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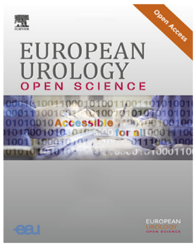

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The First Entirely 3D-Printed Training Model for Robot-assisted Kidney Transplantation: The RAKT Box

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Abstract

Background: Robot-assisted kidney transplantation (RAKT) is increasingly performed at selected referral institutions worldwide. However, simulation and proficiency-based progression training frameworks for RAKT are still lacking, making acquisition of the RAKT-specific skill set a critical unmet need for future RAKT surgeons.
Objective: To develop and test the RAKT Box, the first entirely 3D-printed, perfused, hyperaccuracy simulator for vascular anastomoses during RAKT.
Design, setting and participants: The project was developed in a stepwise fashion by a multidisciplinary team including urologists and bioengineers via an iterative process over a 3-yr period (November 2019–November 2022) using an established methodology. The essential and time-sensitive steps of RAKT were selected by a team of RAKT experts and simulated using the RAKT Box according to the principles of the Vattituki-Medanta technique. The RAKT Box was tested in the operating theatre by an expert RAKT surgeon and independently by four trainees with heterogeneous expertise in robotic surgery and kidney transplantation.
Surgical procedure: Simulation of RAKT.
Measurements: Video recordings of the trainees' performance of vascular anastomoses using the RAKT Box were evaluated blind by a senior surgeon according to

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the Global Evaluative Assessment of Robotic Skills (GEARS) and Assessment of Robotic Console Skills (ARCS) tools.

Results and limitations: All participants successfully completed the training session, confirming the technical reliability of the RAKT Box simulator. Tangible differences were observed among the trainees in both anastomosis time and performance metrics. Key limitations of the RAKT Box include lack of simulation of the ureterovesical anastomosis and the need for a robotic platform, specific training instruments, and disposable 3D-printed vessels.

Conclusions: The RAKT Box is a reliable educational tool to train novice surgeons in the key steps of RAKT and may represent the first step toward the definition of a structured surgical curriculum in RAKT.

Patient summary: We describe the first entirely 3D-printed simulator that allows surgeons to test the key steps of robot-assisted kidney transplantation (RAKT) in a training environment before performing the procedure in patients. The simulator, called the RAKT Box, has been successfully tested by an expert surgeon and four trainees. The results confirm its reliability and potential as an educational tool for training of future RAKT surgeons.

1. Introduction

Robot-assisted kidney transplantation (RAKT) from living donors is currently performed at selected referral institutions worldwide [1]. Despite the greater logistical and technical challenges, RAKT has also been carried out from deceased donors, who are still the main source of grafts for kidney transplantation (KT) [2,3]. Notably, most RAKTs reported to date have been performed by urologists, and the involvement of urologists in RAKT programs is growing [4].

In this context, a critical unmet need is the training of future RAKT surgeons, regardless of their previous robotic and/or KT expertise. A recent systematic review revealed that even surgeons experienced in robotic urologic surgery and open KT must carry out a non-negligible number of cases to reach proficiency [5,6]. Thus, the development of standardized modular training programs is strongly warranted to provide surgeons with the RAKT-specific skill set needed for a “safe” learning curve. This is important, as surgical skill acquisition is probably the most relevant barrier to widespread implementation of RAKT programs worldwide (beyond the availability of robotic platforms and cost considerations).

Mirroring the aviation and military sectors, and as already implemented in other robotic urological settings, the “old-fashioned” learning process based on mentoring of trainees by senior surgeons when directly operating on patients should be progressively transformed towards more transparent, objective, metric-based training frameworks [7].

Such contemporary pathways should rely on surgical simulation [8], whose value has been effectively applied using three-dimensional (3D) printing technology. A recent systematic review concluded that 3D printing shows revolutionary promise for patient counseling, preoperative and intraoperative surgical planning, and education in urology, potentially representing a step towards meeting the expectations of patients and surgeons [9].

Although ex vivo models have been proposed for RAKT [10–16], none of these are universally accepted or currently included in recognized RAKT training programs. Here we describe the RAKT Box, the first entirely 3D-printed, hyperaccuracy simulator for vascular anastomoses during RAKT.

2. Materials and methods

2.1. *Development phase: creation of the RAKT Box*

The project was developed in a stepwise fashion by a multidisciplinary team including urologists and bioengineers from Medics3D (Turin, Italy; www.medics3d.com) via an iterative process and an established methodology [17] over a 3-yr period (November 2019–November 2022).

The project involved several steps:

- Step 1: extensive review of the literature on 3D models for simulation of surgical procedures in urology (eg, radical prostatectomy, partial nephrectomy) and specifically in the field of KT [9].
- Step 2: evaluation of the detailed macroscopic and microscopic anatomic characteristics of the external iliac vessels and renal vessels.
- Step 3: selection of the essential and time-sensitive steps of RAKT according to the Vattituki-Medanta technique [18] that are critical for postoperative outcomes and require modular training for surgeons.
- Step 4: brainstorming between the engineering and medical teams to design a novel, entirely 3D-printed, perfused, hyperaccuracy simulation platform (including a hydraulic circuit) to train novice surgeons in vascular anastomoses for RAKT (project concept and design).
- Step 5: use of 3D printing technology to build the simulation platform.
- Step 6: testing of the simulation platform in the operating room by multiple surgeons using a da Vinci robotic platform.

