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Comparative Analysis of Avicenna Roboflex® and Conventional Ureteroscopy: A Porcine Model Study of Safety and Feasibility in Stone Management

Avicenna Roboflex® Ile Konvansiyonel Üreteroskopinin Karşılaştırılması: Taş Tedavisinde Güvenlik Ve Uygulanabilirliğin Domuz Modelinde Deneysel Analizi

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ABSTRACT

Objective: Robotic-assisted ureteroscopy is increasingly adopted in endourology. We aimed to evaluate the feasibility and safety of the Avicenna Roboflex® Urology system (Elmed, Ankara, Turkey) compared with conventional ureteroscopy in a porcine model.

Materials and Methods: The Avicenna Roboflex® platform was compared with conventional ureteroscopy in a live porcine model (n = 6) in the supine lithotomy position. Two experienced endourologists assessed task performance using Likert scales (1–4) for accuracy/workaround and ease of completion. Intraoperative events and ureteral injury were evaluated using the post-ureteroscopic lesion scale (PULS, 0–5). Histopathological assessment of tissue samples was performed by a blinded pathologist. Paired comparisons were performed using the 2-sided Wilcoxon signed-rank test, with $p < 0.05$ considered statistically significant.

Results: A total of 12 ureteroscopic procedures (6 conventional, 6 robotic) were completed without intraoperative complications. Histopathological analysis revealed no significant differences between groups, with minimal epithelial loss observed only in the proximal ureter. Task performance scores were comparable between groups; however, the robotic system showed a trend toward improved ease in flexible ureteroscope insertion and simulated stone removal. PULS scores were low and similar in both groups.

Conclusion: The Avicenna Roboflex® system demonstrated procedural feasibility and an acute tissue safety profile comparable to conventional ureteroscopy in this porcine model. Given the exploratory nature and small sample size of the study, these findings should be considered preliminary and require validation in adequately powered studies.

Keywords: kidney calculi, robotic surgical procedures, ureteroscopy

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ÖZET

Amaç: Robotik destekli üreteroskopi endoürolojide giderek daha fazla kullanılmaktadır. Bu çalışmada, Avicenna Roboflex® Üroloji sisteminin (Elmed, Ankara, Türkiye) uygulanabilirliği ve güvenliği, konvansiyonel üreteroskopi ile domuz modelinde karşılaştırıldı.

Gereç ve Yöntemler: Avicenna Roboflex® platformu, canlı domuz modelinde (n = 6) supin litotomi pozisyonunda konvansiyonel üreteroskopi ile karşılaştırıldı. İki deneyimli endoürolog, işlemlerin başarıyla tamamlanmasını doğruluk/alternatif çözüm ve görev tamamlama kolaylığı açısından Likert ölçeği (1–4) ile değerlendirdi. İntraoperatif olaylar ve üreter hasarı, post-üreteroskopik lezyon skoru (PULS, 0–5) ile değerlendirildi. Doku örnekleri kör bir patolog tarafından histopatolojik olarak incelendi. Eşleştirilmiş karşılaştırmalarda iki yönlü Wilcoxon işaretli sıralar testi kullanıldı ve $p < 0.05$ anlamlı kabul edildi.

Bulgular: Toplam 12 üreteroskopi işlemi (6 konvansiyonel, 6 robotik) komplikasyonsuz olarak tamamlandı. Histopatolojik değerlendirmede gruplar arasında anlamlı fark saptanmadı; epitel kaybı yalnızca proksimal üreterde minimal düzeyde gözlendi. Görev performans skorları benzerdi; ancak robotik sistem, fleksibl üreteroskopun yerleştirilmesi ve taş çıkarımını simüle eden işlemlerde daha iyi görev tamamlama kolaylığı eğilimi gösterdi. PULS skorları her iki grupta da düşük ve benzerdi.

Sonuçlar: Avicenna Roboflex® sistemi, bu domuz modelinde konvansiyonel üreteroskopi ile karşılaştırıldığında benzer prosedürel uygulanabilirlik ve akut doku güvenliği profili göstermiştir. Çalışmanın keşifsel niteliği ve küçük örneklem büyüklüğü göz önüne alındığında, bu bulgular öncül nitelikte değerlendirilmeli ve yeterli güce sahip ileri çalışmalarla doğrulanmalıdır.

