pathology, n (%)	
Benign	2 (13.3)
Clear cell carcinoma	9 (60)
Papillary carcinoma	2 (13.3)
Chromophobe carcinoma	1 (6.7)
Other malignancies	1 (6.7)
Pathological stage, n (%)	
pT1a	9 (60)
pT1b	5 (33.3)
рТ3а	1 (6.7)
Follow up time, months	

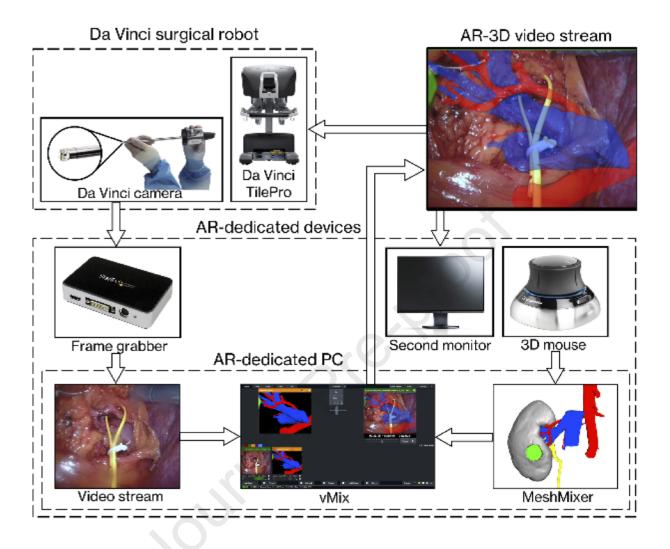
Mean ± SD	4 ± 2
Post-operative serum Creatinine (mg/dl) at last	
follow up	
Mean ± SD	0.85 ± 0.18
WIT We will be a six Time 100 to be a six One of DN	

WIT: Warm Ischemia Time; ICG: Indocyanine Green; PN/RN: Partial

Nephrectomy/Radical Nephrectomy; SD: standard deviation; IQR:

Interquartile range; EBL: estimated blood loss.





## **Clinical practice points**

- 3D models can be used as additional preoperative tools to improve the understanding of the size, location, depth of a renal mass and vascular anatomy before robot assisted partial nephrectomy (RAPN).
- During RAPN, the augmented reality (AR) technology with overlapping of 3D models inside the robotic console, can facilitate a fast and accurate anatomic identification of the renal vasculature and tumour's anatomy in real time manner
- The 3D-guided approach with AR during RAPN allows surgeon to perform selective and super-selective clamping in higher proportion of cases compared to conventional planning based on 2D imaging.
- The effective intraoperative management of renal hilum guided by ARguidance was performed as preoperatively planned in 86.7% of patients.
- 3D models were more accurate than 2D standard imaging to evaluate the surgical complexity of renal masses according to nephrometry score's
- The use of AR for 3D guided renal surgery is useful to improve the intraoperative knowledge of renal anatomy with higher adoption of selective and super-selective clamping approach and safe surgical outcomes.