Multi-Center Phase II Study of the Clinical Use of the Avicenna Roboflex

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Abstract

Objectives: To present the results of a multicentric phase-II study, representing the next step according to the IDEAL-criteria in the evualuation process of robot-assisted flexible ureterorenocopy.

Material and methods: The Avicenna Roboflex consists of a console and the manipulator. Peri-operative data from 266 patients who underwent robotic retrograde intra-renal stone surgery (robRIRS) between January 2015 and March 2016 at two centres (Heilbronn, Ankara) were recorded prospectively. Six surgeons were involved in the study. We treated 90 females and 176 male patients with a mean age of 55 (25-76) years. 118 stones were located on the right and 148 on the left side. Mean number of stones was 1.8 with a mean stone burden of 1620 (98-10600)mm³; 43% of the patients were pre-stented. A 12/14F access sheath was used in all cases; laser fragmentation was accomplished by a high-energy laser device applying actual concepts of laser lithotripsy.

Results: Preparation of the robot required 4:30min (range 3-8min); docking time was 4 min (range 1-29min). Console time to identify the stone amounted 4min (range 1-12min.); total operating time was 96 min (range 58-193min) including a console time of 65(16-174) min. Laser lithotripsy was performed in 245 patients (92%), 112(42%) patients required extraction of larger fragments using N-gage-basket. The stone clearance rate amounted 25(9-101)mmÂ³/min. Total fluoroscopy time was time 2:30min with a radiation dosis of 297 cGy*cm². 117(44%) of our patients were stented post-operatively of which 75(28%) had the stent on a string removed on day 1 together with the Foley catheter. In 2(0.7%) cases we had to convert to classical FURS due to technical failure of the robot. Median post-operative hospital stay was 1(1-30) day. We encountered one case of urosepsis (Clavien 3a) requiring treatment on an intensive care unit.

Conclusion: In this setting, Avicenna Roboflex proved to be robust with only two cases of technical failure requiring conversion to classical FURS. The radiation exposure for the surgeon can be significantly reduced. In conclusion, we were able to integrate the device easily in our daily routine.

Keywords: Avicenna roboflex; Intra-renal stone; Ureteroscopy

Abbreviations: robRIRS: robotic Retrograde Intra-Renal Stone Surgery; SD: Standard Deviation; NIRF: Near-Infrared Fluorescent

Introduction

Management of urolithiasis changed dramatically during the last decades. Whereas in the eighties and nineties of last century extracorporeal shock wave lithotripsy dominated the spectrum of endourological techniques, recently percutaneous surgery and especially retrograde intra-renal surgery has gained significant importance [1]. This was possible because of the continuous improvements of endourological armamentarium and miniaturization of the instruments [2-8]. Nevertheless, flexible ureteroscopy respectively retrograde intra-renal surgery is limited by ergonomic deficiencies including stone manipulation, laser disintegration or extraction of fragments particularly when treating multiple stones or larger renal calculi

[9,10]. Thus, the next level of stone management may represent robot-assisted retrograde intra-renal surgery overcoming most of these technological obstacles.

Similar to robot-assisted laparoscopic surgery, such devices represent master-slave systems (Figure 1) [11-15]. First trials modifying a system designed for cardiology (Hansen, United States) were not very successful due to size limitations and limited mobility in the renal collecting system [11-13]. Since 2010 we were involved in experimental and clinical introduction of the Avicenna Roboflex (Elmed, Ankara, Turkey), which was specifically designed for flexible ureteroscopy [14,15]. Beside proof of safe and efficient applicability, the device underwent

