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SARAS

"Smart Autonomous Robotic Assistant Surgeon"

D1.1 – Requirements for surgical actions

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D1.1–Requirements for surgical actions

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1.0	30-06-2018	First submission to Participant Portal
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Updates on the first version of SARAS Deliverable 1.1

The present re-submission of SARAS Deliverable 1.1 “Requirements for surgical actions” includes:

- *The Risk Analysis of the SARAS benchmark Minimally Invasive Surgeries* (Task 1.2 - Chapter 3): this work has been performed between M7 and M12, according to the project GANTT;
- For the Robotic Assisted Radical Prostatectomy (RARP), *the transperitoneal anterior approach has been preferred to the transperitoneal posterior one* (see Paragraph 2.1.3.4). This change was dictated by pre-testing evidences on the robotic platform and phantoms, and in accordance with OSR surgeons, in order to enlarge the surgical working space and optimize the anatomical reconstruction of the phantom;
- *Changes in the Assistant’s trocars’ positions* (Paragraph 4.1.3): in order to maximize the freedom of movement in the available working space inside on prostate’s phantom, we studied, in pre-testing phase, a different position of assistant’s trocars;
- *Minor stylistic revisions to the text and an update of some Figures.*

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List of acronyms

SARAS	Smart Autonomous Robotic Assistant Surgeon
OSR	Ospedale San Raffaele
PCa	Prostate Cancer
MIS	Minimally Invasive Surgery
OR	Operating Room
AI	Artificial Intelligence
RRP	Retropubic Radical Prostatectomy
LRP	Laparoscopic Radical Prostatectomy
RARP	Robotic Assisted Radical Prostatectomy
LRN	Laparoscopic Radical Nephrectomy
LPN	Laparoscopic Partial Nephrectomy
LR/PN	Laparoscopic Radical/Partial Nephrectomy
BPH	Benign Prostatic Hyperplasia
PSA	Prostate-Specific Antigen
AJCC	American Joint Committee on Cancer
TNM	Tumour Node Metastasis
UICC	International Union against Cancer
AFMS	Anterior Fibro Muscular Stroma
SV	Seminal Vesicle
FT	Fibrovascular Tissue
RsR	Retropubic space of Retzius
EPF	Endo-Pelvic Fascia
DVC	Dorsal Venous Complex
APF	Anterior Prostatic Fat
NVB	Neuro-Vascular Bundle
VUA	Vesico-Urethral Anastomosis
RCC	Renal Cell Carcinoma
TMM	Tissue Mimicking Material
H-FMEA	Healthcare Failure Mode and Effects Analysis
FMs	Failure Modes
CI	Criticality Index
O	Occurrence
S	Severity
D	Detectability

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1 Introduction

The SARAS research project addresses the topic of automatization in surgical procedures, through the development of general methods for cognitive surgical robots capable of combining sensing, dexterity and cognitive capabilities to carry out autonomously simple surgical actions for two reference procedures: Robotic Assisted Radical Prostatectomy (RARP) and Laparoscopic Radical/Partial Nephrectomy (LR/PN).

Therefore, it is of cardinal importance understanding the surgical background for which SARAS technologies are going to be developed, embracing not only the anatomical working space for the selected benchmark procedures, but also the surgical flow of actions and the cooperation between the main surgeon and the assistant during the operation.

To this extent, the role of Work Package 1 (WP1) is to identify the knowledge involved in planning and executing surgical actions, develop a unified representation of their a priori knowledge, and outline the clinical requirements for the reference surgical procedures in terms of:

- Anatomical structures (and their variants), and related characteristics, to be considered for the development of the phantom models on which the automated surgical platforms are going to be trained (WP2);
- Anatomical structures (and their variants) to be considered for navigating into the surgical working space (WP3/6);
- Surgical steps and actions of the assistant surgeons to be replicated by the SARAS robotic arms (WP4/5/6);
- Operational risks to be considered, and possibly handled by SARAS, during the surgical workflow (WP4/5/6).

All these requirements will be translated into a set of system technical specifications and performance thresholds, which will drive the development of the SARAS robotic platforms (WP7).

1.1 *Purpose and structure of the document*

The aim of this document is to collect all the clinical and safety requirements of the SARAS surgical benchmark procedures.

SARAS Deliverable 1.1 is structured as follows:

- The first part (*Chapter 2*) is divided into three main sections each one focusing on a specific surgical procedure (i.e. RARP, LRN and LPN), comprehensive of the anatomical site description, clinical details on the pathology and procedural workflow (pre-operative preparation, position of patient, surgical instruments chosen, procedure and post-operative course). Particular attention has been paid to the interaction and coordination between the first surgeon – operating at the da Vinci console (only for RARP) – and the assistant;
- *Chapter 3* provides a description of the Risk Analysis performed for each procedure;

- *Chapter 4* describes the SARAS simplified models of the RARP and LR/PN procedures, suitable to be translated in mathematical terms for the implementation of project solutions;
- *Chapter 5* separates the clinical requirements into two categories: phantoms-related requirements and procedures-related ones;
- The attached documents (Annexes to Deliverable D1.1) include the appendices which provide further information concerning the researches carried out, but that have not been included in the main part of the text in order to ease the reading of the document:
    - Appendix I reports details about the procedural steps of the **complete** current procedures (i.e. as they're performed into real surgical practice): RARP, LRN and LPN.
    - Appendix II reports details about the Risk Analysis performed for each procedure (RARP, LRN and LPN), dividing the surgical procedures into single actions of both the first surgeon and the assistant. A list of potential Failure Modes that can occur in each sub-process (both main surgeon's and assistant's actions), clarifying also the corresponding possible Failure Causes and Effects.
    - Appendix III describes the modeling of the SARAS **simplified** procedures, in order to develop the actions and knowledge modeling related to assistant's tasks.

It is worth highlighting that the implementation and the experimental execution of the surgical tasks considered in the project may not follow the order in which they have been described within this document. The criterion adopted for the presentation is related to the major or minor availability of information about each surgical task collected during the first six months of the project.

2 Surgical Background

In the context of the SARAS project, two specific surgical benchmarks were chosen to showcase the potentialities of the robotic platforms developed:

- *Robotic Assisted Radical Prostatectomy (RARP)* – which is the resection of the whole prostate gland in patients with prostate cancer, with a secondary aim of preserving urinary continence and erectile function;
- *Laparoscopic Partial or Radical Nephrectomy (LPN/LRN)* – which is a partial or complete removal of the kidney due to a renal cancer.

These two interventions are, respectively, the gold standard procedures for Robotic-Assisted surgeries (i.e. RARP) and laparoscopic ones (i.e. LRN), and constitute the ground from which deriving the reference acceptance thresholds of the objective performance measures (e.g. in terms of execution time, accuracy, surgeon workload) of the SARAS platforms. In particular, RARP will be the surgical test field for the SOLO-SURGERY system and the LP/RN for the LAPARO2.0 one (see Deliverable 9.1 "Project Management Handbook" for more details).

In the following, it is presented the SARAS surgical background comprehensive of the anatomical site description, clinical details on the pathology and procedural workflow of both the reference surgeries. To this extent, the two procedures have been studied through *formal desk research methods*, i.e. literature reviews of both publications and surgical manuals, and *ethnographic researches* conducted by the SARAS team, i.e. brainstorming sessions with Ospedale San Raffaele (OSR) expert urological surgeons and direct observations in the operating room during intervention executions. The part regarding the description of the surgical workflows for both the procedures required a deep investigation on the available literature which was carried out through PubMed database[1] or Google Scholar. A specific list of keywords like "Robotic prostatectomy", "Prostate cancer", "Laparoscopic nephrectomy" and "Surgical technique", was used to assist the research. Only English language publications published within the 2002-2017 timeframe were selected. This last choice was dictated by the need of finding the most up-to-date and standardized procedural descriptions to refer to while developing SARAS technological solutions. Additional inclusion criteria were: *(i)* the description, within the publications, of the entire procedure step by step and *(ii)* a focus on the corresponding surgical actions performed both by the first surgeon and the assistant.

To lay the basis for the definition of the SARAS simplified procedures (see Chapter 4), the RARP and LR/PN surgical workflows were then modeled in a sequence of tasks with a high granularity, in order to provide a formal representation of the patterns of the surgical procedures. The corresponding outcomes can be found in Appendix I (Chapter 7).

[1] https://www.ncbi.nlm.nih.gov/pubmed/

2.1 *The SARAS benchmark procedures: Robotic Assisted Radical Prostatectomy*

Prostate Cancer (PCa) is the most frequent diagnosed malignancy and the fifth leading cause of cancer mortality in men, and represents a substantial public health burden (Jacques Ferlay et al., 2015). Established risk factors for PCa include advanced age, black race, a family history of the disease and certain genetic polymorphisms.

Currently the available therapeutic options for PCa are the following[2]:

- *Radical Prostatectomy* – consists in surgically removing the prostate gland; it could also include the removal of seminal vesicles and some nearby lymph nodes;
- *Radiotherapy* – which uses high-energy X-rays to treat the disease;
- *Hormonal therapy* – the goal is to reduce levels of male hormones, called androgens, or to stop them from feed prostate cancer cells. Androgens stimulate prostate cancer cells to grow. The main androgens in the body are testosterone and dihydrotestosterone. Lowering androgen levels, or stopping them from getting into prostate cancer cells, often makes prostate cancers shrink or grow more slowly for a time.
- *Other therapies* – for example the Cryotherapy (also called cryosurgery or cryoablation) is the use of very cold temperatures to freeze and kill prostate cancer cells.

The therapeutic option for prostate cancer is strongly influenced by the patient and personal preferences as well as by the experience of the treating physician (Wallis et al., 2016).

Surgeons can choose between two different approaches to reach and remove the prostate during a Radical Prostatectomy:

1) *Open prostatectomy*: is the traditional open surgical method, where the surgeon removes the prostatic gland through a vertical 8- to 10-inch incision below the umbilicus;

2) *Minimally Invasive Procedures*, which do not make use of retractors nor require the abdominal wall to be parted and stretched for the duration of the operation:

    a) Laparoscopic Radical Prostatectomy (LRP): to access the prostatic gland, surgeons make 5 small incisions across the abdomen to position the trocars where laparoscopy-specific surgical tools and camera are inserted. Radical Prostatectomy is then performed from outside the body of the patient, while the surgeon views the entire operation on a video screen (Lipke M. & Sundaram C.P., 2005);

    b) Robot-Assisted Radical Prostatectomy (RARP): as in regular LPR, the surgical area is accessed through small incisions in the abdomen and the use of trocars. However, in this case the first surgeon controls an advanced robotic system capable of moving surgical

[2] http://www.roboticoncology.com/prostatectomy/

tools from outside the body. A high-tech interface lets the surgeon use natural wrist movements and a 3D screen during the entire operation.

In 2003, only 9.2% of Radical Prostatectomies were done using Minimally Invasive Procedures; by 2007, that number jumped to 43.2%. In 2009, researchers in Boston reported on a study that compared outcomes, benefits, and complications of open surgery compared to MIS which results are summarised here below (Hu et al., 2009):

- No significant difference was found in the number of deaths or in the need for additional cancer therapy between the two approaches (Laudicella, Walsh, Munasinghe, & Faiz, 2016);
- The median hospital stay is reported to be of two days for MIS and three days for Open Surgery (Engel, 2018);
- Only the 2.7% of patients undergoing laparoscopic surgery required a blood transfusion compared to the 20.8% having open surgery (Hu et al., 2009);
- There were fewer respiratory complications with MIS (4.3%) than with open surgery (6.6%);
- There were lower rates of incontinence and erectile dysfunction with open surgery. The overall rate was 4.7% for laparoscopic surgery and 2.1% for open surgery(Hu et al., 2009).

Since 2004-2005, RARP has gained increasing acceptance among patients and urologists and it became the dominant technique in the United States, Europe and in many other centers worldwide, despite the lack of evidence demonstrating its superiority. So far, there is no multi center-randomized trial comparing RARP to LRP to support the benefits of the first approach. In fact, most of the comparative analyses are derived from single cohorts and meta-analysis of large volume single center prospective studies. In this contexts, RARP has been associated with decreased operative blood loss and decreased risk of transfusion when compared with LRP (Valdivieso, Hueber, & Zorn, 2013a). However, the use of the robotic surgical approach in urology continues to grow across the globe: in a comparative analysis of global practice patterns (Jeong, Kumar, & Menon, 2016)(Seo, Cho, Cho, Kang, & Yoo, 2013) in urologic robotic surgery results that, in the more established robotic environment of Europe and North American continents, robotic radical prostatectomy, robotic radical cholecystectomy and robotic nephrectomy represent nowadays the gold standards.

Risks of Radical Prostatectomy

Radical prostatectomy is characterised by a low risk of serious complications: death or serious disabilities are rarely reported (Hoge et al., 2010). Less than 10% of men experience complications after prostatectomy, and these are usually treatable or short-term. However, as important nerves (Neurovascular Bundle, NVB) travel through the prostate, complications from inadvertent nerve damage can occur after radical prostatectomy (Michaelson et al., 2008).
Tewari et al. reported that patients with greater degrees of nerve-sparing had higher rates of intercourse and return to baseline sexual function and early return of urinary continence without compromising oncologic safety (Tewari et al., 2011).

The most common complications after prostatectomy include:

- Urinary incontinence: the loss of the ability to control urination;
- Erectile dysfunction: Problems with erections are common after prostatectomy; the younger the man, the higher the chance of maintaining potency after prostatectomy.

Other complications of radical prostatectomy include: bleeding after the operation, urinary leaks, blood clots, Infection, poor wound healing, groin hernia, narrowing of the urethra causing the block of the urine flow (Michaelson et al., 2008).

Success of Radical Prostatectomy

The goal of radical prostatectomy is to cure prostate cancer. However, this could be achieved through RP only if prostate cancer is limited to the prostate. During the surgical intervention the removed prostate is examined under a microscope to see if prostate cancer has reached the edge of the prostate. If so, the tumor has probably damaged the tissue of the surrounding anatomical sites. In this case, further treatments may be needed. Men with no evidence of prostate cancer metastases have an 85% chance of surviving 10 years after radical prostatectomy (Veeratterapillay, Goonewardene, Barclay, Persad, & Bach, 2017).

What to Expect After Radical Prostatectomy

The typical hospitalisation after RP is of two to three days. A urinary catheter is inserted during the surgery, and some patients may need to keep on wearing it at home for a few days to a few weeks. Pain after radical prostatectomy can generally be controlled with prescription of analgesics. It can take from some weeks to months for urinary and sexual function to return to normality. After RP, regular follow-up is essential to make sure prostate cancer does not return (Radical Prostatectomy - A Patient Guide, 2014).

2.1.1 Anatomy of the prostate

The prostate is an exocrine gland of the male reproductive system. The mean weight of the healthy adult prostate is about 40 grams, the size is about 5x2x3 centimeters (Good et al., 2014). PCa, however, doesn't change prostate's dimension, but affects it stiffness, making it harder in the area affected by the tumor.

The base of the prostate borders with the bladder neck and the apex with the urogenital diaphragm. The Denonvilliers' fascia, a thin, filmy layer of connective tissue, separates posteriorly the prostate and seminal vesicles from the rectum (see Figure 1). Skeletal muscle fibers, from the urogenital diaphragm, extend into the prostate at the apex and posteriorly up to the mid-prostate (Hammerich, Ayala, & Wheeler, 2008).

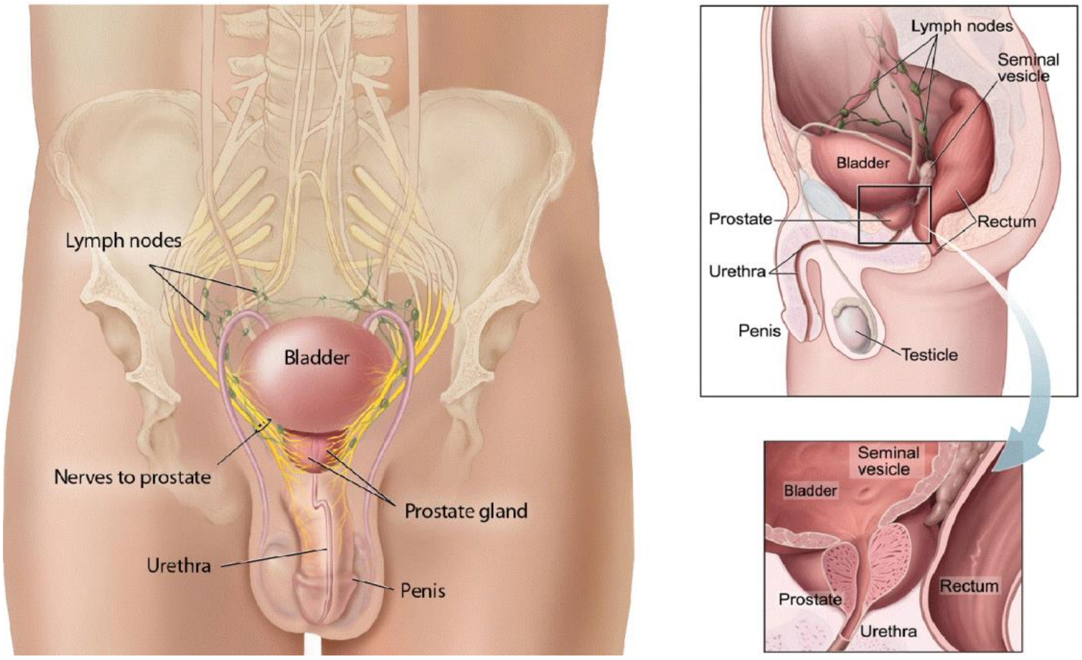


Figure 1: Frontal and lateral sections of Pelvis (from National Cancer Institute)

The anatomy of the prostatic gland can be divided into different zones: the *peripheral zone* comprises all the prostatic glandular tissue at the apex as well as the tissue located posteriorly near the capsule (Figure 2). In this zone, carcinoma, chronic prostatitis, and post inflammatory atrophy are relatively more common than in the other zones. The *central zone* is a cone-shaped area of the gland, with the apex of the cone located at the confluence of the ejaculatory ducts and the prostatic urethra at the seminal colliculus (Figure 2). The *transition zone* consists of two equal portions of glandular tissue lateral to the urethra in the midgland (Figure 2). This portion of the prostate is involved in the development of age-related benign prostatic hyperplasia (BPH) and, less commonly, adenocarcinoma. The *Anterior Fibromuscular Stroma* (AFMS) forms the convexity of the anterior external surface. The apical half of this area is rich in striated muscle, which blends into the gland and the muscle of the pelvic diaphragm. The distal portion of the AFMS is important in voluntary sphincter functions, whereas the proximal portion plays a central role in involuntary sphincter functions.

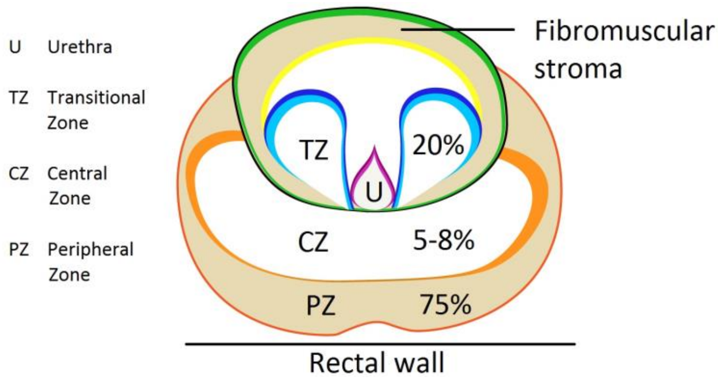


Figure 2: Zonal anatomy of the normal prostate (from Wikimedia Commons)

The histologic architecture of the prostate is that of a branched duct gland. Two cell layers, a luminal secretory columnar cell layer and an underlying basal cell layer, line each gland or duct (Hammerich et al., 2008). The prostate is composed of fibrous tissue surrounding the gland. This capsule is best appreciated posteriorly and posterolaterally as a layer more fibrous than muscular, between the prostatic stroma and extraprostatic fat (Shappell et al., 2004). The Seminal Vesicles (SV) are located superior to the base of the prostate. They undergo confluence with the vas deferens on each side to form the ejaculatory ducts (Figure 1). The ejaculatory duct complex consists of the two ejaculatory ducts, alongside with a second loose stroma rich in vascular spaces. The Seminal Vesicles are resistant to nearly all of disease processes that could affect the prostate. Seminal Vesicle involvement by prostate cancer (PCa) is one of the most important predictors for PCa progression.

<u>Neural anatomy</u>

The prostate is a well-innervated organ: two neurovascular bundles are located postero-laterally adjacent to the gland and form the superior and inferior pedicles on each side. These nerves are important in regulating the physiology, morphology, and growth maturation of the gland. The prostate receives both parasympathetic and sympathetic innervation, the former from the hypogastric and pelvic nerves, and the latter from a peripheral hypogastric ganglion (Jang et al, 2015). The neurovascular bundles are responsible for the penile erection, so urologists have put an increasing interest on nerve-sparing during surgical treatment of PCa (Castiglione, Ralph, & Muneer, 2017).

2.1.2 Pathology

In the prostate, many benign diseases can occur. For example, Benign Prostatic Hyperplasia (BPH) is a very common disease, with an increasing incidence on increasing age, which can result in bladder outlet obstruction with lower urinary tract symptoms. Other benign conditions of the prostate are acute and chronic prostatitis. An acute prostatitis is an acute bacterial infection associated with prostatic swelling, pain and fever, which can lead to urinary retention. A chronic prostatitis is a more diffuse disease.

PCa is most commonly an adenocarcinoma (>95% of cases) developing from the normal gland of the prostate. Other types of tumor are neuroendocrine differentiation and small cell carcinoma (Parimi, Goyal, Poropatich, & Yang, 2014). The current standard practice to evaluate Prostate Cancer, and define the proper treatment for it, is based on the combination of cancer staging and Prostate-Specific Antigen (PSA) evaluation. Cancer staging is the process of determining how much cancer is in the body and where it is located. Staging describes the severity of an individual's cancer based on the magnitude of the original (primary) tumor as well as on the extent cancer has spread in the body. Understanding the stage of the cancer helps doctors to develop a prognosis and design a treatment plan for individual patients.

Since 1977, when the American Joint Committee on Cancer (AJCC) published the first edition of the Cancer Staging Manual (Manual for Staging of Cancer, 1977), the methodological approach is to use the T (tumor extent), N (lymph node invasion), and M (presence or absence of metastasis) classifications to group patients. More specifically, for PCa the Tumour Node Metastasis (TNM) classification from the International Union Against Cancer (UICC) is used; Table 1 shows the 2017 version of the TNM classification (Buyyounouski, Cancer & Manual, 2017):

Table 1: Prostate Cancer TNM Criteria

T		**Primary tumour** (Primary tumour cannot be assessed)
0		No evidence of primary tumour
T1		Clinically unapparent tumour not palpable or visible by imaging
	T1a	Tumour incident histological finding in 5% or less of tissue resected
	T1b	Tumour incident histological finding in more than 5% of tissue retracted
	T1c	Tumour identified by needle biopsy (e.g. because of elevated Prostate-specific antigen, PSA level)
T2		Tumour confined within prostate[1]
	T2a	Tumour involves one half of one lobe or less
	T2b	Tumour involves more than half of one lobe, but not both lobes
	T2c	Tumour involves both lobes
T3		Tumour extends through the prostatic capsule[2]

	T3a	Extracapsular extension (unilateral or bilateral), including microscopic bladder neck involvement
	T3b	Tumour invades seminal vesicles(s)
T4		Tumour is fixed or invades adjacent structures other than seminal vesicles: external sphincter, rectum, elevator muscles, or pelvic wall

Notes:

[1] *Tumour found in one or both lobes by needle biopsy, but not palpable or visible by imaging, is classified as T1c.*

[2] *Invasion into the prostatic apex or into (but not beyond) the prostatic capsule is not classified as T3, but as T2.*

N		**Regional lymph nodes[3]**
	NX	Regional lymph nodes cannot be assessed
	N0	No regional lymph nodes metastasis
	N1	Regional lymph node metastasis4

Notes:

[3] *The regional lymph nodes are the nodes of the true pelvis, which essentially are the pelvic nodes below the bifurcation of the common iliac arteries.*

[4] *Metastasis no larger than 0.2cm.*

M		**Distant metastasis[5]**
	MX	Distant metastasis cannot be assessed
	M0	No distant metastasis
	M1	distant metastasis
	M1a	Non-regional lymph nodes(s)
	M1b	Bone(s)
	M1c	Other site(s)

Notes:

[5] *When more than one site of metastasis is present, the most advanced category should be used.*

2.1.3 RARP surgical operation

After having exposed a brief clinical background on PCa and Radical Prostatectomy, from now on the focus is going to be on the surgical benchmark chosen for SARAS among the possible approaches of MIS: the *Robotic Assisted Radical Prostatectomy (RARP)*. Before starting the narration, few comments should be made which define the choices made in describing the surgical procedure:

1. Two possible approaches exists to access the surgical area within RARP: *(i)* the *transperitoneal,* with the access to the abdomen and the *(ii) extraperitoneal* approach, with pelvic access (Rha, 2009). <u>The majority of RARP is executed through the transperitoneal approach, which is going to be the condition described in the SARAS procedural workflow</u> (Brown, Rodin, Lee, & Dahl, 2005). This preference is attributed to the greater working space and familiar landmarks of the pelvis associated with this kind of access. Although some studies have shown that an extraperitoneal approach has shorter mean operative time, shorter time to full diet, shorter hospital stays and earlier return to continence, other have found little or no difference between the two procedures (Valdivieso et al., 2013a). The use of the extraperitoneal approach may be favoured in patients with obesity or patients who had previous extensive abdominal surgery. In these particular cases, in fact, the peritoneum acts as a natural barrier, minimizing the potential for bowel injury and preventing the bowels from falling into the operative field and obscuring the surgeon's view (Cathelineau et al., 2004). Another potential advantage of this approach is to confine any urine leak that may occur from the vesico-urethral anastomosis within the extraperitoneal space (Kurokawa et al., 2017). On the other hand, the main limitation of the extraperitoneal approach remains the reduced working space as compared with the relatively larger working space of the peritoneal cavity gained with transperitoneal access. Lastly, a higher CO_2 absorption has been reported with extraperitoneal versus transperitoneal insufflation, requiring a higher minute volume to compensate for hypercarbia and associated acidosis (Valdivieso et al., 2013a).

2. Within the *transperitoneal* approach itself, two different modalities to reach the target organs can be used during RARP: *(i)* the first one is the *transperitoneal anterior approach* in which, after transperitoneal access and insufflation, the space of Retzius is immediately entered and the prostate gland, seminal vesicle, and vasa are reached and dissected from the front and *(ii)* the *transperitoneal retrovesical* approach, in which the seminal vesicles and vasa are initially reached and completely dissected behind the bladder. <u>In the SARAS case, the transperitoneal anterior approach will be taken into consideration.</u>

3. As reference surgical procedure, <u>the gold standard with da Vinci® System Xi will be described</u>, which it is the most commonly used robotic system nowadays.

2.1.3.1 Pre-operative preparation

For patients who will undergo a RARP, a minimum period of 6 weeks between the prostate biopsy and the operation is recommended. Anti-platelet agents are discontinued two weeks prior to the surgery and a clear liquid diet is given 18 hrs before the surgery (Colombo et al., 2007).

The surgical team present in the Operating Room (OR) is composed by: the main surgeon-operating at the da Vinci console, a surgical assistant (usually a trained urology resident)-operating at the surgical table with laparoscopic tools, a circulating nurse, a scrub nurse and the anaesthesiologist (Figure 3).

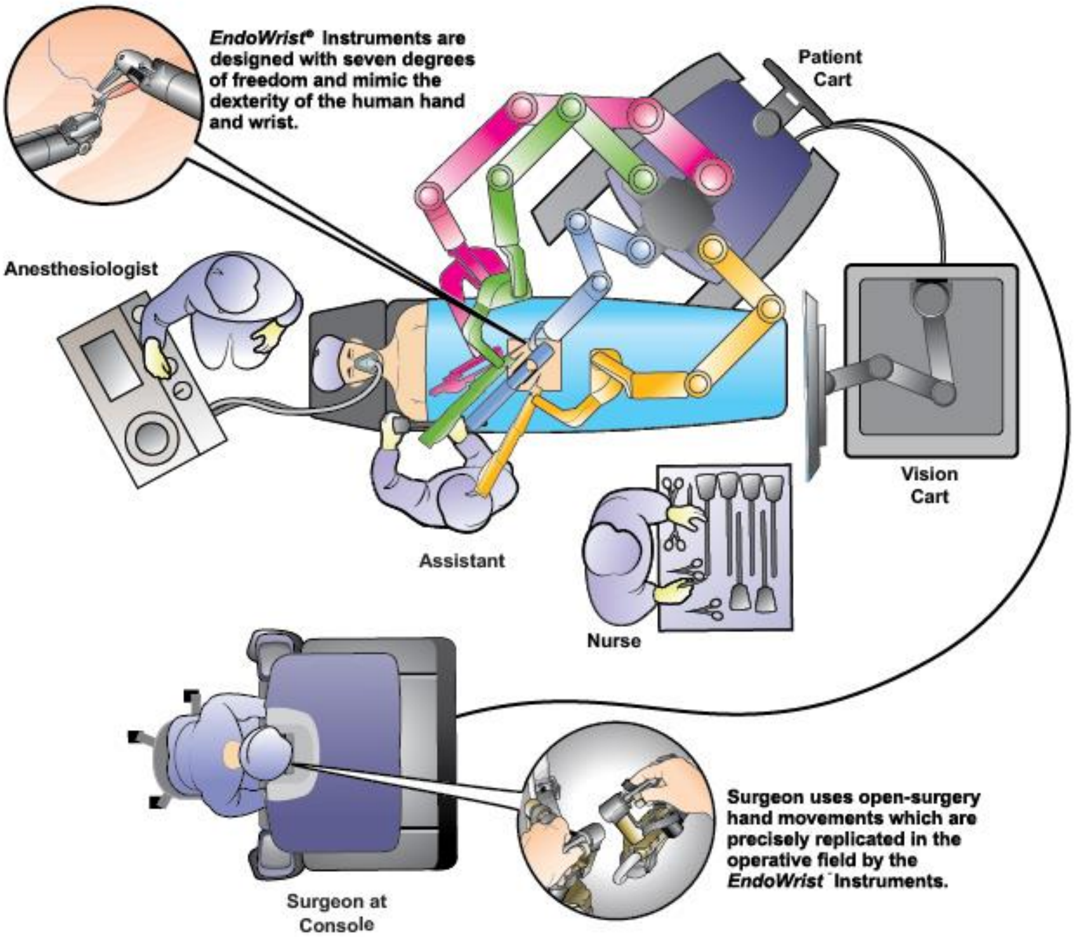


Figure 3: Operating room with da Vinci System Xi-© [2018] Intuitive Surgical, Inc.

2.1.3.2 Patient preparation and trocars' position

The main goals of patient positioning and port placements are maintaining the safety of the patient, avoiding compression injuries, allowing maximum mobility of the robotic arms, and facilitating a smooth and efficient surgery (Chang, Steinberg, Shah, & Gundeti, 2014). In addition, patient preparation is of importance with regard to proper positioning on the operating table, to allow for adequate docking of the robotic arms (Patel, Shah, Thaly, & Lavery, 2007).

The standard position of patient in RARP is *the low lithotomic position* requiring the use of stirrups to hold the patient's legs, with da Vinci Xi ® System in the patient's left side.

Figure 4: Position of the patient and the robotic arms at the end of the side docking operation (Photo courtesy of Luca Maria Vitale)

Only after this preparation has been completed, the patient is put in *Trendelenburg position* at an inclination of 30 degrees to facilitate exposure of the pelvic content (Figure 4). Studies have shown that patients undergoing this procedure in a steep Trendenlenburg position for 3h-4h do not present significant cerebrovascular, respiratory or hemodynamic problems and caution is advised for longer operative time (Valdivieso et al., 2013a).

At the beginning of procedure, an 18-inch Foley catheter is inserted into the bladder and subsequently, the trocars (for both robotic instruments and laparoscopic ones) are inserted in the patient's abdomen. The trocars are medical devices made up of an obturator (in metal or plastic), a cannula (basically a hollow tube), and a seal (Figure 5). They function as portals for the subsequent placement of the surgical instruments (see in the following paragraph 2.1.3.2).

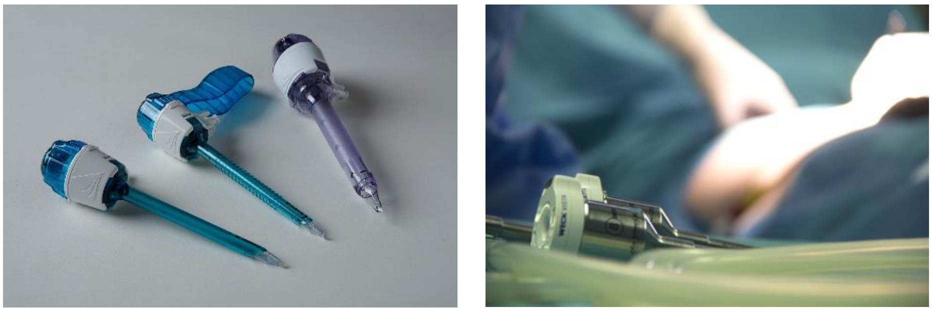


Figure 5: Example of trocars for laparoscopic surgery in plastic or metal (from Wikimedia Commons and Photo courtesy of Luca Maria Vitale)

In the considered RARP procedure, a 6-port placement configuration is drawn on the patient's abdomen prior to skin incisions. There are many options to insert the trocars, as studied from literature reviews, but we have chosen to analyse the current practise carried out at the San Raffaele

Hospital: four metallic robotic trocars are used by the working robotic arms of the first surgeon and two assistant ports are used for laparoscopic instruments by the assistant surgeon. An example of a trocar configuration is shown in Figure 6 and in the following Table 2. All 8mm ports were placed for the robotic arm: the first trocar over the umbilicus for camera port and other three ports for surgical instruments (at the right and two ports at left side of the camera port). A 5mm assistance port was placed at the right lateral to the camera port and the other 15mm assistance port above the right anterior superior iliac crest.

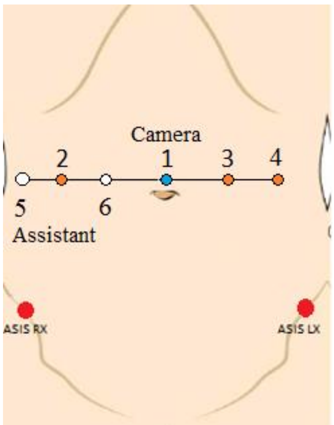


Figure 6: Trocars' position in prostatectomy with da Vinci System Xi

Trocar Number	Ø	Role	Positioning
Trocar 1	8 mm	da Vinci Xi camera	2 cm over the umbilicus
Trocar 2	8 mm	da Vinci Xi instrumental port	In line respect to Trocar 1, 8 cm on the right (patient's) side
Trocar 3	8 mm	da Vinci Xi instrumental port	In line respect to Trocar 1, 8 cm on the left (patient's) side
Trocar 4	8 mm	da Vinci Xi instrumental port	In line respect to Trocar 1, on the left (patient's) side of Trocar 3
Trocar 5	15 mm	Assistant instrumental port	In line with the others, on the right (patient's) side of trocar 2
Trocar 6	5 mm	Assistant instrumental port	In line with the others, between Trocar 1 and 2

Table 2: Description of geometric details for da Vinci Xi and assistant trocars in current procedure

The open Hasson access is done over the umbilicus; this technique consists of creating a small umbilical incision under direct visualization to enter the abdominal cavity followed by the introduction of a trocar. Pneumoperitoneum is then rapidly created, CO_2 insufflation pressure in general is maintained between 12 and 15 mmHg (Nasrallah & Souki, 2018)(Hung et al., 2016)(Collins, 2008).

Following initial trocar placement, secondary trocars are then placed under laparoscopic view.

