


# Three-Dimensional Virtual Model for Robot-Assisted Partial Nephrectomy (RAPN): Development of Study Protocol for Evaluation of the Learning Curve to Optimize the Precision and Accuracy of the 3D Imaging

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**Abstract:** 3D models have been introduced as tools to improve surgeon's precision during Robotic-Assisted Partial Nephrectomy (RAPN). They showed to provide accurate anatomical details, improve operative time and patient safety by reducing complications. Over the last years, several useful models have been developed and proposed. However, literature is still scant regarding if and how the experience of the operator, and the learning curve, may impact the accuracy and precision of the model. In this light, the aim of the study is to evaluate the accuracy, the interpersonal variability of the precision and the learning curve for the segmentation of RAPN 3D preoperative models starting from CT images. This study will identify the influence of operator experience and learning curves on the accuracy of 3D preoperative models in RAPN, optimizing workflows for broader clinical adoption.

**Keywords:** 3D surgery, RAPN, three-dimensional, virtual model, nephrectomy

## Introduction

In recent years, minimally invasive approaches and in particular robotic and laparoscopic surgery have slowly spreading in many sectors of urological surgery, including cancers, functional urology and urolithiasis.<sup>1-4</sup>

Minimally invasive nephron-sparing surgery (NSS) through laparoscopic or robot-assisted approach are currently considered the gold standard for the management of T1 renal tumors, and recently also of T2 masses.<sup>5,6</sup> They allow to reduce the postoperative pain and morbidity compared to open NSS and to preserve precious Glomerular Filtration Rate (GFR) compared to radical nephrectomy.<sup>7,8</sup>

Over the last few years, patient-specific 3D models have been introduced as tools for improving surgeon's precision during Robotic-Assisted Partial Nephrectomy (RAPN). 3D models showed to provide accurate anatomical details of the patient organs for better preoperative planning, to reduce intraoperative complications, the operative time and to improve patient safety.<sup>9-15</sup>

Usually, these models are based on a specific software that allows the drawing of the renal anatomy and of the tumour on the basis of high-resolution imaging such as magnetic resonance (MRI) or computed tomography scans (CT scan).<sup>16-23</sup> However, every software requires an operator who designs and identifies the different anatomical and pathological structures based on radiological images. It follows that the accuracy of the 3D representation depends in part on the skill and experience of the operator/designer.

Up to now is unknown if the experience of the operator may impact the accuracy of the segmentation and if a learning curve is necessary in order to achieve a satisfactory precision. In this light, the aim of the study is to evaluate the accuracy, the interpersonal variability of the precision and the learning curve for the segmentation of RAPN 3D preoperative models starting from CT images. In detail, the primary, secondary and tertiary endpoints are:

- To evaluate the impact of operator experience on the accuracy of 3D models in RAPN.
- To define the learning curve required to achieve operator proficiency.
- To assess inter-operator variability in model segmentation and precision.

## Study Protocol

A prospective study will be carried out December 2024 at a single tertiary academic center (IRCCS Policlinico San Martino – Genova, Italy). All consecutive 3D imaging models of patients undergone RAPN for a T1 renal tumor from December 2023 and November 2024 will be included in the study. All patients were operated by a single experienced surgeon (C.T. > 500 RAPN).

The Inclusion criteria were the radiological diagnosis (contrasted CT-Scan) of renal mass eligible for RAPN. Every renal mass was preoperatively classified by the surgeon through the PADUA, RENAL and C-index nephrometry scores.<sup>24–26</sup> DICOM format images of the preoperative CT scan were processed by dedicated 3D segmentation certified software (Mimics inPrint 3.0.0.249 – Materialise NV Belgium 2018), authorized for medical use. All 3D reconstructions were performed by the same experienced urologist (P.T. > 150 3D reconstructions) and saved in an Institutional database.

Specific authorization was obtained from the ethics committee (Ethics Committee Regione Liguria) to carry out and include in a clinical study the 3D segmentation of patients undergoing surgery in our department. The authorization is registered with the number “CE2470PR241023 - PT44 554/2023\_13518”.

Four Urologists and five residents in urology (> PGY-3), all involved with different experience in renal cancer diagnosis and management, and naïve for the use of this technology, will undergo a video and an in-person tutorial for the use of the Mimics in Print software. Subsequently, they will independently segment the 3D images. In detail, the in-person training will be carried out following two steps: in the first phase, lasting one week, the trainees will have to view video tutorials of the Mimics program. In the second phase, they will try to carry out two reconstructions tutored by the master (P.T.). These reconstructions will not be evaluated for the learning curve analysis.

After reviewing the CT scans and the surgery video records, the main surgeon (C.T.) and an experienced radiologist (V.G.) will independently evaluate the 3D models drawn by the trainees, in comparison to the 3D model of reference performed by the master (P.T.).

In particular, the models will be evaluated in the light of the surgical procedure findings according to a nine-point Likert scale (1 stands for “very low accuracy” and 9 for “extremely high accuracy”) as per the Grading Recommendations, Assessment, Development, and Evaluations (GRADE) working group.<sup>27</sup> The rating will be performed with a blind method, in order to avoid any possible personal bias in the rating.

A curve representing the evolution of the error percentage of the 9 trainees will be drawn. The learning curve will be defined as the time needed for a naïve designer in order to achieve a < 5% error compared to a master in at least three consecutive models.

Statistical analysis will be performed using SPSS (version 22.0; IBM). Continuous variables will be reported as means and standard deviations (SD) and compared between groups using independent-samples *t*-tests. Categorical variables will be expressed as frequencies and compared using Pearson’s chi-square test or Fisher’s exact test when appropriate. A *p*-value of <0.05 was considered statistically significant.

## Conclusions

3D models represent the present and future of minimally invasive surgery also in the urological field. Currently, although multiple 3D models have been evaluated in terms of surgical outcomes, there are no reports regarding the learning curve regarding the preoperative design of accurate 3D models that can be used realistically and reliably during surgery. This study aims to address this gap in the urological literature in the field of renal surgery.

## Ethics Approval and Informed Consent

The study and protocol are in accordance with the Declaration of Helsinki, and the patients' informed consent to review the medical records was not required by the committee due to the retrospective nature of the data. However, the Institutional Review Board (IRB) granted exemption for written informed consent from the patients. Specific authorization was obtained from the ethics committee (Ethics Committee Regione Liguria) to carry out and include in a clinical study the 3D segmentation of patients with surgery in our department. The authorization is registered with the number "CE2470PR241023 - PT44 554/2023 \_ 13518".

## Acknowledgement

This work was carried out within the framework of the project "RAISE - Robotics and AI for Socio- economic Empowerment" and has been supported by European Union - NextGenerationEU.

## Disclosure

Paolo Traverso and Guglielmo Mantica are co-first authors for this study. The authors report no conflicts of interest for this work.

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