constant improvements by the manufacturer. In this article we want to present the results of the multi-centric phase-II study, representing the next step (phase 3) according to the IDEAL (idea, development, evaluation, assessment, long-term study)-criteria [15,16].
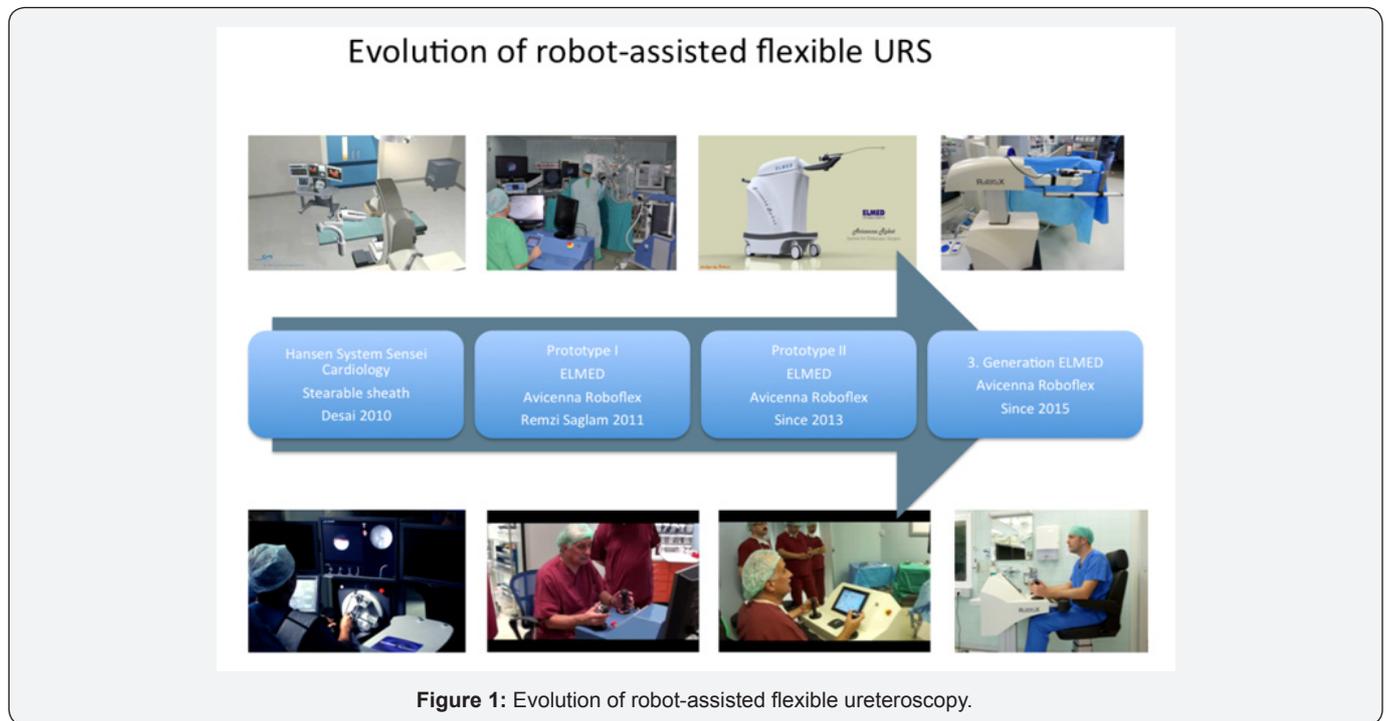

Figure 1: Evolution of robot-assisted flexible ureteroscopy.