2.1.3.3 Surgical instruments

The da Vinci Xi ® robot uses instruments with 6 degrees of freedom that provide the same flexibility of the human wrist. The instruments recommended for the robotic arms within a RARP execution are interchangeable and include: monopolar scissor, bipolar grasper, needle drivers and prograsp forceps. The instruments inserted within the trocars are then connected to the robot arms. The working robotic arms are attached to reusable 8mm trocars, while the camera is placed through a standard 12 mm laparoscopic port (see Table 3). The assistant uses suction-irrigator, Hem-o-lok clip applier, grasper, scissor and needle holder for laparoscopy. To optimize robot function and minimize the risk of collisions the angle created by the camera port and each working robotic port should be obtuse and the distance between the camera port and each working port should be at least 1 hand breadth (Gettman et al., 2003). The instruments used by the surgeon are reported in Table 3 for the modern da Vinci system. The assistant's instruments are analyzed in detail in Table 14 (Chapter 4.1.5).

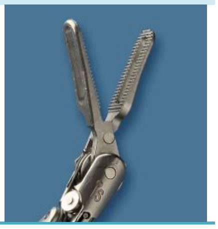
Robotic arms	da Vinci Xi® (4 robotic arms)	Instrument Function	Instruments figure[3]
1st arm	Camera	It is used to look inside the cavity of the body.	
2nd arm	Hot Shears (Monopolar Curved Scissors) – Needle Holder	The scissor is an energized instrument. It is used for cutting, dissection, so also to coagulate the tissue. The needle holders have to be particularly resilient in order to produce a firm grip of the needle.	
3th arm	Bipolar Forceps – Needle Holder	The bipolar forceps is an energized instrument. It is used for grasping, retraction, blunt-tip dissection and bipolar cautery. It allows for gentle tissue handling, these forceps needs less space for working. It is less traumatic for retracting the tissue.	
4th arm	Pro Grasp Forceps	This instrument is non-energized, its use is for holding the tissue, it improves traction for manipulation of the more structures.	

Table 3: Surgical instrument used with da Vinci Xi robot in the current practice of RARP-© [2018] Intuitive Surgical, Inc.

[3] *©[2018] Intuitive Surgical, Inc.*

2.1.3.4 RARP complete procedure

In this paragraph we describe the 15 component steps of the RARP surgical workflow, integrated with two papers found in literature, in which this current procedure is described in detail (Patel et al., 2007)(Valdivieso, Hueber, & Zorn, 2013b).

For the detailed model of the procedure, please see Appendix I.

1) **Incision of the peritoneum and entry into retropubic space of Retzius**

The surgery begins with a direct visualization of the peritoneum overlying the bladder. The assistant is asked to provide upper anterior traction on the peritoneum using the graspers and the monopolar scissor is used to cut the peritoneum.

2) **Dissection of the endopelvic fascia (EPF) and identification of the dorsal venous complex (DVC)**

This is the area with the largest amount of space between the prostate and the levators and the point at which the prostate has most mobility. The umbilical ligaments and urachus are initially divided with the bipolar graspers. The forth arm Prograsp is used to provide traction. Care is made to achieve good haemostasis since occasionally these structures have patent vessels.

3) **Bladder mobilization**

The bladder is then liberated off the anterior surface of the abdominal wall. The avascular plane found is further blunt dissected to the pubic bone and the bladder is placed on stretch. The lateral attachments to the vas deferens are liberated as well.

4) **Anterior prostatic fat (AFP) dissection**

Resting on top of the anterior wall of the prostate, a layer of fat is identified. Removing this layer of fat allows better visualization of the puboprostatic ligaments, the dorsal venous complex as well as the junction between the bladder neck and the prostate. At this point the anterior surface of the prostate is seen.

5) **Dorsal vein complex (DVC) ligation**

A total of two suture ligations are put in place (one distal and another more proximal). The distal suture provides the necessary haemostasis while the proximal suture will be used later for prostate traction. The suture is passed beneath the DVC and anterior to the urethra. Securing the DVC as far away from the prostatic apex as possible can help minimize iatrogenic entry into the prostatic apex during later division of the DVC.

6) **Bladder neck incision**

After identification of the proper plane of dissection, the bladder neck is divided horizontally using monopolar scissor until the urethral catheter is identified. Precaution should be taken to ensure that the anterior bladder neck incision does not extend too laterally to avoid branches of the dorsal vein fanning over the prostate and to prevent unwanted bleeding. These veins will be controlled using Hem-o-lock clips. The Foley catheter balloon is then deflated. While external counter traction is exerted on the penile meatus, via the Foley catheter by the bedside assistant, the prostate is suspended anteriorly towards the abdominal wall by grasping the internal tip of the catheter and lifting it upwards. Thus, with upper traction on one hand by the assistant and downward traction at the level of the bladder neck with the suction tip, the posterior bladder wall is addressed. These structures, along with the seminal vesicles are collectively grasped, pulled through the open bladder neck and handed to the assistant for upper traction.

7) Vas deferens and arteries are exposed

Bipolar graspers are then used to dissect through and divide fibrovascular tissue to the desired plane. Through the dissection of the retroprostatic tissue, the vas deferens and accompanying arteries are exposed.

8) Division of vas deferens

The vas deferens are then divided bilaterally with bipolar control of both arteries. The monopolar scissor blade is used as a spatula to free adjoining vessels. This is done approximately 5 cm from the level of the prostate.

9) Exposure of the seminal vesicles

For this part of the procedure the assistant is asked to provide upper traction of the vas deferens and downward traction with the suction tip to expose the tip of the seminal vesicle. Blunt dissection of the fibrovascular tissue overlying the surface of the seminal vesicles exposes the postero-medial surface of the seminal vesicle. The seminal vesicle is then grasped by the bipolar instrument to help liberate the posterior avascular plane. The dissection is continued to allow complete liberation of the seminal vesicle. Deep posterior dissection is then continued to the level of Denonvillier’s fascia.

10) Neurovascular bundle (NVB) dissection (nerve sparing)

To achieve preservation of the neurovascular bundles, it is imperative for the surgeon to use an athermal dissection technique in the proximity of the nerve bundles but also to limit the amount of stretch, which may cause traction nerve injury. The scissor cutting between them helps liberate the tissue.

11) Urethral division

The urethra is then skeletonized to delineate the boundary of the end of the prostate and the released neurovascular bundles. Sharp scissor cutting through the anterior urethral wall allows for visualization of the Foley catheter, which is then withdrawn to expose its tip. The remaining posterior wall including the rectourethralis fibers are then cut sharply to liberate the prostate.

12) Prostate delocation

The prostate is placed in an endo-catch bag along with the anterior prostatic fat and is placed in the upper abdominal space for later retrieval.

13) Vesico-urethral anastamosis (VUA)

The well-dissected bladder is free and mobile and can be easily descended into the pelvis. The anastomosis is done using a self-cinching unidirectional barbed suture. Posterior reconstruction helps create a posterior plate in which to buffer the anastomosis and reduce bleeding. The assistant reintroduces the tip of the Foley catheter to ensure the grasp of the correct tissues. Prior to cutting the left arm suture, the integrity of the VUA is verified with 300 cc normal saline instilled in the bladder. The needles can be snapped out and removed from the body by the assistant.

14) Endocatch bag extraction

The specimens within the laparoscopic entrapment sack are extracted intact through extension of the periumbilical trocar site (usually 2.5 cm to 3.5 cm in length).

15) Ports closure

The fascial defect is then immediately closed by sutures. The skin defects are then closed with a subcuticular absorbable suture followed by the skin adhesive Dermabond.

2.1.3.5 Post-operative course

Once extubated, the patient is then transferred to the recovery room where vital signs, in/outs are taken as usual for postop patients. Regular diet is offered the evening of the surgery and patients are mobilized out of bed within hours of surgery. Over 95% of our patients are discharged within 24 hours of surgery with planned removal of the Foley catheter on postoperative day 4. Patients are educated on how to take care of the catheter and it is left in place to a leg-bag upon discharge. A trained nurse then removes the catheter during an outpatient appointment. An initial follow up visit is scheduled 4-6 weeks after surgery to review recovery and the result of the final pathology on the surgical specimen is obtained at 3, 6 and 12 months following RARP with subsequent assessments depending on the pathological stage, grade and margin status (Valdivieso et al., 2013b).

2.2 *The SARAS benchmark procedures: Radical/Partial Laparoscopic Nephrectomy*

Generally, Nephrectomy – which is the surgical procedure of removing a kidney or section of a kidney - is performed to treat kidney cancer or to remove a noncancerous (benign) tumor. In some cases, it could also be performed to deal either with a diseased or seriously damaged kidney, or to remove – in case of a donor nephrectomy - a healthy kidney from a donor for transplantation purposes. The estimated number of newly diagnosed patients with renal cancer, and deaths due to renal cancer, is 115.200 worldwide, among which 49.000 cases are in Europe. Renal cancer accounts for 3.3% of all newly diagnosed cancers in Europe (without non-melanoma skin cancer) (J. Ferlay et al., 2013).

Radical Nephrectomy has been the gold standard for treatment of Renal Cell Carcinoma (RCC) since 1963 when Robson (Robson CJ., 1963) first published his landmark article. According to the European guidelines, nephron-sparing surgery (or Partial Nephrectomy), is recommended for T1 tumors (≤7 cm diameter) and is an option for T2 tumors (more than 7 cm limited to the kidney) (Zimmermann & Janetschek, 2008).

The available surgical options to remove the entirety (radical) or part (partial) of a kidney are:

1) *Open (radical or partial) nephrectomy*: is the traditional open surgical method, where the surgeon removes the kidney containing the tumor, through an abdominal incision;
2) *Minimally Invasive Procedures*: encompass surgical techniques that limit the size of incisions needed and so lessen wound healing time, associated pain and risk of infection:
    - <u>Laparoscopic Radical (complete) Nephrectomy (LRN)</u>: the urologic surgeon removes, through 4-5 small incisions across the abdomen, the entire kidney and often some additional structures, such as part of ureter that connects the kidney to the bladder or other adjacent structures such as the adrenal gland or lymph nodes;
    - <u>Laparoscopic Partial Nephrectomy (LPN)</u>: also called kidney-sparing (nephron-sparing) surgery, the surgeon removes diseased tissue from a kidney and leaves healthy tissue in place. As LRN, the surgeons make 4-5 small incisions in the abdomen;
    - <u>Robotic-Assisted Laparoscopic Partial/Radical Nephrectomy</u>: as in laparoscopic nephrectomy, the surgical area is accessed through small incisions in the abdomen. In robotic procedure, the first surgeon controls an advanced robotic system capable of moving surgical tools from outside the body and the assistant uses the laparoscopic instruments, next to the patient.

Laparoscopic Nephrectomy (LN) has been routinely performed since 1990 and the use of laparoscopic renal surgery (LRN/LPN) in minimizing patient morbidity as well as improving patient outcomes, compared to open renal surgery, has been supported by literature (Gill et al., 2002) (Porpiglia et al., 2006). The significant benefits of LN for patients include, as compared to open surgery (Rassweiler, Frede, Henkel, Stock, & Alken, 1998):

- Shorter recovery time;
- Shorter hospital stay;
- Smaller incisions (reduced blood loss and transfusions): while open surgery requires either a large abdominal or flank incision, minimally invasive approaches involve 4-5 incisions in the abdomen;
- Fewer post-operative complications.

In the beginning, LPN was limited to patients with a small, superficial, solitary, peripheral tumor. However, with increasing laparoscopic experience, the indications of LPN have been carefully expanded to include larger, central, hilar and infiltrating tumors (Haber & Gill, 2006). Until recently, elective PN was indicated only for T1a, in which case the tumor is more than 4 cm in size. More recently, these indications have been extended to select patients with anatomically favourably located T1b, in which case the size of tumor is >= 4 cm but <=7 cm (for all tumors stages, see Chapter 2.2.2).

Different techniques have been introduced to perform Laparoscopic Nephrectomy using either the transperitoneal or the retroperitoneal route. The choice of the laparoscopic approach is dictated by the location and the technical complexity of the renal mass. Anterior, anterolateral and lateral tumors are preferentially approached transperitoneally. Posterior, posteromedial and posterolateral tumors are approached retroperitoneoscopically (Haber & Gill, 2006). Nevertheless, despite the demonstrated safety and effectiveness of LRN, the technique has not yet been standardized completely (Moad et al., 2013). For this reason, in the following, we chose to analyse the current practise carried out at the San Raffaele Hospital.

Alternative treatment options to LN include several percutaneous or open ablation approaches. However, the recommended indications for these approaches are small (Stang & Büchel, 2014). With the advent and increase in popularity of the da Vinci® surgical platform, the application of robot-assisted surgery was soon realized also for nephrectomy, however, its application to LN has been limited due to the cost-effectiveness of standard laparoscopy compared to a robot-assisted approach, as well as the established familiarity and ease of a laparoscopic approach for a procedure that is completely extirpative and, thus, requires no suturing (Kerbl, McDougall, Clayman, & Mucksavage, 2011).

Risks of Laparoscopic Nephrectomy

All surgeries embed certain risks and complications; nephrectomy should be performed if the advantages outweigh the disadvantages and this most importantly relates to quality of life. Possible complications of nephrectomy surgery include:

- Infection of the wound or lungs;
- Bleeding (haemorrhage) requiring blood transfusion;
- Injury to surrounding tissues (i.e. intestines, liver, spleen, pleura);
- Post-operative pneumonia;
- Rare allergic reactions to anaesthesia;
- Death.

There is also the small risk of kidney failure in a patient with lowered function or disease in the remaining kidney (Kaphingst, Persky, & Lachance, 2010).

Success of Laparoscopic Nephrectomy

The successful emergence of laparoscopic technique is justified by the many benefits offered such as reduced blood loss, tissue trauma, pain, and hospital stay. However, this comes at the expense of possible physiologic changes and complications because kidneys are particularly sensitive to hemodynamic changes and to the insufflation of the pneumoperitoneum (Nasrallah & Souki, 2018).

What to Expect After Laparoscopic Nephrectomy

At the end of the intervention a drainage pipe is placed in proximity of the renal lodge, which will be removed in the ward generally after 1-2 days, unless complications.

Usually, the bladder catheter is removed on the first or second post-operative day, but this period may vary according to the clinical conditions of the patient. Postoperative pain was minimal and analgesics were generally not required by postoperative day 2. The accuracy of dissection and sutures allowed patients to be discharged home without urethral catheterization starting on postoperative day 3.

2.2.1 Anatomy of the kidney

The kidneys are a paired organ, located in the abdominal cavity on each side of the spine. Each kidney is about the size of a fist, and is approximately 11–14 cm in length, 6 cm wide and 4 cm thick. Each adult kidney weighs between 125 and 170 grams in males and between 115 and 155 grams in females (Zou & Fu, 2017). The outer surface can be divided into anterior side, dorsal side, upper pole and lower pole. The lateral surface is convex. The medial surface is concave, deeply grooved (renal sinus) and forms the renal hilum. The ureter/renal pelvis, renal artery, renal vein, lymphatic vessels and nerves enter or exit the kidney through the renal hilum. Kidneys are part of the urinary system (Figure 7). The urine collects in the renal pelvis and passes into the bladder, through the ureter.

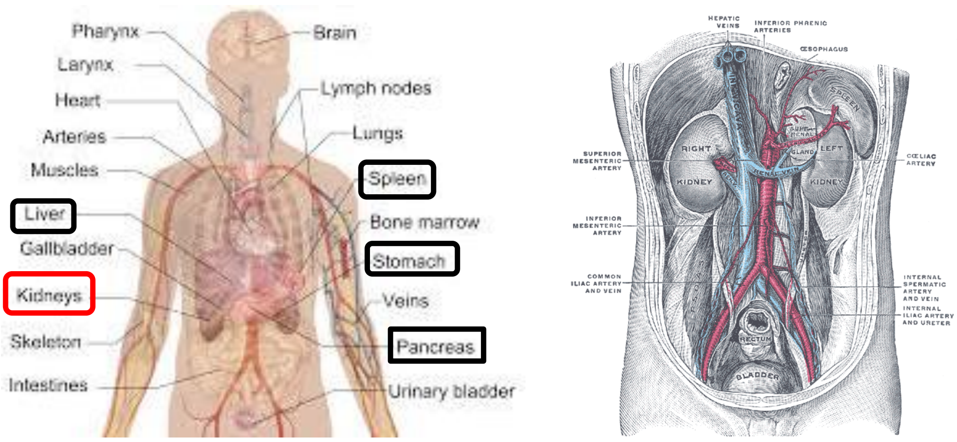


Figure 7: Urinary system (from National Cancer Institute)

The upper (cranial) parts of the kidneys are partially protected by the eleventh and twelfth ribs. Resting on top of each kidney is an adrenal gland. The kidneys are surrounded by a layer of perinephric fat (*Capsula adiposa*). Gerota's fascia (or *Fascia renalis*) surrounds the kidney, including perinephric fat and the adrenal gland (Figure 8). Cranially and laterally, the Gerota's fascia is closed by fusion of the anterior and posterior sheath. Medially and inferiorly, there is no connection between the anterior and posterior sheath of the Gerota's fascia: renal fluid collections can drain into the pelvis. The anterior sheath of the Gerota's fascia lies immediately below the parietal peritoneum.

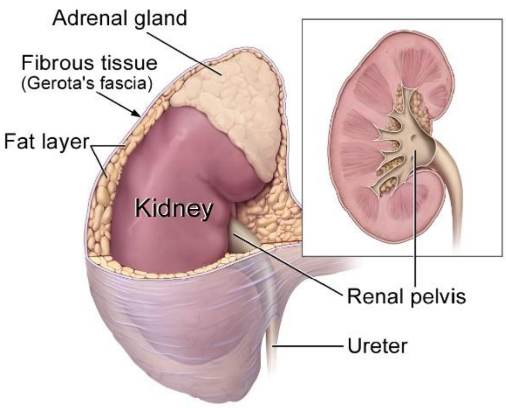


Figure 8: Fascias of the kidney (from National Cancer Institute)

The kidneys are located in the retroperitoneum, right and left of the spine and below the diaphragm. The position of the kidneys is asymmetrical, due to the position of the liver and this results in the right kidney being slightly lower than the left, and left kidney being located slightly more medial than the right (Figure 7). The left kidney is approximately at the vertebral level T12 (i.e. is located in the spinal column of the thoracic region inferior to the T11 vertebra and superior to the first lumbar vertebra) to L3 (i.e. is in the middle of the five lumbar vertebrae in the lower back portion of the spinal column), instead the right is slightly lower. The right kidney sits just below the diaphragm and posterior to the liver, the left below the diaphragm and posterior to the spleen (Figure 9).

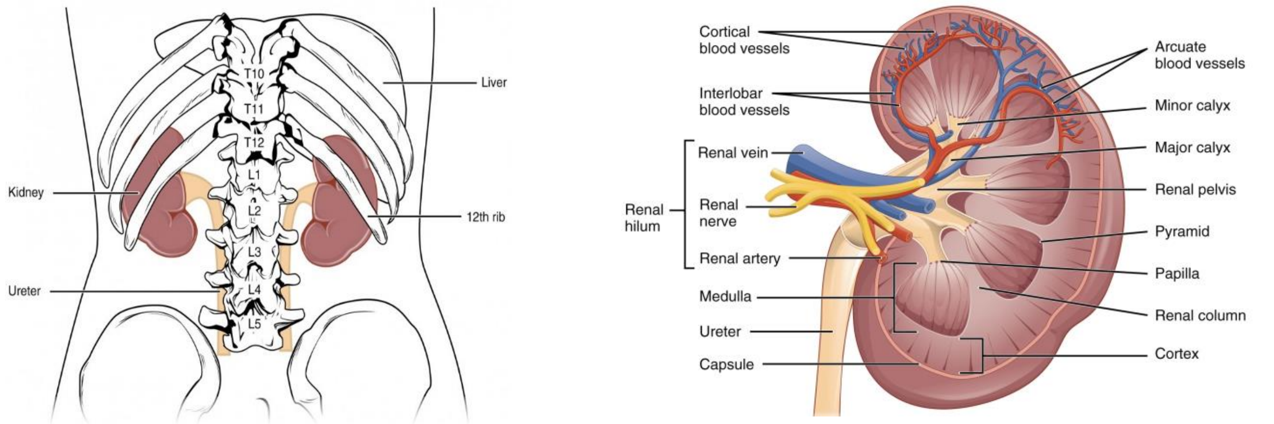


Figure 9: Posterior view of kidneys (left figure) and kidneys' anatomy (right figure) (from National Cancer Institute)

2.2.2 Pathology

The most common type of kidney tumor is the *Renal Cell Carcinoma* (RCC), the RCC accounts for nearly 90% of kidney cancers. The remaining percentage is made up of transitional cell tumors, which is not a common form of kidney cancer, usually beginning in the pelvis of the kidney.
Other causes of kidney's removal are:

- *Kidney excluded* - This condition occurs in calculous cases or in joint syndrome. That is in those benign diseases that cause functional loss of the kidney.
- *Trauma* - There are few cases and moreover the intervention is more commonly performed by open surgery;
- *Kidney donation* - A kidney transplant is the transfer of a healthy kidney from one person into the body of a person who has little or no kidney function.

<u>Kidney tumor</u>

Primary kidney cancer, also called renal cancer, is a malignant tumor that originates in the kidney. The renal cell carcinoma has been classified in different stages, that describe the cancer developmental phase, and are established according to several criteria:

(1) The tumor size;
(2) The cancer location (if the cancer is present in one or both kidneys);
(3) The cancer extent.

This staging system is validated by the American Joint Committee on Cancer (AJCC), as summarised in Figure 10.

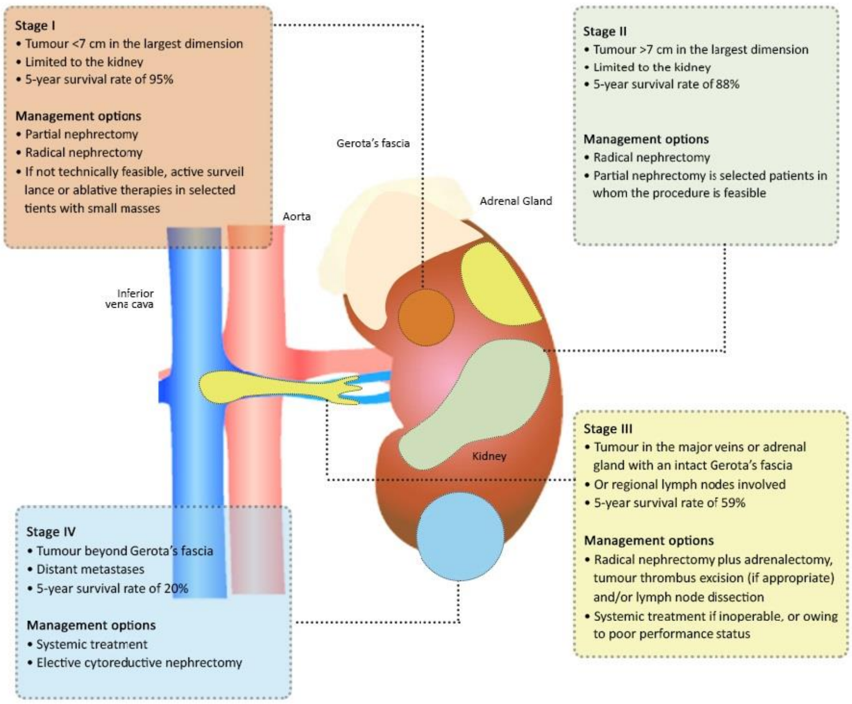


Figure 10: Stages of renal cell carcinoma (RCC)

According the location, tumors are evaluated on the basis of different anatomical aspects, besides the clinical tumour size. Regarding the tumor position, we can consider the following characteristics: *(i)* the side (left or right), *(ii)* the location (upper pole, lower pole, mesorenal – defined as tumor in the central third of the kidney, but not involving the renal sinus), *(iii)* the anterior or posterior face of the kidney, *(iv)* the pattern of growth at computed tomography scan (cortical or corticomedullar). Cortical tumors are defined as those lesions that seem to involve only the renal cortical at CT scan, whereas all other lesions are considered corticomedullar.

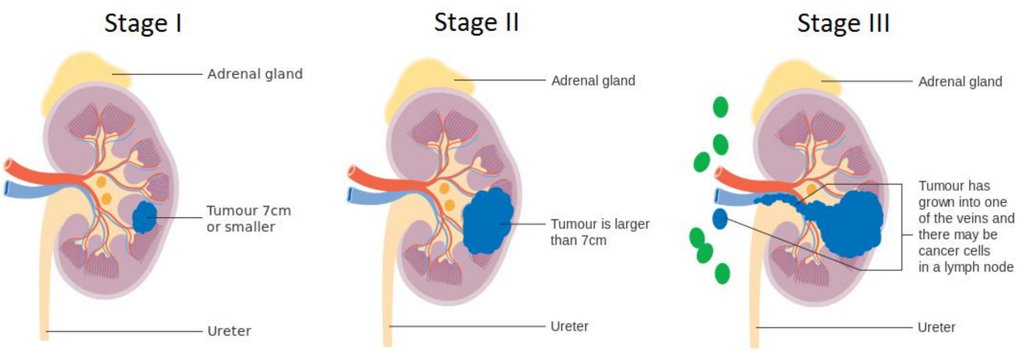


Figure 11: Stages of renal cell carcinoma (from Wikimedia Commons)

The prognosis of kidney cancer is directly linked to the stage of disease. Staging is a process that demonstrates how far the cancer has spread (Moch et al., 2009). Clinical staging is performed with Physical Examination, Abdominal CT scan, and Chest X-Ray. In cases of advanced or high-risk disease, additional testing such as MRI and Bone Scan may be necessary.

One tool that doctors use to describe the stage is the TNM system, as for prostatectomy (see Table 1, Chapter 2.1.2). Using the TNM system, the "T" plus a letter or number (0 to 4) is used to describe the size and location of the tumor. Tumors are measured in centimeters (cm). Some stages are also divided into smaller groups that help describe the tumor in even more detail. This helps the doctor develop the best treatment plan for each patient. If there is more than one tumor, the lowercase letter "M" (multiple) is added to the "T" stage category (Moch et al., 2009).

In the following Table 4 there are more details on each part of the TNM system for kidney cancer.

Table 4: Kidney cancer TNM criteria

T		**Primary tumour** (Primary tumour cannot be assessed)
0		No evidence of primary kidney tumor
T1		Tumor 7 cm or less limited to the kidney
	T1a	Tumor > 4 cm limited to the kidney
	T1b	Tumor >= 4 cm but <=7 cm limited to the kidney

T2		Tumor more than 7 cm limited to the kidney
	T2a	The tumor is only in the kidney and is more than 7 cm but not more than 10 cm at its largest area.
	T2b	The tumor is only in the kidney and is more than 10 cm at its largest area.
T3		Tumor extends into major veins or invades perinephric tissue
	T3a	Tumor invades adrenal gland or perinephric tissue
	T3b	Tumor extends into renal vein or infra-diaphragmatic vena cava
	T3c	Tumor extends into supra-diaphragmatic vena cava
T4		Tumor invades beyond Gerota's fascia

The "N" in the TNM staging system stands for lymph nodes. These tiny, bean-shaped organs help fight infection. Lymph nodes near the kidneys are called regional lymph nodes. Lymph nodes in other parts of the body are called distant lymph nodes (Moch et al., 2009).

N		**Regional lymph nodes**
	N0	No regional lymph node metastasis
	N1	Metastasis in a single regional lymph node

The "M" in the TNM system indicates whether the cancer has spread to other parts of the body, called distant metastasis. Common areas where kidney cancer may spread include the bones, liver, lungs, brain, and distant lymph nodes (Moch et al., 2009).

M		**Distant metastasis**
	M0	The disease has not metastasized.
	M1	The cancer has spread to other parts of the body beyond the kidney area.

2.2.3 Laparoscopic Nephrectomy: surgical operation

After having exposed a brief clinical background on kidney surgery, from now on the focus is going to be on the surgical benchmark chosen for SARAS. In fact in the following paragraphs, LRN and LPN are going to be detailed.

In analysing these procedures, it can be observed how some steps of these two surgeries are the same, in particular, at the beginning and end (see paragraph 2.2.3.4). The common steps are: pre-operative patient preparation, patient positioning, trocars positioning and the instruments choice. In the following paragraphs, each previous point is described in detail.

2.2.3.1 Pre-operative preparation

It is important to discuss with the patient the specific risks that they must be aware of, before consenting to laparoscopic nephrectomy and the potential need to convert to the traditional open operation if difficulties arise. All patients undergo a spiral CT scan with 3-mm sections and 3-dimensional video reconstruction prior to the operation. This CT scan provides information regarding tumor size, location, extent of parenchymal infiltration, proximity to the pelvic system and defines the renal vasculature, with details regarding the number, location, anomalies, and spatial interrelationships of the renal arteries and veins. The choice of the laparoscopic approach is dictated by the location and the technical complexity of the renal mass (Haber & Gill, 2006).

A patient is admitted to the hospital the day before the surgery for bowel preparation and fasting starts at midnight before surgery.

In the operating room there is a surgical team, composed of: the main surgeon, a surgical assistant (usually a trained urology resident), a circulating nurse, a scrub nurse and the anesthetist (Figure 12).

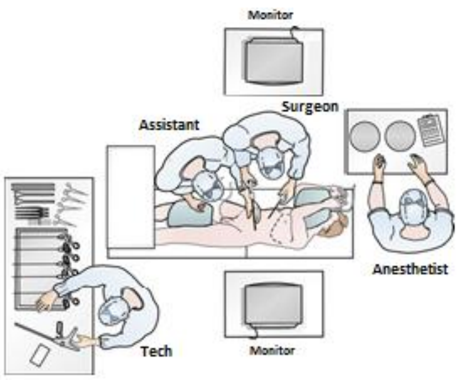


Figure 12: Operating room for laparoscopic nephrectomy (left side)

The surgeon operates from the abdominal side of the patient; the laparoscopic cart is positioned at the back of the patient's chest, the operating team facing the video monitor. The instruments table is positioned at the back of the operating team and steps are positioned for the assistant to avoid instruments’ conflict (Figure 13).

Figure 13: Laparoscopic cart position (A); step for the assistant (B); video monitor is in front of the operating team (C)

2.2.3.2 Patient preparation and trocars' position

The patient is initially positioned supine for intravenous access, the induction of general anaesthesia, and endotracheal intubation. An orogastric tube is placed and the stomach decompressed to avoid puncturing during trocar placement and to allow additional space during abdominal insufflation. A Foley catheter 18Fr with 10 ml in the balloon is introduced for decompression of the bladder.

The umbilicus is placed over the break in the operating table and the patient positioned in a modified lateral decubitus position. The table can be flexed as needed or an inflatable balloon is positioned under the patient at the level of the umbilicus. The table can be flexed to 10°-20° for left sided and 30° for right side (Figure 14).

Padding is used to support the buttocks and back and all potential pressure points are cushioned. An axillary roll is placed to prevent brachial plexus injury and the arms should be positioned as away from the trunk as possible so as not to disturb the movement of the operating team. The patient is taped in position with strips of cloth tape.

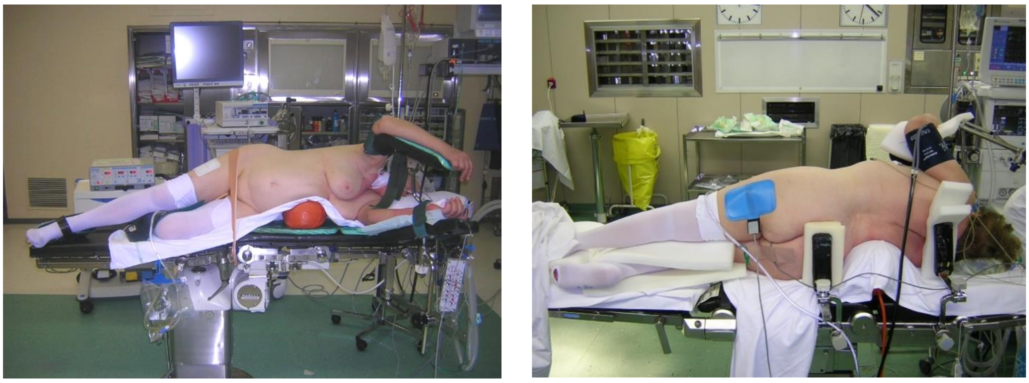


Figure 14: Patient position for right and left nephrectomy, with inflatable balloon under the patient at the level of the umbilicus

In the Laparoscopic Nephrectomy, a placement configuration is drawn on the patient's abdomen prior to skin incisions. Four ports are generally enough to perform the procedure, although a fifth trocar may be necessary for liver retraction during right-sided nephrectomy. Before trocars are placed, the abdomen is insufflated using a Veress needle, CO_2 insufflation pressure is maintained between 12 and 14 mm Hg. An 11 mm trocar is placed on the midclavicular line 2 cm below the costal margin, at the level of the lateral border of the rectus muscle, for the camera; another 11 mm trocar is placed 2 cm above the umbilicus. A 5 mm port can be inserted just under the xyphoid and the last 5 mm trocar is placed 2 cm medial to and sometimes superior to the anterior superior iliac spine. There are two different techniques for trocars' positioning, depending on the side of Nephrectomy (see Figure 15).

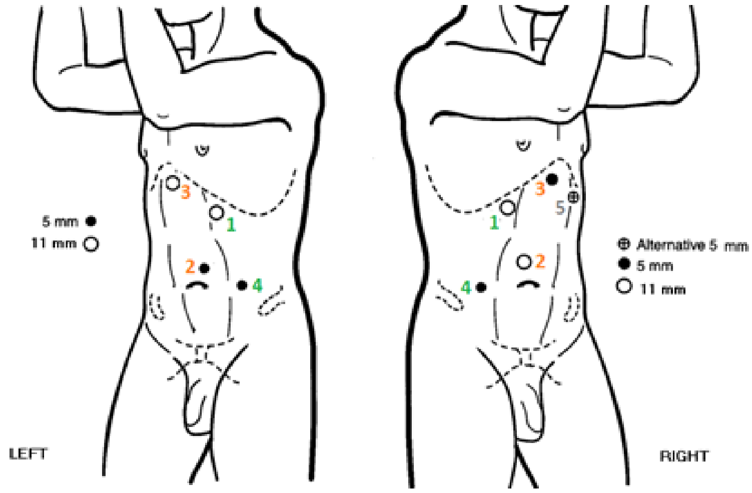


Figure 15: Trocars' position for left and right laparoscopic nephrectomy

The surgeon uses trocars 2 and 3 (in orange in Figure 15) while the assistant works with trocars 1, 4 (in green in Figure 15). The difference between the left and right side are:

- The use of fifth port for Right Nephrectomy to retract the liver;
- The different dimensions of surgeons' trocar (number 2 and 3). The 5 mm port is usually reserved for the most skilled hand, because the movements of the working instruments that are inside the smaller ports are more precise. For this reason, during the Left LN, the surgeon uses the scissor on the right hand, where trocar 2 has a smaller diameter and vice versa, for Right LN, the trocar 3 of 5 mm is used by surgeon for scissor's entry.

Trocars' details are reported in Table 5 below:

Trocar Number	Ø	Role	Positioning
Trocar 1	11 mm	**Assistant** instrumental port	on the midclavicular line 2 cm below the costal margin
Trocar 2	5 or 11 mm	**Surgeon** instrumental port	2 cm above the umbilicus
Trocar 3	5 or 11 mm	**Surgeon** instrumental port	just under the xyphoid
Trocar 4	5 mm	**Assistant** instrumental port	2 cm medial to and sometimes superior to the anterior superior iliac spine
Trocar 5	5 mm	Fixed retraction port	3 cm medially to trocar 4 for a RIGHT nephrectomy

Table 5: Trocars' position for LN

Once the pneumoperitoneum is established, the Veress needle is removed and the 11mm trocar is introduced through the same incision, perpendicularly to the abdominal wall. The optic is introduced through the trocar and the abdomen is then inspected for any injury due to insertion of the Veress needle or the trocar and to identify adhesions in areas where the secondary ports will be placed. For the second port, the triangulation rule must be followed for its placement, as the body habitus changes among patients: four fingerbreadths between the optic trocar and the working trocars (Figure 16 A) and five fingerbreadths between the working trocars (Figure 16 B).