These steps led to the creation of an entirely 3D-printed simulator (Supplementary Fig. 1).

2.2. *RAKT Box components*

The final simulator includes a fixed model of the human pelvis, disposable right iliac vessels, a kidney with a disposable renal artery and vein, and a hydraulic circuit to simulate arterial and venous blood flow (Fig. 1).

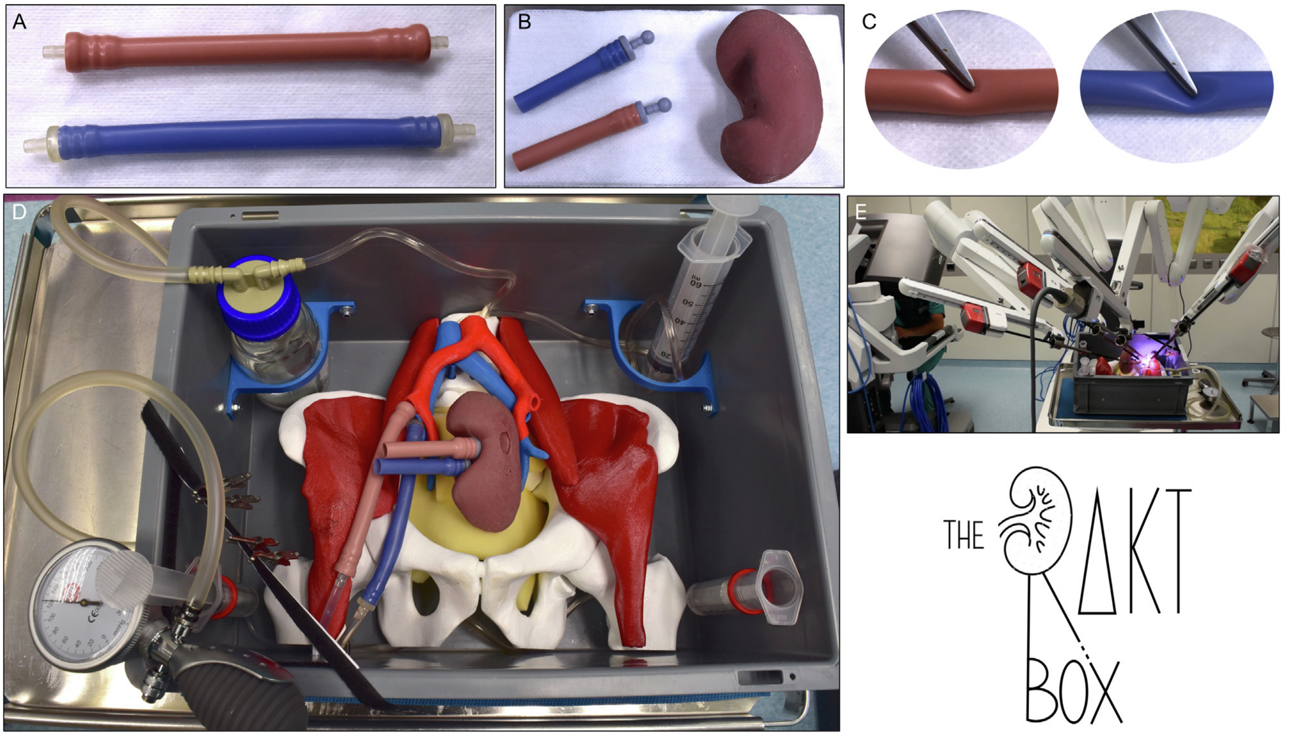

Fig. 1 – Overview of the RAKT Box, an entirely 3D-printed, perfused, hyperaccuracy simulator for vascular anastomoses during robot-assisted kidney transplantation. (A) Disposable 3D-printed iliac vessels (artery in light brown; vein in blue). (B) 3D-printed graft with disposable renal artery (in light brown) and renal vein (in blue). (C) Applying the same pressure on the 3D-printed disposable vessels, the compressibility and consistency of the vessel walls differ, and are significantly greater for the artery than for the vein, mirroring a real-life scenario. (D) Overview of the components of the RAKT Box. To build the 3D-printed model, multiphase computed tomography scan images in DICOM format were processed by Medics3D using dedicated software authorized for medical use (Materialise; Mimics Medical, Leuven, Belgium) to obtain hyperaccuracy 3D reconstructions of the individual patient's anatomy. For bone components, arteries, and veins, fused deposition modeling (FDM) technology and poly(lactic acid) material were chosen to obtain a rigid model. For psoas and iliac muscles and the bladder, a soft material was chosen. For the soft kidney model, the mould was created with FDM technology and rigid material; a silicon elastomer was subsequently injected into the mould. (E) Overview of the RAKT Box in the operating theatre after docking of the robotic platform.