Anahtar Kelimeler: böbrek taşları, robotik cerrahi prosedürler, üreteroskopi

INTRODUCTION

Urolithiasis remains a significant global health burden, with increasing incidence and recurrence rates worldwide (1). Over the past decades, ureteroscopy (URS) has evolved into a cornerstone modality for the management of urinary tract stones due to its minimally invasive nature, high stone-free rates, and favorable safety profile (2,3,4). In particular, flexible ureteroscopy (F-URS) has enabled access to all intrarenal calyces, making it an essential tool for the treatment of renal calculi, especially those <2 cm in size (5,6,7). Despite these advantages, conventional ureteroscopy presents several limitations. The procedure is associated with a steep learning curve, prolonged operative times in complex cases, and significant ergonomic strain for surgeons, including musculoskeletal fatigue and radiation exposure (8,9,10). These challenges have prompted the development of robotic-assisted platforms aimed at improving surgical precision, reducing operator fatigue, and enhancing overall procedural efficiency.

Robotic-assisted ureteroscopy has emerged as a promising innovation in endourology. The Avicenna Roboflex® Urology system (Elmed, Ankara, Turkey) is one of the first dedicated robotic platforms designed specifically for flexible ureteroscopy (11). This system allows the surgeon to control the ureteroscope remotely via a console, offering improved ergonomics, tremor filtration, and stable instrument manipulation (12). Early clinical and experimental studies suggest that robotic URS may reduce physical strain and provide comparable or even improved technical performance compared to conventional approaches (13,14).

However, despite growing interest, the current body of evidence on robotic ureteroscopy remains limited, particularly with respect to objective safety outcomes and tissue effects. Preclinical models, such as porcine studies, are critical for evaluating device performance, reproducibility, and potential tissue injury in a controlled environment prior to widespread clinical adoption (15). In this study, we aimed to compare the safety, feasibility, and usability of the Avicenna Roboflex® system with conventional ureteroscopy in a live porcine model. Specifically, we evaluated procedural performance, surgeon-reported outcomes, ureteral injury using the post-ureteroscopic lesion scale (PULS), and histopathological tissue effects.

MATERIALS AND METHODS

This experimental study was designed to evaluate the safety and feasibility of robotic-assisted ureteroscopy compared to conventional ureteroscopy using a live porcine model. As this was an exploratory pilot animal study evaluating the feasibility and safety of a novel robotic platform, no formal a priori sample size calculation was performed. The sample size was determined pragmatically while adhering to the principles of the 3Rs (Replacement, Reduction, and Refinement) in animal research, with the objective of generating preliminary data for future adequately powered studies. The study was designed, conducted, and reported in accordance with the Animal Research: Reporting of In Vivo Experiments (ARRIVE) 2.0 guidelines (16). A total of six female domestic pigs (Sus scrofa domesticus), weighing 41–55 kg (mean, 48.2 kg), were included in the study. Before inclusion in the experimental protocol, all animals underwent a preprocedural veterinary health assessment, including evaluation of vital signs, general physical condition, behavior, activity, breathing, and nutritional status. Only animals considered clinically healthy and suitable for the experimental study by the veterinarian were included; animals with abnormal findings on the preprocedural veterinary assessment were considered ineligible. All procedures were performed under general anesthesia in the supine lithotomy position. Each animal underwent bilateral ureteroscopy, with one ureter assigned to conventional ureteroscopy and the contralateral ureter to robotic-assisted ureteroscopy using the Avicenna Roboflex® system, thereby allowing each animal to serve as its own control. Treatment-side allocation and procedural order were determined using a sealed-envelope randomization method. This resulted in a total of 12 procedures, comprising six conventional and six robotic-assisted ureteroscopies. The porcine model was selected due to its anatomical and physiological similarity to the human urinary tract, allowing a realistic simulation of endourological interventions.

This study was conducted in accordance with institutional and national guidelines for the care and use of laboratory animals. Ethical approval was obtained from the Acıbadem Mehmet Ali Aydınlar University Animal Experiments Local Ethics Committee (Approval No: HDK-2024/33).

Flexible ureteroscopy was performed using a 7.5-Fr flexible ureteroscope (Hugemed). A 9.5/11.5-Fr ureteral access sheath (GUA1,138, Geotek) and a Roadrunner® Hydrophilic PC Wire Guide were used for ureteral access. Irrigation was provided with isotonic saline using a gravity-based system, with the irrigation fluid positioned 60 cm above the operative field. In the robotic group, the flexible ureteroscope was mounted onto the Avicenna Roboflex® Urology system (Elmed, Ankara, Turkey) and manipulated remotely using the dedicated surgeon console, whereas in the conventional group, the ureteroscope was manipulated manually. All procedures were performed by two experienced endourologists familiar with both conventional and robotic techniques.