Figure 16: The triangulation rule for left nephrectomy

For fifth port, a cutaneous incision is done approximately two fingerbreadths below the level of second port and introduction of a 5mm port in case of liver retraction for right-sided nephrectomy (see right- Figure 17)

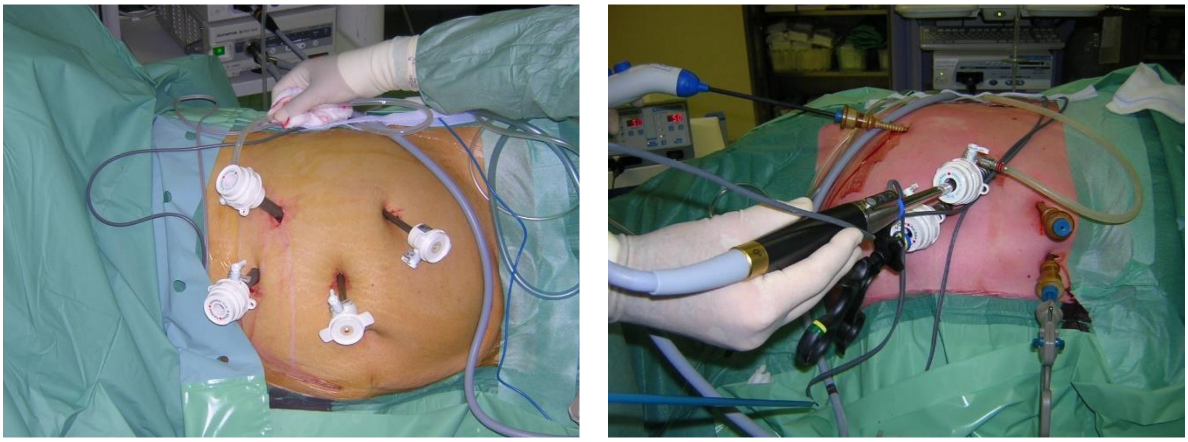


Figure 17: Left and right nephrectomy side port

2.2.3.3 Surgical instruments

In the Laparoscopic Nephrectomy, the following instruments are required for the performance of surgeries (see Figure 18):

1) Laparoscope
2) Monopolar scissor
3) Ultrasonic scissors (depending on surgeon's preference)
4) Bipolar forceps
5) Grasper
6) Vascular stapler
7) Clip applier
8) Suction device
9) Retrieval bag
10) Urinary catheter

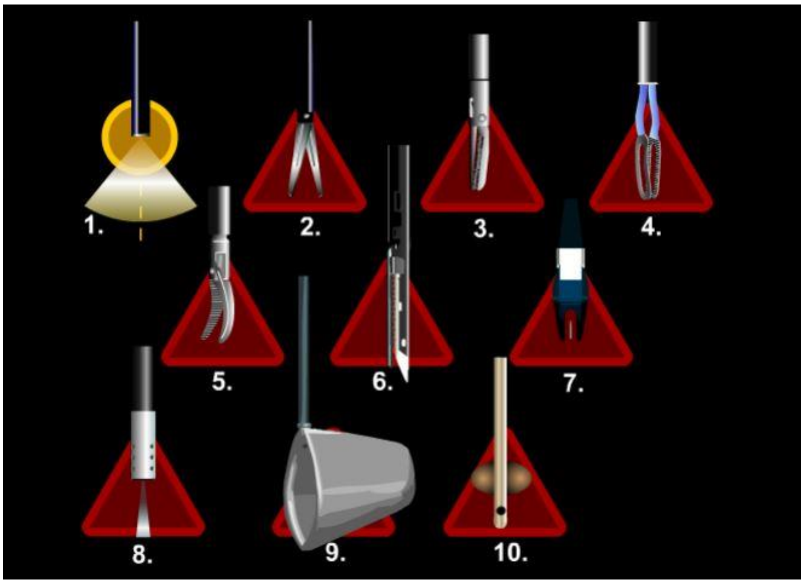


Figure 18: Laparoscopic Nephrectomy instruments

In LN current practice, the assistant uses, in the right hand, the laparoscopic optic (1) and in the left hand the grasper (5) or the suction device (8).
Instead, the main surgeon uses the scissor (monopolar or ultrasonic), the bipolar forceps, the vascular stapler and the clip applier. These instruments change often their position in all trocars.

2.2.3.4 Laparoscopic Nephrectomy procedure

In this paragraph the current techniques of LRN and LPN for both body side, carried out at the San Raffaele Hospital (OSR) are going to be described.

All patients undergo a three-dimensional CT scan prior to the operation. OSR established technique involves preoperative ureteral catheterization. The affected kidney is then dissected and exposed from surrounding organs such as the liver, spleen and intestines. The blood supply to the kidney is clipped and divided, allowing for safe and efficient removal of the kidney with minimal blood loss. The tumor within the kidney and surrounding fat, and visible surrounding lymph nodes, are removed. The adjacent adrenal gland may also be removed if the tumor is large or in close proximity to it. Once the tumor and/or kidney are excised, they are immediately placed within a plastic sack and the specimens are removed from the abdomen intact by extraction through an extension of one of the pre-existing abdominal incisions. Finally, the skin incisions are closed using plastic surgery techniques to minimize scarring.

In the following Figure 19, the differences and similarities between the two procedures LRN (in red) and LPN (in blue) are analysed. Furthermore, depending on which kidney is affected by the tumor, and has to be treated, the anatomical differences coming into play while operating are:

- On the *left side*: in order to reach the kidney, the surgeon has to remove the spleen and the pancreas;
- On the *right side*: the surgeon visualizes the duodenum and the vena cava, with Kocher maneuver, and uses the retractor grasper instrument to remove the liver.

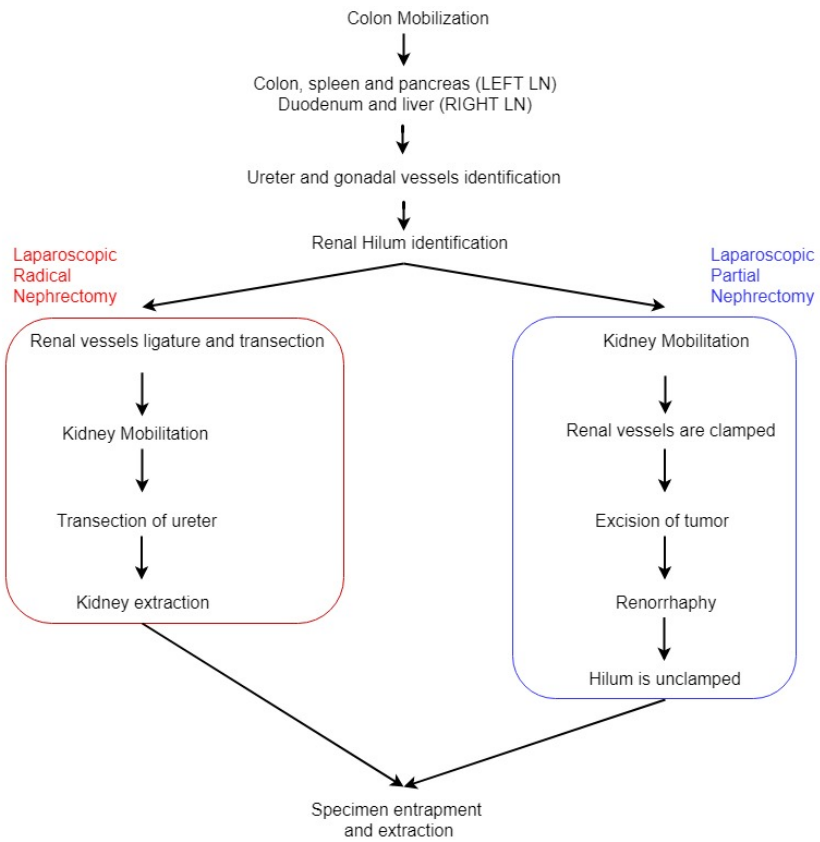


Figure 19: Model of laparoscopic Radical Nephrectomy (on left) and Laparoscopic Partial Nephrectomy (on right)

2.2.3.4.1 Laparoscopic Radical Nephrectomy (LRN) procedure

In this paragraph the 8 components steps of the LRN surgical workflow, that are currently used in San Raffaele Hospital, are described; for the detailed complete procedure see Appendix I (Chapter 7).

1) Colon mobilization

For a left nephrectomy, the plane between the descending colon and the underlying Gerota's fascia is developed to allow the colon to fall medially. This plane of dissection is carried out cranially, the splenorenal and lienocolic ligaments are incised allowing the spleen and the tail of the pancreas to be separated from the upper pole of the kidney. The *en bloc* dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein. For the right nephrectomy, the liver is cranially retracted using a grasper that is fixed to the abdominal wall. The ascending colon is mobilized and dissected from the underlying Gerota's fascia. The mobilization of the colons continues caudally to the common iliac vessels.

2) Ureter and gonadal vessels identification

Following the medial mobilization of the colon and mesocolon, the gonadal vessels are visualized. After the colon is retracted medially, the Gerota’s fatty tissue at the level of the lower pole of the kidney is incised and lifted to locate the psoas muscle. The psoas is followed to expose the ureter just lateral and deep to the gonadal vessels. By tracking the cephalad course of the ureter, the plane is followed up to the renal pedicle. Caudally, the ureter is dissected and liberated until the crossing of the iliac vessels. The ureter and gonadal vessels are not divided at this time. Both structures are elevated and along with the visualization of the psoas muscle (and the gonadal vessels on the left side), followed proximally to the lower pole and hilum of the kidney. The dissection of the right gonadal vein is not necessary, as it enters the vena cava on this side. Attachments between the psoas muscle and Gerota’s fascia are released with sharp and blunt dissection with the monopolar scissors, and small vessels to the ureter and branches of the gonadal vein are coagulated with the bipolar grasper.

3) Exposure and Dissection of the Renal Hilum

On the left side, by tracking the course of the left gonadal vein into the renal vein and by firm elevation of the lower pole of the kidney on both sides, the surgeon assists in the identification and blunt dissection of the renal hilum. The renal vessels should be dissected separately. The renal vein is dissected taking care of the lumbar veins that drains posteriorly to the vessel. The left adrenal vein is preserved if the ipsilateral adrenal gland is not removed (dissection of the right renal vein is usually less demanding as the gonadal and lumbar veins are normally absent at this side). The renal artery is exposed posterior to the renal vein and dissected.

4) Renal Hilum Ligature and Transection

Hem-O-lok clips are applied to the artery (one large clip secures the renal artery before the renal vein is clipped). The same clips are used on the renal vein, which is then carefully divided (the renal vein should be empty after the renal artery clip is placed; if the vein is still filling, another renal artery should be looked for). Following division of the renal vein, the clipping of the renal artery is completed and it is then divided.

5) Mobilization of the Kidney and Adrenal Gland

Once all the hilar vessels have been divided, the dissection continues posteriorly and superiorly to the upper pole. The attachments of the kidney to the posterior and lateral abdominal wall are released by blunt and sharp dissection, taking care to coagulate the bleeding vessels. The adrenal gland can be preserved in simple nephrectomy and particular cases of mid and lower pole tumors, or it is removed intact with the specimen. This is accomplished by incising Gerota’s fascia anteriorly just above the hilum. Gerota's fat is then gently peeled off circumferentially above the upper pole of the kidney. At this point during the dissection, care must be taken with the short adrenal vein on the right side that drains postero-lateral into the vena cava. On the right, superior retraction of the liver facilitates the dissection of the plane between this organ and the upper pole of the kidney.

6) Transection of the ureter

Inferiorly, the ureter is ligated with large Hem-O-lok clips and transected to allow the kidney to be fully mobilized. Facilitating the dissection and incision of the latero-posterior and uppermost attachments under direct vision (the ureter is ligated on both ends to avoid urine spillage in case there is a transitional cell carcinoma associated).

7) Kidney Extraction

A lower ilio-inguinal incision is performed but the muscle attached to the peritoneum is not incised. A large laparotomy bag is introduced through a small opening of the ilio-inguinal incision. The kidney is placed intact inside the Endocatch bag and the specimen is removed.

8) Closure of the Abdominal Wall

The abdominal wall is closed and the pneumoperitoneum is again developed. The optic is introduced to check for small bleeding vessels.

2.2.3.4.2 Laparoscopic Partial Nephrectomy (LPN) procedure

Before starting the description of LPN procedure, another main concept present in Partial Nephrectomy has to be pointed out: the ischemia. This process is a restriction in blood supply to tissues, causing a shortage of oxygen that is needed for cellular metabolism (Eltzschig & Eckle, 2011).

During renal ischemia, when the hilum is clamped, the hypoxia caused by cessation of renal blood flow, and finally reperfusion caused by instant release of blood flow, triggers a complex series of events that lead to tissue injury and acute tubular necrosis. The essential feature of injury caused by ischemia and reperfusion is that the initial damage caused by the ischemic insult is exacerbated by the reintroduction of blood flow to the relevant area (Wein et al., 2007). Bloodless surgical field for optimal tumor excision can only be achieved by establishing renal ischemia, which can be applied by either cold ischemia or warm ischemia. Cold ischemia is the clamping of blood vessels with kidney cooling. Warm ischemia is a term used to describe ischemia of cells and tissues under normothermic conditions, i.e. it is the clamping of blood vessels without cooling the kidney.

Renal ischemia can be global, when the artery or the whole pedicle is clamped or regional when renal parenchymal compression is used. Cold ischemia is applied in cases where longer ischemic time is expected. Due to its safety and easiness of application, global renal warm ischemia is most widely used in most partial nephrectomies (Janetschek et al., 2004). Ischemia time, however, is critical for renal function which is traditionally restricted to a maximum of 30 minutes (Finelli et al., 2005).

As previously described, the first 4 steps (colon mobilization, ureter and gonadal vessels identification, renal hilum identification, specimen entrapment and extraction) are the same steps of LRN, otherwise, for the detailed complete procedure see Appendix I:

1) **The colon is reflected medially.** For the left nephrectomy, the dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein. For the right nephrectomy, the liver is retracted using a grasper that is fixed to the abdominal wall.
2) **The ureter is elevated anteriorly.** Dissection is carried cranially to the renal hilum, which is cleared of fat and adventitial tissue to allow for occlusion with bulldog or Satinsky clamps. Gerota's fascia is opened and dissection is carried out along the renal capsule until the mass is exposed.
3) **Kidney mobilitation.** The kidney is mobilized within Gerota's fascia and defatted, maintaining perirenal fat over the tumor. Intraoperative flexible laparoscopic ultrasonography is performed.
4) **Renal vessels are clamped**. The renal artery and vein are individually dissected and divided. The renal vein is usually identified first and is dissected circumferentially. The lumbar vein are identified and clamped taking care not to include the ureter.
5) **Excision of tumor.** The laparoscopic ultrasound probe is used to plan excision margins and the renal capsule is scored to delineate the boundaries of resection. The tumor is then resected along the previously scored margin using cold scissors (Figure 20 A).
6) **Renorrhaphy.** A suture with a knot and Hem-o-lok clip fixed to the free end is used as a running suture of the tumor excision bed to oversew larger vessels as well as entries into the collecting system (Figure 20 B). The suture is brought through the renal capsule with the final throw and secured with 2 sliding Hem-o-lok clips. The renal capsule is reapproximated using a continuous, horizontal mattress suture with a sliding Hem-o-lok clip placed after each suture passed through the capsule (Figure 20 C).

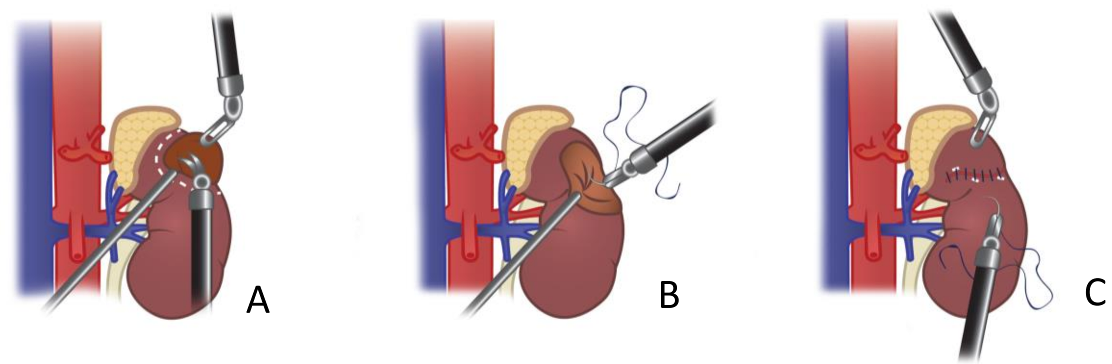


Figure 20: The main steps of renorrhaphy (Image courtesy of Luca Maria Vitale)

7) **Hilum is unclamped** and the renorrhaphy is inspected for haemostasis. Sometimes the hilum is unclamped before capsular suturing in an early unclamping technique to minimize warm ischemia time. This is usually performed if the deep suture line seemed to approximate the deep excision bed adequately.

8) **Kidney extraction.** For the last step, a large Endocatch bag is introduced through a small opening of the ilio-inguinal incision. The part of kidney is placed intact inside the Endocatch (the string is pulled out to close the bag and the arm of the device retracted to liberate the metal ring) and the specimen is removed.

2.2.3.5 Post-operative course

The nasogastric tube is removed at the end of the procedure and the intravenous perfusion is stopped on day 1. Pain frequently is easily controlled with scheduled intramuscular anti-inflammatory drugs and oral analgesics. Intramuscular anti-inflammatory drugs are often discontinued after 24 hours. A light diet can generally be resumed on day 1 after surgery. The Foley catheter and suction drain are usually removed on day 1 after surgery. The patient leaves hospital on the 3rd or 4th postoperative day. Patients can immediately resume normal light activities after hospital discharge, but vigorous activities and heavy lifting are limited for at least 1 month after surgery.

3 SARAS surgical procedures Risk Analysis

Nowadays, Patient Safety[4] is one of the key objectives to be pursued in the process of care, seen as a coordinated effort in preventing harm to patients while receiving health-care treatments (Morandi, 2013), where medical and surgical errors may have important implications (Montesi & Lechi, 2009). Different approaches can be put in place to prevent and detect these kind of errors, mainly drawing inspiration from the proactive risk approaches exerted in high-risk industrial environments, like nuclear power plants (Bonnabry et al., 2006). Among these, Healthcare Failure Mode and Effects Analysis (H-FMEA) is one of the most currently used methodology for risk detection in healthcare processes and treatments, like drug administration (Lago et al., 2012) and radiotherapy (Giardina, 2016).

H-FMEA is a qualitative methodology for detecting and correcting latent system errors in health care processes, before they lead to adverse events (Linkin, 2005). Through a detailed analysis of the possible Failure Modes (FM) embedded into the procedural phases, carried out by multidisciplinary teams of field experts, it evaluates the acceptability of the FMs, prioritizes them and assesses the expected benefits of the corrective actions selected to improve safety. As previously said, H-FMEA has been applied to various medical processes but there is no evidence in literature of the use of H-FMEA to evaluate the risk of a surgical procedure for each FM (Guida et al., 2015).

However, leveraging on the experience gained in this specific field by the OSR research team (Morandi, 2013) (Dodi, 2014), H-FMEA has been applied to the two SARAS surgical benchmarks, in order to identify the main risks which may impair patient safety and, at the same time, the positive outcome of the procedures. On this basis, the SARAS System technological solutions could be properly tuned in order to reduce or overcome the most important hazards and possibly improve the clinical outcomes.

In the following, the methodology of the SARAS H-FMEA is described alongside with the results obtained for the RARP and the LR/PN.

3.1 *SARAS H-FMEA methodology*

The SARAS H-FMEA was conducted following the formal five-steps-methodology for health care risk management described in Giardina et al. (2016), with the peculiar difference that this analysis has been brought forward dividing the surgical procedures into single actions of both the first surgeon and the assistant. This choice has been dictated by the fact that the SARAS System is intended as a robotic assistant, therefore particular attention has to be paid to the possible hazards coming from the related actions and from the cooperation between the two surgeons.

[4] "Patient safety is the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum" – WHO [http://www.who.int/patientsafety/en/]

We decided to apply H-FMEA for the complete RARP and LR/PN (first step: "*Define the H-FMEA topic*"), previously described in Chapter 2 and modelled as in Appendix I (second step: "*Describe the process*"). In order to carry out the study, we assembled two teams (one for each surgery) of 5 expert urological surgeons, capable of performing both the main surgeon's and the assistant's roles, so as to take advantage from various points of view and to underline as much as possible the critical factors (third step: "*Assemble the team*").

Then, we conducted the hazard analysis (fourth step: "*Conduct the hazard analysis*"). To achieve this, the involved teams of surgeons brainstormed to identify, for each procedure, a list of potential FMs that can occur in each sub-process (both main surgeon's and assistant's actions), clarifying also the corresponding possible Failure Causes (FC) and Failure Effects (FE).

As described in Scorsetti et al., 2010, the potential risk of each surgical action or step, named *Criticality Index* (Alba Mesa, 2015), was calculated with the interpretation of three FM indicators that consider the *Severity* (S: assesses the implications of the failure), the *Occurrence* (O: assesses the probability of the failure to appear in each step) and the *Detection* (D: assesses in each step the probability of detecting a failure). The O, S and D of each FM were estimated according to the ranking scales reported in Table 6 (Scorsetti et al., 2010).

OCCURENCE (O)	**Description**	**Score**
Remote	It is not likely to occur (it can happen every 5 or 10 years)	1
Occasional	It could happen (in about 2-5 years)	2
Probable	It is likely to happen some times in 2 years	3
Frequent	It is likely to happen frequently in one year (or immediately)	4
SEVERITY (S)	**Description**	**Score**
No damage	There are no consequences on the patients	1
Minor damage	Delay in treatment	2
Medium damage	Damage requiring only observation of the patient and minor treatment (e.g. bandage, analgesic compress). Minor side effect/unexpected toxicity)	3
Serious damage	Damage requiring an additional treatment with major therapies that can cause a delay in the patient's discharge from hospital. Serious side effect/unexpected toxicity. Inadeguate treatment	4
Very severe damage	Damage requiring a delay in patient's discharge leaving permanent consequences on the patient or damage that can cause serious permanent disabilities or the patient's death	5
DETECTABILITY (D)	**Description**	**Score**
Remote	It is unlikely to be detected	4
Low	It is possible to detect the Failure Mode	3
Medium	It could be detected	2
High	It is very likely to be detected	1

Table 6: Occurrence, severity and detectability categories used for risk estimation (Scorsetti et al., 2010).

The *Criticality Index* (CI) is defined by multiplying the estimated occurrence (O) by the expected severity (S) and the detectability (D) of the FM:

$$CI_i = O_i \times S_i \times D_i$$

where i is the ith FM listed for the analysis of the process.

On this basis, the SARAS H-FMEA team members compiled a dedicated worksheet for each FM, as shown in Table 7, rating on the basis of their personal experience the 3 indexes.

Phase Code	Phase	Step	FM (Failure Modes)	FC (Failure Causes)	FE (Failure Effects)	O [range: 1-4]	S [range: 1-5]	D [range: 1-4]
R5	**Renal Hilum liberation**	1	HemOlock misplacement, hemorrage, suboptimal exposure	poor traction	no progression			

Table 7: An extract of the LPN schema of the simplified Failure Mode and Effect Analysis

As suggested by Scorsetti et al., 2010, the CI of each FM in the process was calculated as the geometric average of the estimates provided by the experts:

$$CI_i = \sqrt[n]{\prod_{k=1}^{n} (O_{i,k} \cdot S_{i,k} \cdot D_{i,k})}$$

where: i =1, ..., M are the FMs identified in the process; k =1, ..., N are the team members.

Finally, the CI of each FM was compared to a risk matrix (Table 8), obtained by inserting in columns the product of the O and the D scale and in rows the S scale. The risk matrix evaluates the risk level according to four different ranges of values for the CI (Scorsetti et al., 2010):

- acceptable risk (in green, CI from 1 to 8): only continuous monitoring of the process is needed;
- low risk (in yellow, CI from 9 to 24): a mid-term planning of corrective actions is suggested;
- medium risk (in orange, CI from 25 to 45): urgent interventions are required;
- high risk (in red, CI from 46 to 80): emergency interventions are required.

Occurrence* Detectability \ Severity	1	2	3	4	5
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
6	6	12	18	24	30
8	8	16	24	32	40
9	9	18	27	36	45
12	12	24	36	48	60
16	16	32	48	64	80

Table 8: Risk matrix

Starting from the critical study of all the FMs that could affect the RARP and LR/PN, we evaluated the CIs for each step of the first surgeon and the assistant, so as to identify which surgical phases are most critical and could hamper the patient safety or the quality of the surgery. Firstly we concentrated exclusively only on the assistant H-FMEA, in order to determine possible technological implementations, in terms of SARAS System's requirements, which could mitigate the identified procedural FMs and the corresponding risk level of each surgical steps.

In addition to this, we asked to the teams to evaluate the probability of correlation between the FMs of the two surgeons, according to specific degrees of the dependence ((Kyung S. Park, 1987)– Table 9), which represents the probability that an assistant's FM affects the first surgeon's one in the corresponding surgical step .

Degree of dependence (%dep)	
zero	0%
low	5%
medium	15%
high	50%
complete	100%

Table 9: Degree of dependence evaluated from surgeons

This wider perspective was meant to understand if any low-medium risks strictly pertinent to the assistant's actions, and therefore not so much affecting the flow of the surgery, could have a direct impact on patient safety, by influencing in a negative manner the performances of the first surgeon. If this happens, SARAS technological implementation should pay particular attention to the coordination part of the corresponding surgical phases and provide an appropriate solution.

3.2 *SARAS H-FMEA results*

The list of CIs pertinent to the assistant role obtained for RARP and LR/PN can be found in Table 10, Table 11 and Table 12 alongside with the corresponding surgical phases and actions as well as their FMs, FCs and FEs. The complete procedural H-FMEA analyses are reported in Appendix II.

3.2.1 RARP Process Risk Analysis

Table 10: Analysis of the RARP risks

Phase Code	Phase	Step	Assistant Task	Surgical Action	Instrument type	Failure Modes Assistant	Failure Effects Assistant	Failure Effects Assistant	Criticality Index (CI)
1	**Incision of the peritoneum and entry into the retropubic space of Retzius**	1							
		2	Upper anterior traction on the peritoneum	Traction	Locking grasper	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	6,2
			Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	5,7
The peritoneum is dissected to the following boundaries: the pubic bone superiorly, the median umbilical ligaments laterally, and the vas deferens inferolaterally									
2	**Incision of the endopelvic fascia (EPF) and identification of the dorsal venous complex (DVC)**		The assistant provide the bladder's counter-traction	Traction	Locking grasper	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	6,2
3	**Bladder mobilization**		Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	7,1
4	**Anterior prostatic fat (AFP) dissection**	1	Upper traction of the prostatic fat/ Suction and cleaning of blood	Traction / Suction	Suction	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	5,7
			The assistant provides the prostatic fat's traction	Holding (Traction)	Grasper	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	6,2
		2	The assistant changes the instruments (2 and 3) and passes the needle and the suture thread to the surgeon	Holding (Needle)	Locking grasper	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed, needle lost in the abdomen	6,2
5	**DVC control and suture**		The assistant cuts the suture's thread	Cutting	Scissor	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	6,2
			The needles can be snapped out and removed from the body	Holding (Needle)	Grasper	slow or not accurate	Surgeon’s inattention and skills	slow surgery, main surgeon is annoyed	7,1

6	**Bladder neck incision**	1	Upper traction/ Suction and cleaning blood	Traction / Suction	Suction/Irrigator	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		2	The Foley catheter balloon is then deflated by the nurse						
		3	Move the catheter from a surgeon's grasper to assistant's grasper	Holding	Grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		4	Catheter and seminal vesicles are handed to the assistant for upper traction	Holding (Traction)	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		5	To avoid branches of the dorsal vein fanning over the prostate and to prevent unwanted bleeding	Putting Hemoclip/s	Hem-o-lok clip	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed, bleeding	6,2
7	**Vas deferens and arteries are exposed**	1	Upper anterior traction on the peritoneum	Traction	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
			Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	5,7
8	**Division of vas deferens**	1	The vas deferens are controlled using the clips	Putting Hemoclip/s	clip Hem-o-lock	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	5,7
		2	Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
9	**Exposure of the seminal vesicles**	1	The fibrovascular tissue is controlled using the clips	Putting Hemoclip/s	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	5,7
		2	Upper traction of the seminal vesicles and vas deferens	Traction	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
			The vas deferens are controlled using the clips	Putting Hemoclip/s	clip Hem-o-lock	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		3	The seminal vesicle is grasped to help liberate the posterior avascular plane	Holding (Traction)	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	5,7
		4	Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2

10	**Neurovascular bundle (NVB) dissection (nerve sparing)**	1	Allows for proximal control and the clips have been placed	Putting Hemoclip/s	Hem-o-lok clip	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed, bleeding	6,6
		2	Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
11	**Urethral division**	1	Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		2	Vas deferens and the seminal vesicles are collectively grasped	Holding (Traction)	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
			Suction and cleaning of smoke and blood	Suction	Suction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	5,7
12	**Prostate delocation**	1	Move the prostate from a surgeon's grasper to assistant's grasper	Holding	Endocatch bag	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
			The prostate is placed in an endocatch bag along with the anterior prostatic fat and is placed in the upper abdominal space for later retrieval	Holding	Endocatch bag	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
13	**Vesicourethral anastomosis**	1	The assistant chages the instruments (2 and 3) and passes the needle and the suture thread to the surgeon	Holding (Needle)	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		2							
		3	The needles can be snapped out and removed from the body	Holding (Needle)	Suction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		4	The hemostatic materials are inserted in the body	Holding	Locking grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2
		5	The string for the laparoscopic entrapment sack is transferred to the camera port site at the umbilicus and the abdomen is completely deflated	Holding	Endocatch bag				3,7

14	**Endocatch bag Extraction**		The specimens within the laparoscopi entrapment sack are extracted intact through extension of the periumbilical trocar site (usually 2.5 cm to 3.5 cm in length)	Holding		Rupture of the bag	Surgeon's inattention and skills		5,0
End	**Ports closure**		The fascial defect is then immediately closed by sutures. The skin defects are then closed with a subcuticular absorbable suture followed by the skin adhesive Dermabond			Hernia formation at port site and blood clot formation in the legs or pelvic region Wound infection at port site	Difficult venous blood circulation Contact with not sterile tools	Pulmonary embolism Deep venous thrombosis Prolonged recovery time Prolonged recovery time	6,1

3.2.2 LRN Process Risk Analysis

Table 11: Analysis of the LRN risks

Phase Code	Phase	Step	Assistant Task	Surgical Action	Instrument type	Failure Modes Assistant	Failure Effects Assistant	Failure Effects Assistant	Criticality Index (CI)
R1	**Colon mobilization**	1	Along the white line of Toldt, the colon is reflected	Traction	Grasper	aggressive manipulation of the colon excessive traction on the colon suboptimal exposure tissue tearing	misappliaction of the retracting forceps or wrong instrument poor traction excessive traction	tissue tearing or perforation, sepsis, death no progression tissue tearing or perforation, sepsis, death	13,4
		2	Visualization of the anterior surface of Gerota's fascia.		Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	5,7
		3							
RL2	**Colon, spleen and pancreas dissection**	1	Visualization of the colon, spleen and pancreas.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	6,7
		2							6,7
RR2	**Mobilization of duodenum and vena cava visualization (with Kocher maneuver)**		Visualization of the Duodenum and Vena cava.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	6,7
RR3	**Retraction of the liver**		The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5-mm trocar below the ribs in the anterior axillary line.	Traction	Retractor Grasper	suboptimal exposure lesion of the liver	poor traction, clumsy movement, excessive traction, large liver	no progression bleeding	7,7

R3	**Ureter and gonadal vein are identified and retracted laterally**	1	The midureter is located in the retroperitoneal fat medial to the psoas muscle.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	5,7
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	Movement	Grasper	suboptimal exposure tissue tearing	poor traction excessive traction	no progression vein lesion, ureter leasion	8,0
		3							
		4							
		5	Suction and cleaning of smoke and blood	Suction	suction device	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	10,5
R4	**Renal Hilum Identification**	1	The ureter and lower pole of the kidney are elevated	Traction	Grasper	tissue tearing	excessive traction	bleeding	8,2
		2	The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator						
		3							
		4							
R5	**Renal Hilum Transection**	1	The renal artery is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	HemOlock misplacement, hemorrage, suboptimal exposure	poor traction	no progression	12,0
			Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	14,3
		2	The renal vein is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	HemOlock misplacement, hemorrage, suboptimal exposure	poor traction	no progression	9,1
			Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	9,8
		3	The lumbar veins are controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	HemOlock misplacement, hemorrage,suboptimal exposure	poor traction	no progression	9,1
			Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	11,7

R6	**Mobilization of the Lower Pole, Dissection of the Upper Pole and Adrenal gland**	1							
		2	Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	8,2
		3	Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	8,2
		4							
R7	**Transection of the Ureter**		Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	6,9
R8	**Specimen Entrapment and Extraction**		Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Holding	Endocatch bag	endobag rupture	inadeguate endobag dimesions	tumour rupture and spillage	5,8
End	**Ports closure**		All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures.						

3.2.3 LPN Process Risk Analysis

Table 12: Analysis of the LPN risks

Phase Code	Phase	Step	Assistant Task	Surgical Action	Instrument type	Failure Modes Assistant	Failure Effects Assistant	Failure Effects Assistant	Criticality Index (CI)
P1	**Colon mobilization**	1	Along the white line of Toldt, the colon is reflected	Traction	Grasper	aggressive manipulation of the colon excessive traction on the colon suboptimal exposure tissue tearing	misappliaction of the retracting forceps or wrong instrument poor traction excessive traction	tissue tearing or perforation, sepsis, death no progression tissue tearing or perforation, sepsis, death	16,6
		2	Visualization of the anterior surface of Gerota's fascia.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	7,4
		3							15,7
PL2	**Colon, spleen and pancreas dissection**	1	Visualization of the colon, spleen and pancreas.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	10,5
		2							10,5
PR2	**Mobilization of duodenum and vena cava visualization (with Kocher maneuver)**		Visualization of the Duodenum and Vena cava.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	8,0
PR3	**Retraction of the liver**		The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5-mm trocar below the ribs in the anterior axillary line.	Traction	Retractor Grasper	suboptimal exposure lesion of the liver	poor traction clumsy movement, excessive traction, large liver	no progression bleeding	6,4

P3	**Ureter and gonadal vein are identified and retracted laterally**	1	The midureter is located in the retroperitoneal fat medial to the psoas muscle.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	9,5
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	Movement	Grasper	suboptimal exposure tissue tearing	poor traction excessive traction	no progression vein lesion, ureter leasion	16,0
		3							
		4							
		5	Suction and cleaning of smoke and blood	Suction	suction device	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	7,4
P4	**Renal Hilum Identification**	1	The ureter and lower pole of the kidney are elevated	Traction	Grasper	tissue tearing	excessive traction	bleeding	8,2
		2	The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator						
		3							
		4							
P5	**Kidney is mobilized**	1	Visualization of the Gerota's fascia.	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	16,5
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	Movement	Grasper	tissue tearing	excessive traction	bleeding	17,5

P6	**Securing the Renal Blood Vessels**	1	Visualization of the renal artery and vein	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	16,5
			Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	15,8
		2	Visualization of the renal vein	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	16,5
			Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	15,8
		3	Visualization of the renal artery	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	16,5
			Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	15,8
P7	**The tumor is excised**		Visualization of the tumor	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	16,5
			Suction and cleaning of smoke and blood	Suction	Suction	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	15,8
P8	**Renorrhaphy**	1	Visualization of the tumoral zone	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	16,5
			A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	uncorrect clip placement	wrong distance, wrong location	parenchymal tearing, bleeding, clip migration	14,3
		2	Visualization of the renal parenchymal surface	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	12,5
			Holding the tissues near to cut surface	Holding	Grasper	unapproprite countertraction	sub-optimal vision	poositive surgical margin, poor ocnologic control	21,7
		3	Visualization of renal surface	Visualization	Laparoscope	Poor vision	uncorrect endoscope targeting	no progression	12,5
			A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	uncorrect clip placement	wrong distance, wrong location	parenchymal tearing, bleeding, clip migration	18,2

P9	**The hilum is unclamped (it is removed only once hemostasis is confirmed)**								
P10	**Specimen Entrapment and Extraction**		Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Holding	Endocatch bag	endobag rupture	inadeguate endobag dimesions	tumour rupture and spillage	14,9
P11	**Ports closure**		All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures.						7,9

3.3 *Discussion*

On the basis of the results obtained by the procedural risk analyses we can derive the following evidences to be taken into consideration in the next work of defining the SARAS simplified surgical procedures:

- In the **RARP** case, all the evaluated surgical actions of the assistant are characterized by a CI positioning in the area of low risk and the linked FMs are all concerning the level of accuracy and skills of the assistant. This could be explained by the fact that, nowadays, this procedure is so standardised and performed with the help of a sophisticated robotic platform (the da Vinci® one) that not only the role of the assistant is of supporting very specific tasks thought the all procedure and does not have a direct impact on the patient safety, but also the CI associated to the first surgeon's action are themselves in the low-medium area of risk (see Appendix II, Paragraph 8.1). However, through the FMs correlation study (see Appendix II), we noticed that there are some particularly delicate passages (e.g. phase 9 "Exposure of the seminal vesicles") where the assistant's possible FM has a not negligible level of influence on the procedure, due to its medium-high correlation index to the first surgeon's FM in the same surgical step.
- In the **LR/PN** cases, instead, the assistant's actions are evaluated in a medium-low area of risk and the correlation of the surgeons' FMs is higher than in the RARP case (see Appendix II, Paragraphs 7.2 and 7.3). This is explained by the fact that the surgery is operated into a more delicate anatomical area, made more risky by the presence of great bundles of vessels and by the proximity of various other organs which all have to be spared.