Two different geometries were studied for arteries and veins to obtain a more realistic exercise for anastomosis. The arterial wall is thicker and stiffer than the venous wall, which is more elastic. The arterial and venous models were processed by Bysini (Gyeonggi-do, Korea; www.bysini.com). Different diameters and wall thicknesses were tested and validated. The optimal result for the artery model is 10 mm in diameter with a wall thickness of 1.2 mm (six layers of 0.2 mm), while for the vein model the diameter is 10 mm with a wall thickness of 0.6 mm (three layers of 0.2 mm).

An arterial and venous hydraulic circuit was developed to simulate blood flow with water stream to obtain a more realistic exercise for teaching the surgical technique. The circuit was composed of a bottle reservoir filled half with water and half with air. A hand pump with a gauge was connected to the bottle cap to increase the free surface air pressure to 120 mm Hg (ie, systolic arterial pressure) and fill the arterial model with water at the same hydrostatic pressure. For the venous tract, the vessel was filled with water through a syringe and kept at atmospheric pressure.

To assemble the model, the reusable renal and external iliac vessels are inserted into the model before starting the training session using a predefined connection. Then the pressure in the arterial system is set at 120 mm Hg using a sphygmomanometer. The venous system is connected without setting any active pressure, and the circuit is then filled with water.

The renal vessels are inserted into the silicon model of the kidney, which is then placed in the box on a soft support base simulating the pelvic floor. Supplementary Video 1 shows a detailed overview of the step-by-step installation of the simulator.

2.3. Testing phase: simulation of vascular anastomoses using the RAKT Box

The main steps for vascular anastomoses performed by trainees using the RAKT Box are summarized as follows (shown in the accompanying Video).

(1) Once the robotic platform is docked in a four-arm configuration, mirroring the real procedure for RAKT [18], four bulldog clamps are placed on a strip at the right-upper corner of the box.

(2) The first step of the training exercise is to correctly place the kidney into the pelvis, close to the external iliac vessels, to allow subsequent performance of vascular anastomoses. This step mirrors the real-life need to place the kidney close to the external iliac vessels after having introduced the graft through either a periumbilical incision or a Pfannenstiel incision [19]. The RAKT Box allows the surgeon to reproduce this critical step of the intervention, which could significantly increase the second warm ischemia time (SWIT) during RAKT, especially when performed by less experienced surgeons.

(3) Once the graft is in the correct position next to the iliac vessels, the renal artery is gently flipped and kept down on the kidney, mirroring the real-life configuration of the graft during bench surgery. This is another critical step of the procedure, as it facilitates performance of the venous anastomosis, potentially reducing SWIT.

(4) The bulldog clamps are then placed on the external iliac vein (first on the distal portion of the vein and then on the proximal portion) after proper identification of the anastomosis site. Then

a venotomy is performed to achieve an ogival hole in the external iliac vein, tailored to the length of the renal vein. For this step, the RAKT Box allows the trainee to become familiar with the following key RAKT tasks:

a. To reduce the time required to correctly place the bulldog clamps as much as possible, with the goal of minimizing SWIT;
b. To correctly identify the best site for the venotomy and subsequent venous anastomosis; and
c. To practice venotomy with different instruments (eg, cold scissors, robotic Potts scissors).

(5) The venous anastomosis is performed in an end-to-side fashion to the external iliac vein using a 6-0 GORE-TEX suture (Gore Medical, Flagstaff, AZ, USA), exactly mirroring the real-life procedure. The 3D-printed material for both the renal and external iliac veins allows simulation of the venous anastomosis with a high degree of fidelity and without any unwarranted damage to the vessels by the needle or the robotic instruments. After completion of the posterior wall of the anastomosis using a running suture, the anterior wall is completed using the same thread in a running fashion.

(6) Once the venous anastomosis is completed, a third bulldog clamp is placed on the renal vein (oriented distally toward the “patient’s feet”). Then the external iliac vein is unclamped (removing the proximal bulldog clamp first, and then the distal clamp). This phase allows a realistic test of the watertightness of the venous anastomosis thanks to the hydraulic circuit of the RAKT Box (the test is easily performed by the trainee by injecting some water into the venous circuit).

(7) The next training step is to clamp the external iliac artery using two bulldog clamps (which should be placed first proximally and then distally). The site of the arterial anastomosis is critical and should be carefully identified, avoiding a site that is too medial in order to minimize the risk of kinking after the graft is flipped over the iliac vessels for placement in the extraperitoneal pouch.

(8) A linear arteriotomy is performed (using a robotic scalpel or standard monopolar scissors) and subsequently converted to a circular arteriotomy (using either monopolar scissors or a laparoscopic aortic punch) to facilitate the anastomosis. It is important to note that the model allows realistic appreciation of arterial “flow” and “pressure” thanks to the perfused hydraulic circuit, for which the pressure is set to 120 mm Hg.