Material and Methods
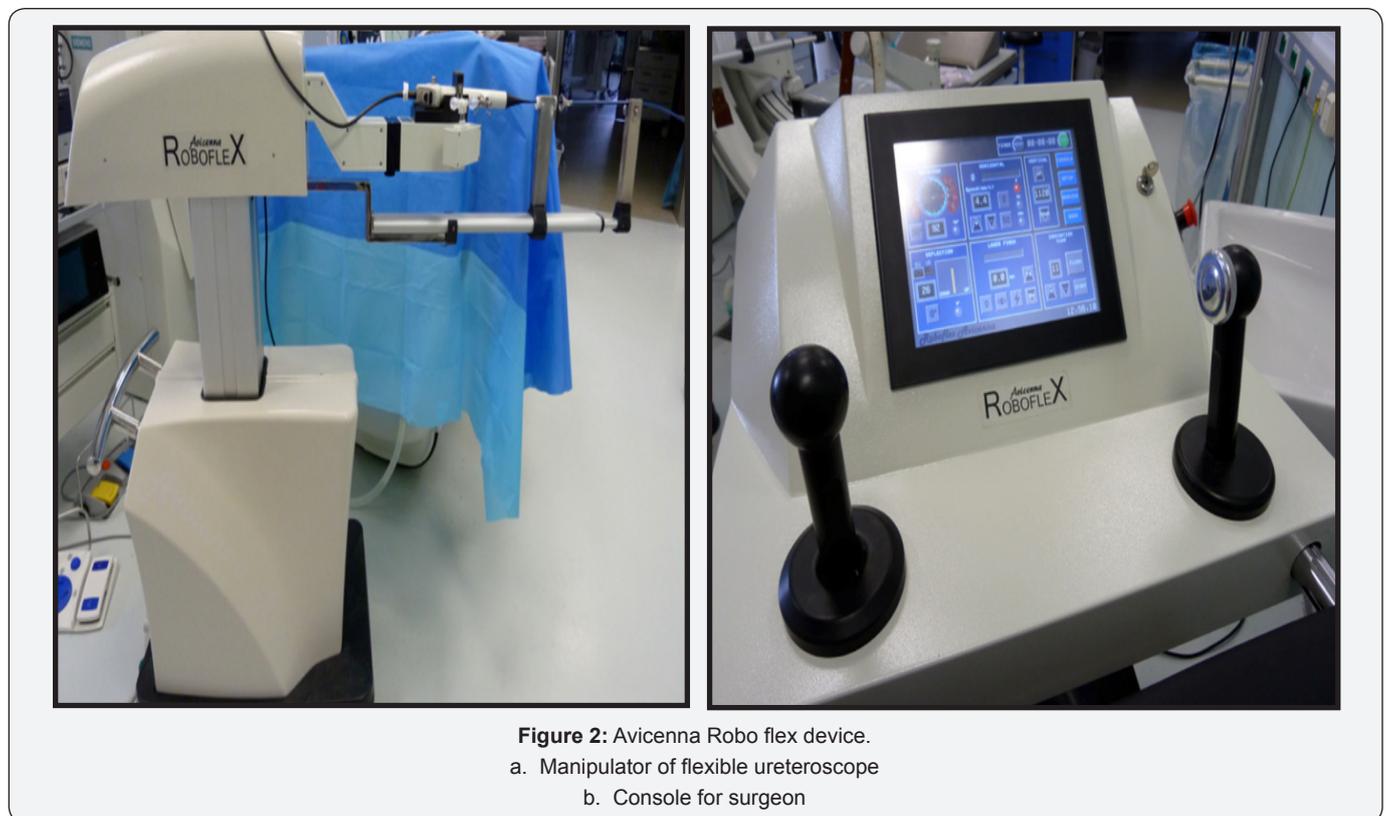
Specification of the robotic device

Figure 2: Avicenna Robo flex device.
a. Manipulator of flexible ureteroscope
b. Console for surgeon

The Avicenna Roboflex consists of a console and the manipulator (Figure 2). The basic functions of the device have been described previously. The main improvements include:

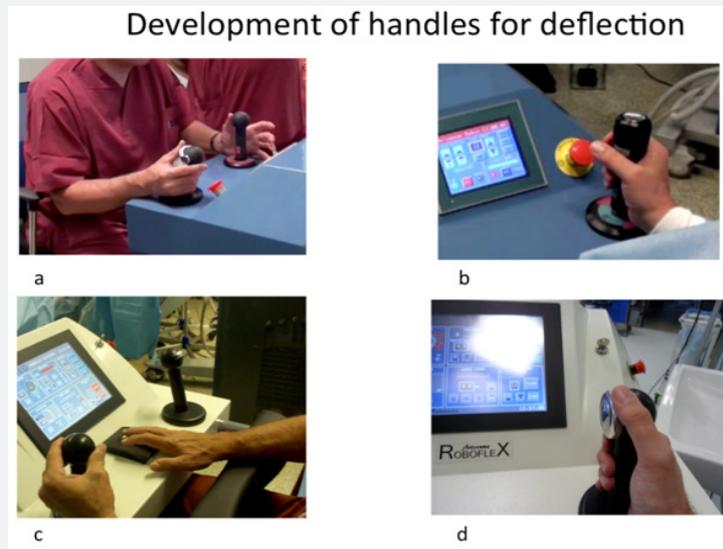o   Control of deflection using a wheel for the right hand (Figure 3).

Development of handles for deflection

Figure 3: Developmental steps of right handle for deflection.

a. Prototype with small joy-stick, no fine adjustments.

b. Prototype with adjustable handle like hand-piece of classical ureteroscope.

c. Handlle with hand-piece like hand-piece of classical ureteroscope plus central wheel for fine-adjustment.

d. "Magic" wheel for fine and classical movements of the ureteroscope.