Concluding, aiming to an improvement in terms of patient safety through the introduction of the project solutions, the SARAS system will have to guarantee technical performances capable to improve the level of precision and dexterity of the assistant's actions, especially in those surgical steps in which either the CI of the assistant is evaluated as medium or the coordination of the two surgeons is cardinal.

4 SARAS approach to surgical procedures

In this section we analyse the medical knowledge (described in the previous chapters) for turning the two SARAS benchmark procedures (RARP and LN) into simplified models, suitable to be translated in mathematical terms for the implementation of project solutions. To obtain this result, particular attention has been paid to reach a good compromise between surgical sensitivity and technical feasibility, by balancing different concurrent factors: (*i*) to have a reproduction of the surgical procedures that, although simplified, could cover a good part of the RARP and LN phases, (*ii*) to stabilise the maximum execution time of the SARAS-enhanced procedures on approximately 30-45 minutes (*iii*) to maintain high technological and scientific challenges in the selected procedural steps, (*iv*) to consider some of the surgical risks/unforeseen events which could be moderated by using the SARAS technologies, (*v*) to formalise the interaction and coordination between the first surgeon – operating at the da Vinci console – and the assistant – handling standard laparoscopic tools –.

Based on these premises, the work of re-engineering of the two surgical procedures into simplified models was carried out in close collaboration not only with Ospedale San Raffaele urological surgical team but also discussed with the technical partners of the Consortium. In the following paragraphs, the obtained results are reported.

4.1 *Robotic-Assisted Radical Prostatectomy – description of the rationale*

In Chapter 2, and related Annexes, the complete RARP procedure, as it is performed nowadays, has been described. From this comprehensive analysis, the first steps towards its simplified model have been undertaken focusing on the technology at disposal, within the project, for the main surgeon: the *da Vinci® System IS1200*[5] from Intuitive Surgical Inc, available in the Altair robotic lab in Verona. This was the first basic version of the da Vinci® platforms, called Standard and launched back in 2000, and constituted the starting point for robotic surgery. This kind of platform is no more in service and it is the only da Vinci surgical platform currently available for research purposes[6]. This system has important differences with respect to the last modern versions, used to describe the gold standard procedure (e.g. da Vinci® System Xi), but the main one is that the surgical robot is equipped with three robotic arms instead of four (Ballantyne & Moll, 2003).

Therefore, firstly, the RARP procedure has been reframed according to the characteristics of the da Vinci® IS1200. All the first surgeon's actions have been re-modulated (on the basis of the literature findings and the OSR surgeons' expertise) on the use of only two robotic arms for the surgical instrumentation plus one for the endoscopic camera. The assistant's tasks followed accordingly (see Appendix I, Chapter 7.1).

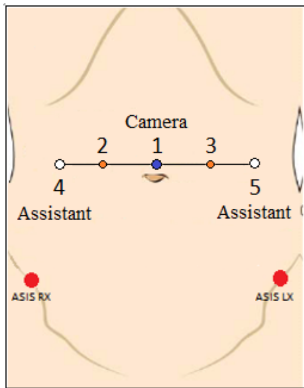
[5] https://www.intuitivesurgical.com/company/indications-for-use.php

[6] https://research.intusurg.com/?title=Main_Page

As a consequence of this design constrain, a specific trocars layout has been studied for the SARAS case, both for the da Vinci® system and the assistant (i.e. for the SARAS robotic arms), to maximise the operating field of view. In addition to that, for what concerns the SARAS robotic platform, the dimensions of the corresponding trocars have been chosen in order to facilitate the instrumental change during the procedure. In this regard, the laparoscopic surgical instruments for the assistant role have been carefully selected to be mounted on the SARAS robotic arms.

Summarising, the first differences between the complete RARP procedure (from gold standard) and the SARAS simplified one, driven by technological and design constraints, are (see Figure 21):

a) the da Vinci® robotic system used (IS1200) for the first surgeon;
b) overall trocars' position and the SARAS assistant's ones dimensions;
c) the laparoscopic instruments chosen for the SARAS system.



TROCAR 1 (da Vinci®, 12mm): VIDEO. Main surgeon directing camera movements

TROCAR 2 (da Vinci®, 8 mm): EndoWrist ® Hot Shears (Monopolar Curved Scissors)

TROCAR 3 (da Vinci®, 8 mm): Bipolar Forceps

TROCAR 4: Assistant port
TROCAR 5: Assistant port

Current practice	**SARAS simplified procedure**
TROCAR 4: 15 mm TROCAR 5: 5 mm	**TROCAR 4**: 12 mm **TROCAR 5**: 12 mm
Assistant's instruments Grasper Suction-irrigator Scissor Hem-o-lok clip applier Needle Holder Endocatch bag	**Assistant's instruments** Grasper (also used as Needle Holder) Scissor Suction-irrigator Automatic Clip Applier

Figure 21: Difference between da Vinci robot in the current practice of RARP and da Vinci (IS1200) in SARAS simplified procedure

Secondly, on the basis of the new da Vinci® IS1200 based procedure, a selection of the RARP surgical steps to be reproduced within SARAS has been done taking into consideration (as previously highlighted) the technological feasibility and the surgical relevance of the actions by the SARAS robotic assistant.

In the following paragraphs, the different aspects that led to the definition of the simplified procedure are detailed.

4.1.1 SARAS first surgeon robotic system: da Vinci® Standard IS1200

The *da Vinci® system IS1200* is a master-slave type of surgical robot. It consists of a slave or work unit and a master or control unit, which are connected by a computer-based system (see Figure 22). The slave unit is placed near the patient and includes a surgical cart with a camera arm, 2 instrument arms and a vision cart. The master unit is located in an area adjacent to the operating room. It consists of a surgeon console with an integrated 3-dimensional (3-D) display stereo viewer. The surgeon sitting at the console holds master joysticks for remote controlling the instruments and laparoscope, which are attached to the arms of the surgical cart near the patient. The head of the surgeon rests between sensors on both sides of the view port so that s/he can see the 3D display in the stereo viewer. The surgeon controls the camera, mounted on one of the robotic arms, using her/his console commands and pedals allowing to zoom in and out, or move the vision field. The instrument tips viewed in the display are aligned with the master to ensure natural and predictable instrument motion. Motion scaling reduces hand movements to correspondingly smaller instrument tip movements in the surgical field. The manipulators have a total of 6 degrees of freedom plus the grip, and at the tip, 2 more degrees than traditional endoscopic instruments. Tip articulations mimic the wrist up and down and side-to-side flexibility. With these features, the surgeon is able to perform the entire procedure, including dissection, intra-corporeal suturing and knot tying. The assistant is on the right (of the patient) side and works in laparoscopy (Abbou et al., 2017).

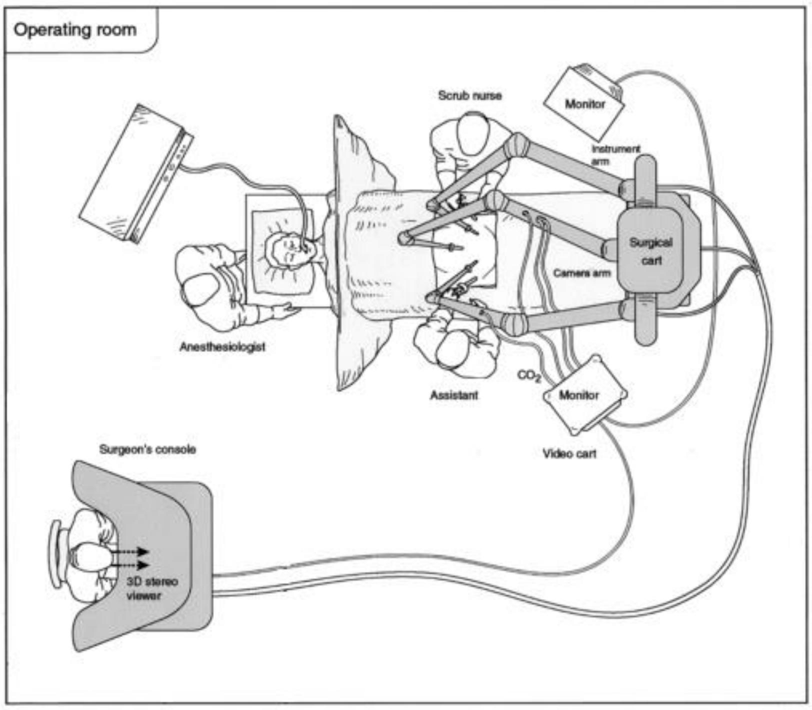


Figure 22: da Vinci system (IS1200) in operating room (Abbou et al., 2017)

4.1.2 Patient (phantom) preparation

In the SARAS simplified RARP the patient (i.e. the SARAS phantom model) is positioned in the supine position, as it is in the real practice; the legs are separated in semi flexion (lithotomy position) and the Trendelenburg position is 30° from horizontal to facilitate exposure of the pelvic content (Figure 23). The low lithotomy positioning of the legs includes a slight bend of the hip and knee, to prevent traction nerve injury. Furthermore, sequential compressive devices are placed over anti-embolic stockings to reduce the incidence of thromboembolic events.

Figure 23: Patient positioning for robot assisted radical prostatectomy (Valdivieso et al., 2013a)

4.1.3 Trocars' position and dimension

As previously mentioned, in the SARAS configuration for the first surgeon, there are three Da Vinci® arms and two assistant ports. It has been decided, together with OSR surgeons, to align all these ports to the first port (i.e. the camera port), located approximatively 2 cm above the umbilicus (Figure 24). This simplified configuration in fact standardized the model and maximises the vision of the operating workspace for both the first surgeon and the assistant.

Three metallic robotic trocars are used by the working robotic arms of the surgeon (Figure 24):

1. *Trocar 1* - the first port is used to create the pneumoperitoneum, subsequently, when the Veress needle is retrieved and a 12 mm trocar is placed for insertion of the stereo endoscope;
2. *Trocar 2* – is located on the patient's right side, is a 8 mm trocar and used for the arm holding the scissors during the procedure;
3. *Trocar 3* - is located on the patient's left side, is an 8 mm trocar and used for the arm holding the bipolar grasper during the procedure.

The surgeon's assistant provides retraction, suction, and irrigation and passes clips and sutures via the fourth and fifth trocars, positioned on the right and left patient's sides respectively, externally to the second and third trocar as shown in Figure 24. Furthermore, it was decided to keep the assistant's trocar dimension to 12 mm for both Trocar 4 and 5, in order to simplify the instrumental change for the SARAS robotic assistant.

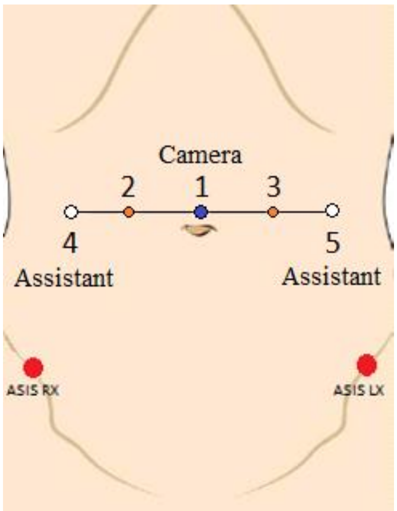


Figure 24: Trocars' position in prostatectomy with da Vinci (IS1200).

A description of the geometric layout of the trocars can be found in Chapter 5, paragraph 5.1.1. It is worth noting that all the geometric relations between the trocars have to be intended with the pneumoperitoneum already insufflated.

4.1.4 SARAS simplified RARP

Starting from the complete IS1200 based RARP procedure (reported in Appendix I, paragraph 7.1), according to the feedbacks from OSR surgeons and the technical challenges for the project solutions, a subset of surgical steps has been selected to be replicated with the SARAS robotic platforms during the surgical demonstrators (see Appendix III, paragraph 9.1).

The following Table 13 reports the details of the surgical actions of the assistant which the SARAS system is supposed to handle. The proposed model consists of the list of the chosen **surgical steps** with description of the linked assistant's actions and tasks, the **anatomical sites** involved, the eventual **forbidden regions** (i.e. anatomical structures that constitute physical dangerous limits), the **instruments used**, and related access points (**trocars**). Whenever an instrumental change occurs, it is shown in the last column of table ("Notes"). It has to be noted that some surgical steps are reported in grey: these parts of the simplified procedure are currently under discussion, on the basis the progress of the technical implementation of the SARAS surgical platform and experimental phantom models.

Phase Code	Phase	Step	Assistant Task	Surgical Action	Of What?	Instrument type	Trocar	*NOTES*
1	**Incision of the peritoneum and entry into the retropubic space of Retzius**	2	Upper anterior traction on the peritoneum	Holding (Traction)	Retropubic space of Retzius	Grasper	5	*****Grasper in port 5 for the entire procedure***
			Upper anterior traction / Suction and cleaning of blood	Traction / Suction	Peritoneum / Blood	Suction-irrigator	4	
2	**Incision of the endopelvic fascia (EPF) and identification of the dorsal venous complex (DVC)**		Suction and cleaning of smoke and blood	Suction	Blood	Suction-irrigator	4	*To be discussed*
			The assistant provides the bladder's counter-traction	Holding (Traction)	Bladder	Grasper	5	*To be discussed*
3	**Bladder mobilization**	1	Upper traction of the bladder/ Suction and cleaning of blood	Traction / Suction	Bladder / Blood	Suction-irrigator	4	
4	**Anterior prostatic fat (AFP) dissection**	1	Upper traction of the prostatic fat/ Suction and cleaning of blood	Traction / Suction	Prostatic fat/ Blood	Suction-irrigator	4	
		2	The assistant provides the prostatic fat's traction	Holding (Traction)	Prostatic fat	Grasper	5	
5	**DVC control and suture**		The assistant cuts the suture's thread	Cutting	Suture's thread	Scissor	4	*To be discussed*
			The needles can be snapped out and removed from the body	Holding (Needle)	Needle	Grasper	5	*To be discussed*
6	**Bladder neck incision**	1	Upper traction/ Suction and cleaning blood	Traction / Suction	Bladder / Blood	Suction-irrigator	4	
		3	Move the catheter from a surgeon's grasper to assistant's grasper	Holding	Catheter Seminal vesicles	Grasper	5	

		4	Catheter and seminal vesicles are collectively grasped, pulled through the open bladder neck and handed to the assistant for upper traction	Holding (Traction)	Catheter	Grasper	5	
7	**Vas deferens and arteries are exposed**		Upper anterior traction on the peritoneum	Holding (Traction)	Retroprostatic tissue	Grasper	5	
			Suction and cleaning of smoke and blood	Suction	Smoke	Suction-irrigator	4	*****ATTENTION! Instrument change in port 4: Suction to Automatic Clip Applier in step 8.1***
8	**Division of vas deferens**	1	The vas deferens are controlled using the clips	Putting Hemoclip/s	Vas deferens	Automatic Clip Applier	4	
		2	Suction and cleaning of smoke and blood	Suction	Smoke	Suction-irrigator	4	
9	**Exposure of the seminal vesicles**	1	The fibrovascular tissue is controlled using the clips	Putting Hemoclip/s	Fibrovascular tissue	Automatic Clip Applier	4	
		2	Upper traction of the seminal vesicles	Holding (Traction)	Seminal vesicles	Grasper	5	
			The seminal vesicles are controlled using the clips	Putting Hemoclip/s	Seminal vesicles	Automatic Clip Applier	4	*****ATTENTION! Instrument change in port 4: Automatic Clip Applier to Suction in step 11.1***
		3	The seminal vesicle is grasped to help liberate the posterior avascular plane.	Holding (Traction)	Seminal vesicle	Grasper	5	

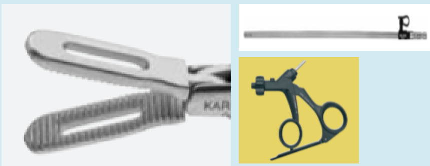
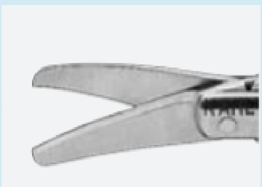
10	**Neurovascular bundle (NVB) dissection (nerve sparing)**	1	Allows for proximal control and the clips have been placed	Putting Hemoclip/s	Fibrovascular tissue	Automatic Clip Applier	4	*To be discussed*
		2	Traction/ Suction and cleaning blood	Traction / Suction	Fibrovascular tissue	Suction-irrigator	4	*To be discussed*
11	**Urethral division**	1	Traction/ Suction and cleaning blood	Traction / Suction	Urethra / Blood	Suction-irrigator	4	
		2	Seminal vesicles are collectively grasped	Holding (Traction)	Seminal vesicle	Grasper	5	
			Suction and cleaning of smoke and blood	Suction	Blood	Suction-irrigator	4	
12	**Prostate delocation**		Move the prostate from a surgeon's grasper to assistant's grasper	Holding	Endocatch bag with prostate	Endocatch bag	5	*To be discussed*
			The prostate is placed in an Endocatch bag along with the anterior prostatic fat and is placed in the upper abdominal space for later retrieval	Holding	Endocatch bag with prostate	Endocatch bag	5	*To be discussed*
13	**Vesicourethral anastomosis**	1	The assistant passes the needle and the suture thread to the surgeon	Holding (Needles)	Needles	Grasper	5	
		3	The assistant cuts the suture's thread	Cutting	Suture's thread	Scissor	4	***Remove the tip cover**
			The needles can be snapped out and removed from the body	Holding (Needles)	Needles	Grasper	5	

Table 13: RARP surgical actions of the second assistant which the SARAS system is supposed to handle

4.1.5 Surgical Instruments chosen

Referring to the surgical instruments, described in Chapter 2, further simplifications have been made.

Regarding the assistant's instruments, being in the SARAS approach a robotic system, it has to be taken into account that the risk of major injury through negligent robotic instrument exchange still exists (see Table 14). In SARAS we had not planned to develop an autonomous system to change the instruments at the end-effector of the SARAS manipulators. The main reason is that the robotic arms are passive and only the mechatronics systems attached to the end-effector are active (i.e. they have to handle the laparoscopic tools). Therefore, in order to reduce the instrumental change in the SARAS robotic platform, for the assistant we choose to consider only the most frequently used instrument to be mounted on SARAS robotic arms and to stick to the following approach: maintain the Grasper in one of the two SARAS trocars (Trocar 5) during all the simplified procedure and handling the instrument changes (i.e. Suction-irrigator, Automatic Clip Applier and Scissor) in the other one (Trocar 4).

Assistant's instrument current practice		Assistant's instrument SARAS simplified procedure[7]	
Grasper		**Grasper (1)**	(same instrument as being used in current practice)
Suction- irrigator		**Suction- irrigator (2)** For more details see D7.1	
Scissor		**Scissor (2)**	(same instrument as being used in current practice)
Hem-o-lok clip applier		**Automatic clip applier (3)**	

[7] https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3403645.pdf

Needle Holder		**Grasper (1)**
Endocatch bag		-

Table 14: Assistant's instruments for RARP current practice and SARAS simplified procedure (Karl Storz Instruments, 2017)

The assistant's instruments used in the SARAS simplified procedure (see Table 14) are:

(1) Grasper (also used for Needle Holder)

We use the Forcep Handle from Karl Storz Company, consisting of:

- The forceps insert;
- The metal outer sheath;
- The plastic handle: it's a comfort grip plastic handle, with larger contact area at the finger ring.

A grasper-type instrument is able to provide retraction in a pulling fashion, allowing for retraction at different angles and forces. A toothed grasper is able to securely latch onto tissues providing retraction to one side or the other, which frees up the fourth robotic arm to retract elsewhere. As surgical conditions change in real time, traction planes will shift, and the grasper needs to be adjusted (Karl Storz Instruments, 2017).

(2) Scissor

The instrument is a scissor from Karl Storz Company, which in the SARAS simplified procedure is going to be used to cut the suture's thread, after the vesico-urethral anastomosis.

(3) Automatic clip applier

Metallic clips are commonly used for haemostasis and for vessels closing.
The clip applier may initially be controlled with two hands to provide support and more accurate articulation for placement, as with a stapler. With more experience, clip articulation and firing can be easily performed with one hand. Whenever clips are placed, it is important to make sure that the tips of the clip are not entrapping other possibly vital tissue. The hooked end of an interlocking clip can be snagged on structures and can occasionally cause injury.

A direct drive feeding mechanism allows for smooth, controlled clip advancement during feeding with minimal tip movement during clip placement. (Aesculap EndoscopicTechnology & Ti).

4.2 *Radical/Partial Laparoscopic Nephrectomy – description of the rationale*

In order to develop a fully autonomous platform, it is absolutely necessary to achieve a complete understanding of the role of the assistant surgeon and to be able to model in a quantitative way his/her behaviour and interaction with the main surgeon. To this extent, in Chapter 2 and related Annexes, the complete LR/PN procedures have been described as performed in the current surgical practice. In the present section, their simplified modelling for SARAS purposes is going to presented. As for the RARP case, a selection of the LR/PN surgical steps to be reproduced has been done, taking into consideration the technological feasibility and the surgical relevance of the actions performed by the SARAS robotic assistant. It will be noted that, in this second benchmark, the surgical practice and the SARAS simplified procedures correspond (net of the unselected surgical steps). It is not necessary to modify the procedure in the modelling phase since the laparoscopic instrumentations of the main surgeon do not undergo any change for the SARAS testing aim (differently for the RARP case). In the following paragraphs the Nephrectomy-related simplified procedures are detailed.

4.2.1 Patient (phantom/embalmed human cadaver) preparation

In the SARAS LR/PN simplified procedures a specific phantom is going to be used for training the robotic systems, while for the final demonstration an embalmed human cadaver will be exerted. In both the cases, patient's (i.e. phantom/ embalmed human cadaver) preparation and positioning are the same of those used in the current surgical practice, namely, the umbilicus is placed over the break in the operating table and the patient is positioned in a modified lateral decubitus position. The table can be flexed as needed, or an inflatable balloon is positioned under the patient at the level of the umbilicus, a position that simplifies patient positioning and provides much better space for SARAS robotic arms movement in front of the patient. In the LN, carried out at the San Raffaele Hospital, the table is flexed to 10°-20° for left sided and 30° for right side (see Figure 14, Chapter 2.2.3.2).

4.2.2 Trocars' position and dimension

As previously described, the surgeons operate in front of the patient, from the abdominal side. In particular, the first surgeon and the assistant stand closer to the head and the feet of patient respectively (see Figure 25). The scrub nurse stands in front of the patient, near the feet. In the SARAS configuration the assistant is replaced to the SARAS robot. In order to maintain unchanged the current practice LN, the SARAS robot is going to be arranged in order to maximise the vision of the operating workspace for both the first surgeon and the assistant.

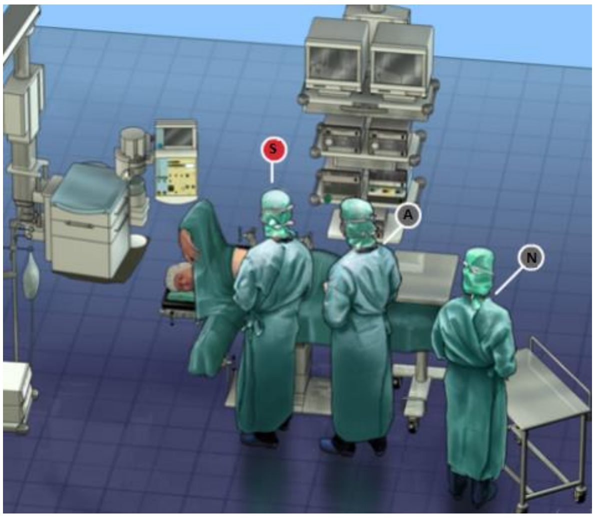


Figure 25: Surgeons' position for left LN, where (S) is the first surgeon, (A) the assistant and (N) the nurse

It has been decided, together with OSR surgeons, to preserve the current configuration of trocars; for trocars' position of LR/PN with geometric details please refer to Figure 15 and Table 5 (Chapter 2.2.3.2).

Two trocars are used by the main surgeon (Trocar 2 and Trocar 3) and two trocars by the SARAS arms (Trocar 1 and Trocar 4):

1. *Trocar 1* - the first trocar is on the midclavicular line, 2 cm below the costal margin for the insertion of the stereo endoscope, maneuvered by the assistant;
2. *Trocar 2* – is located 2 cm above the umbilicus, it is used to create the pneumoperitoneum and is one of the trocars used by the first surgeon;
3. *Trocar 3* - is located just under the xyphoid, used by the main surgeon;
4. *Trocar 4* - is located 2 cm medial to, and sometimes superior to, the anterior superior iliac spine and used by the assistant;
5. The fifth port is used approximately 5 cm below the level of second port and the instrument is the retractor grasper in case of liver retraction only for right-sided nephrectomy.

It has to be noted that all the geometric relations between the trocars have to be intended with the pneumoperitoneum already insufflated.

For SARAS purposes, it was decided to keep *the assistant's trocar dimension to 12 mm for both Trocar 1 and 4*, in order to facilitate the instrumental change for the SARAS robotic assistant. Also the *main surgeon's trocars (Trocar 2 and 3) are going to be both of 12 mm.*

4.2.3 Instruments chosen

Referring to the surgical instruments, described in Chapter 2, a further simplification has been made for the instrumental choice: in SARAS context, the robotic arms will be projected to hold, and properly move, the endoscope and another laparoscopic tool in order to reduce the instrumental change.

Therefore, for SARAS robotic arms (assistant side) see Table 15, we choose to:

- Maintain the Laparoscope in Trocar 1 for the entire procedure;
- Handle only one instrument change (i.e. Grasper and Automatic Clip Applier) in Trocar 4.

The first surgeon, in the SARAS LR/PN will use all the instruments described in the surgical background, with the addition of the suction/irrigator (used by the assistant in the current practice).

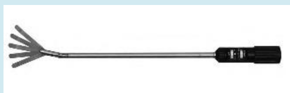
Trocar	Instruments	Action	Instruments figure[8]
1st – SARAS port	Laparoscope	Direct visualization of tissue	
2nd – Surgeon port	Monopolar or ultrasonic scissors	Cutting + haemostasis	
	Suction-irrigator	Suction and cleaning	
3th – Surgeon port	Bipolar Forceps	Holding tissues	
4th – SARAS port	Grasper	Holding tissues	
	Clip applier	Clipping vessels	
5th – Fixed port	Retractor grasper	Holding organs	

Table 15: Surgical instruments in LN

[8] *©[2018] Intuitive Surgical, Inc.*

4.2.4 SARAS simplified LRN and LPN procedures

Starting from the complete LN procedure (reported in Appendix I, paragraphs 7.2 and 7.3) according to the feedbacks from OSR surgeons and the technical challenges for the project solutions, a subset of surgical steps has been selected to be replicated with the SARAS LAPARO 2.0 platform. The detailed description of the LR/PN simplified procedures are reported in Appendix III, paragraphs 9.2 and 9.3.

As for the prostatectomy's study, the following Table 16 reports the details of the surgical actions of the only assistant which the SARAS system is supposed to handle: i.e. visualization of the working field, retraction of anatomical structures and putting Hemoclips.

Table 16 represents the Laparoscopic Radical Nephrectomy and the second Table 17 is the model of Laparoscopic Partial Nephrectomy. Also in these cases, the Tables consist of a list of the chosen **surgical steps** with description of the linked assistant's actions and tasks, the **anatomical sites** involved, the eventual **forbidden regions** (i.e. anatomical structures that constitute physical dangerous limits), the **instruments used**, and related access points (**trocars**). Whenever an instrumental change occurs, it is shown in the last column of table ("Notes").

In the following Nephrectomy-related models it has to be noted that:

- The phases' numeration is R (where R is for Radical) and P (for Partial) followed by the surgical step number. For example: R1 is the first step of Radical nephrectomy;
- To indicate the different side of surgery, to the previous nomenclature is added the initial letter of the operating side: R for right side and L for left side. For example: RL2 is the second step of Radical nephrectomy on Left side and PR2 is the second step of Partial nephrectomy on Right side;
- For helping to understand this numeration, the phases' cells have been colored in two different colors: red and blue for left and right side respectively;
- Some assistant's surgical steps are reported in light green and the corresponding descriptions are crossed out: these parts of the procedures, for the SARAS case, have been decided to be moved as main surgeon's responsibilities (see Appendix III, paragraphs 9.2 and 9.3).

Phase Code	Phase	Step	Assistant Task	Surgical Action	Instrument type	Trocar	*NOTES*
R1	**Colon mobilization**	1	Along the white line of Toldt, the colon is reflected	Traction	Grasper	4	
		3	Visualization of the anterior surface of Gerota's fascia.	Visualization	Laparoscope	1	*****Laparoscope in port 1 for the entire procedure***
RL2	**Colon, spleen and pancreas dissection**		Visualization of the colon, spleen and pancreas.	Visualization	Laparoscope	1	
RR2	**Mobilization of duodenum and vena cava visualization (with Kocher maneuver)**		Visualization of the Duodenum and Vena cava.	Visualization	Laparoscope	1	
RR3	**Retraction of the liver**		Visualization of the liver	Visualization	Laparoscope	1	
R3	**Ureter and gonadal vein are identified and retracted laterally**	1	The midureter is located in the retroperitoneal fat medial to the psoas muscle.	Visualization	Laparoscope	1	
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	Movement	Grasper	4	
		5	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4	
R4	**Renal Hilum identification and dissection**	1	The ureter and lower pole of the kidney are elevated	Traction	Grasper	4	*****ATTENTION! Instrument change in port 4: from Grasper to Automatic Clip Applier in step R5.1***

		2	~~The vessels entering the renal hilum can be identified and bluntly dissected using the tip of the irrigator-aspirator.~~	~~Suction~~	~~Suction~~	~~4~~	
R5	**Renal Hilum Transection**	1	The renal artery is visualized	Visualization	Laparoscope	1	
			The renal artery is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~4~~	
		2	The renal vein is visualized	Visualization	Laparoscope	1	
			The renal vein is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~4~~	
		3	The lumbar veins are visualized	Visualization	Laparoscope	1	
			The lumbar veins are controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~4~~	
R6	**Mobilization of the Lower Pole, Dissection of the Upper Pole and Adrenal gland**	2	The lower pole of kidney is visualized	Visualization	Laparoscope	1	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~4~~	
		3	The inferior Gerota's fascia of kidney is visualized	Visualization	Laparoscope	1	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~4~~	
		4	The Adrenal gland of kidney is visualized	Visualization	Laparoscope	1	

R7	**Transection of the Ureter**	1	The ureter is visualized	Visualization	Laparoscope	1	
		2	The ureter is controlled using the clips	Putting Hemoclip/s	Hem-o-lok clip	4	
		4	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~4~~	

Table 16: LRN surgical actions of the second assistant which the SARAS system

Phase Code	Phase	Step	Assistant Task	Surgical Action	Instrument type	Trocar	NOTES
P1	**Colon mobilization**	1	Along the white line of Toldt, the colon is reflected	Traction	Grasper	4	
		2	Visualization of the anterior surface of Gerota's fascia.		laparoscope	1	*****Laparoscope in port 1 for the entire procedure***
PL2	**Colon, spleen and pancreas dissection**	1	Visualization of the colon, spleen and pancreas.	Visualization	Laparoscope	1	
		2					
PR2	**Mobilization of duodenum and vena cava visualization (with Kocher maneuver)**		Visualization of the Duodenum and Vena cava.	Visualization	Laparoscope	1	
PR3	**Retraction of the liver**		Visualization of the liver.	Traction	Retractor Grasper	5	****Fixed retraction port***
P3	**Ureter and gonadal vein are identified and retracted laterally**	1	The midureter is located in the retroperitoneal fat medial to the psoas muscle.	Visualization	Laparoscope	1	
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	Movement	Grasper	4	
		5	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4	

P4	**Renal Hilum Identification**	1	The ureter and lower pole of the kidney are elevated	Traction	Grasper	4	
		2	~~The vessels entering the renal hilum can be identified and bluntly dissected using the tip of the irrigator-aspirator.~~	~~Suction~~	~~Suction~~	4	
		3	Visualization of the Renal Hilum	Visualization	Laparoscope	1	
		4	The hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis.	Traction	Grasper	4	
P5	**Kidney is mobilized**	1	Visualization of the Gerota's fascia.	Visualization	Laparoscope	1	
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	Movement	Grasper	4	
P6	**Securing the Renal Blood Vessels**	1	Visualization of the renal artery and vein	Visualization	Laparoscope	1	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4	
			Holding the tissues near to renal artery and vein	Holding	Grasper	4	
		2	Visualization of the renal vein	Visualization	Laparoscope	1	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4	
			Holding the tissues near to renal vein	Holding	Grasper	4	
		3	Visualization of the renal artery	Visualization	Laparoscope	1	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4	
			Holding the tissues near to renal artery	Holding	Grasper	4	*****ATTENTION! Instrument change in port 4: from Grasper to Automatic Clip Applier in step P8.1***

P7	**The tumor is excised**		Visualization of the tumor	Visualization	Laparoscope	1	
			~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4	
P8	**Renorrhaphy**	1	Visualization of the tumoral zone	Visualization	Laparoscope	1	
			A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	4	
		2	Visualization of the renal parenchymal surface	Visualization	Laparoscope	1	
			Holding the tissues near to cut surface	Holding	Hem-o-lok clip	4	**** Instrument in port 4 (Automatic Clip Applier) is used for holding the tissues***
		3	Visualization of renal surface	Visualization	Laparoscope	1	
			A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	4	
P10	**Specimen Entrapment and Extraction**		Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Holding	Endocatch bag	1	
P11	**Ports closure**		All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures.				

Table 17: LPN surgical actions of the second assistant which the SARAS system

5 SARAS clinical requirements for surgical procedures

This section outlines and discusses the clinical and procedure-specific requirements to be translated into system specifications later (see Deliverable 7.1 “Technical specifications”), which then will guide the implementation process of both the single components and the integrated SARAS platforms in the next years. In particular, clinical requirements are going to be presented into two main categories: *(i) phantoms-related requirements* which are going to be used into WP2 developmental phases and *(ii) procedures-related requirements*, which attain to the work of formalising into mathematical models and actuators (WP3 to 6) the SARAS simplified procedures described in Chapter 4 and integrating the various project solutions into the final robotic platforms (WP7).

5.1 *Phantoms requirements*

So far, adequately complex and anatomically accurate synthetic human-like phantom models do not exist. Many phantoms for minimally invasive surgery (MIS) are commercially available to mimic organs and other models also exist which are adapted for image guided therapies (IGT) and treatments. However, these models are generally static models and none of them provides the combination of functional characteristics such as respiratory motion and vascular perfusion simulation.

The SARAS system will be trained and benchmarked using complex synthetic tissue mimicking material (TMM) anthropomorphic phantom model platforms for pelvic and abdominal anatomy regions. These will be generated from 3D reconstructed anonymised medical data and predominantly additive manufacture fabrication technologies. This process will be developed and optimised during the SARAS project time frame to enable accurate anatomical tissue and organ geometries to be captured and reproduced using materials selected for best tactile simulation and closest mechanical properties to targeted tissues.