(9) The renal artery is anastomosed in an end-to-side fashion to the external iliac artery using one or two 6-0 GORE-TEX sutures, mirroring the real-life technique for RAKT [3]. Of note, the consistency is significantly higher for the arterial vessels than for the venous vessels, allowing reliable simulation of needle passages through the arterial wall.

(10) After completion of the arterial anastomosis, the renal artery is clamped, orienting the bulldog clamp proximally towards the “patient’s head”. The bulldogs clamps positioned on the external iliac artery can be now removed, while checking for the watertightness of the arterial anastomosis.

(11) The graft is then revascularized by removing the bulldog clamps from the renal vessels (venous clamp first, followed by the arterial clamp).

2.4. *Evaluation of trainees’ performance with the RAKT Box*

The RAKT Box was tested in the operating theatre by an expert RAKT surgeon and independently by four trainees with heterogeneous expertise in robotic surgery and kidney KT. For the simulation exercises, all surgeons followed an established technique [3] using GORE-TEX 6.0 running sutures for both anastomoses.

The Video recordings of the trainees’ performance were evaluated blind by a senior surgeon who was not involved in the test according to the Global Evaluative Assessment of Robotic Skills (GEARS) and Assessment of Robotic Console Skills (ARCS) tools [20,21].

Supplementary Video 2 shows the key steps of the training exercise performed by all trainees.

3. Results

All participants successfully completed the training session, confirming the technical reliability of the RAKT Box simulator.

While all participants completed the vascular anastomoses, there were tangible differences between the trainees in both the anastomosis time and the performance metrics (Figures 2–5). In particular, the time required to perform the arterial and venous anastomosis was <15 min for the expert RAKT surgeon and up to 36 min for trainees.

4. Discussion

In the current era, simulation and proficiency-based progression training are becoming essential components of modular surgical programs [22]. A randomized trial showed that simulation-based training yielded better surgical proficiency and more favorable outcomes [8]. Notably, the more technically demanding the operative procedures, the greater is the requirement for carefully constructed training curricula that offer skill maturation in a safe environment [23]. Thus, immediate feedback from skilled instructors and an opportunity for deliberate practice are essential components of technique mastery; these strategies are best implemented in a laboratory setting such as with the RAKT Box.

In the RAKT scenario, although previous ex vivo models have been proposed [10–16], the RAKT Box represents a user-friendly, easy-to-transport (40 cm × 30 cm × 16 cm) box with unique features that might be of value for surgeons in training. To the best of our knowledge, it is the first entirely 3D-printed simulator allowing trainees to perform arterial and venous anastomoses with disposable vessels and a reliable hydraulic circuit (simulating blood flow and pressure). Second, the model was specifically designed using fixed and disposable items, allowing their easy replacement after each exercise (Supplementary Video 1).

Third, to simulate the differential intraoperative feeling of venous and arterial anastomoses, the disposable vessels were designed using different 3D-printed geometric configurations.

Fourth, the RAKT Box may allow the surgeon to simulate vascular anastomoses in the case of grafts with multiple vessels (Supplementary Fig. 2). By increasing the number of renal vessels connected to the “hilum” of the graft model, the surgeon may perform a variety of techniques, with or without ex vivo reconstruction techniques for bench surgery. For instance, in case of a graft with two renal arteries and one renal vein, the surgeon may perform two separate anastomoses or a single anastomosis to the external iliac artery after conjoined (side-to-side) arterial anastomosis (pantaloon fashion).