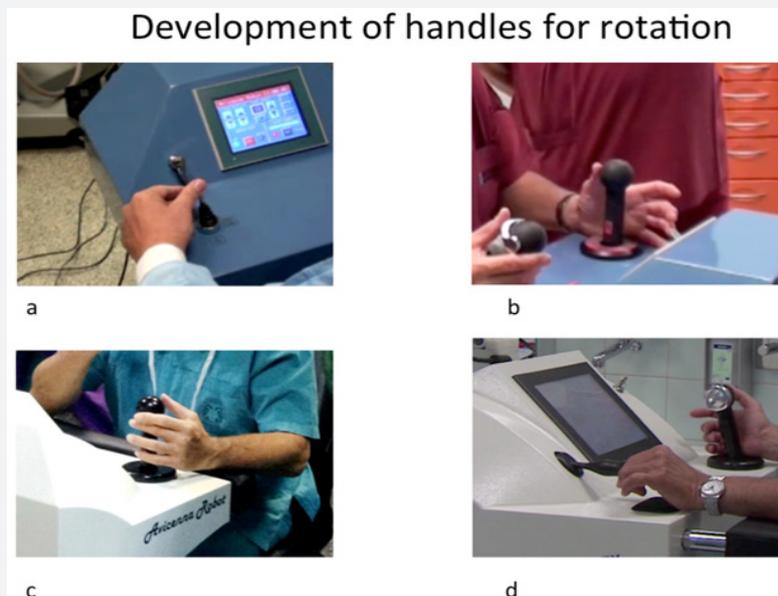o   Control of rotation and horizontal movements via refined joy-stick (Figure 4).

Development of handles for rotation

Figure 4: Developmental steps of left handle for rotation and advancement.

a. Prototype with small verticaljoy-stick, no fine adjustments.

b. Prototype with large vertical handle no fine adjustments.

c. Vertical handle with variable speed adjustable at console.

d. Horizontal joy-stick with variable speed adjustable at console.

o	Integrated HD-monitor displaying the endoscopic view and major data defining the position of the tip of the flexible ureteroscope (Figure 5).
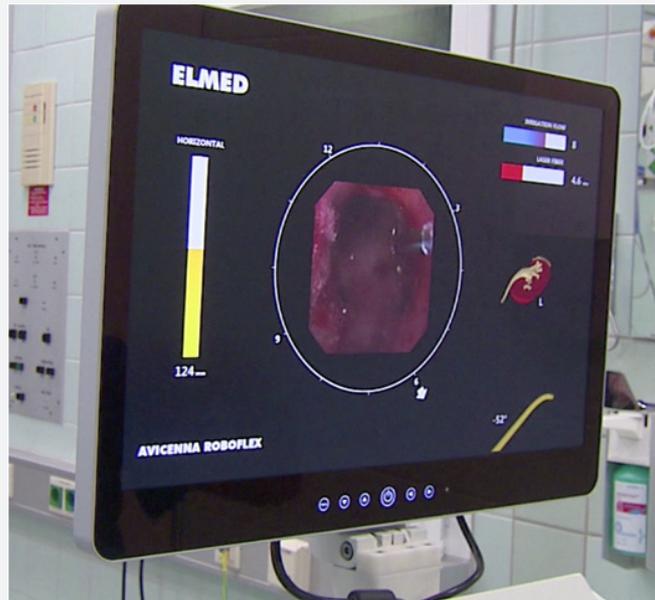

Figure 5: Screen at console showing the endoscopic HD-video with display of additional information (rotation, insertion, positionofscope in collecting system).

o	Exchangeable handle for three different digital flexible ureterorenoscopes (Karl Storz Flex X2; Olympus URF-V2; Wolf Cobra digital)

o	Air driven control unit to activate foot pedals of laser and fluoroscopy

Patient data (Table 1)

Table 1: Summary of patients data of robot-assisted flexible ureteroscopy (N=266).

Criteria	Value	Range	Comment
Age (yrs)	55	25-76	No children included
Gender			
Male	176		
Female	90		
Body mass index (BMI)	29.1	20.6-43.3	
ASA-score (mean)	2.3		
Side of Kidney			
right	118		
left	148		
Mean number of calculi	1.8	1-5	N=192 cases with multiple stones
Stone size (mm)	14	5-30	Multiple calculi: sum of lenghts
Stone volume (mm^3)	1620	98 -10600	Calculated based on preoperative CT
No. of patients with stent	114		

Following the introduction of the robot in 2 European stone centres (2013 Ankara TR; 2014 Heilbronn, Germany) we collected prospectively peri-operative data from all patients (n=266) who underwent robotic retrograde intra-renal stone surgery (robRIRS) between January 2015 and March 2016. Six different surgeons were involved in the study. We treated 90 females and 176 male patients with a mean age of 55(25-76) years. The body mass index was 29.1(20.6-43.3) and ASA-score was 2.3. 118 stones were located on the right and 148 on the left side. Mean number of stones was 1.8 with a mean stone burden of 1620(98-10600)mm^3. 43% of the patients were presented.