The focus of the present investigation is the identification of the clinical requirements of the surgical environment for the two SARAS procedures, namely the *phantom anatomy* (i.e. topologies and dimensions of the organs) and related *organs’ tissues properties* (i.e. mechanical ones and tissue patterns), in order to obtain phantom models which are a good compromise between anatomical accuracy and reproducibility of the model (since, being used in the SARAS testing phases, must be produced in series).

Starting for the surgical background reported in Chapter 2, the anatomies related to both the RARP and LR/PN are described. In cooperation with OSR expert surgeons, a first selection of the anatomical organs and structures, which should be taken into consideration for the development of the phantom models for the SARAS simplified benchmark procedures, was carried out. This choice was made based on the following rationale:

1. The phantoms have to reproduce the pre-operative conditions of the patient, considering both the insufflation of the abdomen and the trocars positions;
2. All the organs and anatomical structures involved in the selected actions of both the first and second operators in the two SARAS simplified procedures (for details please see Chapter 4, paragraphs 4.1 and 4.2) must be present;
3. All organs and anatomical structures that constitute physical limits (i.e. forbidden regions) for surgical actions must be present;
4. The complexity of the organs and anatomical structures reconstructed in each phantom must allow both the first operator (i.e. the surgeon operating with da Vinci) and the SARAS system (whether in case it is in tele-operated mode or in fully autonomous mode) to orientate within it and be able to correctly plan and perform the surgical tasks of each of the benchmark procedures.

Subsequently, once the list of the anatomical structures has been identified, a second simplification has been carried out in collaboration with OSR surgeons to define which of them should be reproduced with a realistic anatomy and which ones could be approximated. For both procedures the approximated structures resulted to be all those not directly interested by the surgical actions, being mainly anatomical boundaries. For example, for the RARP, the endopelvic fascia is going to be approximated as it is only a physical boundary of the operative working space, but the peritoneum is going to be reproduced with anatomical fidelity as it is incised during the operation by the first surgeon and manipulated by the assistant. In addition to that, it has been proposed to produce the organs and structures, which are going to be damaged during the testing of the SARAS surgical benchmarks (i.e. cut or dissected), as disposable pieces so as to replace only part of the overall phantom after each test instead of the entire one. These simplifications have ben dictated by the need of finding an effective and well-balanced compromise among the realization of realistic phantom models, their cost, and their stability and reproducibility for testing purposes.

In the following, for both the SARAS benchmark procedures, the clinical requirements of the related phantoms are described.

5.1.1 Simplified model for the RARP

Given the anatomical description previously provided and the process of modelling and simplification carried out with surgeons, the clinical requirements for the phantom model of the Robot-Assisted Radical Prostatectomy are the following:

1. The RARP phantoms have to replicate the human pelvic region with the right and left groins and the umbilical region with the right and left flanks (see Figure 26);

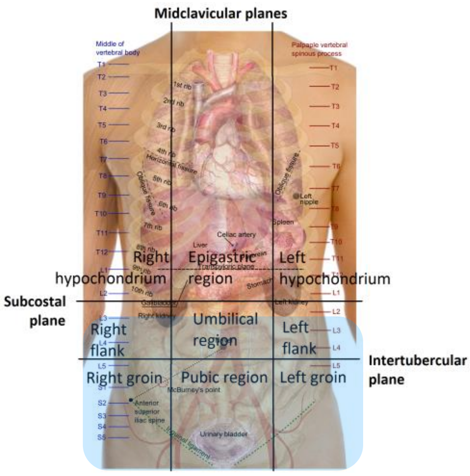


Figure 26: Nine-quadrants topographical representation of the human trunk (from Wikipedia)

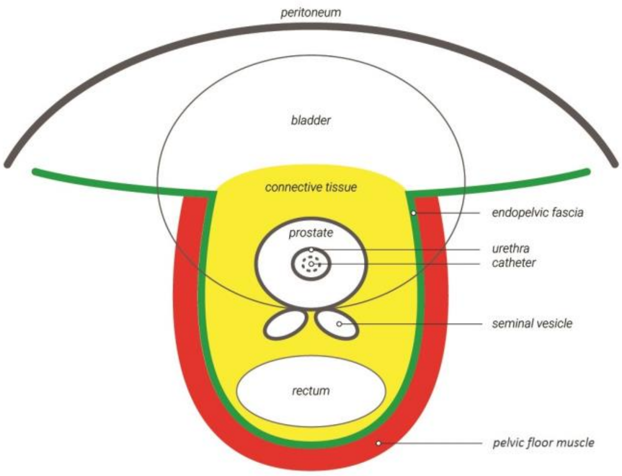
2. The RARP phantoms have to reproduce the pneumoperitoneum insufflated at 12 mmHg in the patient's abdomen;
3. The RARP phantoms have to present the housing for the da Vinci and assistant (SARAS robotic platform) trocars, in the arrangement described in Chapter 4, paragraph 4.1.3: 5 trocars in line, positioned 2 cm over the umbilicus line. Please refer to the following Table 18 for the details of the geometric relations between them.

Trocar Number	Ø	Role	Positioning
Trocar 1	12 mm	da Vinci IS1200 camera	2 cm over the umbilicus
Trocar 2	8 mm	da Vinci IS1200 instrumental port	In line respect to Trocar 1, 8 cm on the right (patient's) side
Trocar 3	8 mm	da Vinci IS1200 instrumental port	In line respect to Trocar 1, 8 cm on the left (patient's) side
Trocar 4	12 mm	Assistant (SARAS robot) instrumental port	In line with the others, on the right (patient's) side of trocar 2
Trocar 5	12 mm	Assistant (SARAS robot) instrumental port	In line with the others, on the left (patient's) side of trocar 3

Table 18: Description of geometric details for da Vinci and assistant (SARAS robotic platform) trocars

It is worth remarking that all the geometric relations between the trocars have to be intended with the pneumoperitoneum already insufflated.

4. The RARP phantoms have to include the organs and anatomical structures shown in Table 19 with the specifications on their anatomical fidelity, if they're going to be disposable and the corresponding mechanical and pattern tissue properties. In Figure 27 it is reported a schematised cross-sectional view of a simplified RARP model and related structures alongside with the details of the vessels and nerves bundles to be considered.



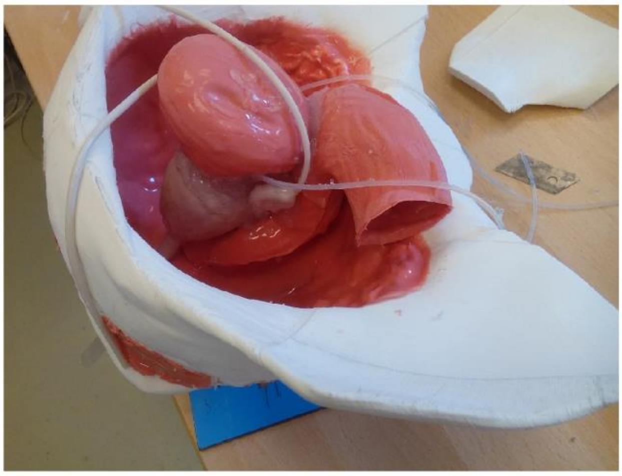


Figure 27: Exemplificative cross-section of the RARP phantom

Organs and Anatomical Structures	Organs dimensions and features	Mechanical tissue properties (Stiffness)	Tissue patterns	Anatomical Fidelity
Peritoneum	It is the serous membrane, the thickness is 0.2-0.5 mm. Thin and transparent serosal membrane composed of a layer of endothelial cells and a fibrous connective lamina	Young's modulus=0.932 MPa (Bashkatov et al., 2016)		YES
Muscle of the pelvic floor	-	Young's modulus=12 kPa (Nagle, 2014) Density = 1090.4 Kg/m^3 (Hasgall PA et al., 2015)		NO
Rectum	The adult human rectum is about 12 centimeters long (Tanaka et al., 2012). The color is visually dark red-brown	Young's Modulus = 5.18 MPa (Christensen, 2015)		NO
Seminal vesicle	The average seminal vesicle length was 31 ± 10.3 mm and its average volume 7.1± 5.2 ml (Gofrit et al., 2009). They are opaque white and appear grainy tissue	Density = 1045 Kg/m^3 (Hasgall PA at al., 2015)		YES
Connective tissue	Adipose tissue is white or yellow, composed mostly of adipocytes (fat cells) (Miller, Watkin, & Chen, 2002).	Density= 1026.5 Kg/m^3 (Hasgall PA at al., 2015)		NO

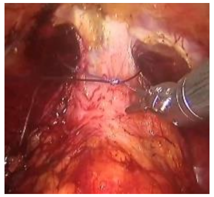
Dorsal venous complex				YES
Neurovascular bundle (To be Discussed)	It is important owing to its relationship with postoperative functions of continence and potency. (Park, Jeong, & Lee, 2013)	Young's modulus = 0.570 GPa (In-vitro) (Stager, 1996)		YES
Bladder	The typical human bladder will hold between 300 and 500 mL before the urge to empty occurs. Its weight is 42 g. (Mahfouz, Elsalmy, Corcos, & Fayed, 2013).	Young's modulus=4 kPa (Mahfouz et al., 2013) Density= 1086 Kg/m^3 (Hasgall PA at al., 2015)		YES
Urethra	It is roughly 15-25 cm long in the adult.	Young's modulus=10-20 kPa (Orabi et al., 2013)		YES
Prostate	The size of a healthy prostate is about 5x2x3cm and the weight is about 30g. The presence of a tumor doesn't change the organ dimensions.	*Healthy prostate data*: 16kPa (Zhang et al., 2008) Density= 1045 Kg/m^3 (Hasgall PA at al., 2015) *Prostate with cancer*: the tumor has an effect on the organ's stiffness, that's increased in correspondence of the tumor volume.		YES
Catheter	2-Way Foley Catheter ch/fr 18	-		NO

Table 19: Summary Table of the clinical requirements of the organs and anatomical and non- anatomical structures need for the RARP

5.1.2 Simplified model for the Nephrectomy

As for the prostatectomy's study, taking into consideration the LR/PN anatomical description and the related process of modelling and simplification carried out with surgeons (see paragraphs: 2.2.1 and 4.2), the clinical requirements for the phantom model of the Laparoscopic Radical/Partial Nephrectomy are the following:

1. The LP/RN phantoms have to replicate the human abdominal region with the right and left upper quadrants region (see Figure 28);

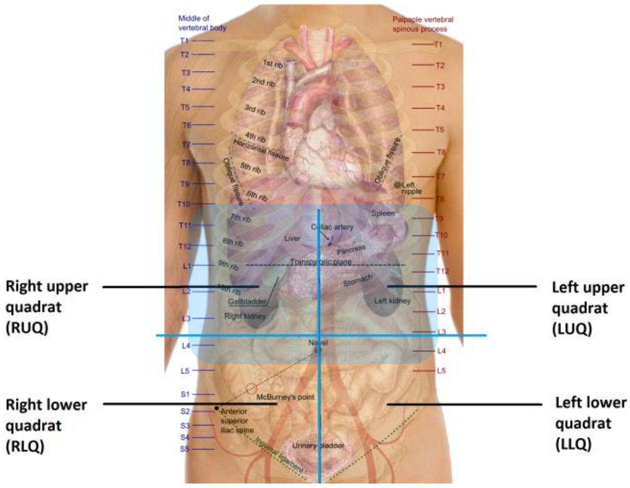


Figure 28: The four abdominopelvic quadrats of the human trunk (from Wikipedia)

2. The LP/RN phantoms have to reproduce the pneumoperitoneum insufflated at 12-14 mmHg in the patient's abdomen;
3. The LP/RN phantoms in the arrangement described in Chapter 4, paragraph 4.1.3: 5 trocars in line, positioned 2 cm over the umbilicus line. Please refer to the following Table 20 and Figure 29 for the details of the geometric relations between them:

Trocar Number	Ø	Role	Positioning
Trocar 1	12 mm	**Assistant** instrumental port	on the midclavicular line 2 cm below the costal margin
Trocar 2	12 mm	**Surgeon** instrumental port	2 cm above the umbilicus
Trocar 3	12 mm	**Surgeon** instrumental port	just under the xyphoid
Trocar 4	12 mm	**Assistant** instrumental port	2 cm medial to and sometimes superior to the anterior superior iliac spine
Trocar 5	12 mm	Fixed retraction port	3 cm medially to trocar 4 for a RIGHT nephrectomy

Table 20: Description of geometric details for surgeon and assistant (SARAS robotic platform) trocars of LN

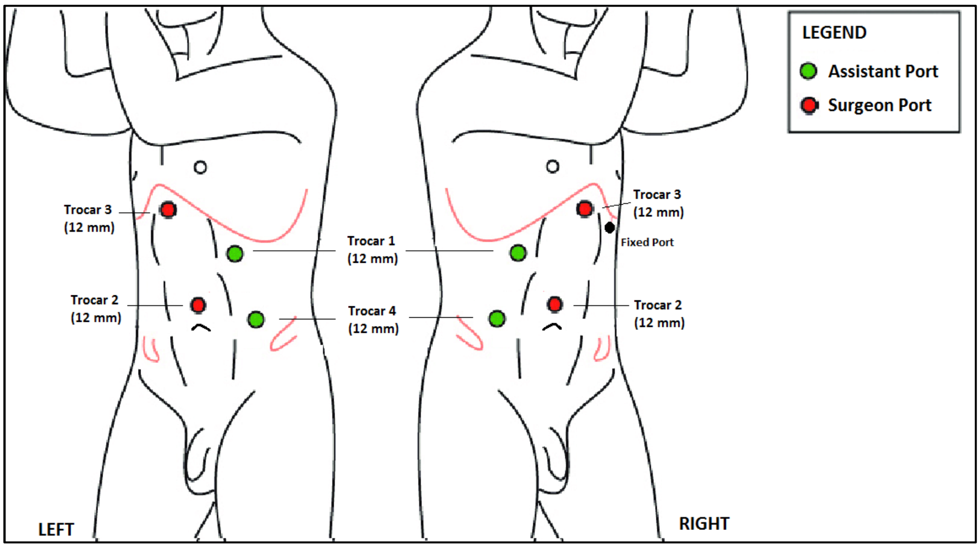


Figure 29: Outline of the anatomic disposition of the L R/P N trocars

It is worth remarking that all the geometric relations between the trocars have to be intended with the pneumoperitoneum already insufflated.

4. The LP/RN phantoms have to include the organs and anatomical structures with the specifications on their anatomical fidelity. In Figure 30 two images of organs above the kidneys (front view of human body) are reported.

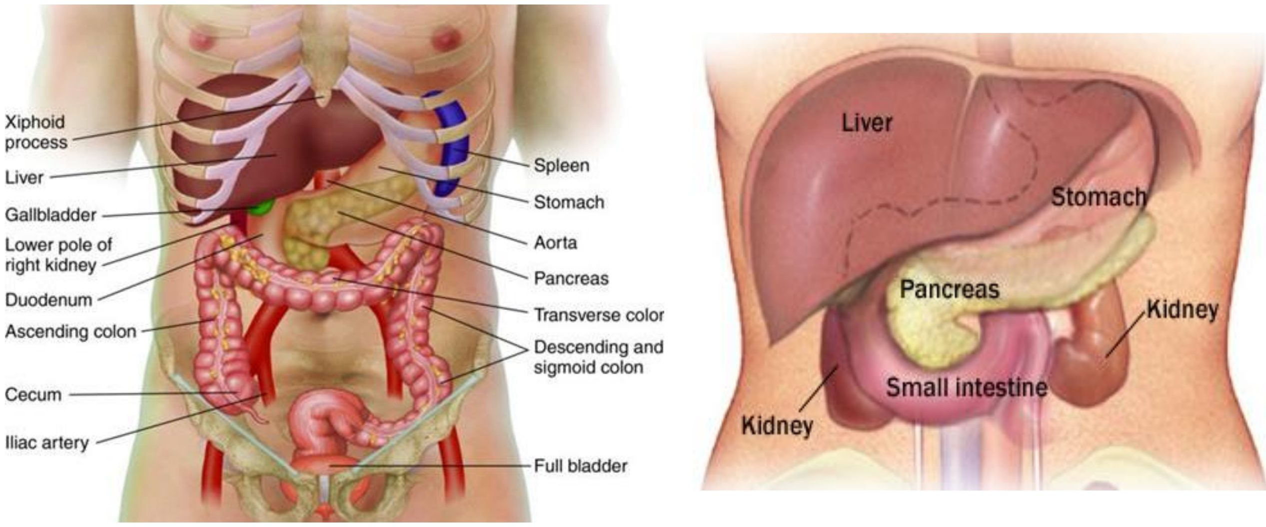


Figure 30: Example of structures to be studied in LN (radical and partial) phantoms

As described in Paragraph 2.2.1, the kidneys are located in the retroperitoneum. The position of the kidneys is asymmetrical, the left kidney being located slightly more medial than the right.
The surrounded regions on the anterior and posterior side of the <u>left kidney</u> are:

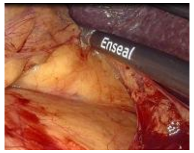
- Dorsally, 11th and 12th rib;
- Cranially, adrenal gland, spleen;

- Medially, psoas major muscle, aorta, ovarian/testicular vein, ureter;
- Ventrally, spleen, pancreas, stomach, descending colon.

Instead, the neighbor areas on the anterior and posterior side of the right kidney are:

- Dorsally, 12th rib, subcostal nerve;
- Cranially, adrenal gland;
- Medially, psoas major muscle, inferior vena cava, ovarian/testicular vein, ureter,
- Ventrally, liver, duodenum, ascending colon.

These structures should be taken into consideration for the development of the phantom models for the SARAS simplified benchmark procedures.

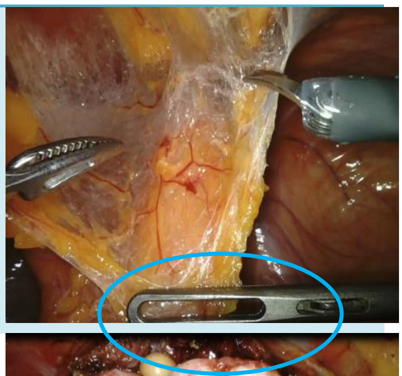
Organs and Anatomical Structures	Organs dimensions and features	Mechanical tissue properties (Stiffness)	Tissue patterns	Anatomical Fidelity
Kidney	11–14 cm in length, 6 cm wide and 4 cm thick. Weighs: between 125 and 170 grams (Zou & Fu, 2017)	Young's modulus = 4.12±0.24 kPa (Bensamoun, 2011) Density= 1066.25 Kg/m^3 (Hasgall PA at al., 2015)		YES
Gerota's fascia	It is a layer of connective tissue encapsulating the kidneys and the adrenal glands			NO
Renal vessels (vein and artery)	The diameter is 5.04 ± 0.74 mm (Kem, Lyons, Wenzl, Halverstadt, & Yu, 2005)	Young's modulus = 10.7±0.18 kPa (Korsmo et al., 2013)		YES
Ureter	Length: 4 ± 1.2 cm. Diameter: 4.1± 0.34	Young's modulus = 0.1 MPa (Kambic and Yokobori, 1994) Density= 1101 Kg/m^3 (Hasgall PA at al., 2015)		YES
Colon	It's a tube about 25–38 cm long	-		NO
Spleen	It varies in size and shape but it is usually 12 cm long, 5 cm thickness, and 7 cm wide (Ehimwenma & Tagbo, 2011).	Young's modulus = 4.75±0.70 kPa (Bensamoun, 2011) Density= 1089 Kg/m^3 (Hasgall PA at al., 2015)		NO
Pancreas	It is a 12-15–cm long J-shaped, soft, lobulated	Young's modulus = 1.9±0.40 kPa (Hatano et al., 2015) Density= 1089 Kg/m^3		NO

		(Hasgall PA at al., 2015)	
Liver	The mean liver size is 7 cm for women and 10.5 cm for men. The liver weighs 1200-1400 g in woman and 1400-1500 g in the adult man. (Wolf, 1990)	Young's modulus = 2.07±0.25 kPa (Bensamoun, 2011) Density= 1079 Kg/m^3 (Hasgall PA at al., 2015)	NO
Inferior vena cava and descending aorta	Vena cava: length is 22 cm and diameter is 25 mm. Aorta: length is 30 cm and 16 mm	Young's modulus = 3.7 ± 0.8 kPa	NO
psoas muscle	The Length is 270±0.12 mm, thickness is 20.12 ± 4.04 mm (Ilayperuma & Nanayakkara, 2008)	Young's modulus = 2.60±0.25 kPa (Bensamoun, 2011) Density = 1090.4 Kg/m^3 (Hasgall PA at al., 2015)	NO

Table 21: Summary Table of the clinical requirements of the organs and anatomical structures need for the LN

5.2 *Clinical requirements for modelling surgical procedures*

Referring to the SARAS simplified RARP and LN procedures, described in Chapter 4, and focusing only on the assistant's part (which role the SARAS robotic system is supposed to take up), the list of key surgical actions (or assistant tasks) to be replicated by the SARAS robots has been identified, as reported in Table 22 below:

ASSISTANT'S TASKS	DESCRIPTION	INSTRUMENT	EXAMPLE
Holding (tissue/s or organ) with traction	Is the action providing a retraction in a pulling fashion (with different angles and forces) a tissue or an organ in order to facilitate the first surgeon approaching a specific anatomical structure or dissecting it (Yuh, 2013).	Grasper (lever type 3)	
Traction	Is the action of providing a leaning retroactive force to push tissues/nerves or vessels away from the dissection point to enhance the visualization of the operating field or as a safety measure (Yuh, 2013).	Suction/irrigator	
Putting Hemo clip/s	Is the action of putting plastic clips for hemostasis (i.e. stop and control bleeding) (Yuh, 2013).	(Automatic) Clip Applier (lever type 3)	
Holding Needle/s	When an intracorporal suture is envisioned, needles need to be passed between the operators within the surgical working cavity. It is the action of holding between the instrument tips the needle (with its thread) and passing it to/back from the first surgeon without making any harm to the surrounding anatomical structures (Yuh, 2013).	Needle holder (in the SARAS simplified procedures it is replaced by the Grasper)	

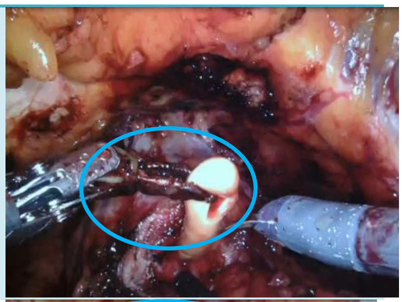
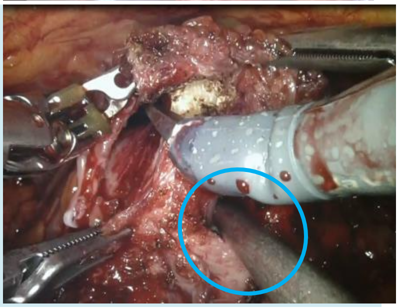
Holding	Catheter	It is the action of holding between the instrument tips the urethral Catheter, after having received it from the first surgeon’s grasper	Grasper	
Cutting		Is the action of severing with scissors (for MIS) a specific target object (e.g. in the SARAS RARP the surgical thread).	Scissors for MIR	
Suction		Is the action of sucking (blood or cauterization smoke) in order to keep the immediate surgical working field clear (Yuh, 2013).	Suction/Irrigator	
Visualization		Is the action necessary to achieve the organs or tissues, in order to observe the working field.	Laparoscope	-

Table 22: List of key surgical actions (or assistant tasks) to be replicated by the SARAS robots

In the following, for each SARAS benchmark procedure, the assistant’s surgical tasks are going to be split in elementary sub-tasks and described in detail step by step (referring to Table 13 for RARP and Table 16, Table 17 for LN of Chapter 4), highlighting also the connection with the corresponding SARAS solution they have an impact on.

5.2.1 Robotic-Assisted Radical Prostatectomy

The procedure-related requirements for the RARP case are listed in the following Table 23, which is derived from Table 15 (see Chapter 4, paragraph 4.1.5) of the simplified procedure. It describes, for each assistant's task, the corresponding target organ or anatomical structure, the instrument used and the component sub-tasks. Where necessary, the detail of the anatomical regions to be spared (i.e. forbidden regions) is provided, as long as of the da Vinci instruments to avoid collisions. For each sub-task it is then indicated the SARAS platform module involved in the fulfilment of the specific requirement.

It has to be noted that Table 23 reports the procedural requirements for the SOLO-SURGERY platform, where the assistant role is played by the SARAS robotic arms. This is, in fact, the most complete case where all the platform's modules are present and activated. The same list of requirements is still valid for the MULTI-SURGERY case with the difference that, being the assistant a real surgeon, all the sub-tasks linked to the Perception module are not to be taken into consideration (as they're "implemented" by the human mind).

Phase Code	Phase	Step	Assistant Task	Surgical action	Of What?	Instrument type	Requirements for surgical actions (sub-task)		Forbidden region/s	SARAS architecture modules involved
1	**Incision of the peritoneum and entry into the retropubic space of Retzius**	2	Upper anterior traction on the peritoneum	**Holding (Traction)**	Peritoneum	Grasper	R.1.2.A.1	Identify the Peritoneum	-	Perception Module
							R.1.2.A.2	Identify the region of the Peritoneum to be grasped	-	Perception Module
							R.1.2.A.3	Plan the trajectory to reach the target region	*Anatomical:* Pelvic walls and bowel, iliac artery and vein, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.1.2.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Pelvic walls and bowel, iliac artery and vein, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.1.2.A.5	Grasp the target region	*Anatomical:* Pelvic walls and bowel, iliac artery and vein, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.1.2.A.6	Plan the direction of the requested upper-anterior traction	-	Perception, Cognitive and Planning Modules
							R.1.2.A.7	Implement and maintain the traction	-	Planning Module

			Upper anterior traction / Suction and cleaning of blood	**Traction / Suction**	Peritoneum / Blood	Suction-irrigator	R.1.2.B.1	Identify the Peritoneum	-	Perception Module
							R.1.2.B.2	Identify the region of the Peritoneum to be pushed	-	Perception Module
							R.1.2.B.3	Plan the trajectory to reach the target region	*Anatomical:* Pelvic walls and bowel *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.1.2.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Pelvic walls and bowel *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.1.2.B.5	Plan the direction for the upper traction	*Anatomical:* Pelvic walls and bowel *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.1.2.B.6	Implement and maintain the traction	-	Perception, Cognitive and Planning Modules
3	**Bladder mobilization**	1	Upper traction of the bladder/ Suction and cleaning of blood	**Traction / Suction**	Bladder / Blood	Suction-irrigator	R.3.1.1	Identify the Bladder	-	Perception Module
							R.3.1.2	Identify the region of the Bladder to be moved	-	Perception Module
							R.3.1.3	Plan the trajectory to reach the target region	*Anatomical:* Pelvic walls, pubic bone	Planning Module

									Non-anatomical: da Vinci bipolar grasper and scissors	
							R.3.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.3.1.5	Plan the direction for the upper traction	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.3.1.6	Implement and maintain the traction	-	Cognitive and Planning Modules
4	**Anterior prostatic fat (AFP) dissection**	1	Upper traction of the prostatic fat/ Suction and cleaning of blood	**Traction / Suction**	Prostatic fat/ Blood	Suction-irrigator	R.4.1.1	Identify the Prostatic Fat	-	Perception Module
							R.4.1.2	Identify the region of the Prostatic Fat to be moved	-	Perception Module
							R.4.1.3	Plan the trajectory to reach the target region	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Planning Module
							R.4.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules

							R.4.1.5	Plan the direction for the upper traction	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.4.1.6	Implement and maintain the traction	-	Perception, Cognitive and Planning Modules
		2	The assistant provides the prostatic fat's traction	**Holding (Traction)**	Prostatic fat	Grasper	R.4.2.1	Identify the Prostatic Fat	-	Perception Module
							R.4.2.2	Identify the region of the Prostatic Fat to be grasped	-	Perception Module
							R.4.2.3	Plan the trajectory to reach the target region	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.4.2.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.4.2.5	Grasp the target region	*Anatomical:* Pelvic walls, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.4.2.6	Plan the direction of the requested traction	-	Perception, Cognitive and Planning Modules

							R.4.2.7	Implement and maintain the traction	-	Cognitive and Planning Modules
6	**Bladder neck incision**	1	Upper traction/ Suction and cleaning blood	**Traction / Suction**	Bladder / Blood	Suction-irrigator	R.6.1.1	Identify the Bladder	-	Perception Module
							R.6.1.2	Identify the region of the Bladder to be moved	-	Perception Module
							R.6.1.3	Plan the trajectory to reach the target region	*Anatomical:* bladder, prostate (cut in the middle) *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.6.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* bladder, prostate (cut in the middle) *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.6.1.5	Plan the direction for the upper traction	*Anatomical:* bladder, prostate (cut in the middle) *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.6.1.6	Implement and maintain the traction	-	Perception, Cognitive and Planning Modules
		3	Move the catheter from a surgeon's grasper to assistant's grasper	**Holding** **(Catheter)**	Catheter	Grasper	R.6.3.1	Identify the Catheter and the da Vinci grasper holding it		Perception Module
							R.6.3.2	Identify the region of the Catheter to be grasped		Perception Module
							R.6.3.3	Plan the trajectory to reach the target region	*Anatomical:* bladder, prostate	Cognitive and Planning Modules

									Non-anatomical: da Vinci bipolar grasper	
							R.6.3.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* bladder, prostate *Non-anatomical*: da Vinci bipolar grasper	Perception, Cognitive and Planning Modules
							R.6.3.5	Grasp the chosen Catheter region	*Anatomical:* bladder, prostate *Non-anatomical*: da Vinci bipolar grasper	Cognitive and Planning Modules
							R.6.3.6	Maintain it in position		Cognitive and Planning Modules
		4	Catheter and seminal vesicles are handed to the assistant for upper traction	**Holding (Traction)**	Catheter Seminal vesicles (SV)	Grasper	R.6.4.1	Identify the Catheter and the SV	-	Perception Module
							R.6.4.2	Identify the region of the Catheter and the SV to be grasped together	-	Perception Module
							R.6.4.3	Plan the trajectory to reach the target regions	*Anatomical:* bladder, prostate *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.6.4.4	Reach the target regions without colliding critical anatomical structures and/or other instruments	*Anatomical:* bladder, prostate *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.6.4.5	Grasp the target regions	*Anatomical:* bladder, prostate *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules

							R.6.4.6	Plan the direction of the requested upper-traction	-	Perception, Cognitive and Planning Modules
							R.6.4.7	Implement and maintain the traction	-	Cognitive and Planning Modules
7	**Vas deferens and arteries are exposed**	1	Upper anterior traction on the peritoneum	**Holding (Traction)**	Peritoneum	Grasper	R.7.1.A.1	Identify the Peritoneum	-	Perception Module
							R.7.1.A.2	Identify the region of the Peritoneum to be grasped	-	Perception Module
							R.7.1.A.3	Plan the trajectory to reach the target region	*Anatomical:* Pelvic walls and bowel, iliac artery and vein, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.7.1.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Pelvic walls and bowel, iliac artery and vein, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.7.1.A.5	Grasp the target region	*Anatomical:* Pelvic walls and bowel, iliac artery and vein, pubic bone *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.7.1.A.6	Plan the direction of the requested upper-anterior traction	-	Perception, Cognitive and Planning Modules

							R.7.1.A.7	Implement and maintain the traction	-	Planning Module
			Suction and cleaning of blood	**Suction**	Smoke	Suction-irrigator	R.7.1.B.1	Identify the Peritoneum	-	Perception Module
							R.7.1.B.2	Identify the region of the Peritoneum to be pushed	-	Perception Module
							R.7.1.B.3	Plan the trajectory to reach the target region	*Anatomical:* Pelvic walls and bowel *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.7.1.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Pelvic walls and bowel *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.7.1.B.5	Plan the direction for the upper traction	*Anatomical:* Pelvic walls and bowel *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.7.1.B.6	Implement and maintain the traction	-	Perception, Cognitive and Planning Modules
8	**Division of vas deferens**	1	The vas deferens are controlled using the clips	**Putting Hemoclip /s**	Vas deferens	Automatic Clip Applier	R.8.1.1	Identify the Vas deferens	-	Perception Module
							R.8.1.2	Identify the region/s of the Vas deferens that are bleeding	-	Perception Module

							R.8.1.3	Plan the trajectory/ies to reach the target regions	*Anatomical:* Bladder, rectum *Non-anatomical*: da Vinci bipolar grasper and scissors	Planning Modules
							R.8.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Bladder, rectum *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.8.1.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	*Anatomical:* Bladder, rectum	Cognitive and Planning Module
							R.8.1.6	Put the Hem-o clip/s where planned	*Anatomical:* Bladder, rectum	Perception, Cognitive and Planning Modules
							R.8.1.7	Pull back the applier	-	Cognitive and Planning Modules
9	**Exposure of the seminal vesicles**	1	The fibrovascular tissue is controlled using the clips	**Putting Hemoclip /s**	Fibrovascular tissue (FT)	Automatic Clip Applier	R.9.1.1	Identify the Fibrovascular tissue (FT)	-	Perception Module
							R.9.1.2	Identify the region/s of the Ft that are bleeding	-	Perception Module
							R.9.1.3	Plan the trajectory/ies to reach the target regions	*Anatomical:* Bladder, rectum *Non-anatomical*: da Vinci bipolar grasper and scissors	Planning Modules
							R.9.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Bladder, rectum *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules

							R.9.1.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	*Anatomical:* Bladder, rectum	Cognitive and Planning Module
							R.9.1.6	Put the Hem-o clip/s where planned	*Anatomical:* Bladder, rectum	Perception, Cognitive and Planning Modules
							R.9.1.7	Pull back the applier	-	Cognitive and Planning Modules
		2	Upper traction of the seminal vesicles	**Holding (Traction)**	Seminal vesicles (SV)	Grasper	R.9.2.A.1	Identify the Seminal vesicles	-	Perception Module
							R.9.2.A.2	Identify the region of the Seminal vesicles to be grasped	-	Perception Module
							R.9.2.A.3	Plan the trajectory to reach the target region	*Anatomical:* Bladder, rectum	Planning Module
							R.9.2.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* Bladder, rectum	Perception, Cognitive and Planning Modules
							R.9.2.A.5	Grasp the target region	*Anatomical:* Bladder, rectum	Cognitive and Planning Modules
							R.9.2.A.6	Plan the direction of the requested upper traction	-	Perception, Cognitive and Planning Modules
							R.9.2.A.7	Implement and maintain the traction	-	Cognitive and Planning Modules

			The seminal vesicles are controlled using the clips	**Putting Hemoclip /s**	Seminal vesicles (SV)	Automatic Clip Applier	R.9.2.B.1	Identify the Seminal vesicles (SV)	-	Perception Module
							R.9.2.B.2	Plan the trajectory/ies to reach the Seminal vesicles	*Anatomical:* Bladder, rectum	Cognitive and Planning Modules
							R.9.2.B.3	Reach the Sv without colliding critical anatomical structures and/or other instruments	*Anatomical:* Bladder, rectum	Perception, Cognitive and Planning Modules
							R.9.2.B.4	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	*Anatomical:* Bladder, rectum	Cognitive and Planning Module
							R.9.2.B.5	Put the Hemo clip/s where planned	*Anatomical:* Bladder, rectum	Perception, Cognitive and Planning Modules
							R.9.2.B.6	Pull back the applier	-	Cognitive and Planning Modules
		3	The seminal vesicle is grasped to help liberate the posterior avascular plane.	**Holding (Traction)**	Seminal vesicle (SV)	Grasper	R.9.3.1	Identify the Seminal vesicles	-	Perception Module
							R.9.3.2	Identify the region of the Seminal vesicles to be grasped	-	Perception Module
							R.9.3.3	Plan the trajectory to reach the target region/s	*Anatomical:* Bladder, rectum	Cognitive and Planning Modules
							R.9.3.4	Reach the target region without colliding critical	*Anatomical:* Bladder, rectum	Perception, Cognitive and Planning Modules

								anatomical structures and/or other instruments		
							R.9.3.5	Grasp the target region	*Anatomical:* Bladder, rectum	Cognitive and Planning Modules
							R.9.3.6	Plan the direction of the requested counter-traction	-	Perception, Cognitive and Planning Modules
							R.9.3.7	Implement and maintain the traction	-	Cognitive and Planning Modules
11	**Urethral division**	1	Traction/ Suction and cleaning blood	**Traction / Suction**	Urethra / Blood	Suction-irrigator	R.11.1.1	Identify the Urethra	-	Perception Module
							R.11.1.2	Identify the region of the Urethra to be moved	-	Perception Module
							R.11.1.3	Plan the trajectory to reach the target region	*Anatomical:* urethra, prostate (cut in the middle) *Non-anatomical*: da Vinci bipolar grasper and scissors	Planning Module
							R.11.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	*Anatomical:* urethra, prostate (cut in the middle) *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.11.1.5	Plan the direction for the upper traction	*Anatomical:* urethra, prostate (cut in the middle) *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.11.1.6	Implement and maintain the traction	-	Perception, Cognitive and Planning Modules
		2					R.11.2.A.1	Identify the SV	-	Perception Module

			Seminal vesicles are collectively grasped	**Holding (Traction)**	Seminal vesicle (SV)	Grasper	R.11.2.A.2	Identify the region of SV to be grasped	-	Perception Module
							R.11.2.A.3	Plan the trajectory to reach the target region	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.11.2.A.4	Reach the target regions without colliding critical anatomical structures and/or other instruments	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.11.2.A.5	Grasp the target region	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci bipolar grasper and scissors	Cognitive and Planning Modules
							R.11.2.A.6	Plan the direction of the requested traction	-	Perception, Cognitive and Planning Modules
							R.11.2.A.7	Implement and maintain the traction	-	Cognitive and Planning Modules
			Suction and cleaning of smoke and blood	**Suction**	Blood	Suction-irrigator	R.11.2.B.1	Identify the bleeding/smoke	-	Perception Module
							R.11.2.B.2	Plan the trajectory to reach the target bleeding region/smoke	-	Cognitive and Planning Modules
							R.11.2.B.3	Reach the target regions without colliding critical anatomical structures and/or other instruments	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci bipolar grasper and scissors	Perception, Cognitive and Planning Modules
							R.11.2.B.4	Suck the blood/smoke until the surgical working space is clear	-	Perception, Cognitive and Planning Modules

13	**Vesicoureteral anastomosis**	1	The assistant passes the needle and the suture thread to the surgeon	**Holding (Needles)**	Needle/s	Grasper	R.13.1.1	Identify the surgical needle + thread and the da Vinci needle holder	-	Perception Module
							R.13.1.2	Identify the region of the needle to be grasped	-	Perception Module
							R.13.1.3	Plan the trajectory to reach the da Vinci needle holder	*Anatomical:* pelvic walls	Cognitive and Planning Modules
							R.13.1.4	Reach the da Vinci needle holder without colliding critical anatomical structures and/or other instruments	*Anatomical:* pelvic walls	Perception, Cognitive and Planning Modules
							R.13.1.5	Keep on holding the surgical needle and wait for the da Vinci needle holder to grab it	*Anatomical:* pelvic walls	Cognitive and Planning Modules
							R.13.1.6	Release the surgical needle	-	Cognitive and Planning Modules
		3	The assistant cuts the suture's thread	**Cutting**	Suture's thread	Scissor	R.13.3.A.1	Identify the surgical thread and the da Vinci needle holder	-	Perception Module
							R.13.3.A.2	Identify the region of the thread to be cut	-	Perception Module
							R.13.3.A.3	Plan the trajectory to reach the target region of the thread	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci needle holder	Cognitive and Planning Modules
							R.13.3.A.4	Reach it without colliding critical anatomical	*Anatomical:* pelvic walls	Perception, Cognitive and Planning Modules

							structures and/or other instruments	*Non-anatomical*: da Vinci needle holder	
						R.13.3.A.5	Cut the tread	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci needle holder	Cognitive and Planning Modules
			The needles can be snapped out and removed from the body	**Holding (Needles)**	Needle/s	Grasper	R.13.3.B.1	Identify the surgical needle + thread and the da Vinci needle holder	-	Perception Module
							R.13.3.B.2	Identify the region of the needle to be grasped	-	Perception Module
							R.13.3.B.3	Plan the trajectory to reach the surgical needle	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci needle holder	Cognitive and Planning Modules
							R.13.3.B.4	Reach the needle without colliding critical anatomical structures and/or other instruments	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci needle holder	Perception, Cognitive and Planning Modules
							R.13.3.B.5	Grasp the needle	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci needle holder	Cognitive and Planning Modules
							R.13.3.B.6	Plan the path to take it out from the surgical workspace	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci needle holder	Cognitive and Planning Modules
							R.13.3.B.7	Take the needle out from the surgical workspace	*Anatomical:* pelvic walls *Non-anatomical*: da Vinci needle holder	Cognitive and Planning Modules

Table 23: Procedure-related requirements for the RARP case

5.2.2 Radical/Partial Laparoscopic Nephrectomy

The procedure-related requirements for the LRN case are listed in the following Table 24, for LPN in Table 25. They describe, for each assistant's task, the corresponding target organ or anatomical structure, the instrument used and the component sub-tasks.