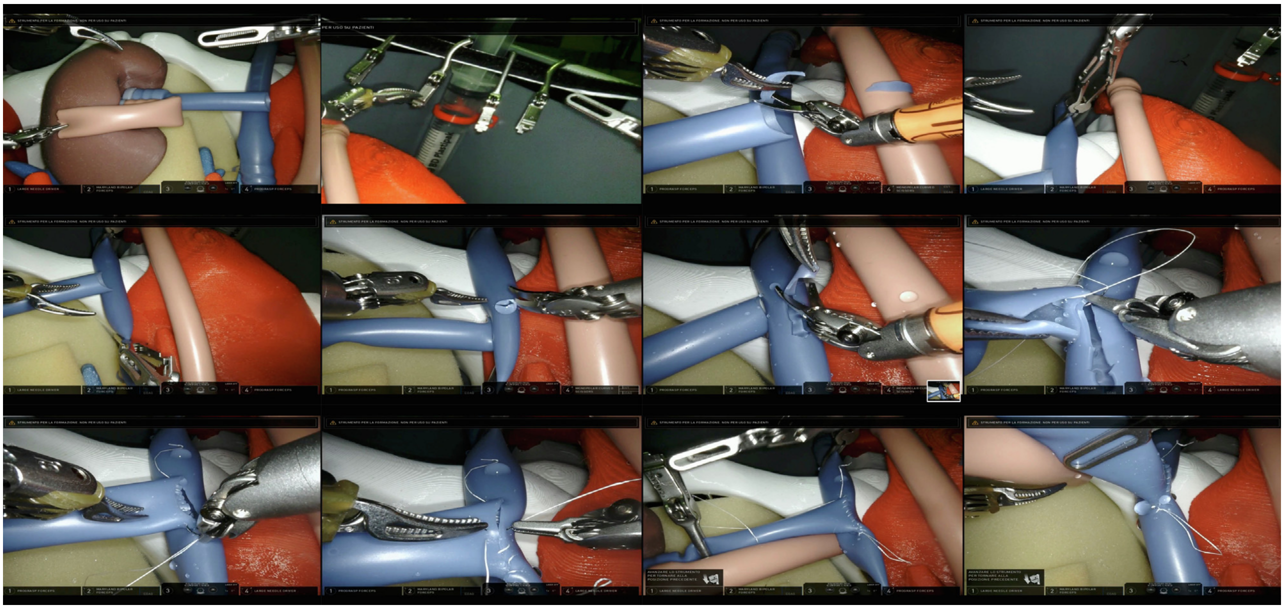

Fig. 2 – **Intraoperative images captured during training exercises using the RAKT Box showing the main phases of the venous anastomosis. The venous anastomosis is completed in an end-to-side fashion to the external iliac vessels using a 6-0 GORE-TEX suture with a CV-6 TTc-9 needle (Gore Medical), as described in Section 2.3, according to the principles of the Vattikuti-Medanta technique [3].**

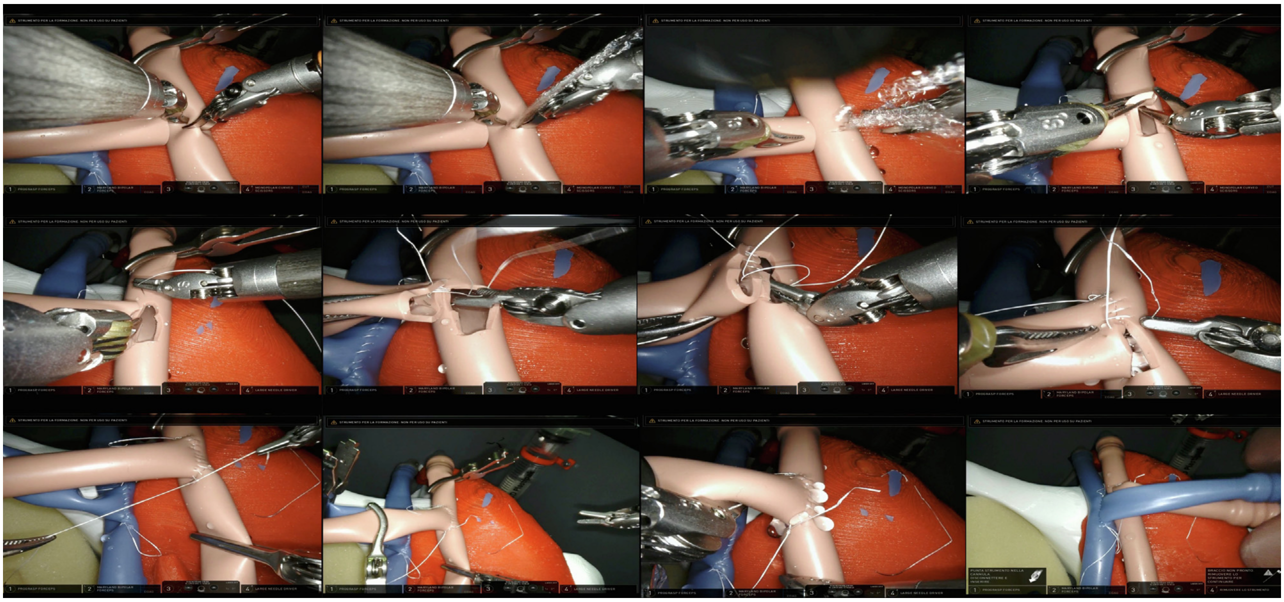

Fig. 3 – **Intraoperative images captured during training exercises using the RAKT Box showing the main phases of the arterial anastomosis. The arterial anastomosis is completed using two half-running sutures with 6-0 GORE-TEX with a CV-6 TTc-9 needle, as described in Section 2.3, according to the principles of the Vattikuti-Medanta technique [3].**

Lastly, while it was specifically designed for RAKT, the RAKT Box can also be easily used for training in open vascular anastomoses.

The RAKT Box allows replication of vascular anastomoses and other key steps of the procedure with a high degree of fidelity in comparison to the real-life scenario, as shown in the accompanying Video.