All procedures followed a standardized protocol. Following induction of anesthesia, ureteral access was obtained over the guidewire, the ureteral access sheath was positioned, and the flexible ureteroscope was advanced into the renal collecting system. Ureteral navigation and manipulation within the upper and lower poles were then performed. Basket manipulation was performed using a Zero Tip™ Nitinol Stone Retrieval Basket (Boston Scientific) to simulate the procedural steps of stone retrieval; no actual stone extraction was performed. No laser lithotripsy was performed during the experimental procedures. The same procedural steps were performed in both groups, differing only in robotic versus manual manipulation of the flexible ureteroscope.

Procedural performance was assessed by the operating endourologists using a 4-point Likert scale for task accuracy and ease of task completion (1=poor, 2=fair, 3=good, and 4=excellent).

All intraoperative events were recorded. At the completion of each procedure, following withdrawal of the ureteroscope and removal of the ureteral access sheath, the ureter was inspected endoscopically for procedure-related injury. Ureteral injury was assessed using the Post-Ureteroscopic Lesion Scale (PULS), ranging from grade 0 to grade 5. The PULS score was assigned by the operating endourologist immediately after completion of the procedure.

Following completion of all experimental procedures, the animals were euthanized under general anesthesia by intravenous administration of 20 mL of 22.5% potassium chloride. Tissue samples were obtained and evaluated by an experienced veterinary pathologist who was blinded to the intervention groups (Figure 1). Histopathological assessment was performed on samples obtained from the renal pelvis, upper pole, lower pole, and proximal ureter. A total of 48 tissue samples were evaluated, with samples obtained from at least three different areas of each tissue. Specimens were fixed in 10% buffered formaldehyde, processed using standard histological procedures, embedded in paraffin, sectioned at a thickness of 4 µm, and stained with hematoxylin and eosin (H&E). Histomorphological findings were assessed according to the predefined scoring matrix specified in the animal study protocol.

Statistical analyses were performed using R software (Version 4.4.1; R Foundation for Statistical Computing, Vienna, Austria). Owing to the small sample size and the ordinal nature of several study variables, non-parametric methods were used. Continuous and ordinal variables were summarized as median (range). Given the paired experimental design, with each animal serving as its own control, comparisons between robotic and conventional ureteroscopy were performed using the 2-sided Wilcoxon signed-rank test. Because the data contained ties and zero differences, *p*-values were calculated using the normal approximation with continuity correction; zero differences were excluded from the ranking procedure, and tied observations were assigned average ranks. A *p*-value <0.05 was considered statistically significant.

RESULTS

A total of 12 ureteroscopic procedures were successfully completed, including six conventional and six robotic-assisted interventions, without any intraoperative complications or technical failures. All predefined procedural steps were achieved in both groups. No statistically significant differences were observed between the conventional and robotic groups for any evaluated parameter (all $p > 0.05$).

Surgeon-based evaluation demonstrated comparable performance between conventional and robotic ureteroscopy. For insertion of the flexible ureteroscope into the renal pelvis, the robotic system showed a higher median accuracy/workaround score of 4 (3–4) compared to 3 (3–4) in the conventional group, while ease of task completion was