Also in this cases, the procedural requirements are to be intended for the autonomous SARAS platform (LAPARO2.0), where the assistant role is played by the SARAS robotic arms. This is, in fact, the most complete case where all the platform's modules are present and activated. The same list of requirements is still valid for the MULTI-SURGERY case with the difference that, being the assistant a real surgeon, all the sub-tasks linked to the Perception module are not to be taken into consideration (as they're "implemented" by the human mind).

Phase Code	Phase	Step	Assistant Task	Surgical action	Of What?	Instrument type	Requirements for surgical actions (sub-task)		Forbidden region/s
R1	**Colon mobilization**	1	Along the white line of Toldt, the colon is reflected	**Holding (Traction)**	Colon	Grasper	R.R1.1.1	Identify the colon	Perception Module
							R.R1.1.2	Identify the region of the colon to be grasped	Perception Module
							R.R1.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R1.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.R1.1.5	Grasp the target region	Cognitive and Planning Module
							R.R1.1.6	Plan the direction of the requested upper-anterior traction	Perception, Cognitive and Planning Modules
							R.R1.1.7	Implement and maintain the traction	Cognitive and Planning Module

		3	Visualization of the anterior surface of Gerota's fascia	**Visualization**	Anterior surface of Gerota's fascia	Laparoscope	R.R1.3.1	Identify the Gerota's fascia	Perception Module
							R.R1.3.2	Identify the region of the Peritoneum to be visualized	Perception Module
							R.R1.3.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R1.3.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
RL2	**Colon, spleen and pancreas dissection**	1	Visualization of the colon, spleen and pancreas	**Visualization**	Colon, spleen, Pancreas	Laparoscope	R.RL2.1.1	Identify the colon, spleen and pancreas	Perception Module
							R.RL2.1.2	Identify the regions to be visualized	Perception Module
							R.RL2.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.RL2.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
RR2	**Mobilization of duodenum and vena cava visualization (with Kocher maneuver)**	1	Visualization of the Duodenum and Vena cava	**Visualization**	Duodenum and vena cava	Laparoscope	R.RR2.1.1	Identify the Duodenum and vena cava	Perception Module
							R.RR2.1.2	Identify the region to be visualized	Perception Module
							R.RR2.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.RR2.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
RR3	**Retraction of the liver**	1	Visualization of the liver	**Visualization**	liver	Laparoscope	R.RR3.1.1	Identify the liver	Perception Module
							R.RR3.1.2	Identify the region to be visualized	Perception Module
							R.RR3.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.RR3.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules

R3	**Ureter and gonadal vein are identified and retracted laterally**	1	The midureter is located in the retroperitoneal fat medial to the psoas muscle.	**Visualization**	Midureter	Laparoscope	R.R3.1.1	Identify the midureter	Perception Module
							R.R3.1.2	Identify the region of the midureter to be visualized	Perception Module
							R.R3.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R3.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	**Holding (Traction)t**	Gonadal vein	Grasper	R.R3.2.1	Identify the gonadal vein	Perception Module
							R.R3.2.2	Identify the region of the gonadal vein to be grasped	Perception Module
							R.R3.2.3	Plan the trajectory to reach the target region/s	Cognitive and Planning Modules
							R.R3.2.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.R3.2.5	Grasp the target region	Cognitive and Planning Module
							R.R3.2.6	Plan the direction of the requested counter-traction	Perception, Cognitive and Planning Modules
							R.R3.2.7	Implement and maintain the traction	Cognitive and Planning Module
R4	**Renal Hilum identification and dissection**	1	The midureter is located in the retroperitoneal fat medial to the psoas muscle	**Holding (Traction)**	Ureter and lower pole of the kidney	Grasper	R.R4.1.1	Identify the Ureter and lower pole of the kidney	Perception Module
							R.R4.1.2	Identify the region of the Ureter and lower pole of the kidney to be grasped	Perception Module
							R.R4.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R4.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.R4.1.5	Grasp the target region	Cognitive and Planning Module
							R.R4.1.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.R4.1.7	Implement and maintain the traction	Cognitive and Planning Module

R5	**Renal Hilum Transection**	1	The renal artery is visualized	**Visualization**	Renal artery	Laparoscope	R.R5.1.A.1	Identify the renal artery	Perception Module
							R.R5.1.A.2	Identify the region of the renal artery to be visualized	Perception Module
							R.R5.1.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R5.1.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			The renal artery is controlled using the Hemoclips	**Putting Hemoclip/s**	Renal artery	Hem-o-lok clip	R.R5.1.B.1	Identify the renal artery	Perception Module
							R.R5.1.B.2	Identify the region/s of the renal artery that should be cut	Perception Module
							R.R5.1.B.3	Plan the trajectory/ies to reach the target regions	Cognitive and Planning Modules
							R.R5.1.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.R5.1.B.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	Cognitive and Planning Module
							R.R5.1.B.6	Put the Hem-o clip/s where planned	Perception, Cognitive and Planning Modules
							R.R5.1.B.7	Pull back the applier	Cognitive and Planning Modules
		2	The renal vein is visualized	**Visualization**	Renal vein	Laparoscope	R.R5.2.A.1	Identify the renal vein	Perception Module
							R.R5.2.A.2	Identify the region of the renal vein to be visualized	Perception Module
							R.R5.2.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R5.2.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules

			The renal vein is controlled using the Hemoclips	**Putting Hemoclip/s**	Renal vein	Hem-o-lok clip	R.R5.2.B.1	Identify the renal vein	Perception Module
							R.R5.2.B.2	Identify the region/s of the renal vein that should be cut	Perception Module
							R.R5.2.B.3	Plan the trajectory/ies to reach the target regions	Cognitive and Planning Modules
							R.R5.2.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.R5.2.B.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	Cognitive and Planning Module
							R.R5.2.B.6	Put the Hem-o clip/s where planned	Perception, Cognitive and Planning Modules
							R.R5.2.B.7	Pull back the applier	Cognitive and Planning Modules
		3	The lumbar veins are visualized	**Visualization**	Lumbar veins	Laparoscope	R.R5.3.A.1	Identify the lumbar veins	Perception Module
							R.R5.3.A.2	Identify the region of the lumbar veins to be visualized	Perception Module
							R.R5.3.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R5.3.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			The lumbar veins are controlled using the Hemoclips	**Putting Hemoclip/s**	Lumbar veins	Hem-o-lok clip	R.R5.3.B.1	Identify the lumbar veins	Perception Module
							R.R5.3.B.2	Identify the region/s of the lumbar veins that should be cut	Perception Module
							R.R5.3.B.3	Plan the trajectory/ies to reach the target regions	Cognitive and Planning Modules
							R.R5.3.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules

							R.R5.3.B.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	Cognitive and Planning Module
							R.R5.3.B.6	Put the Hem-o clip/s where planned	Perception, Cognitive and Planning Modules
							R.R5.3.B.7	Pull back the applier	Cognitive and Planning Modules
R6	**Mobilization of the Lower Pole, Dissection of the Upper Pole and Adrenal gland**	2	The lower pole of kidney is visualized	**Visualization**	Lower pole	Laparoscope	R.R6.2.1	Identify the lower pole of kidney	Perception Module
							R.R6.2.2	Identify the region of the lower pole of kidney to be visualized	Perception Module
							R.R6.2.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R6.2.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
		3	The inferior Gerota's fascia of kidney is visualized	**Visualization**	Gerota's fascia	Laparoscope	R.R6.3.1	Identify the Gerota's fascia	Perception Module
							R.R6.3.2	Identify the region of the Gerota's fascia to be visualized	Perception Module
							R.R6.3.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R6.3.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
		4	The Adrenal gland of kidney is visualized	**Visualization**	Adrenal gland	Laparoscope	R.R6.4.1	Identify the Adrenal gland	Perception Module
							R.R6.4.2	Identify the region of the Adrenal gland to be visualized	Perception Module
							R.R6.4.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R6.4.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules

R7	**Transection of the Ureter**	1	The ureter is visualized	**Visualization**	Ureter	Laparoscope	R.R7.1.1	Identify the Ureter	Perception Module
							R.R7.1.2	Identify the region of the Ureter to be visualized	Perception Module
							R.R7.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.R7.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
		2	The ureter is controlled using the clips	**Putting Hemoclip/s**	Ureter	Hem-o-lok clip	R.R7.2.1	Identify the Ureter	Perception Module
							R.R7.2.2	Identify the region of the Ureter that should be cut	Perception Module
							R.R7.2.3	Plan the trajectory/ies to reach the target regions	Cognitive and Planning Modules
							R.R7.2.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.R7.2.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	Cognitive and Planning Module
							R.R7.2.6	Put the Hem-o clip/s where planned	Perception, Cognitive and Planning Modules
							R.R7.2.7	Pull back the applier	Cognitive and Planning Modules

Table 24: Procedure-related requirements for the LRN case

Phase Code	Phase	Step	Assistant Task	Surgical action	Of What?	Instrument type	Requirements for surgical actions (sub-task)		Forbidden region/s
P1	**Colon mobilization**	1	Along the white line of Toldt, the colon is reflected	**Holding (Traction)**	Colon	Grasper	R.P1.1.1	Identify the colon	Perception Module
							R.P1.1.2	Identify the region of the colon to be grasped	Perception Module
							R.P1.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P1.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P1.1.5	Grasp the target region	Cognitive and Planning Module
							R.P1.1.6	Plan the direction of the requested upper-anterior traction	Perception, Cognitive and Planning Modules
							R.P1.1.7	Implement and maintain the traction	Cognitive and Planning Module
		3	Visualization of the anterior surface of Gerota's fascia	**Visualization**	Anterior surface of Gerota's fascia	Laparoscope	R.P1.3.1	Identify the Gerota's fascia	Perception Module
							R.P1.3.2	Identify the region of the Peritoneum to be visualized	Perception Module
							R.P1.3.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P1.3.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
PL2	**Colon, spleen and pancreas dissection**	1	Visualization of the colon, spleen and pancreas	**Visualization**	Colon, spleen, Pancreas	Laparoscope	R.PL2.1.1	Identify the colon, spleen and pancreas	Perception Module
							R.PL2.1.2	Identify the regions to be visualized	Perception Module
							R.PL2.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.PL2.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules

PR2	**Mobilization of duodenum and vena cava visualization (with Kocher maneuver)**	1	Visualization of the Duodenum and Vena cava	**Visualization**	Duodenum and vena cava	Laparoscope	R.PR2.1.1	Identify the Duodenum and vena cava	Perception Module
							R.PR2.1.2	Identify the region to be visualized	Perception Module
							R.PR2.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.PR2.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
PR3	**Retraction of the liver**	1	Visualization of the liver	**Visualization**	Liver	Laparoscope	R.PR3.1.1	Identify the liver	Perception Module
							R.PR3.1.2	Identify the region to be visualized	Perception Module
							R.PR3.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.PR3.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
P3	**Ureter and gonadal vein are identified and retracted laterally**	1	The midureter is located in the retroperitoneal fat medial to the psoas muscle.	**Visualization**	Midureter	Laparoscope	R.P3.1.1	Identify the midureter	Perception Module
							R.P3.1.2	Identify the region of the midureter to be visualized	Perception Module
							R.P3.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P3.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
		2	During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	**Holding (Traction)t**	Gonadal vein	Grasper	R.P3.2.1	Identify the gonadal vein	Perception Module
							R.P3.2.2	Identify the region of the gonadal vein to be grasped	Perception Module
							R.P3.2.3	Plan the trajectory to reach the target region/s	Cognitive and Planning Modules
							R.P3.2.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules

							R.P3.2.5	Grasp the target region	Cognitive and Planning Module
							R.P3.2.6	Plan the direction of the requested counter-traction	Perception, Cognitive and Planning Modules
							R.P3.2.7	Implement and maintain the traction	Cognitive and Planning Module
P4	**Renal Hilum identification**	1	The ureter and lower pole of the kidney are elevated	**Holding (Traction)**	Ureter and lower pole of the kidney	Grasper	R.P4.1.1	Identify the Ureter and lower pole of the kidney	Perception Module
							R.P4.1.2	Identify the region of the Ureter and lower pole of the kidney to be grasped	Perception Module
							R.P4.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P4.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P4.1.5	Grasp the target region	Cognitive and Planning Module
							R.P4.1.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.P4.1.7	Implement and maintain the traction	Cognitive and Planning Module
		3	Visualization of the Renal Hilum	**Visualization**	Renal Hilum	Laparoscope	R.P4.3.1	Identify the renal hilum	Perception Module
							R.P4.3.2	Identify the region of the renal hilum to be visualized	Perception Module
							R.P4.3.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P4.3.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
		4	The hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis.	**Holding (Traction)**	Renal Hilum	Grasper	R.P4.4.1	Identify the renal hilum	Perception Module
							R.P4.4.2	Identify the region of the renal hilum to be grasped	Perception Module
							R.P4.4.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules

							R.P4.4.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P4.4.5	Grasp the target region	Cognitive and Planning Module
							R.P4.4.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.P4.4.7	Implement and maintain the traction	Cognitive and Planning Module
P5	**Kidney is mobilized**	1	Visualization of the Gerota's fascia.	**Visualization**	Gerota's fascia	Laparoscope	R.P5.1.A.1	Identify the Gerota's fascia	Perception Module
							R.P5.1.A.2	Identify the region of the Gerota's fascia to be visualized	Perception Module
							R.P5.1.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P5.1.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure.	**Holding (Traction)**	Ureter and lower pole of kidney	Grasper	R.P5.1.B.1	Identify the Ureter and lower pole of the kidney	Perception Module
							R.P5.1.B.2	Identify the region of the Ureter and lower pole of the kidney to be grasped	Perception Module
							R.P5.1.B.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P5.1.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P5.1.B.5	Grasp the target region	Cognitive and Planning Module
							R.P5.1.B.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.P5.1.B.7	Implement and maintain the traction	Cognitive and Planning Module

P6	**Securing the Renal Blood Vessels**	1	Visualization of the renal artery and vein	**Visualization**	renal artery and vein	Laparoscope	R.P6.1.A.1	Identify the renal artery and vein	Perception Module
							R.P6.1.A.2	Identify the region of the renal artery and vein to be visualized	Perception Module
							R.P6.1.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P6.1.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			Holding the tissues near to renal artery and vein	**Holding**	Renal artery and vein	Grasper	R.P6.1.B.1	Identify the renal vein	Perception Module
							R.P6.1.B.2	Identify the region of the renal vein to be grasped	Perception Module
							R.P6.1.B.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P6.1.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P6.1.B.5	Grasp the target region	Cognitive and Planning Module
							R.P6.1.B.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.P6.1.B.7	Implement and maintain the traction	Cognitive and Planning Module
		2	Visualization of the renal vein	**Visualization**	Renal vein	Laparoscope	R.P6.2.A.1	Identify the renal vein	Perception Module
							R.P6.2.A.2	Identify the region of the renal vein to be visualized	Perception Module
							R.P6.2.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P6.2.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules

			Holding the tissues near to renal vein	**Holding**	Renal vein	Grasper	R.P6.2.B.1	Identify the renal vein	Perception Module
							R.P6.2.B.2	Identify the region of the renal vein to be grasped	Perception Module
							R.P6.2.B.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P6.2.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P6.2.B.5	Grasp the target region	Cognitive and Planning Module
							R.P6.2.B.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.P6.2.B.7	Implement and maintain the traction	Cognitive and Planning Module
		3	Visualization of the renal artery	**Visualization**	Renal artery	Laparoscope	R.P6.3.A.1	Identify the renal artery	Perception Module
							R.P6.3.A.2	Identify the region of the renal artery to be visualized	Perception Module
							R.P6.3.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P6.3.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			Holding the tissues near to renal artery	**Holding**	Renal artery	Grasper	R.P6.3.B.1	Identify the renal artery	Perception Module
							R.P6.3.B.2	Identify the region/s of the renal artery that should be cut	Perception Module
							R.P6.3.B.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P6.3.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P6.3.B.5	Grasp the target region	Cognitive and Planning Module
							R.P6.3.B.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.P6.3.B.7	Implement and maintain the traction	Cognitive and Planning Module
P7		1		**Visualization**	Tumor	Laparoscope	R.P7.1.1	Identify the tumor	Perception Module

	The tumor is excised		Visualization of the tumor				R.P7.1.2	Identify the region of the tumor to be visualized	Perception Module
							R.P7.1.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P7.1.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
P8	**Renorrhaphy**	1	Visualization of the tumoral zone	**Visualization**	Kidney's tumoral zone	Laparoscope	R.P8.1.A.1	Identify the kidney's the tumoral zone	Perception Module
							R.P8.1.A.2	Identify the region of kidney's the tumoral zone to be visualized	Perception Module
							R.P8.1.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P8.1.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			A Hem-o-Lok clip secured on the suture	**Putting Hemoclip/s**	Kidney's tumoral zone	Hem-o-lok clip	R.P8.1.B.1	Identify the kidney's the tumoral zone	Perception Module
							R.P8.1.B.2	Identify the region/s of kidney's the tumoral zone that should be cut	Perception Module
							R.P8.1.B.3	Plan the trajectory/ies to reach the target regions	Cognitive and Planning Modules
							R.P8.1.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P8.1.B.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	Cognitive and Planning Module
							R.P8.1.B.6	Put the Hem-o clip/s where planned	Perception, Cognitive and Planning Modules
							R.P8.1.B.7	Pull back the applier	Cognitive and Planning Modules
		2	Visualization of the renal parenchymal surface	**Visualization**	Renal parenchymal surface	Laparoscope	R.P8.2.A.1	Identify the renal parenchymal surface	Perception Module
							R.P8.2.A.2	Identify the region of renal parenchymal surface to be visualized	Perception Module
							R.P8.2.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules

							R.P8.2.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			Holding the tissues near to cut surface	**Holding**	Renal parenchymal surface	Grasper	R.P8.2.B.1	Identify the renal parenchymal surface	Perception Module
							R.P8.2.B.2	Identify the renal parenchymal surface that should be cut	Perception Module
							R.P8.2.B.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P8.2.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P8.2.B.5	Grasp the target region	Cognitive and Planning Module
							R.P8.2.B.6	Plan the direction of the requested traction	Perception, Cognitive and Planning Modules
							R.P8.2.B.7	Implement and maintain the traction	Cognitive and Planning Module
		3	Visualization of renal surface	**Visualization**	Renal surface	Laparoscope	R.P8.3.A.1	Identify the renal surface	Perception Module
							R.P8.3.A.2	Identify the region of the renal surface to be visualized	Perception Module
							R.P8.3.A.3	Plan the trajectory to reach the target region	Cognitive and Planning Modules
							R.P8.3.A.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
			A Hem-o-Lok clip secured on the suture	**Putting Hemoclip/s**	Renal surface	Hem-o-lok clip	R.P8.3.B.1	Identify the renal surface	Perception Module
							R.P8.3.B.2	Identify the region/s of renal surface that should be cut	Perception Module
							R.P8.3.B.3	Plan the trajectory/ies to reach the target regions	Cognitive and Planning Modules
							R.P8.3.B.4	Reach the target region without colliding critical anatomical structures and/or other instruments	Perception, Cognitive and Planning Modules
							R.P8.3.B.5	Plan the best location where to put the Hemoclip/s avoiding entrapping other anatomical structures	Cognitive and Planning Module
							R.P8.3.B.6	Put the Hem-o clip/s where planned	Perception, Cognitive and Planning Modules

							R.P8.3.B.7	Pull back the applier	Cognitive and Planning Modules

Table 25: Procedure-related requirements for the LPN case

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7 Appendix I

In the current Appendix, we describe the approach chosen to model the reference SARAS surgical procedures in a way that makes possible to translate the surgical knowledge into a logic/mathematic formalization from which deriving the technical requirements to be implemented the robotic systems.

The concept of a *formal modelling of surgical procedures* was first introduced for analysis purposes in Minimally Invasive Surgeries (MIS) (MacKenzie, Ibbotson, Cao, & Lomax, 2001), as well as for surgical planning, intra-operative image management and for robotics systems. The term Surgical Process (SP) has been defined by Lalys et al. as “a set of one or more linked procedures or activities that collectively realise a surgical objective within the context of an organisational structure”. This term is generally used to describe the steps involved in a surgical procedure (Lalys & Jannin, 2014).

In addition to that, MacKenzie at al. defined the “granularity level” as the level of abstraction at which the surgical procedure can described (MacKenzie et al., 2001).

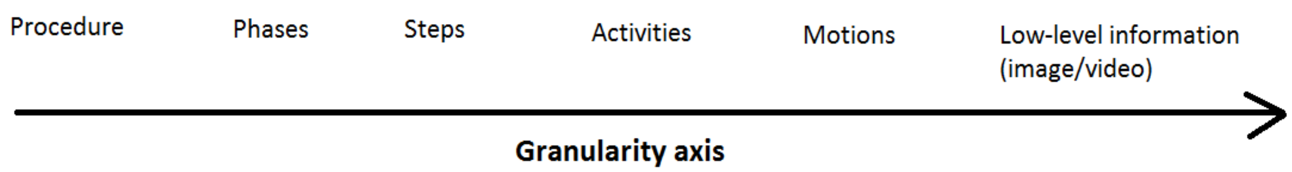


Figure 31: Different levels of granularity of a surgical procedure

As showed in Figure 31, the highest level is the **procedure** itself. The procedure is composed of a list of phases. A **phase** is similar to the each surgical episode, defined as the major types of events occurring during surgery. Each phase is composed of several steps. A **step** is considered to be a sequence of activities used to achieve a surgical objective (in literature has been called “task”). An **activity** is defined as a physical task. Each activity is composed of a list of motions. The **motion** can be considered to be a surgical task. For the last level of granularity, the images or videos are could be used for understanding the details of procedures. The underlying assumption is that each granularity level describes the surgical procedure as a sequential list of events (Lalys & Jannin, 2014).

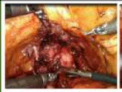
On these bases, the RARP and partial/radical LN have been studied and modelled through the reference granularity levels, to which (in order to provide a comprehensive overview of the surgical process) have been added also the following: *(i)* the anatomical sites in which the surgical action are performed, *(ii)* the anatomical forbidden regions, *(iii)* the surgical instruments used and *(iv)* the access points - trocars.

7.1 *Robotic Assisted Radical Prostatectomy model*

Phase code	Phase	Step	Anatomical site	Forbidden Region	Main Surgeon task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
Initial Phase	Patient positioning		NA	NA	The patient is positioned supine. In da Vinci SARAS Standard: the legs are separated in semi flexion (lithotomy position). Trendelenburg position is 30° from horizontal and a 18 ch Foley catheter is inserted into the bladder						NA		
	Pneumoperitoneum		Peritoneum		A Veress needle (or Hasson trocar) is inserted at the periumbilical position (at 12 mmHg)						Hasson trocar	1	
	Port placement		Peritoneum		There are four robotic arms and two assistant ports. The Veress needle is replaced by a 12 mm port and the laparoscope is introduced for initial abdomen inspection. Two 8mm ports are placed for the robotic arm (separate at the right and left side of the camera port). One 5mm assistance port is placed at the right lateral to the camera port and the other 15mm assistance port above the right anterior superior iliac crest.								
1	Incision of the peritoneum and entry into the retropubic space of Retzius	1	Peritoneum		Direct visualization of the peritoneum overlying the bladder		Laparoscope	1					 
		2	Retropubic space of Retzius	Bladder, Pelvic wall	A peritoneal incision is made through the median umbilical ligament to enter in the retropubic space	Traction	Bipolar grasper	3	Upper anterior traction on the peritoneum	Holding (Traction)	Grasper	5	
						Incision	Scissor	2	Upper anterior traction / Suction and cleaning of blood	Traction / Suction	Suction/ irrigator	6	
The peritoneum is dissected to the following boundaries: the pubic bone superiorly, the median umbilical ligaments laterally, and the vas deferens inferolaterally													
2	Incision of the endopelvic fascia (EPF) and identification of the dorsal venous complex (DVC)	1	Endopelvic fascia	Pelvic wall	Incision of the endopelvic fascia: this is the area with the largest amount of space between the prostate and the levators and the point at which the prostate has most mobility	Incision	Cold Scissor	2	Suction and cleaning of smoke and blood	Suction	Suction/ irrigator	6	
									The assistant provides the bladder's counter-traction	Holding (Traction)	Grasper	5	
3	Bladder mobilization	1	Bladder		The bladder is then liberated off the anterior surface of the abdominal wall	Movement	Grasper	3	Upper anterior traction / Suction and cleaning of blood	Traction / Suction	Suction/ irrigator	6	

Phase code	Phase	Step	Anatomical site	Forbidden Region	Main Surgeon task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
4	Anterior prostatic fat (AFP) dissection	1	Anterior surface of the prostate		The layer of fat is removed to allow better visualization of the puboprostatic ligaments, the dorsal venous complex as well as the junction between the bladder neck and the prostate	Dissection	Monopolar scissor	2	Upper traction of the prostatic fat/ Suction and cleaning of blood	Traction / Suction	Suction/ irrigator	6	
							Grasper	3	The assistant provides the prostatic fat's traction	Holding (Traction)	Grasper	5	
		2	Anterior surface of the prostate						Passes the needle and the suture thread to the surgeon	Holding (Needle)	Locking grasper	5	
5	DVC control and suture	1	DVC	Pubic bone	A total of two suture ligations are put in place (one distal and another more proximal). The distal suture provides the necessary hemostasis while the proximal suture will be used later for prostate traction	Surgical sutures	Needle Driver	2 + 3	The assistant cuts the suture's thread	Cutting	Scissor	6	
									The needles are snapped out and removed from the body	Holding (Needle)	Grasper	5	
6	Bladder neck incision	1	Bladder Neck	Bladder and prostate	The bladder neck is divided horizontally until the urethral catheter is identified	Transection	Cold Scissor	2	Upper traction/ Suction and cleaning blood	Traction / Suction	Grasper	5	
		2	Urethra		The Foley catheter balloon is then deflated by the nurse								
		3	Urethra	Bladder and prostate	Move the catheter from a surgeon's grasper to assistant's grasper	Holding	Bipolar grasper	3	Move the catheter from a surgeon's grasper to assistant's grasper	Holding	Grasper	5	
		4	Prostate	Bladder and prostate	Catheter and seminal vesicles are collectively grasped, pulled through the open bladder neck	Holding (Traction)	Bipolar grasper	3	Catheter and seminal vesicles are handed to the assistant for upper traction	Holding (Traction)	Grasper	5	
		5	Prostate	Bladder and prostate	The prostate is suspended anteriorly towards the abdominal wall by grasping the internal tip of the catheter and lifting it upwards	Traction	Bipolar grasper	3	Hemoclips are applied to avoid branches of the dorsal vein fanning over the prostate and to prevent unwanted bleeding	Putting Hemoclip/s	clip Hem-o-lock	5	
7	Vas deferens and arteries are exposed	1	Seminal vesicles	Ureter and bladder	Dissection of the retroprostatic tissue, the vas deferens and accompanying arteries are exposed	Traction	Bipolar grasper	3	Upper anterior traction on the peritoneum	Traction	Locking grasper	5	
						Dissection	Monopolar scissor	2	Suction and cleaning of smoke and blood	Suction	Suction	6	
8	Division of vas deferens	1	Surroundings of seminal vesicles	Ureter and bladder	Uses the grasper as a spatula to free adjoining vessels	Movement	Bipolar grasper	3	The vas deferens are controlled using the Hemoclips	Putting Hemoclip/s	clip Hem-o-lock	5	
		2	Surroundings of seminal vesicles	Ureter and bladder	Incision of vas deferens	Incision	Monopolar scissor	2	Suction and cleaning of smoke and blood	Suction	Suction	6	

Phase code	Phase	Step	Anatomical site	Forbidden Region	Main Surgeon task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
9	Exposure of the seminal vesicles	1	Vas deferens	Ureter and bladder	Blunt dissection of fibrovascular tissue is overlying the surface of the seminal vesicles	Dissection	Monopolar scissor	2	Upper traction of the vas deferens	Traction	Locking grasper	5	
		2	Vas deferens	Ureter and bladder	The surgeon indicates to the assistant where s/he can put the clips				Upper traction of the seminal vesicles and vas deferens	Traction	Locking grasper	5	 
									The vas deferens are controlled using the Hemoclips	Putting Hemoclip/s	clip Hem-o-lock	5	
		3	Seminal vesicles	Ureter and bladder	The seminal vesicle is grasped by the bipolar instrument to help liberate the posterior avascular plane. Meticulous blunt dissection is continued to allow complete liberation of the seminal vesicle.	Grab and move	Locking grasper	4					
		4	Denonvillier's fascia	Rectum	Deep posterior dissection is then continued to the level of Denonvillier's fascia	Dissection	Monopolar scissor	2	Suction and cleaning of smoke and blood	Suction	Suction	6	
10	Neurovascular bundle (NVB) dissection (nerve sparing)	1	Prostate		Uses an athermal dissection technique in the proximity of the nerve bundles	Dissection	Monopolar cauterization	2	Allows for proximal control placing Hemoclips	Putting Hemoclip/s	clip Hem-o-lok	5	
		2	Prostate		Sharp scissor cutting between the nerves to help liberate the tissue	Dissection	Sharp scissor	2	Suction and cleaning of smoke and blood	Suction	Suction	6	
11	Urethral division	1	Urethra		The urethra is skeletonized to delineate the boundary of the end of the prostate and the released neurovascular bundles	Cut	Sharp scissor	2	Suction and cleaning of smoke and blood	Suction	Suction	6	
		2	Prostate		The remaining posterior wall, including the rectourethralis fibers, is then cut sharply to liberate the prostate	Dissection	Sharp scissor	2	Vas deferens and the seminal vesicles are collectively grasped	Grab and move	Locking grasper	5	
									Suction and cleaning of smoke and blood	Suction	Suction	6	

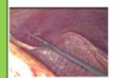
Phase code	Phase	Step	Anatomical site	Forbidden Region	Main Surgeon task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
12	Prostate delocation	1	Prostate		Move the prostate from a surgeon's grasper to assistant's grasper		Bipolar grasper	3	Move the prostate from a surgeon's grasper to assistant's grasper	Holding	Endocatch bag	6	
									The prostate is placed in an endocatch bag along with the anterior prostatic fat and is placed in the upper abdominal space for later retrieval	Holding	Endocatch bag	6	
13	Vesicourethral anastomosis	1	Urethra Bladder	Pelvic wall	The well-dissected bladder is free and mobile and can be easily descended into the pelvis.	Surgical sutures	Needle Driver	2 + 3	Passes the needle and the suture thread to the surgeon	Holding (Needle)	Locking grasper	5	  
		2	Urethra Bladder	Pelvic wall	The nurse fills up the bladder with water to check the correct operation								 
		3	Urethra Bladder	Pelvic wall					The needles are snapped out and removed from the body	Removal	Suction	6	
		4	Urethra Bladder	Pelvic wall					The hemostatic materials are inserted in the body	Movement	Locking grasper	6	 
		5	Urethra Bladder	Pelvic wall					The string for the laparoscopic entrapment sack is transferred to the camera port site at the umbilicus and the abdomen is completely deflated	Removal	Endocatch bag	5	
14	Endocatch bag Extraction								The specimens within the laparoscopic entrapment sack are extracted intact through extension of the periumbilical trocar site (usually 2.5 cm to 3.5 cm in length)	Removal		1	
End	Ports closure								The fascial defect is then immediately closed by sutures. The skin defects are then closed with a subcuticular absorbable suture followed by the skin adhesive Dermabond				