Taken together, these features of the RAKT Box allow the creation of a training environment to simulate a variety of real-life surgical scenarios beyond a “standard” RAKT (eg, challenging anastomoses, vascular lesions, erroneous placement of bulldog clamps). Therefore, trainees could progressively improve not only pure technical skills (finesse and time efficiency) but also nontechnical skills (situation awareness, leadership, teamwork, and communication [24]). Moreover, the RAKT Box could theoretically allow training not only for the operating surgeon but also for the assistant regarding the key technical phases of the pro-

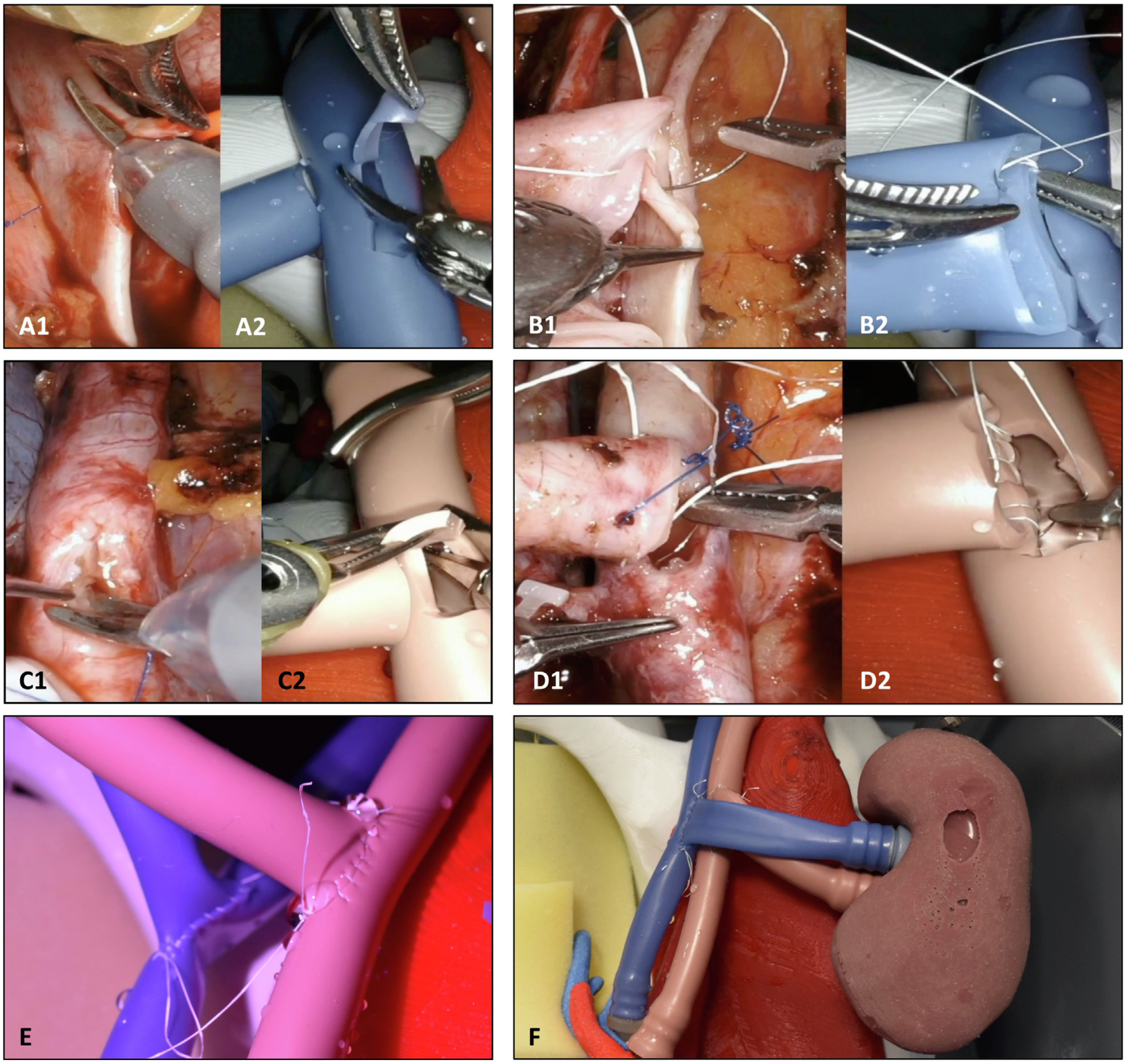

Fig. 4 – Intraoperative images showing the performance of venous (A1–B2) and arterial (C1–D2) anastomoses during a real-life robot-assisted kidney transplantation and during a simulation exercise using the RAKT Box. (A1, A2) Venotomy in the external iliac vein. (B1, B2) End-to-side venous anastomosis between the graft renal vein and the external iliac vein using a running suture. (C1, C2) Arteriotomy in the external iliac artery. (D1, D2) End-to-side arterial anastomosis between the graft renal artery and the external iliac artery using a running suture. (E) Overview of the completed venous and arterial anastomoses in the RAKT Box. (F) After completion of the vascular anastomoses, the graft is flipped over the anastomoses and positioned into the "extraperitoneal pouch" (in the RATK box, over the psoas muscle).

cedures and their timing, as well as the specific instruments required for RAKT. Coordination between the surgeon and the bedside assistant is a critical factor affecting the overall SWIT, as well as the intraoperative safety of RAKT.

In the future, the box might even allow analysis of surgical gestures as a method to quantify surgical performance [25], potentially improving clinical outcomes and reducing the burden and cost of the learning curve.

However, surgical simulators should not be used as standalone tools. The RAKT Box should ideally be integrated into comprehensive, standardized surgical curricula for RAKT that aim to achieve a reproducible learning process while ensuring patient safety. For instance, surgeons could use this simulator as a preliminary exercise before more advanced training sessions on animal models during structured RAKT courses [26].