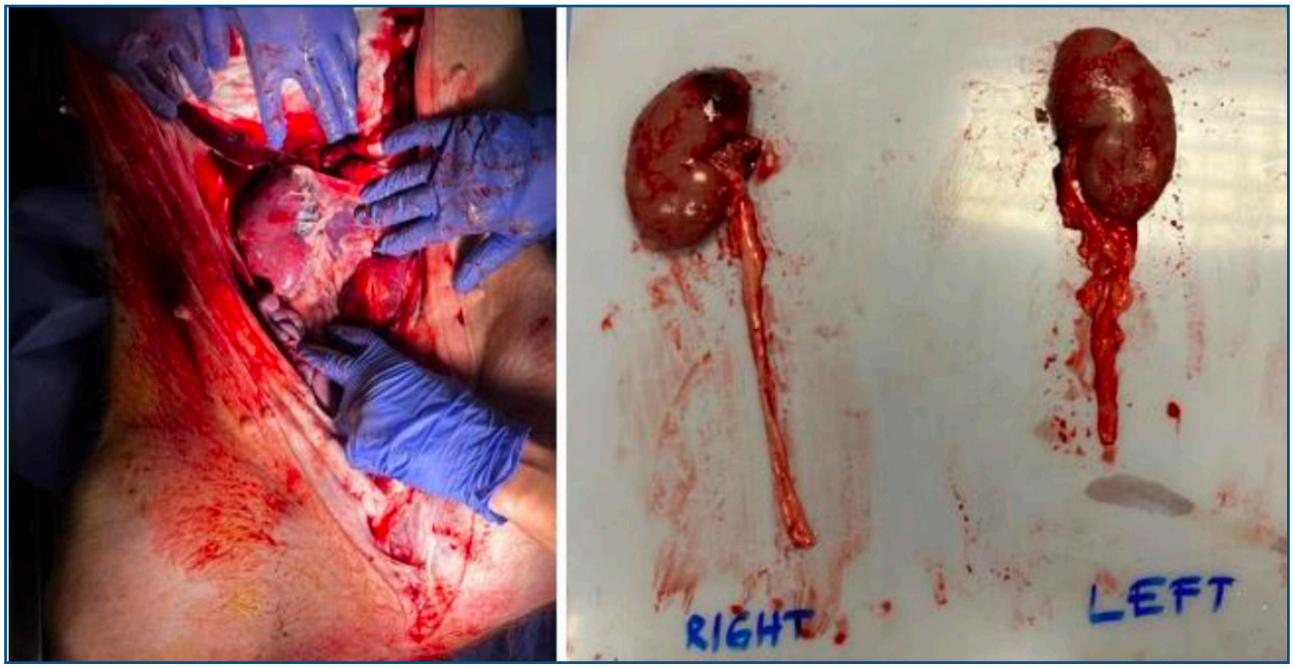


Figure 1. Intraoperative harvesting and macroscopic view of renal and ureteral specimens in the porcine model (right, conventional side; left, robotic-assisted side)

identical in both groups, with a median of 4 (3–4). During manipulation within the upper and lower poles, both approaches achieved maximal performance, with median accuracy/workaround scores of 4 (4–4) and ease of task completion scores of 4 (3–4) (Table 1).

In the simulated stone removal task, which involved retraction of the flexible ureteroscope into the ureteral access sheath followed by re-advancement, both groups demonstrated similar ease of task completion with a median score of 4 (3–4). However, the robotic system maintained a consistent maximal accuracy/workaround score of 4 (4–4), whereas the conventional approach showed a slightly wider range with a median of 4 (3–4).

Assessment of ureteral injury using the Post-Ureteroscopic Lesion Scale (PULS) revealed no clinically relevant differences between the groups, with both approaches demonstrating a median score of 0 (range 0–1), indicating minimal or no ureteral trauma.

Histopathological evaluation demonstrated minimal tissue alterations in both groups. Epithelial loss was confined to the proximal ureter and was focal, involving <25% of the ureteral mucosa (Figure 2). The median epithelial loss score was 1 (1–1) in the conventional group and 1 (0–1) in the robotic group, whereas no epithelial loss was observed in the renal pelvis, upper pole, or lower pole in either group. Focal inflammatory infiltrates consisting of lymphocytes and neutrophils were identified in selected renal specimens from both groups. Based on their histological characteristics, these findings were considered consistent with pre-existing focal nephritis rather than procedure-related acute injury. No pathological alterations were observed in the renal tubules or glomeruli. Overall, no substantial acute histopathological injury was identified in either group.

Table 1. Comparison of histopathological findings, task performance scores, and PULS outcomes between conventional and robotic ureteroscopy in a porcine model

	Control (Conventional)		Test (Avicenna Roboflex®)		p value	
Histopathology Assessment Category						
Epithelial Loss						
Proximal Ureter	1 (1-1)		1 (0-1)		1.000	
Upper Pole	0 (0-0)		0 (0-0)		1.000	
Renal Pelvis	0 (0-0)		0 (0-0)		1.000	
Lower Pole	0 (0-0)		0 (0-0)		1.000	
General Observation						
Proximal Ureter	0 (0-0)		0 (0-0)		1.000	
Upper Pole	0 (0-0)		0 (0-1)		0.500	
Renal Pelvis	0 (0-1)		0 (0-1)		1.000	
Lower Pole	0 (0-1)		0 (0-1)		1.000	
Task Completion Category	Accuracy/ Workaround	Ease of task completion	Accuracy/ Workaround	Ease of task completion	Accuracy/ Workaround	Ease of task completion
Insertion of F-URS in the renal pelvis	3 (3-4)	4 (3-4)	4 (3-4)	4 (3-4)	0.250	1.000
Manipulation within the upper pole with F-URS	4 (4-4)	4 (3-4)	4 (4-4)	4 (3-4)	1.000	1.000
Manipulation within the lower pole with F-URS	4 (4-4)	4 (3-4)	4 (4-4)	4 (3-4)	1.000	1.000
The F-URS is retracted from the renal pelvis into the UAS, then advanced back (simulating stone removal)	4 (3-4)	4 (3-4)	4 (4-4)	4 (3-4)	1.000	1.000
PULS Score	0 (0-1)		0 (0-1)		1.000	