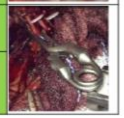
7.2 *Laparoscopic Radical Nephrectomy model*

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
Initial Phase	Patient positioning		NA		The patient is placed in a modified flank position, with the umbilicus over the break in the operating table. The table can be flexed to 10°-20° for left kidney and 30° for right kidney						NA		
	Pneumoperitoneum		Peritoneum		Hasson trocar is inserted at the level of the umbilicus (at 12-14 mmHg)						Hasson trocar	1	
	Port placement		Peritoneum		A four-trocar technique is utilized to complete the dissection. A 11 mm trocar is placed on the midclavicular line 2 cm below the costal margin for the camera; another 11 mm trocar is placed 2 cm above the umbilicus. A 5 mm port can be inserted just under the xyphoid and the last 5 mm trocar is placed 2 cm medial to and sometimes superior to the anterior superior iliac spine. Four ports are generally sufficient to complete the procedure, although a fifth trocar may be necessary for organ entrapment and to retract the left mesocolon during left-sided nephrectomy								
R1	Colon mobilization	1	Line of Toldt	Bowel	Line of Toldt incision	Incision	Scissor	2	Along the white line of Toldt, the colon is reflected	Traction	Grasper	4	
		2	Colon	Bowel					Visualization of the anterior surface of Gerota's fascia.	Visualization	Laparoscope	1	
		3	Colon	Bowel	The plane between the descending colon and the underlying Gerota's fascia is developed to allow the colon to fall medially	Traction	Grasper	3					
RL2	Colon, spleen and pancreas dissection	1	The splenorenal and lienocolic ligaments	Bowel, pancreas and spleen	The splenorenal and lienocolic ligaments are incised allowing the spleen and the tail of the pancreas to be separated from the upper pole of the kidney	Incision	Monopolar scissor	2	Visualization of the colon, spleen and pancreas.	Visualization	Laparoscope	1	
		2	Colon, spleen, Pancreas	Bowel, pancreas and spleen	The dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein	Dissection	Monopolar scissor	2					
RR2	Mobilization of duodenum and vena cava visualization (with Kocher maneuver)		Duodenum Vena cava	Bowel	The duodenum is mobilized medially, using the Kocher maneuver, until the vena cava is clearly visualized	Kocher maneuver	Kocher maneuver	2	Visualization of the Duodenum and Vena cava.	Visualization	Laparoscope	1	
RR2B	Retraction of the liver		Liver	Gallbladder					The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5mm trocar below the ribs in the anterior axillary line	Traction	Retractor Grasper	5	
R3	Ureter and gonadal vein are identified and retracted laterally	1	Midureter	Vena cava and Aorta					The midureter is located in the retroperitoneal fat medial to the psoas muscle	Visualization	Laparoscope	1	
		2	Ureter	Vena cava and Aorta					During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located posterior to this structure	Movement	Grasper	4	
		3	Ureter Psoas muscle	Vena cava and Aorta	Once located, the ureter is elevated, revealing the psoas muscle and traced proximally to identify the renal hilum	Traction	Bipolar forceps	3					
		4	Ureter Psoas muscle	Vena cava and Aorta	The grasper is placed beneath the ureter and used to provide anterolateral elevation	Traction	Bipolar forceps	3					
		5	Ureter Psoas muscle	Vena cava and Aorta					Suction and cleaning of smoke and blood	Suction	Suction	1	

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
R4	Renal Hilum Identification	1	Kidney's lower pole	Vena cava and Aorta					The ureter and lower pole of the kidney are elevated	Traction	Grasper	4	
		2	Vessels	Vena cava and Aorta					The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator	Suction	Suction	4	
		3	Kidney's lower pole	Vena cava and Aorta	Firm elevation of the lower pole of the kidney assists in identification and dissection of the renal hilar vessels. This is accomplished by gently placing the lateral grasper under the ureter and kidney until it abuts against the abdominal sidewall	Traction	Bipolar forceps	3					
		4	Renal hilum	Vena cava and Aorta	The surgeon places the renal hilum on tension by lifting the lower pole laterally. With the use of the electrosurgical scissors and the suction-irrigator, the hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis	Isolation	Monopolar scissor	2					
R5	Renal Hilum Transection	1	Renal artery	Vena cava and Aorta	The renal artery is identified and is dissected	Dissection	Monopolar scissor	2	The renal artery is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4	
									Suction and cleaning of smoke and blood	Suction	Suction	4	
		2	Renal vein	Vena cava and Aorta	The renal vein is usually identified first and is dissected circumferentially	Dissection	Monopolar scissor	2	The renal vein is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4	
									Suction and cleaning of smoke and blood	Suction	Suction	4	
		3	Lumbar veins	Vena cava and Aorta	Lumbar veins must be identified and divided through a pair of double Hemoclips	Dissection	GIA stapler or Hem-O-lock	2	The lumbar veins are controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4	
									Suction and cleaning of smoke and blood	Suction	Suction	4	
R6	Mobilization of the Lower Pole, Dissection of the Upper Pole and Adrenal gland	1	Ureteropelvic junction	Vena cava and aorta, tail of the pancreas	Once the ureter is mobilized up to the ureteropelvic junction, forceps are inserted beneath Gerota's fascia and lower pole along the psoas fascia	Blunt dissection	Bipolar forceps	3					
		2	Ureteropelvic junction	Vena cava and aorta, tail of the pancreas	The specimen is lifted superolaterally, and, with the use of the suction-irrigator and electrosurgical scissors, the inferior and posterior sidewall attachments are divided	Blunt dissection	Monopolar scissor	2	Suction and cleaning of smoke and blood	Suction	Suction	4	
		3	Gerota's fascia	Vena cava and aorta, tail of the pancreas	The inferior cone of Gerota's fascia lateral to the ureter is also divided.	Blunt dissection	Bipolar forceps	3	Suction and cleaning of smoke and blood	Suction	Suction	4	
		4	Kidney's upper pole	Vena cava and aorta, tail of the pancreas	(The adrenal gland can be preserved in simple nephrectomy and particular cases of mid and lower pole tumors, or it is removed intact with the specimen) On the right side, dissection cephalad along the vena cava identifies the adrenal vein. Once it is divided, the superior, medial, and posterior attachments of the adrenal gland are mobilized								
R7	Transection of the Ureter		Ureter		The ureter is cut through a sharp scissor	Cut	Monopolar scissor	2	Suction and cleaning of smoke and blood	Suction	Suction	4	
R8	Specimen Entrapment and Extraction			Bowel					Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Holding	Endocatch bag	1	
End	Ports closure			Bowel					All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures				

7.3 *Laparoscopic Partial Nephrectomy model*

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
Initial Phase	Patient positioning		NA		The patient is placed in a modified flank position, with the umbilicus over the break in the operating table. The table can be flexed to 10°-20° for left kidney and 30° for right kidney.						NA		
	Pneumoperitoneum		Peritoneum		Hasson trocar is inserted at the level of the umbilicus (at 12-14 mmHg)						Hasson trocar	1	
	Port placement		Peritoneum		A four-trocar technique is utilized to complete the dissection. A 11 mm trocar is placed on the midclavicular line 2 cm below the costal margin for the camera; another 11 mm trocar is placed 2 cm above the umbilicus. A 5 mm port can be inserted just under the xyphoid and the last 5 mm trocar is placed 2 cm medial to and sometimes superior to the anterior superior iliac spine. Four ports are generally sufficient to complete the procedure, although a fifth trocar may be necessary for organ entrapment and to retract the left mesocolon during left-sided nephrectomy								
P1	Colon mobilization	1	Line of Toldt	Bowel	Line of Toldt incision	Incision	Scissor	2	Along the white line of Toldt, the colon is reflected	Traction	Grasper	4	
		2	Colon	Bowel					Visualization of the anterior surface of Gerota's fascia.	Visualization	Laparoscope	1	
		3	Colon	Bowel	The plane between the descending colon and the underlying Gerota's fascia is developed to allow the colon to fall medially	Traction	Grasper	3					
PL2	Colon, spleen and pancreas dissection	1	The splenorenal and lienocolic ligaments	Bowel, pancreas and spleen	The splenorenal and lienocolic ligaments are incised allowing the spleen and the tail of the pancreas to be separated from the upper pole of the kidney	Incision	Monopolar scissor	2	Visualization of the colon, spleen and pancreas	Visualization	Laparoscope	1	
		2	Colon, spleen, Pancreas	Bowel, pancreas and spleen	The dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein	Dissection	Monopolar scissor	2					
PR2	Mobilization of duodenum and vena cava visualization (with Kocher maneuver)	1	Duodenum Vena cava	Bowel	The duodenum is mobilized medially, using the Kocher maneuver, until the vena cava is clearly visualized	Kocher maneuver	Kocher maneuver	2	Visualization of the Duodenum and Vena cava	Visualization	Laparoscope	1	
PR3	Retraction of the liver	1	Liver	Gallbladder					The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5-mm trocar below the ribs in the anterior axillary line	Traction	Retractor Grasper	5	

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
P3	Ureter and gonadal vein are identified and retracted laterally	1	Midureter	Vena cava and Aorta					The midureter is located in the retroperitoneal fat medial to the psoas muscle	Visualization	Laparoscope	1	
		2	Ureter	Vena cava and Aorta					During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure	Movement	Grasper	4	
		3	Ureter Psoas muscle	Vena cava and Aorta	Once located, the ureter is elevated, revealing the psoas muscle and traced proximally to identify the renal hilum	Traction	Bipolar forceps	3					
		4	Ureter Psoas muscle	Vena cava and Aorta	The grasper is placed beneath the ureter and used to provide anterolateral elevation	Traction	Bipolar forceps	3					
		5	Ureter Psoas muscle	Vena cava and Aorta					Suction and cleaning of smoke and blood	Suction	Suction	1	
P4	Renal Hilum Identification	1	Kidney's lower pole	Vena cava and Aorta					The ureter and lower pole of the kidney are elevated	Traction	Grasper	4	
		2	Vessels	Vena cava and Aorta					The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator	Suction	Suction	4	
		3	Kidney's lower pole	Vena cava and Aorta	Firm elevation of the lower pole of the kidney assists in identification and dissection of the renal hilar vessels. This is accomplished by gently placing the lateral grasper under the ureter and kidney until it abuts against the abdominal sidewall	Traction	Bipolar forceps	3					
		4	Renal hilum	Vena cava and Aorta	The surgeon places the renal hilum on tension by lifting the lower pole laterally. With the use of the electrosurgical scissors and the suction-irrigator, the hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis	Isolation	Monopolar scissor	2					
P5	Kidney is mobilized	1	Gerota's fascia; Perirenal Fat		The kidney is mobilized within Gerota's fascia and defatted, maintaining perirenal fat over the tumor	Blunt Dissection	Monopolar scissor	2	Visualization of the Gerota's fascia	Visualization	Laparoscope	1	
		2	Gerota's fascia; Perirenal Fat			Traction	Grasper	3	During proximal mobilization, the gonadal vein is usually first encountered and swept medially. The ureter is located posterior to this structure	Movement	Grasper	4	
P6	Securing the Renal Blood Vessels	1	Renal artery and vein	Vena cava and Aorta	The renal artery and vein are individually dissected. The renal vein is usually identified first and is dissected circumferentially	Dissection	Monopolar scissor	2	Visualization of the renal artery and vein	Visualization	Laparoscope	1	
									Suction and cleaning of smoke and blood	Suction	Suction	4	
		2	Renal vein	Vena cava and Aorta	Renal vein must be identified and clamped taking care not to include the ureter	Dissection	Satinsky clamp	2	Visualization of the renal vein	Visualization	Laparoscope	1	
									Suction and cleaning of smoke and blood	Suction	Suction	4	
		3	Renal artery	Vena cava and Aorta	The renal artery is identified and clamped, taking care not to include the ureter	Dissection	Satinsky clamp	2	Visualization of the renal artery	Visualization	Laparoscope	1	
									Suction and cleaning of smoke and blood	Suction	Suction	4	

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar	Figure
P7	The tumor is excised	1	Kidney		Tumor dissection is preferentially developed in a medial-to-lateral direction	Dissection	cold Endoshears	2	Visualization of the tumor	Visualization	Laparoscope	1	
									Suction and cleaning of smoke and blood	Suction	Suction	4	
P8	Renorrhaphy	1	Kidney	Renal calyx	Three to 5 interrupted sutures are placed over a pre-prepared Surgicel bolster that has been positioned over the cut surface of the kidney. A Hem-o-Lok clips secured on the suture to prevent it from pulling through	Surgical sutures	Niddle Driver	2	Visualization of the tumoral zone	Visualization	Laparoscope	1	
						Surgical sutures	Niddle Driver	3	A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	4	
		2	Kidney	Renal calyx	Biologic hemostatic gelatin-matrix-thrombin tissue sealant FloSeal is applied to the cut renal parenchymal surface underneath the bolster.	Surgical sutures	Niddle Driver	2	Visualization of the renal parenchymal surface	Visualization	Laparoscope	1	
						Surgical sutures	Niddle Driver	3	Holding the tissues near to cut surface	Holding	Grasper	4	
		3	Kidney	Renal calyx	An Hem-o- Lok clip is applied to the suture flush in order to adjoin the opposite renal surface, compressing the kidney. The suture is then tightly tied across the bolster, maintaining adequate parenchymal compression	Surgical sutures	Niddle Driver	2	Visualization of renal surface	Visualization	Laparoscope	1	
						Surgical sutures	Niddle Driver	3	A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	4	
P9	The hilum is unclamped (it is removed only once hemostasis is confirmed)	1	Renal hilum		The Satinsky clamps are removed only once hemostasis is confirmed	Removal	Satinsky clamps	2					
P10	Specimen Entrapment and Extraction	1		Bowel					Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Holding	Endocatch bag	1	
End	Ports closure	1		Bowel					All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures				

8 Appendix II

8.1 *H-FMEA Risk Analysis - Robotic Assisted Radical Prostatectomy*

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
Initial Phase	Patient positioning		The patient is positioned supine. In da Vinci SARAS Standard: the legs are separated in semi flexion (lithotomy position). Trendelenburg position is 30° from horizontal and a 18 ch Foley catheter is inserted into the bladder	Nerve compression injuries including calf compartment and/or gluteal compartment for patient positioning	Prolonged position of patient (usually surgery lasts about 4-5 hours)	Lesion due to nerves compressions					7,1		5
				Shoulder compression	Prolonged position of patient (usually surgery lasts about 4-5 hours)	Patient discomfort after surgery					5,9		
				Cardiovascular and respiratory problems due to steep Trendelenburg position of the of patient	Not correct position of the patient	Higher intracranial pressure; Ischemic complications in the lower extermities					7,6		
				Hernia formation at port site and blood clot formation in the legs or pelvic region	Difficult venous blood circulation	Pulmonary embolism; Deep venous thrombosis; Prolonged recovery time					5,7		
	Pneumoperitoneum		A Veress needle (or Hasson trocar) is inserted at the periumbilical position (at 12 mmHg)	Access-related injuries such as to abdominal aorta, vascular injuries (particularly to the Epigastric vesseles) and damage to intestinal loop	Due to trocar placement	Bleeding, lesions to organs; Prolonged surgery					7,3		5
	Port placement		There are four robotic arms and two assistant ports. The Veress needle is replaced by a 12 mm port and the laparoscope is introduced for initial abdomen inspection. Two 8mm ports are placed for the robotic arm (separate at the right and left side of the camera port). One 5mm assistance port is placed at the right lateral to the camera port and the other 15mm assistance port above the right anterior superior iliac crest.	Wound infection at port site	Contact with not sterile tools	Prolonged recovery time					4,1		15
				Access-related injuries such as to abdominal aorta, vascular injuries (particularly to the Epigastric vesseles) and damage to intestinal loop	Due to trocar placement	Bleeding; Prolonged surgery					6,5		
				Partial or missed visualization of the robotic instruments as they are positioned in the pelvis	Technical malfunctions in the optical tool/camera; Surgeon's inattention	Difficulty in proceeding the surgery					9,2		
				External Interferences between robot and human limbs	Incorrect position of the robot	The surgical procedure requires more time					6,6		
				Mal-placed robotic arms: External Interference between robotic arms	Mechanical failure and breakage	Frustating and time-consuming collisions; Conversion to open surgery					6,7		
				Mal-placed robotic arms: Internal Interference between robotic arms	Unrecognised damage, commonly bleeding from pelvic bones	Frustating and time-consuming collisions; Conversion to open surgery					5,4		
1	Incision of the peritoneum and entry into the retropubic space of Retzius	1	Direct visualization of the peritoneum overlying the bladder	none	none	none							
		2	A peritoneal incision is made through the median umbilical ligament to enter in the retropubic space				Upper anterior traction on the peritoneum	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	15
				Vascular injuries, particularly to the Epigastric vesseles	Surgeon's inattention and skills	Bleeding	Upper anterior traction / Suction and cleaning of blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,2	5,7	15
The peritoneum is dissected to the following boundaries: the pubic bone superiorly, the median umbilical ligaments laterally, and the vas deferens inferolaterally													

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
2	Incision of the endopelvic fascia (EPF) and identification of the dorsal venous complex (DVC)	1	Incision of the endopelvic fascia: this is the area with the largest amount of space between the prostate and the levators and the point at which the prostate has most mobility	Damage to the rectum	Blind intraperitoneal manipulation of sharp instrument	Peritonitis and life-threatening situations	Suction and cleaning of smoke and blood				11,1		
							The assistant provide the bladder's counter-traction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	0
3	Bladder mobilization	1	The bladder is then liberated off the anterior surface of the abdominal wall				Suction and cleaning of smoke and blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		7,1	0
4	Anterior prostatic fat (AFP) dissection	1	The layer of fat is removed to allow better visualization of the puboprostatic ligaments, the dorsal venous complex as well as the junction between the bladder neck and the prostate				Upper traction of the prostatic fat/ Suction and cleaning of blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		5,7	0
							The assistant provides the prostatic fat's traction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		5,7	0
		2					Passes the needle and the suture thread to the surgeon	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	15
5	DVC control and suture	1	A total of two suture ligations are put in place (one distal and another more proximal). The distal suture provides the necessary hemostasis while the proximal suture will be used later for prostate traction. A total of four square knots are used	Catheter tying	Surgeon's inattention and skills	Bleeding	The assistant cuts the suture's thread	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	10,2	6,2	0
							The needles can be snapped out and removed from the body	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	15
6	Bladder neck transection	1	The bladder neck is divided horizontally until the urethral catheter is identified	Damage to the bladder or ureters	Surgeon's inattention and skills	Additional surgery; Extension of the hospital stay; Urethral stricture and urinary difficulties	Upper traction/ Suction and cleaning blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	6,4	7,1	0
		2	The Foley catheter balloon is then deflated by the nurse										
		3	Move the catheter from a surgeon's grasper to assistant's grasper				Move the catheter from a surgeon's grasper to assistant's grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	0
		4	Catheter and seminal vesicles are collectively grasped, pulled through the open bladder neck				Catheter and seminal vesicles are handed to the assistant for upper traction	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	15
		5	The prostate is suspended anteriorly towards the abdominal wall by grasping the internal tip of the catheter and lifting it upwards				Hemoclips are applied to avoid branches of the dorsal vein fanning over the prostate and to prevent unwanted bleeding	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed, bleeding		6,2	15

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
7	Vas deferens and arteries are exposed	1	Dissection of the retroprostatic tissue, the vas deferens and accompanying arteries are exposed				Upper anterior traction on the peritoneum	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	15
				Lesion of the ureter	Surgeon's inattention and skills	Ureter re-anastomosis	Suction and cleaning of smoke and blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	12,1	5,7	15
8	Division of vas deferens	1	Uses the grasper as a spatula to free adjoining vessels				The vas deferens are controlled using the Hemoclips	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		5,7	15
		2	Incision of vas deferens	Damage to the ureters	Surgeon's inattention and skills	Bleeding	Suction and cleaning of smoke and blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	13,5	6,2	15
9	Exposure of the seminal vesicles	1	Blunt dissection of fibrovascular tissue is overlying the surface of the seminal vesicles				The fibrovascular tissue is controlled using the clips	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		5,7	15
		2	The surgeon indicates to the assistant where s/he can put the clips				Upper traction of the seminal vesicles and vas deferens	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	15
							The vas deferens are controlled using the Hemoclips	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	15
		3	The seminal vesicle is grasped by the bipolar instrument to help liberate the posterior avascular plane. Meticulous blunt dissection is continued to allow complete liberation of the seminal vesicle.				The seminal vesicle is graspedto help liberate the posterior avascular plane.	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		5,7	15
		4	Deep posterior dissection is then continued to the level of Denonvillier's fascia	Damage to the ureters	Surgeon's inattention and skills	Bleeding	Suction and cleaning of smoke and blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	15,8	6,2	15
10	Neurovascular bundle (NVB) dissection (nerve sparing)	1	Uses an athermal dissection technique in the proximity of the nerve bundles	Nerves damage during resection of prostate	Depends on surgeon's technical skills	Inability to get erection and other sexual difficulties; Impotence	Allows for proximal control placing Hemoclips	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed, bleeding	26,1	6,2	15
		2	Sharp scissor cutting between the nerves to help liberate the tissue	Nerves damage during resection of prostate	Depends on surgeon's technical skills	Inability to get erection and other sexual difficulties; Impotence	Suction and cleaning of smoke and blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	26,1	6,6	15
11	Urethral division	1	Sharp scissor cutting through the anterior urethral wall allows for visualization of the Foley catheter				Suction and cleaning of smoke and blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	0
		2	The remaining posterior wall, including the rectourethralis fibers, is then cut sharply to liberate the prostate	Damage to the rectum	Depends on surgeon's skills	Rectum repair	Vas deferens and the seminal vesicles are collectively grasped	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	11,7	6,2	0
							Suction and cleaning of smoke and blood	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	0
12	Prostate delocation		Move the prostate from a surgeon's grasper to assistant's grasper				Move the prostate from a surgeon's grasper to assistant's grasper	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		5,7	0
							The prostate is placed in an endocatch bag along with the anterior prostatic fat and is placed in the upper abdominal space for later retrieval	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	5

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
13	Vesicourethral anastomosis	1	The well-dissected bladder is free and mobile and can be easily descended into the pelvis. The anastamosis is done using a self-cinching unidirectional barbed suture (2 knotless, interlocked 6-inches 3-0 V-Loc-180 suture)	Not proper Urethrovescial Anastomosis	Depends on surgeon's technical skills	Urinary leakage and continued catheter drainage for a longer period Fistulization	Passes the needle and the suture thread to the surgeon	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed	16,4	6,2	15
		2	The nurse fills up the bladder with water to check the correct operation										
		3					The needles are snapped out and removed from the body	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	5
		4					The hemostatic materials are inserted in the body	slow or not accurate	Surgeon's inattention and skills	slow surgery, main surgeon is annoyed		6,2	0
		5					The string for the laparoscopic entrapment sack is transferred to the camera port site at the umbilicus and the abdomen is completely deflated						0
14	Endocatch bag Extraction						The specimens within the laparoscopi entrapment sack are extracted intact through extension of the periumbilical trocar site (usually 2.5 cm to 3.5 cm in length)	Rupture of the bag	Surgeon's inattention and skills			3,7	0
End	Ports closure			Hernia formation at port site and blood clot formation in the legs or pelvic region	Difficult venous blood circulation	Pulmonary embolism; Deep venous thrombosis; Prolonged recovery time	The fascial defect is then immediately closed by sutures. The skin defects are then closed with a subcuticular absorbable suture followed by the skin adhesive Dermabond	Hernia formation at port site and blood clot formation in the legs or pelvic region	Difficult venous blood circulation	Pulmonary embolism; Deep venous thrombosis Prolonged recovery time	7,7	5,0	0
				Wound infection at port site	Contact with not sterile tools	Prolonged recovery time		Wound infection at port site	Contact with not sterile tools	Prolonged recovery time	6,7	6,1	0

8.2 *H-FMEA Risk Analysis - Laparoscopic Radical Nephrectomy*

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
Initial Phase	Patient positioning		The patient is placed in a modified flank position, with the umbilicus over the break in the operating table. The table can be flexed to 10°-20° for left kidney and 30° for right kidney	Nerve compression injuries including calf compartment and/or gluteal compartment for patient positioning	Prolonged position of patient (usually surgery lasts about 4-5 hours)	Lesion due to nerves compressions					8,0		
				Shoulder compression	Prolonged position of patient (usually surgery lasts about 4-5 hours)	Patient discomfort after surgery							
				Cardiovascular and respiratory problems due to steep Trendelenburg position of the patient	Not correct position of the patient	Higher intracranial pressure; Ischemic complications in the lower extremities							
				Hernia formation at port site and blood clot formation in the legs or pelvic region	Difficult venous blood circulation	Pulmonary embolism; Deep venous thrombosis; Prolonged recovery time							
	Pneumoperitoneum		Hasson trocar is inserted at the level of the umbilicus (at 12-14 mmHg)								3,4		
	Port placement		A four-trocar technique is utilized to complete the dissection. A 11 mm trocar is placed on the midclavicular line 2 cm below the costal margin for the camera; another 11 mm trocar is placed 2 cm above the umbilicus. A 5 mm port can be inserted just under the xyphoid and the last 5 mm trocar is placed 2 cm medial to and sometimes superior to the anterior superior iliac spine. Four ports are generally sufficient to complete the procedure, although a fifth trocar may be necessary for organ entrapment and to retract the left mesocolon during left-sided nephrectomy	Wound infection at port site	Contact with not sterile tools	Prolonged recovery time					7,1		
				Access-related injuries such as to abdominal aorta, vascular injuries (particularly to the Epigastric vesseles) and damage to intestinal	Due to trocar placement	Bleeding; Prolonged surgery							
				Partial or missed visualization of the robotic instruments as they are positioned in the pelvis	Technical malfunctions in the optical tool/camera; Surgeon's inattention	Difficulty in proceeding the surgery							
				External Interferences between robot and human limbs	Incorrect position of the robot	The surgical procedure requires more time							
				Mal-placed robotic arms: External Interference between robotic arms	Mechanical failure and breakage	Frustating and time-consuming collisions; Conversion to open surgery							
				Mal-placed robotic arms: Internal Interference between robotic arms	Unrecognised damage, commonly bleeding from pelvic bones	Frustating and time-consuming collisions; Conversion to open surgery							
R1	Colon mobilization	1	Line of Toldt incision	Wrong plane dissection	Unrecognised anatomical landmarks	Bleeding Bleeding, prolonged operative time	Along the white line of Toldt, the colon is reflected	aggressive manipulation of the colon excessive traction on the colon	misappliaction of the retracting forceps or wrong instrument	tissue tearing or perforation, sepsis, death	6,7	16,2	15
								suboptimal exposure;	poor traction	no progression		6,6	
								tissue tearing	excessive traction	tissue tearing or perforation, sepsis, death		19,7	
		2					Visualization of the anterior surface of Gerota's fascia	Poor vision	uncorrect endoscope targeting	no progression		5,3	15
		3	The plane between the descending colon and the underlying Gerota's fascia is developed to allow the colon to fall medially	Wrong plane dissection	Unrecognised anatomical landmarks	Bleeding, prolonged operative time					8,2		
				Aggressive manipulation of the colon excessive traction on the colon	misappliaction of the retracting forceps or wrong instrumen	tissue tearing or perforation, sepsis, death					20,6		
RL2	Colon, spleen and pancreas dissection	1	The splenorenal and lienocolic ligaments are incised allowing the spleen and the tail of the pancreas to be separated from the upper pole of the kidney	damage to diaphragm or pleural lesion	clumsy dissection	pneumothorax	Visualization of the colon, spleen and pancreas	Poor vision	uncorrect endoscope targeting	no progression	13,0	6,1	5
		2	The dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein	damage to diaphragm or pleural lesion	misappliaction of the retracting forceps or wrong instrument	tissue tearing or perforation					18,3		5
RR2	Mobilization of duodenum and vena cava visualization (with Kocher maneuver)		The duodenum is mobilized medially, using the Kocher maneuver, until the vena cava is clearly visualized	aggressive manipulation of the duodenum excessive traction on the duodenum	misappliaction of the retracting forceps or wrong instrument	tissue tearing or perforation, sepsis, death	Visualization of the Duodenum and Vena cava	Poor vision	uncorrect endoscope targeting	no progression	25,0	6,6	5
RR2B	Retraction of the liver						The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5-mm trocar below the ribs in the anterior axillary line	suboptimal exposure lesion of the liver	poor traction, clumsy movement, excessive traction, large liver	no progression bleeding		7,3	15

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
R3	Ureter and gonadal vein are identified and retracted laterally	1					The midureter is located in the retroperitoneal fat medial to the psoas muscle	Poor vision	uncorrect endoscope targeting	no progression		6,1	5
		2					During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located posterior to this structure	suboptimal exposure tissue tearing	poor traction excessive traction	no progression vein lesion, ureter leasion		10,0	15
		3	Once located, the ureter is elevated, revealing the psoas muscle and traced proximally to identify the renal hilum	Lesion of the ureter	tissue tearing, misapplied bipolar/monopolar energy	lesion of the ureter, fistula, ureter stricture, Hidronephrosis					11,7		
				Lesion of the gonadal vein	traction, inappropriate dissection	bleeding					7,3		
		4	The grasper is placed beneath the ureter and used to provide anterolateral elevation	uncorrect placement	Unrecognised anatomical landmarks	lesion of the ureter					11,3		10
		5					Suction and cleaning of smoke and blood	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression		9,4	15
R4	Renal Hilum Identification	1					The ureter and lower pole of the kidney are elevated	tissue tearing	excessive traction	bleeding		8,9	
		2					The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator						
		3	Firm elevation of the lower pole of the kidney assists in identification and dissection of the renal hilar vessels. This is accomplished by gently placing the lateral grasper under the ureter and kidney until it abuts against the abdominal sidewall	no exposure	inadeguate traction	no progression of the surgery					3,5		
				damage to tumour surface	excessive traction	bleeding from the kidney					6,7		
				damage to renal parenchyma	excessive traction	tumour rupture and spillage					8,6		
		4	The surgeon places the renal hilum on tension by lifting the lower pole laterally. With the use of the electrosurgical scissors and the suction-irrigator, the hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis	same as above	same as above	same as above					7,1		
R5	Renal Hilum Transection	1	The renal artery is identified and is dissected	HemOlock misplacement, hemorrage	unsufficient hisolation, wrong interptretation of hilum anatomy, arterial branch missed	major bleeding, death	The renal artery is controlled using the Hemoclips	HemOlock misplacement, hemorrage, suboptimal exposure	poor traction	no progression	9,8	12,0	50
							Suction and cleaning of smoke and blood	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression		12,0	15
		2	The renal vein is usually identified first and is dissected circumferentially	HemOlock misplacement, hemorrage	unsufficient hisolation, wrong interptretation of hilum anatomy, venous branch missed	major bleeding	The renal vein is controlled using the Hemoclips	HemOlock misplacement, hemorrage, suboptimal exposure	poor traction	no progression	12,4	9,6	50
							Suction and cleaning of smoke and blood	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression		8,9	15
		3	Lumbar veins must be identified and divided through a pair of double clips	HemOlock misplacement, hemorrage	unsufficient hisolation, wrong interptretation of hilum anatomy, venous branch missed	major bleeding	The lumbar veins are controlled using the Hemoclips	HemOlock misplacement, hemorrage, suboptimal exposure	poor traction	no progression	9,8	9,6	50
							Suction and cleaning of smoke and blood	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression		11,7	15

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
R6	Mobilization of the Lower Pole, Dissection of the Upper Pole and Adrenal gland	1	Once the ureter is mobilized up to the ureteropelvic junction, forceps are inserted beneath Gerota's fascia and lower pole along the psoas fascia	tumour violation/opening	dissection in the wrong plane	disease relapse, poor oncologic outcomes					17,5		
		2	The specimen is lifted superolaterally, and, with the use of the suction-irrigator and electrosurgical scissors, the inferior and posterior sidewall attachments are divided	tumour violation/opening	dissection in the wrong plane	disease relapse, poor oncologic outcomes	Suction and cleaning of smoke and blood	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	17,5	7,7	15
				lesion of diaphragm	accidental clumsy manouver	panumothrax, respitarory failure, pulmonary infarction					12,7		
				lesion of the abdominal wall	minor bleeding	postoperative anaemia/haematoma					14,9		
		3	The inferior cone of Gerota's fascia lateral to the ureter is also divided.	tumour violation/opening	dissection in the wrong plane	prolonged stay	Suction and cleaning of smoke and blood	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression	14,1	7,7	15
		4	(The adrenal gland can be preserved in simple nephrectomy and particular cases of mid and lower pole tumors, or it is removed intact with the specimen) On the right side, dissection cephalad along the vena cava identifies the adrenal vein. Once it is divided, the superior, medial, and posterior attachments of the adrenal gland are mobilized	tumour violation/opening	dissection in the wrong plane	disease relapse, poor oncologic outcomes					13,5		
				lesion of the adrenal gland	dissection in the wrong plane	bleeding					14,3		
R7	Transection of the Ureter		The ureter is cut through a sharp scissor	lesion of the adrenal gland	dissection in the wrong plane	bleeding	Suction and cleaning of smoke and blood	excessive suction	collaspe of surgical field due to low inreaperitoneal pressure	no progression		6,2	
R8	Specimen Entrapment and Extraction			endobag rupture	inadeguate endobag dimesions	tumour rupture and spillage	Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	endobag rupture	inadeguate endobag dimesions	tumour rupture and spillage	6,6	6,2	50
End	Ports closure			Accidentally position of a stitch on the intestine during suturing the pelvic fascia	Depends on surgeon's technical skills - poor exposure	Intestinal occlusion in the post-operative phase Necrosis of the intestinal loop interested	All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures.				20,1		
				Hernia formation at port site	failure to include fascia in the suture	Ileus, incarceration and perforation					14,6		
				Wound infection at port site	Contact with not sterile tools	Prolonged recovery time					4,7		

8.3 *H-FMEA Risk Analysis - Laparoscopic Partial Nephrectomy*

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
Initial Phase	Patient positioning		The patient is placed in a modified flank position, with the umbilicus over the break in the operating table. The table can be flexed to 10°-20° for left kidney and 30° for right kidney	Nerve compression injuries including calf compartment and/or gluteal compartment for patient positioning	Prolonged position of patient (usually surgery lasts about 4-5 hours)	Lesion due to nerves compressions					8,4		
				Shoulder compression	Prolonged position of patient (usually surgery lasts about 4-5 hours)	Patient discomfort after surgery					8,4		
				Cardiovascular and respiratory problems due to steep Trendelenburg position of the patient	Not correct position of the patient	Higher intracranial pressure; Ischemic complications in the lower extermities					7,3		
				Hernia formation at port site and blood clot formation in the legs or pelvic region	Difficult venous blood circulation	Pulmonary embolism; Deep venous thrombosis; Prolonged recovery time					10,7		
	Pneumoperitoneum		Hasson trocar is inserted at the level of the umbilicus (at 12-14 mmHg)								2,6		
	Port placement		A four-trocar technique is utilized to complete the dissection. A 11 mm trocar is placed on the midclavicular line 2 cm below the costal margin for the camera; another 11 mm trocar is placed 2 cm above the umbilicus. A 5 mm port can be inserted just under the xyphoid and the last 5 mm trocar is placed 2 cm medial to and sometimes superior to the anterior superior iliac spine. Four ports are generally sufficient to complete the procedure, although a fifth trocar may be necessary for organ entrapment and to retract the left mesocolon during left-sided nephrectomy	Wound infection at port site	Contact with not sterile tools	Prolonged recovery time					7,3		
				Access-related injuries such as to abdominal aorta, vascular injuries (particularly to the Epigastric vesseles) and damage to intestinal loop	Due to trocar placement	Bleeding; Prolonged surgery					8,3		
				Partial or missed visualization of the robotic instruments as they are positioned in the pelvis	Technical malfunctions in the optical tool/camera; Surgeon's inattention	Difficulty in proceeding the surgery					5,5		
				External Interferences between robot and human limbs	Incorrect position of the robot	The surgical procedure requires more time					6,0		
				Misplaced robotic arms: External Interference between robotic arms	Mechanical failure and breakage	Frustating and time-consuming collisions; Conversion to open surgery					6,4		
				Misplaced robotic arms: External Interference between robotic arms	Unrecognised damage, commonly bleeding from pelvic bones	Frustating and time-consuming collisions; Conversion to open surgery					7,7		