Treatment protocol

All stones of this study were treated with the Flex X2-ureteroscope (Karl Storz, Tuttlingen, Germany). In all cases we used a 12/14F access sheath, laser fragmentation was accomplished by use of a high-energy laser device (Lumenis Pulse 100W, United States) applying actual concepts of laser lithotripsy [17] including dusting (low energy (0.2-0.5 J), high frequency (20-40 Hz)), fragmentation (high energy (1.0-1.5 J), low frequency (10-15 Hz)), and the pop-corn/jacuzzi-effect (mid energy (0.5-1.0 J), mid frequency (20-30 Hz)). Larger fragments (2-4 mm) were extracted by use of the NGage-device (Cook, Ireland). Recorded performance parameter included set-up time of the robot, docking time of the robot, console time to stone contact, overall console time, treatment time, stone clearance rate, x-ray parameters (fluoroscopy time, radiation exposure and desimetry).

Statistics

Numerical data were expressed as mean with standard deviation (SD) including range; categorical data as number. SPSS program version 15 was used for data analysis. Categorical variables were analysed using Chi-squared test (or Fisher's exact test). Mann-Whitney test was used for numeric variables. P-values less than 0.05 were considered statistically significant.

Results

Intra-operative data (Table 2)

Table 2: Summary of perioperative results of robot-assisted flexible ureteroscopy (N=266).

Criteria	Value	Range	Comment
Time to prepare robot (min)	4.5	3-8	Performed parallel to placement of access sheath
No. of patients with access sheath	266		According to protocol
Docking time of robot (min)	4	1-29	
Time to identify stone	4	1-12	Including inspection of collecting system
Operating time			
Total	96	58-193	
Console time	65	16-174	
No of case with laserlithotripsy	245		Dusting, popcorn / Jacuzzi
Stone clearance rate (mm^3/min)	25	9-101	
Radiation exposure			
Mean fluoroscopic time (min)	2.5		No radiation exposure for surgeon at console
Radiation dosis ($cGy*cm^2$)	297		
Technical failure of robot	2		Conversion to classical FURS / RIRS (0.7 %)
Major complications	1		Urosepis (0.35 %)
Mean hospital stay (d)	1	1-30	

Preparation of the robot required 4:30min (range 3-8min); docking time was 4min (range 1-29min).Console time to visible identification of the stone amounted 4min (range 1-12min.), which included inspection of the entire collecting system.

The total operating time was 96min (range 58-193min) including a console time of 65(16-174) min. Laser lithotripsy was performed in 245 patients (92%), 112(42%) patients required extraction of larger fragments using N-gage-basket. The stone clearance rate amounted 25(9-101)mm³/min. Total fluoroscopy time was time 2:30min with a radiation dosis of 297 cGy*cm². In 117(44%) of our patients were stented postoperatively of which 75(28%) had the stent on a string removed on day 1 together with the Foley catheter. In 2(0.7%) cases we had to convert to classical FURS due to technical failure of the robot.

Post-operative data

Median postoperative hospital stay was 1(1-30) day. We encountered one case of urosepsis (Clavien 3a) requiring treatment on an intensive care unit.

Discussion

During the last 15 years robot-assisted surgery has gained an established and irreversible role in urologic laparoscopic surgery [18,19]. In 2016, installations of da Vinci-systems increased by 21% to more than 2,500 units worldwide, and robotic procedures leaped by 25% to more than 450,000, mainly performed in urology, gynaecology and visceral surgery [19]. The main advantages of robot-assisted surgery concern significant improvement of ergonomics, which enabled widespread

application of laparoscopic techniques with acceptable learning curves. Additionally, the use of the robot resulted in better results mainly concerning reconstructive parts of the procedure: e.g. postoperative stenosis of the urethro-vesical anastomosis could be basically eliminated.