Values: median (range)

Paired comparisons between conventional and robotic ureteroscopy were performed using the 2-sided Wilcoxon signed-rank test.

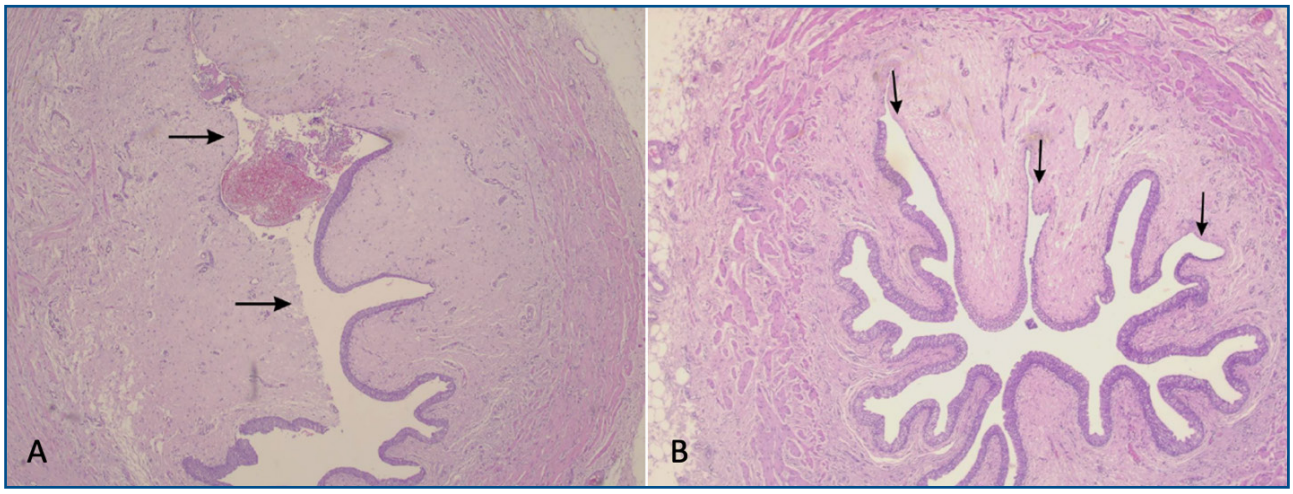


Figure 2. Representative histopathological findings of the proximal ureter following conventional and robotic-assisted ureteroscopy. (A) Conventional ureteroscopy showing focal epithelial loss involving <25% of the ureteral mucosa (arrows; H&E, ×4). (B) Robotic-assisted ureteroscopy showing similarly limited focal epithelial loss involving <25% of the ureteral mucosa (arrows; H&E, ×4).

DISCUSSION

In this experimental study, we evaluated the safety and feasibility of robotic-assisted ureteroscopy using the Avicenna Roboflex® system compared to conventional ureteroscopy in a live porcine model. Our findings demonstrated comparable procedural performance and safety outcomes between the two approaches, with no intraoperative complications, no clinically relevant ureteral injuries, and minimal histopathological alterations. These results are in line with previous studies demonstrating that ureteroscopy is a highly effective and safe modality for the management of urinary stone disease (17,18).

A key observation in this study is the comparable performance between robotic and conventional ureteroscopy across all evaluated tasks. Both techniques achieved high scores in accuracy and ease of task completion. Notably, the robotic platform showed a trend toward improved performance during ureteroscope insertion and simulated stone manipulation. Previous studies evaluating robotic flexible ureteroscopy have similarly reported enhanced instrument stability, improved dexterity, and better control of endoscope movements, which may contribute to improved technical performance (19,20).