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
P1	Colon mobilization	1	Line of Toldt incision	Wrong plane dissection	Unrecognised anatomical landmarks	Bleeding; Bleeding, prolonged operative time	Along the white line of Toldt, the colon is reflected	Aggressive manipulation of the colon excessive traction on the colon	Misappliaction of the retracting forceps or wrong instrument	Tissue tearing or perforation, sepsis, death	4,3	14,1	
								suboptimal exposure	Poor traction	No progression		7,1	
								Tissue tearing	Excessive traction	Tissue tearing or perforation, sepsis, death		13,8	
		2					Visualization of the anterior surface of Gerota's fascia	Poor vision	Uncorrect endoscope targeting	No progression		4,6	15
		3	The plane between the descending colon and the underlying Gerota's fascia is developed to allow the colon to fall medially	Wrong plane dissection	Unrecognised anatomical landmarks	Bleeding; prolonged operative time					5,0		
				Aggressive manipulation of the colon excessive traction on the colon	Misappliaction of the retracting forceps or wrong instrument	Bleeding, prolonged operative time					8,7		
PL2	Colon, spleen and pancreas dissection	1	The splenorenal and lienocolic ligaments are incised allowing the spleen and the tail of the pancreas to be separated from the upper pole of the kidney	Damage to diaphragm or pleural lesion	Clumsy dissection	Pneumothorax	Visualization of the colon, spleen and pancreas	Poor vision	Uncorrect endoscope targeting	No progression	12,3	8,7	5
		2	The dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein	Aggressive manipulation of the colon excessive traction on the colon	misappliaction of the retracting forceps or wrong instrument	tissue tearing or perforation					10,3		5
PR2	Mobilization of duodenum and vena cava visualization (with Kocher maneuver)	1	The duodenum is mobilized medially, using the Kocher maneuver, until the vena cava is clearly visualized	Aggressive manipulation of the duodenum excessive traction on the duodenum	misappliaction of the retracting forceps or wrong instrument	tissue tearing or perforation, sepsis, death	Visualization of the Duodenum and Vena cava	Poor vision	Uncorrect endoscope targeting	No progression	21,0	7,6	5
PR3	Retraction of the liver	1					The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5-mm trocar below the ribs in the anterior axillary line	Suboptimal exposure Lesion of the liver	Poor traction Clumsy movement, excessive traction, large liver	No progression Bleeding		5,9	15
P3	Ureter and gonadal vein are identified and retracted laterally	1					The midureter is located in the retroperitoneal fat medial to the psoas muscle	Poor vision	Uncorrect endoscope targeting	No progression		8,0	5
		2					During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure	Suboptimal exposure Tissue tearing	Poor traction Excessive traction	No progression Vein lesion, ureter leasion		12,1	15
		3	Once located, the ureter is elevated, revealing the psoas muscle and traced proximally to identify the renal hilum	Lesion of the ureter	Tissue tearing, misapplied bipolar/monopolar energy;	Lesion of the ureter, fistula, ureter stricture, Hidronephrosis;					17,4		
				Lesion of the gonadal vein	traction, inappropriate dissection	bleeding					12,0		
		4	The grasper is placed beneath the ureter and used to provide anterolateral elevation	Uncorrect placement	Unrecognised anatomical landmarks	Lesion of the ureter					13,0		
		5					The ureter and lower pole of the kidney are elevated	Excessive suction	Collaspe of surgical field due to low inreaperitoneal pressure	No progression		6,6	15

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
P4	Renal Hilum Identification	1					The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator	Tissue tearing	Excessive traction	Bleeding		7,7	50
		2	The vessels entering the renal hilum can be identified and bluntly dissected using the tip of the irrigator-aspirator										
		3	Firm elevation of the lower pole of the kidney assists in identification and dissection of the renal hilar vessels. This is accomplished by gently placing the lateral grasper under the ureter and kidney until it abuts against the abdominal sidewall	No exposure	Inadeguate traction	No progression of the surgery					3,8		
				Damage to renal parenchyma	Excessive traction	Bleeding from the kidney					7,1		
				Damage to tumour surface	Excessive traction	Tumour rupture and spillage					7,9		
		4	The surgeon places the renal hilum on tension by lifting the lower pole laterally. With the use of the electrosurgical scissors and the suction-irrigator, the hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis	Damage to renal parenchyma	Excessive traction	Bleeding from the kidney					7,7		
P5	Kidney is mobilized	1	The kidney is mobilized within Gerota's fascia and defatted, maintaining perirenal fat over the tumor	Renal de-capsulation	Toxic peri-renal fat	Bleeding, long term detriment in renal funciton	Visualization of the Gerota's fascia	Poor vision	Uncorrect endoscope targeting	No progression	6,7	12,4	
		2		Renal de-capsulation	Toxic peri-renal fat	Bleeding, long term detriment in renal funciton	During proximal mobilization, the gonadal vein is usually first encountered and swept medially. The ureter is located posterior to this structure	Tissue tearing	Excessive traction	Bleeding	6,2	13,0	5
P6	Securing the Renal Blood V	1	The renal artery and vein are individually dissected. The renal vein is usually identified first and is dissected circumferentially	Lesion of the vein, lesion of collateral vessels	Clumsy dissection	Bleeding, conversion to radical nephrectomy	Visualization of the renal artery and vein	Poor vision	Uncorrect endoscope targeting	No progression	12,5	13,5	5
							Suction and cleaning of smoke and blood	Excessive suction	Collaspe of surgical field due to low inreaperitoneal pressure	No progression		12,0	5
		2	Renal vein must be identified and clamped, taking care not to include the ureter	Inadeguate clamping	Uncorrect positioning of the clamp	Bleeding during tumour resection	Visualization of the renal vein	Poor vision	Uncorrect endoscope targeting	No progression	12,3	13,5	5
							Suction and cleaning of smoke and blood	Excessive suction	Collaspe of surgical field due to low inreaperitoneal pressure	No progression		12,0	5
		3	The renal artery is identified and clamped, taking care not to include the ureter	Inadeguate clamping	Uncorrect positioning of the clamp	Bleeding during tumour resection	Visualization of the renal artery	Poor vision	Uncorrect endoscope targeting	No progression	8,9	12,4	5
							Suction and cleaning of smoke and blood	Excessive suction	Collaspe of surgical field due to low inreaperitoneal pressure	No progression		12,0	5
P7	The tumor is excised	1	In a near-bloodless field; dissection is preferentially developed in a medial-to-lateral direction	Dissection into the tumour	Bledding, sub-optimal vision and traction on kidney and tumour	Positive surgical margin, tumour local relapse	Visualization of the tumor	Poor vision	Uncorrect endoscope targeting	No progression	13,0	12,4	50
				Dissection in renal calyx when not necessary	Wrong dissection plane	Excretory tract opening, fistula	Suction and cleaning of smoke and blood	Excessive suction	Collaspe of surgical field due to low inreaperitoneal pressure	No progression	21,4	12,0	50

Phase Code	Phase	Step	Main Surgeon Tasks	Failure Modes Main surgeon	Failure Causes Main surgeon	Failure Effects Main surgeon	Assistant Task	Failure Modes Assistant	Failure Causes Assistant	Failure Effects Assistant	CI Main Surgeon	CI Assistant	Degree of dependence (%dep)
P8	Renorrhaphy	1	Three to 5 interrupted sutures are placed over a pre-prepared Surgicel bolsterthat has been positioned over the cut surface of the kidney. A Hem-o-Lok clips secured on the suture to prevent it from pulling through	Prolonged ischemia time	Slow suturing	Renal function detriment	Visualization of the tumoral zone	Poor vision	Uncorrect endoscope targeting	No progression	11,7	12,4	15
				Tissue tearing	Misapplied force durgin suture pulling	Bleeding	A Hem-o-Lok clips secured on the suture	Uncorrect clip placement	Wrong distance, wrong location	Parenchymal tearing, bleeding, clip migration	15,5	12,7	100
				Arteriae arcuatae closure, proximal branches of renal artery closure	Suture placed too deep	Renal function detriment					13,0		
		2	Biologic hemostatic gelatin-matrix-thrombin tissue sealant FloSeal is applied to the cut renal parenchymal surface underneath the bolster	Misapplied hemostatic agent	Clumsy placement	Agent ineffective	Visualization of the renal parenchymal surface	Poor vision	Uncorrect endoscope targeting	No progression	9,1	10,0	15
							Holding the tissues near to cut surface	Unapproprite countertraction	Sub-optimal vision	Positive surgical margin, poor ocnologic control		19,3	50
		3	An Hem-o- Lok clip is applied to the suture flush in order to adjoin the opposite renal surface, compressing the kidney. The suture is then tightly tied across the bolster, maintaining adequate parenchymal compression	Prolonged ischemia time	Slow suturing	Renal function detriment	Visualization of the renal surface	Poor vision	Uncorrect endoscope targeting	No progression	11,1	10,0	15
				Tissue tearing	Misapplied force durgin suture pulling	Bleeding	A Hem-o-Lok clips secured on the suture	Uncorrect clip placement	Wrong distance, wrong location	Parenchymal tearing, bleeding, clip migration	16,8	13,5	100
P9	The hilum is unclamped (it is removed only once hemostasis is confirmed)	1	The Satinsky clamps are removed only once hemostasis is confirmed	Damage to renal artery or vein during satinsky removal	Clumsy satinsky manipulation	Bleeding					9,6		
P10	Specimen Entrapment and Extraction	1		Endobag rupture	Inadeguate endobag dimesions	Tumour rupture and spillage	Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Endobag rupture	Inadeguate endobag dimesions	Tumour rupture and spillage	4,1	12,4	50
End	Ports closure	1		Accidentally position of a stitch on the intestine during suturing the pelvic fascia	Depends on surgeon's technical skills - poor exposure	Intestinal occlusion in the post-operative phase; Necrosis of the intestinal loop interested	All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures.				16,9	7,5	
				Hernia formation at port site	failure to include fascia in the suture	Ileus, incarceration and perforation; Prolonged recovery time					11,3		
				Wound infection at port site	Contact with not sterile tools	Prolonged recovery time					4,4		

9 Appendix III

In the following Table 9.1 is reported the complete RARP procedure integrated with use of the da Vinci® IS1200 (first basic version). Instead, in the Table 9.2 e 9.3 are shown respectively the complete LRN and LPN procedures.

After the description of complete procedures of RARP and L R/P N (see Chapter 2 and Appendix I), the first steps towards its simplified model have been undertaken focusing on the technology at disposal, within the project, for the main surgeon (see Chapters 4.1 and 4.2).

We have described in detail for both surgeons the chosen **surgical steps** with described the linked assistant's actions and tasks, the **anatomical sites** involved, the eventual **forbidden regions** (i.e. anatomical structures that constitute physical dangerous limits), the **instruments used** and related access points (**trocars**).

For the RARP: The grey parts will be later discussed with the progress of the technical implementation of the project.
For the LN: The phases' cells have been colored in two different color, red and blue for left and right side respectively. Moreover, some surgical steps are reported in light green (and the corresponding description is crossed out) /orange: these parts of the procedures were originally of pertinence of the assistant, but in the simplified model have been switched to be of responsibility of the first surgeon.

9.1 *SARAS Robotic Assisted Radical Prostatectomy simplified model*

Phase code	Phase	Step	Anatomical site	Forbidden Region	Main Surgeon task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Of What?	Instrument type	Trocar
Initial Phase	Patient positioning		NA	NA	The patient is positioned in the supine position. In da Vinci SARAS Standard: the legs are separated in semi flexion (lithotomy position). Trendelenburg position is 30° from horizontal and a 18 ch Foley catheter is inserted into the bladder						NA	NA	
	Pneumoperitoneum		Peritoneum		A Veress needle (or Hasson trocar) is inserted at the periumbilical position (at 12 mmHg)							Hasson trocar	1
	Port placement		Peritoneum		There are three robotic arms and two assistant ports. The Veress needle is replaced by a 12 mm port and the laparoscope is introduced for initial abdomen inspection. Two 8mm ports are placed for the robotic arm (separate at the right and left side of the camera port). One 5mm assistance port is placed at the right lateral to the camera port and the other 15mm assistance port above the right anterior superior iliac crest.								
1	Incision of the peritoneum and entry into the retropubic space of Retzius	1	Peritoneum		Direct visualization of the peritoneum overlying the bladder		Laparoscope	1					
		2	Retropubic space of Retzius	Bladder pelvic wall	A peritoneal incision is made through the median umbilical ligament to enter in the retropubic space	Traction	Bipolar grasper	3	Upper anterior traction on the peritoneum	Holding (Traction)	Retropubic space of Retzius	Grasper	5
						Incision	Scissor	2	Upper anterior traction / Suction and cleaning of blood	Traction / Suction	Peritoneum / Blood	Suction/ irrigator	4
2	Incision of the endopelvic fascia (EPF) and identification of the dorsal venous complex (DVC)	1	Endopelvic fascia	Pelvic wall	Incision of the endopelvic fascia (EPF)	Incision	Scissor	2	Suction and cleaning of smoke and blood	Suction	Blood	Suction/ irrigator	4
									The assistant provides the bladder's counter-traction	Holding (Traction)	Bladder	Grasper	5
3	Bladder mobilization	1	Bladder		The bladder is then liberated off the anterior surface of the abdominal wall	Movement	Bipolar grasper	3	Upper traction of the bladder/ Suction and cleaning of blood	Traction / Suction	Bladder / Blood	Suction/ irrigator	4
4	Anterior prostatic fat (AFP) dissection	1	Anterior surface of the prostate		The layer of fat is removed to allow better visualization of the puboprostatic ligaments, the dorsal venous complex as well as the junction between the bladder neck and the prostate	Dissection	Scissor	2	Upper traction of the prostatic fat/ Suction and cleaning of blood	Traction / Suction	Prostatic fat/ Blood	Suction/ irrigator	4
									The assistant provides the prostatic fat's traction	Holding (Traction)	Prostatic fat	Grasper	5
		2							The assistant passes the needle and the suture thread to the surgeon	Holding (Traction)		Locking grasper	5
5	DVC control and suture	1	DVC	Pubic bone	A total of two suture ligations are put in place (one distal and another more proximal).	Surgical sutures	Needle Driver	2+3	The assistant cuts the suture's thread	Cutting	Suture's thread	Scissor	5
									The needles are snapped out and removed from the body	Holding (Needle)	Needle	Grasper	4
6	Bladder neck incision	1	Bladder Neck	Bladder and prostate	The bladder neck is divided horizontally until the urethral catheter is identified	Transection	Scissor	2	Upper traction/ Suction and cleaning blood	Traction / Suction	Bladder / Blood	Suction/ irrigator	4
		2	Urethra		The Foley catheter balloon is then deflated by the nurse								
		3	Urethra		Move the catheter from a surgeon's grasper to assistant's grasper		Bipolar grasper	3	Move the catheter from a surgeon's grasper to assistant's grasper	Holding	Catheter Seminal vesicles	Grasper	5
		4	Prostate		Catheter and seminal vesicles are collectively grasped, pulled through the open bladder neck		Bipolar grasper	3	Catheter and seminal vesicles are handed to the assistant for upper traction	Holding (Traction)	Catheter	Grasper	5
		5	Prostate		The prostate is suspended anteriorly towards the abdominal wall by grasping the internal tip of the catheter and lifting it upwards	Traction	Bipolar grasper	3	Hemoclips are applied to avoid branches of the dorsal vein fanning over the prostate and to prevent unwanted bleeding	Putting Hemoclip/s	Fibrovascular tissue	Automatic Clip Applier	4
7	Vas deferens and arteries are exposed	1	Vas deferens Seminal vesicles	Ureter and bladder	Dissection of the retroprostatic tissue, the vas deferens and accompanying arteries are exposed	Traction	Bipolar grasper	3	Upper anterior traction on the peritoneum	Holding (Traction)	Retroprostatic tissue	Grasper	4
						Dissection	Scissor	2	Suction and cleaning of smoke and blood	Suction	Smoke	Suction/ irrigator	5
8	Division of vas deferens	1	Surroundings of seminal vesicles	Ureter and bladder	Uses the grasper as a spatula to free adjoining vessels	Movement	Bipolar grasper	3	The vas deferens are controlled using the Hemoclips	Putting Hemoclip/s	Vas deferens	Automatic Clip Applier	4
		2			Incision of vas deferens	Incision	Scissor	2	Suction and cleaning of smoke and blood	Suction	Smoke	Suction/ irrigator	5

Phase code	Phase	Step	Anatomical site	Forbidden Region	Main Surgeon task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Of What?	Instrument type	Trocar
9	Exposure of the seminal vesicles	1	fibrovascular tissue	Ureter and bladder	Blunt dissection of fibrovascular tissue is overlying the surface of the seminal vesicles	Dissection	Scissor	2	The fibrovascular tissue is controlled using the clips	Putting Hemoclip/s	Fibrovascular tissue	Automatic Clip Applier	4
		2	Seminal vesicles	Ureter and bladder	The surgeon indicates to the assistant where s/he can put the clips				Upper traction of the seminal vesicles	Holding (Traction)	Seminal vesicles	Grasper	5
									The seminal vesicles are controlled using the clips	Putting Hemoclip/s	Seminal vesicles	Automatic Clip Applier	4
		3	Seminal vesicles	Ureter and bladder					The seminal vesicle is graspedto help liberate the posterior avascular plane.	Holding (Traction)	Seminal vesicle	Grasper	5
		4	Denonvillier's fascia	Rectum	Deep posterior dissection is then continued to the level of Denonvillier's fascia (or rectovesical space)	Dissection	Scissor	2	Suction and cleaning of smoke and blood	Suction	Blood	Suction-irrigator	5
10	Neurovascular bundle (NVB) dissection (nerve sparing)	1	Neurovascular bundle		Uses an athermal dissection technique in the proximity of the nerve bundles	Dissection	Monopolar cauterization	2	Allows for proximal control placing Hemoclips	Putting Hemoclip/s	Fibrovascular tissue	Automatic Clip Applier	4
		2	Neurovascular bundle		Sharp scissor cutting between the nerves to help liberate the tissue	Cut	Sharp scissor	2	Traction/ Suction and cleaning blood	Traction / Suction	Fibrovascular tissue	Suction/ irrigator	4
11	Urethral division	1	Urethra		Sharp scissor cutting through the anterior urethral wall allows for visualization of the Foley catheter	Cut	Scissor	2	Traction/ Suction and cleaning blood	Traction / Suction	Urethra / Blood	Suction/ irrigator	4
		2	Prostate		The remaining posterior wall, including the rectourethralis fibers, is then cut sharply to liberate the prostate	Dissection	Scissor	2	Seminal vesicles are collectively grasped	Holding (Traction)	Seminal vesicle	Grasper	5
									Suction and cleaning of smoke and blood	Suction	Blood	Suction/ irrigator	4
12	Prostate delocation		Prostate		Move the prostate from a surgeon's grasper to assistant's grasper		Bipolar grasper	3	Move the prostate from a surgeon's grasper to assistant's grasper	Holding	Endocatch bag with prostate	Endocatch bag	5
									The prostate is placed in an endocatch bag along with the anterior prostatic fat and is placed in the upper abdominal space for later retrieval	Holding	Endocatch bag with prostate	Endocatch bag	5
13	Vesicourethral anastomosis	1	Urethra/ Bladder	Pelvic wall	The well-dissected bladder is free and mobile and can be easily descended into the pelvis.	Surgical sutures	Bipolar grasper	3	The assistant passes the needle and the suture thread to the surgeon	Holding (Needles)	Needles	Grasper	5
		2		Pelvic wall	The nurse fills up the bladder with water to check the correct operation								
		3							The assistant cuts the suture's thread	Cutting	Suture's thread	Scissor	4
									The needles are snapped out and removed from the body	Holding (Needles)	Needles	Grasper	5
		4	Urethra/ Bladder	Pelvic wall					The hemostatic materials are inserted in the body	Holding	Hemostatic materials	Grasper	4
		5		Pelvic wall					The string for the laparoscopic entrapment sack is transferred to the camera port site at the umbilicus and the abdomen is completely deflated	Holding	Endocatch bag	Endocatch bag	5
14	Endocatch bag Extraction								The specimens within the laparoscopic entrapment sack are extracted intact through extension of the periumbilical trocar site (usually 2.5 cm to 3.5 cm in length)				1
End	Ports closure								The fascial defect is then immediately closed by sutures. The skin defects are then closed with a subcuticular absorbable suture followed by the skin adhesive Dermabond				

9.2 *SARAS Laparoscopic Radical Nephrectomy simplified model*

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar
Initial Phase	Patient positioning		NA		The patient is placed in a modified flank position, with the umbilicus over the break in the operating table. The table can be flexed to 10°-20° for left kidney and 30° for right kidney						NA	
	Pneumoperitoneum		Peritoneum		Hasson trocar is inserted at the level of the umbilicus (at 12-14 mmHg)						Hasson trocar	1
	Port placement		Peritoneum		A four-trocar technique is utilized to complete the dissection. A 11 mm trocar is placed on the midclavicular line 2 cm below the costal margin for the camera; another 11 mm trocar is placed 2 cm above the umbilicus. A 5 mm port can be inserted just under the xyphoid and the last 5 mm trocar is placed 2 cm medial to and sometimes superior to the anterior superior iliac spine. Four ports are generally sufficient to complete the procedure, although a fifth trocar may be necessary for organ entrapment and to retract the left mesocolon during left-sided nephrectomy							
R1	Colon mobilization	1	Line of Toldt	Bowel	Line of Toldt incision	Incision	Scissor	2	Along the white line of Toldt, the colon is reflected	Traction	Grasper	4
		2	Colon	Bowel					Visualization of the anterior surface of Gerota's fascia.	Visualization	Laparoscope	1
		3	Colon	Bowel	The plane between the descending colon and the underlying Gerota's fascia is developed to allow the colon to fall medially	Traction	Grasper	3				
RL2	Colon, spleen and pancreas dissection	1	The splenorenal and lienocolic ligaments	Bowel, pancreas and spleen	The splenorenal and lienocolic ligaments are incised allowing the spleen and the tail of the pancreas to be separated from the upper pole of the kidney	Incision	Monopolar scissor	2	Visualization of the colon, spleen and pancreas.	Visualization	Laparoscope	1
		2	Colon, spleen, Pancreas	Bowel, pancreas and spleen	The dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein	Dissection	Monopolar scissor	2				
RR2	Mobilization of duodenum and vena cava visualization (with Kocher maneuver)		Duodenum Vena cava	Bowel	The duodenum is mobilized medially, using the Kocher maneuver, until the vena cava is clearly visualized	Kocher maneuver	Kocher maneuver	2	Visualization of the Duodenum and Vena cava.	Visualization	Laparoscope	1
RR2B	Retraction of the liver		Liver	Gallbladder					The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5mm trocar below the ribs in the anterior axillary line	Traction	Retractor Grasper	5
R3	Ureter and gonadal vein are identified and retracted laterally	1	Midureter	Vena cava and Aorta					The midureter is located in the retroperitoneal fat medial to the psoas muscle	Visualization	Laparoscope	1
		2	Ureter	Vena cava and Aorta					During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located posterior to this structure	Movement	Grasper	4
		3	Ureter Psoas muscle	Vena cava and Aorta	Once located, the ureter is elevated, revealing the psoas muscle and traced proximally to identify the renal hilum	Traction	Bipolar forceps	3				
		4	Ureter Psoas muscle	Vena cava and Aorta	The grasper is placed beneath the ureter and used to provide anterolateral elevation	Traction	Bipolar forceps	3				
		5	Ureter Psoas muscle	Vena cava and Aorta	Suction and cleaning of smoke and blood	Suction	Suction	2	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~1~~

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar
R4	Renal Hilum Identification	1	Kidney's lower pole	Vena cava and Aorta					The ureter and lower pole of the kidney are elevated	Traction	Grasper	4
		2	Vessels	Vena cava and Aorta	The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator	Suction	Suction	2	~~The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator~~	~~Suction~~	~~Suction~~	4
		3	Kidney's lower pole	Vena cava and Aorta	Firm elevation of the lower pole of the kidney assists in identification and dissection of the renal hilar vessels. This is accomplished by gently placing the lateral grasper under the ureter and kidney until it abuts against the abdominal sidewall	Traction	Bipolar forceps	3				
		4	Renal hilum	Vena cava and Aorta	The surgeon places the renal hilum on tension by lifting the lower pole laterally. With the use of the electrosurgical scissors and the suction-irrigator, the hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis	Isolation	Monopolar scissor	2				
R5	Renal Hilum Transection	1	Renal artery	Vena cava and Aorta	The renal artery is identified and is dissected	Dissection	Monopolar scissor	2	The renal artery is visualized	Visualization	Laparoscope	1
					The surgeon shows the point where put the clips	Dissection	Monopolar scissor	2	The renal artery is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
		2	Renal vein	Vena cava and Aorta	The renal vein is usually identified first and is dissected circumferentially	Dissection	Monopolar scissor	2	The renal vein is visualized	Visualization	Laparoscope	1
					The surgeon shows the point where put the clips	Dissection	Monopolar scissor	2	The renal vein is controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
		3	Lumbar veins	Vena cava and Aorta	Lumbar veins must be identified and divided through a pair of double clips	Dissection	GIA stapler or Hem-O-lock	2	The lumbar veins are visualized	Visualization	Laparoscope	1
					The surgeon shows the point where put the clips	Dissection	Monopolar scissor	2	The lumbar veins are controlled using the Hemoclips	Putting Hemoclip/s	Hem-o-lok clip	4
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar
R6	Mobilization of the Lower Pole, Dissection of the Upper Pole and Adrenal gland	1	Ureteropelvic junction	Vena cava and aorta, tail of the pancreas	Once the ureter is mobilized up to the ureteropelvic junction, forceps are inserted beneath Gerota's fascia and lower pole along the psoas fascia	Blunt dissection	Bipolar forceps	3				
		2	Ureteropelvic junction	Vena cava and aorta, tail of the pancreas	The specimen is lifted superolaterally, and, with the use of the suction-irrigator and electrosurgical scissors, the inferior and posterior sidewall attachments are divided	Blunt dissection	Monopolar scissor	2	The lower pole of kidney is visualized	Visualization	Laparoscope	1
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
		3	Gerota's fascia	Vena cava and aorta, tail of the pancreas	The inferior cone of Gerota's fascia lateral to the ureter is also divided.	Blunt dissection	Bipolar forceps	3	The inferior Gerota's fascia of kidney is visualized	Visualization	Laparoscope	1
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
		4	Kidney's upper pole	Vena cava and aorta, tail of the pancreas	(The adrenal gland can be preserved in simple nephrectomy and particular cases of mid and lower pole tumors, or it is removed intact with the specimen) On the right side, dissection cephalad along the vena cava identifies the adrenal vein. Once it is divided, the superior, medial, and posterior attachments of the adrenal gland are mobilized				The Adrenal gland of kidney is visualized	Visualization	Laparoscope	1
R7	Transection of the Ureter		Ureter						The ureter is visualized	Visualization	Laparoscope	1
			Ureter		The surgeon shows the point where put the clips	Dissection	Monopolar scissor	2	The ureter is controlled using the clips	Putting Hemoclip/s	Hem-o-lok clip	4
			Ureter		The surgeon cuts the ureter	Dissection	Monopolar scissor	2				
			Ureter		Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
R8	Specimen Entrapment and Extraction			Bowel					Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Holding	Endocatch bag	1
End	Ports closure			Bowel					All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures			

9.3 *SARAS Laparoscopic Partial Nephrectomy simplified model*

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar
Initial Phase	Patient positioning		NA		The patient is placed in a modified flank position, with the umbilicus over the break in the operating table. The table can be flexed to 10°-20° for left kidney and 30° for right kidney.						NA	
	Pneumoperitoneum		Peritoneum		Hasson trocar is inserted at the level of the umbilicus (at 12-14 mmHg)						Hasson trocar	1
	Port placement		Peritoneum		A four-trocar technique is utilized to complete the dissection. A 11 mm trocar is placed on the midclavicular line 2 cm below the costal margin for the camera; another 11 mm trocar is placed 2 cm above the umbilicus. A 5 mm port can be inserted just under the xyphoid and the last 5 mm trocar is placed 2 cm medial to and sometimes superior to the anterior superior iliac spine. Four ports are generally sufficient to complete the procedure, although a fifth trocar may be necessary for organ entrapment and to retract the left mesocolon during left-sided nephrectomy							
P1	Colon mobilization	1	Line of Toldt	Bowel	Line of Toldt incision	Incision	Scissor	2	Along the white line of Toldt, the colon is reflected	Traction	Grasper	4
		2	Colon	Bowel					Visualization of the anterior surface of Gerota's fascia.	Visualization	Laparoscope	1
		3	Colon	Bowel	The plane between the descending colon and the underlying Gerota's fascia is developed to allow the colon to fall medially	Traction	Grasper	3				
PL2	Colon, spleen and pancreas dissection	1	The splenorenal and lienocolic ligaments	Bowel, pancreas and spleen	The splenorenal and lienocolic ligaments are incised allowing the spleen and the tail of the pancreas to be separated from the upper pole of the kidney	Incision	Monopolar scissor	2	Visualization of the colon, spleen and pancreas	Visualization	Laparoscope	1
		2	Colon, spleen, Pancreas	Bowel, pancreas and spleen	The dissection of the colon, spleen and pancreas must be completed for the adequate exposure of the renal vein	Dissection	Monopolar scissor	2				
PR2	Mobilization of duodenum and vena cava visualization (with Kocher maneuver)	1	Duodenum Vena cava	Bowel	The duodenum is mobilized medially, using the Kocher maneuver, until the vena cava is clearly visualized	Kocher maneuver	Kocher maneuver	2	Visualization of the Duodenum and Vena cava	Visualization	Laparoscope	1
PR3	Retraction of the liver	1	Liver	Gallbladder					The retraction of the liver to improve the visualization of the renal hilum is done by atraumatic grasper placed through an extra 5-mm trocar below the ribs in the anterior axillary line	Traction	Retractor Grasper	5
P3	Ureter and gonadal vein are identified and retracted laterally	1	Midureter	Vena cava and Aorta					The midureter is located in the retroperitoneal fat medial to the psoas muscle	Visualization	Laparoscope	1
		2	Ureter	Vena cava and Aorta					During proximal mobilization, the gonadal vein is usually first encountered and should be swept medially. The ureter is located just posterior to this structure	Movement	Grasper	4
		3	Ureter Psoas muscle	Vena cava and Aorta	Once located, the ureter is elevated, revealing the psoas muscle and traced proximally to identify the renal hilum	Traction	Bipolar forceps	3				
		4	Ureter Psoas muscle	Vena cava and Aorta	The grasper is placed beneath the ureter and used to provide anterolateral elevation	Traction	Bipolar forceps	3				
		5	Ureter Psoas muscle	Vena cava and Aorta	Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	~~1~~

D1.1 Requirements for surgical actions

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar
P4	Renal Hilum Identification	1	Kidney's lower pole	Vena cava and Aorta					The ureter and lower pole of the kidney are elevated	Traction	Grasper	4
		2	Vessels	Vena cava and Aorta	The vessels entering the renal hilum can be identified and bluntly dissected using the tip of the irrigator-aspirator.	Suction	Suction	2	~~The vessels entering the renal hilum are identified and bluntly dissected using the tip of the suction-irrigator~~	~~Suction~~	~~Suction~~	4
		3	Kidney's lower pole	Vena cava and Aorta	Firm elevation of the lower pole of the kidney assists in identification and dissection of the renal hilar vessels. This is accomplished by gently placing the lateral grasper under the ureter and kidney until it abuts against the abdominal sidewall	Traction	Bipolar forceps	3				
		4	Renal hilum	Vena cava and Aorta	The surgeon places the renal hilum on tension by lifting the lower pole laterally. With the use of the electrosurgical scissors and the suction-irrigator, the hilum is identified by moving cephalad along the medial aspect of the ureter and renal pelvis	Isolation	Scissor	2				
P5	Kidney is mobilized	1	Gerota's fascia; Perirenal Fat		The kidney is mobilized within Gerota's fascia and defatted, maintaining perirenal fat over the tumor	Blunt Dissection	Monopolar scissor	2	Visualization of the Gerota's fascia	Visualization	Laparoscope	1
		2	Gerota's fascia; Perirenal Fat			Traction	Grasper	3	During proximal mobilization, the gonadal vein is usually first encountered and swept medially. The ureter is located posterior to this structure	Movement	Grasper	4
P6	Securing the Renal Blood Vessels	1	Renal artery and vein	Vena cava and Aorta	The renal artery and vein are individually dissected. The renal vein is usually identified first and is dissected circumferentially	Dissection	Scissor	2	Visualization of the renal artery and vein	Visualization	Laparoscope	1
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
									Holding the tissues near to renal artery and vein	Holding	Grasper	4
		2	Renal vein	Vena cava and Aorta	Renal vein must be identified and clamped taking care not to include the ureter	Dissection	Satinsky clamp	2	Visualization of the renal vein	Visualization	Laparoscope	1
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
									Holding the tissues near to renal vein	Holding	Grasper	4
		3	Renal artery	Vena cava and Aorta	The renal artery is identified and clamped, taking care not to include the ureter	Dissection	Satinsky clamp	2	Visualization of the renal artery	Visualization	Laparoscope	1
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
									Holding the tissues near to renal artery	Holding	Grasper	4

Phase code	Phase	Step	Anatomical site	Forbidden Regions	Main Surgeon Task	Surgical Action	Instrument type	Trocar	Assistant Task	Surgical Action	Instrument type	Trocar
P7	The tumor is excised	1	Kidney		Tumor dissection is preferentially developed in a medial-to-lateral direction	Dissection	cold Endoshears	2	Visualization of the tumor	Visualization	Laparoscope	1
					Suction and cleaning of smoke and blood	Suction	Suction	3	~~Suction and cleaning of smoke and blood~~	~~Suction~~	~~Suction~~	4
P8	Renorrhaphy	1	Kidney	Renal calyx	Three to 5 interrupted sutures are placed over a pre-prepared Surgicel bolsterthat has been positioned over the cut surface of the kidney. A Hem-o-Lok clips secured on the suture to prevent it from pulling through	Surgical sutures	Niddle Driver	2	Visualization of the tumoral zone	Visualization	Laparoscope	1
						Surgical sutures	Niddle Driver	3	A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	4
		2	Kidney	Renal calyx	Biologic hemostatic gelatin-matrix-thrombin tissue sealant FloSeal is applied to the cut renal parenchymal surface underneath the bolster.	Surgical sutures	Niddle Driver	2	Visualization of the renal parenchymal surface	Visualization	Laparoscope	1
						Surgical sutures	Niddle Driver	3	Holding the tissues near to cut surface	Holding	Grasper	4
		3	Kidney	Renal calyx	An Hem-o- Lok clip is applied to the suture flush in order to adjoin the opposite renal surface, compressing the kidney. The suture is then tightly tied across the bolster, maintaining adequate parenchymal compression	Surgical sutures	Niddle Driver	2	Visualization of renal surface	Visualization	Laparoscope	1
						Surgical sutures	Niddle Driver	3	A Hem-o-Lok clips secured on the suture	Putting Hemoclip/s	Hem-o-lok clip	4
P9	The hilum is unclamped (it is removed only once hemostasis is confirmed)	1	Renal hilum		The Satinsky clamps are removed only once hemostasis is confirmed	Removal	Satinsky clamps	2				
P10	Specimen Entrapment and Extraction	1		Bowel					Intra-abdominal entrapment of the specimen is performed to facilitate removal. If it is to be removed intact through an incision, an Endocatch device is recommended. Once the specimen is placed into the sack, the opening is withdrawn through the trocar site. Using electrocautery, the trocar site is enlarged to allow extraction of the specimen	Holding	Endocatch bag	1
End	Ports closure	1		Bowel					All port sites are irrigated with betadine and closed with Vicryl and Ethilon sutures			