However, the use of robotic master-slave-systems is not limited to laparoscopic surgery. Already, in 2008 Desai et al. accomplished to use the Sensei-Magelan-system (Hansen Medical, Mountain View, USA) designed for cardio-vascular interventions by Fred Moll, the inventor of the da Vinci-system to perform robot-assisted flexible ureterorenoscopy [12,13]. In this system, the surgeon sits also in front of a console manipulating a steerable flexible tube (Figure 1) usually used for trans-vascular intra-cardiac interventions. The robotic flexible catheter system consists of an outer catheter sheath (14/12F) and inner catheter guide (12/10F). A 7.5F fibre-optic flexible ureteroscope was inserted through the inner catheter guide. Remote manipulation of the catheter system manoeuvres the ureteroscope tip, which was glued in place to the inner guide. The tip of the outer sheath was positioned at uretero pelvic junction to stabilize navigation of inner guide inside the collecting system. This means that the ureteroscope is manipulated only passively [13]. However, this project has been discontinued because it was difficult to manipulate the ureteroscope passively by use of the steerable tube.

Since 2012, ELMED (Ankara, Turkey) is working on of a robot specifically designed for FURS [14]. Roboflex Avicenna was continuously developed to perform flexible ureteroscopy providing all necessary functions for FURS. It enables the use of different kind of ureteroscopes and holmium-YAG-lasers. The surgeon sits at a console using both hands and feet to control all movements of the endoscope. Compared to manual FURS several functions could be integrated: it enables fine-tuning of the movements, motorized insertion and retraction of the laser fibre, automatic repositioning for introduction of the fibre. This means, that robotic FURS has superior performance qualities compared to the classic procedure. In the first clinical study the positive impact of the system on ergonomics could be verified using a validated questionnaire [15]. However, in this study one urologist (R.S.) being involved in development and clinical introduction of the device proctored all seven surgeons during their cases.

The present study was conducted to assess the *real-live scenario* when using the device on a daily base in two urologic departments involving six different surgeons. Furthermore, new technical improvements of Avicenna Roboflex were evaluated. Comparing our results with the initial study docking time of the robot was longer (4 vs. 1min), time to visualize the stone was similar (4 vs. 3.7min) and the console time was longer (96 vs. 53min). However, the stone volume was larger (1620 vs. 1300mm^3). Moreover, we were able to demonstrate that we could safely and successfully apply all modern techniques and protocols of flexible URS, such as laser dusting, using pop-corn/Jacuzzi-effect, and extraction of larger fragments [17].

In this setting, Avicenna Roboflex proved to be robust with only two cases of technical failure requiring conversion to classical FURS. The radiation exposure for the surgeon can be significantly reduced. In conclusion, we were able to integrate the device easily in our daily routine.

The first two clinical studies of Avicenna Roboflex were able to demonstrate safety and efficacy of the system providing significant ergonomic advantages with a very short learning curve for an FURS-experienced surgeon (max 5 cases). Of course, retrograde intra-renal surgery is less complicated compared to laparoscopic radical prostatectomy, particularly in case of small stones, which can be extracted by use of a Nitinol-basket [20]. On the other side, the introduction of the device provides a safe and non-exhausting environment for the surgeon. Based on this we were able to extent the indication of FURS/RIRS to larger intra-renal calculi resulting to decrease of extracorporeal shock wave lithotripsy and percutaneous nephrolithotomy [21,22].

Further studies should now focus to evaluate further the impact of these advantages on the results compared to classical FURS/RIRS. This has to include the analysis of lifetime of the ureteroscopes, requirement of secondary treatment, post-operative complications and radiation exposure to the surgeon [23-26]. The outcomes of these studies are relevant when discussing the costs of the device. In contrast to radiology, where new imaging devices are introduced without proving any cost-effectiveness, in surgery the introduction of robotic systems is always associated by cost-discussions.

However, development of robotic systems will never stop. Beyond surgical robots as master-slave devices, the role of robotics might be even extended: Shademan et al. described *in-vivo* supervised autonomous soft tissue surgery in an open surgical setting, enabled by a plenoptic three-dimensional and near-infrared fluorescent (NIRF) imaging system supporting an autonomous suturing algorithm to complete complex surgical tasks on deformable soft tissue, such as suturing an intestinal anastomosis [27]. Similarly, robot-assisted water-jet-ablation (Procept, Redwood Shores, United States) showed significantly better ablation efficacy compared to standard transurethral resection [28]. Next years will be fascinating to evaluate the impact of robot-assistance for laparoscopy, but also for robot-assisted flexible ureterorenoscopy.

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