Ergonomic challenges are well recognized in conventional ureteroscopy, particularly in prolonged or complex procedures. Surgeons are frequently exposed to awkward postures and repetitive movements, which may lead to musculoskeletal strain over time. Robotic systems have been proposed as a solution to these limitations by allowing console-based operation and reducing physical burden. Prior studies have demonstrated that robotic ureteroscopy may significantly improve surgeon ergonomics and reduce fatigue, potentially translating into improved procedural efficiency (21).

In line with our findings, a recent systematic review and meta-analysis reported that robotic ureteroscopy achieves high stone-free rates of approximately 86%, supporting its effectiveness as a minimally invasive treatment option (22). Although our study is preclinical, the comparable safety profile and procedural performance observed between robotic and conventional approaches are consistent with these clinical data, further supporting the feasibility of robotic-assisted ureteroscopy while highlighting the need for future standardized and comparative studies.

From a safety standpoint, our results are particularly reassuring. The absence of significant differences in PULS scores between groups indicates that robotic manipulation does not increase the risk of ureteral injury. Furthermore, histopathological analysis revealed only minimal epithelial changes without evidence of deeper tissue damage. These findings are consistent with existing literature showing that ureteroscopy, when performed under controlled conditions, is associated with low complication rates and minimal tissue trauma (14,23).

The use of a porcine model represents a major strength of this study, allowing controlled evaluation of both procedural performance and tissue effects in a setting that closely mimics human anatomy. However, several limitations should be acknowledged. This study should be interpreted as a hypothesis-generating pilot investigation rather than a definitive comparative study. The limited sample size, which was determined according to ethical principles governing animal experimentation, substantially restricts statistical power and increases the possibility of type II error. Consequently, the absence of statistically significant differences should not be interpreted as evidence of equivalence between the two approaches. Instead, these findings provide preliminary proof-of-concept data that may inform the design and sample size estimation of future adequately powered preclinical and clinical studies. Another limitation is the lack of objective measurement of radiation exposure and ergonomic parameters, which are increasingly recognized as important factors in endourological practice. In addition, task performance was subjectively assessed by the operating surgeons rather than by independent observers, introducing the possibility of observer and performance bias. Similarly, PULS assessment was performed by the operating surgeon and was therefore not blinded to the intervention, introducing the possibility of assessment bias. Furthermore, the experimental protocol simulated stone retrieval maneuvers rather than actual stone treatment, and no laser lithotripsy was performed; therefore, the findings may not fully reflect tissue effects occurring during clinical stone surgery. Finally, tissue harvesting and histopathological assessment were performed immediately after the procedures, allowing evaluation of acute tissue injury only. Consequently, delayed inflammatory responses, tissue remodeling, fibrosis, and subsequent ureteral stricture formation could not be assessed.

CONCLUSION

In this experimental porcine model, robotic-assisted ureteroscopy using the Avicenna Roboflex® system demonstrated procedural feasibility and an acute tissue safety profile comparable to conventional ureteroscopy. Both approaches were successfully completed without intraoperative complications or clinically relevant ureteral injury, and only minimal acute histopathological alterations were observed. Given the exploratory nature and small sample size of this study, these findings should be interpreted as preliminary preclinical evidence, and further adequately powered studies are required to evaluate the clinical performance and potential benefits of robotic-assisted ureteroscopy.

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Informed Consent: Not applicable. This study was conducted in an experimental animal model.

Conflict of Interest: The authors declare no conflict of interest.

Funding: Elmed (Ankara, Turkey), the manufacturer of the Avicenna Roboflex® system, provided the robotic system and material support for the study by covering the procurement costs of the experimental animals. The manufacturer had no role in the study design, data collection, histopathological assessment, statistical analysis, interpretation of the results, manuscript preparation, or the decision to submit the manuscript for publication.

Ethical Approval: This study was approved by the Acıbadem Mehmet Ali Aydınlar University Local Ethics Committee

on Animal Experiments (Approval No: HDK-2024/33, Date: June 5, 2024).

Author Contributions:

RBE: Study conception and design, acquisition of data, data analysis and interpretation, drafting of the manuscript. FAA: Study design, acquisition of data, and critical revision of the manuscript. ASK: Study design, technical support, and critical revision of the manuscript. ZT: Acquisition of data, procedural support, and critical revision of the manuscript. ABA: Acquisition of data. PCE: Experimental study coordination, animal model preparation, and procedural support. SSA: Histopathological evaluation, interpretation of pathological findings, and critical revision of the manuscript. MS: Study conception and design, supervision, data interpretation, and critical revision of the manuscript. TT: Study conception and design, supervision, interpretation of results, and critical revision of the manuscript

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