Despite its novelty, the model has a few limitations. First, it does not allow simulation of ureterovesical anastomosis. However, while ureterovesical anastomosis is a key step in KT, it is not time-dependent and could be safely performed during other urologic procedures for training purposes. Second, the RAKT Box does not entirely replace training on animal models, which allow surgeons to reliably experience the challenges and stress of real-life RAKT. However, the model can be a complementary preliminary step that could ensure adequate training in basic technical skills for vascular anastomoses. Third, the RAKT Box requires a robotic platform, specific training instruments, and disposable 3D-printed vessels. Although a formal cost-effectiveness analysis was beyond the aim of our study and the RAKT Box is not yet commercially available, the estimated costs for the RAKT Box, as provided by Medics3D, are €5000 for the entire box (including all fixed 3D-printed elements, the graft, and the hydraulic circuit) and €100 for disposable 3D-printed renal and iliac vessels, to be renewed after two to four training exercises.

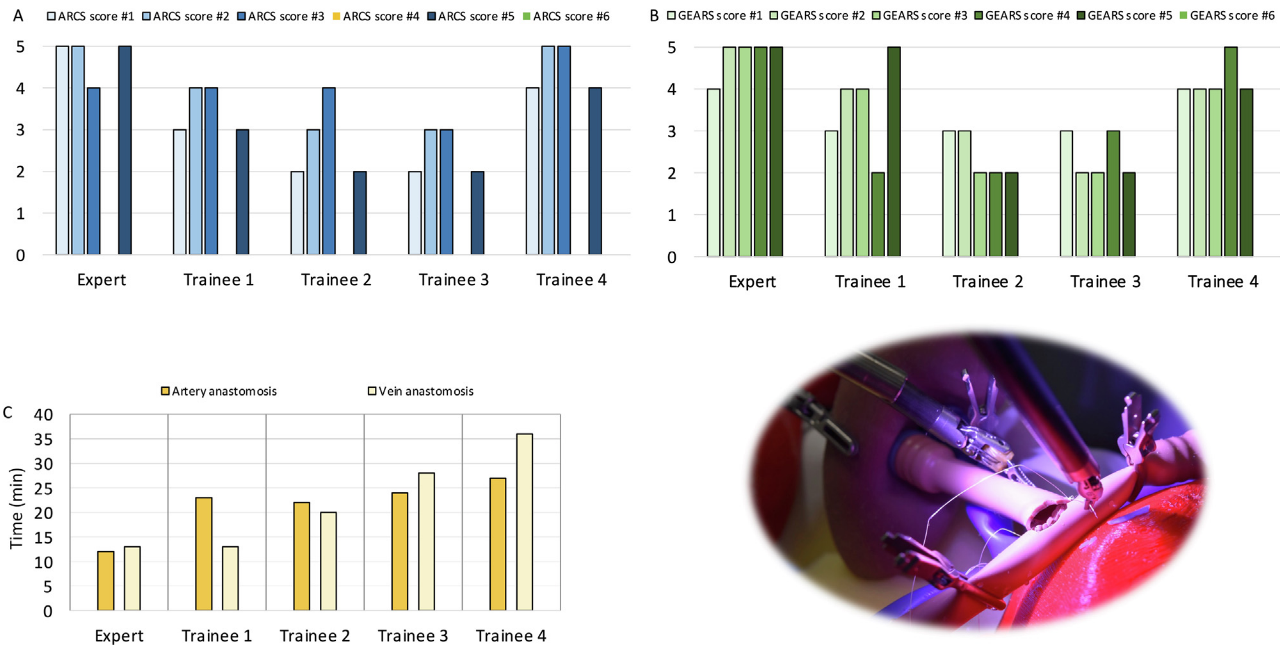

Fig. 5 – Graphical overview of the trainees' performance in vascular anastomoses using the RAKT Box. (A) Assessment of trainees' performance according to the Assessment of Robotic Console Skills (ARCS) tool. The ARCS domains included: (1) dexterity with multiple wristed instruments (1 = attempts to complete most tasks without taking advantage of wristed degrees of freedom; 5 = efficiently uses wristed degrees of freedom for all tasks); (2) optimizing the field of view (1 = does not attempt to optimize the view before or during task performance; 5 = consistently and efficiently optimizes the view); (3) instrument visualization (1 = does not visualize the instrument tips before moving them; 5 = consistently and efficiently visualizes the instrument tips before moving them, or has situational and spatial awareness of the instrument tips to move them safely even when off-screen); (4) optimizing the master manipulator workspace (not evaluated); (5) force sensitivity and control (1 = repeatedly damages tissue or sutures due to unintentional excessive force; 5 = consistently applies correct technique to prevent any damage to tissue or sutures); and (6) basic energy pedal skills (not evaluated). (B) Assessment of trainees' performance according to the Global Evaluative Assessment of Robotic Skills (GEARS) tool. The GEARS tool includes: (1) depth perception (1 = constantly overshoots the target, wide swings, slow to correct; 5 = accurately directs instruments in the correct plane to the target); (2) bimanual dexterity (1 = uses only one hand, ignores nondominant hand, poor coordination; 5 = expertly uses both hands in a complementary way to provide the best exposure); (3) efficiency (1 = inefficient efforts; many uncertain movements; constantly changing focus or persisting without progress; 5 = confident, efficient, and safe conduct, maintains focus on task, fluid progression); (4) force sensitivity (1 = rough moves, tears tissue, injures nearby structures, poor control, frequent suture breakage; 5 = applies appropriate tension, negligible injury to adjacent structures, no suture breakage); (5) autonomy (1 = unable to complete the entire task, even with verbal guidance; 5 = able to complete task independently without prompting); and (6) robotic control (not evaluated). (C) Overview of the time required to complete the venous and arterial anastomoses by each surgeon involved in the training exercises using the RAKT Box.

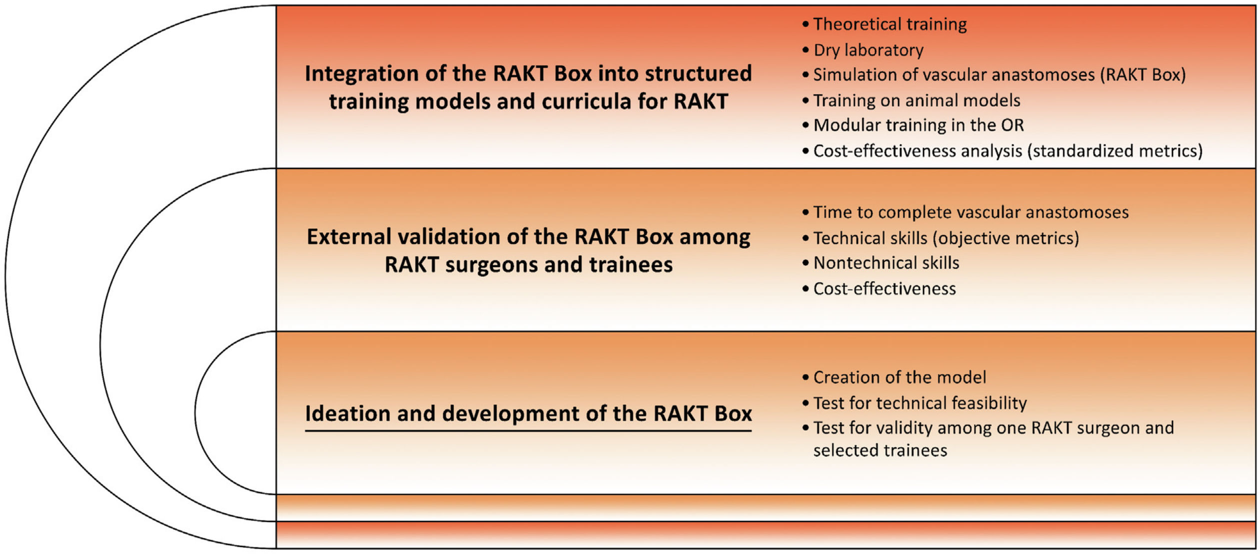

Fig. 6 – Project design and further steps required to integrate the RAKT Box in a structured surgical curriculum for robot-assisted kidney transplantation (RAKT). After the ideation and development of the RAKT Box (the subject of the current study), external validation of the simulator among RAKT surgeons and trainees is needed to evaluate the impact of this tool on surgeons' learning curve and patient outcomes, as well as its cost effectiveness. Finally, the RAKT Box should be integrated into structured proficiency-based curricula for RAKT that include simulation, training on animal models, and modular training in the operating room (OR).

Having acknowledged these limitations, our newly developed, entirely 3D-printed simulator, which was designed by RAKT surgeons, is a reliable and useful educational tool for training novice surgeons.

The RAKT Box might open new horizons in the field of robotic kidney transplantation from clinical, educational, and research standpoints (Fig. 6). In particular, while our aim was to provide surgeons with a reliable instrument for training in the basic skills required for RAKT, further research is needed to validate the model among RAKT surgeons and to integrate the RAKT Box into structured curricula for RAKT.

5. Conclusions

The RAKT Box is the first entirely 3D-printed, hyperaccuracy simulator for vascular anastomoses during RAKT. It is a reliable educational tool for training novice surgeons in the key steps of RAKT, and may represent the first step towards definition of a structured surgical curriculum in RAKT, as well as an opportunity to minimize the learning curve of future surgeons.

Author contributions: Riccardo Campi had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Campi, Vignolini, Breda, Serni.
Acquisition of data: Campi, Pecoraro.
Analysis and interpretation of data: Campi, Pecoraro.
Drafting of the manuscript: Campi, Pecoraro.
Critical revision of the manuscript for important intellectual content: Campi, Pecoraro, Vignolini, Spatafora, Sebastianelli, Sessa, Li Marzi, Territo, Decaestecker, Breda, Serni.
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Appendix A. Supplementary data

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