



Use of a Novel Articulating Laparoscopic Needle Driver for Partial nephrectomy: An Initial Experience

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OBJECTIVES	To demonstrate the clinical feasibility of an articulated laparoscopic needle driver to assist in the performance of laparoscopic partial nephrectomy (LPN). Previous studies have demonstrated under-utilization of minimally invasive techniques for patients undergoing partial nephrectomy (PN).
METHODS	Consecutive patients with renal masses amenable to PN underwent LPN with an articulating laparoscopic needle driver. A consecutive cohort of patients who previously underwent robot assisted laparoscopic PN (RALPN) was selected as a comparison cohort. Preoperative, perioperative, and postoperative variables were retrospectively collected.
RESULTS	A total of 20 patients underwent PN with 10 patients assigned to each of the LPN and RALPN cohorts. Median R.E.N.A.L. nephrometry scores assigned to the LPN and RALPN cohorts were 7 and 6 respectively ($P = .31$). Median warm ischemia time for patients in the LPN and RALPN groups was 25.5 and 18.5 minutes respectively ($P = .36$). Median estimated blood loss for LPN and RALPN was 200 and 50 mL ($P = .03$). Median operative time for LPN and RALPN was 203 and 194 minutes respectively ($P = .76$). Median Length of stay after LPN and RALPN was similar (3.0 vs 2.5 nights, $P = .26$). Following LPN, 3 patients required blood transfusion as compared to 2 patients in the RALPN cohort ($P = .61$).
CONCLUSION	Our initial results demonstrated the clinical safety and feasibility of a new surgical device for performing LPN. Patients who underwent LPN with a novel articulating needle driver demonstrated equivalent results to RALPN across several key outcomes. UROLOGY 132: 123–129, 2019. © 2019 Elsevier Inc.

The rising incidence of kidney cancer is a well-described phenomenon during the past 3 decades with an estimated 53% increase from 279,000 to 425,000 annual diagnoses worldwide between 2005 and 2015.¹⁻³ The greatest increase of these cases has been for localized tumors which is likely due to increased diagnostic capabilities with both increased quality and utilization of cross-sectional imaging.⁴ During this time, the preferred treatment paradigm has been surgical excision which for localized renal tumors has changed from radical nephrectomy to partial nephrectomy (PN) when feasible.⁵ Both the American Urological Association and European Association of Urology acknowledge that PN is the preferred modality of extirpation for localized renal cell carcinoma (RCC).^{6,7} In the United States the rates of PN for small

renal mass (SRM, ≤ 4 cm in dimension) have gradually increased, however PN remains underutilized, particularly in smaller, rural, and nonacademic hospitals and only half of all patients with SRMs receiving surgery undergo PN.⁸⁻¹⁰

In 2000, while approximately 30% of all radical nephrectomies were performed laparoscopically, only 2% of all PNs were done laparoscopically.¹³ This relatively slow adaptation of laparoscopic PN (LPN) has been attributed to the considerable technical difficulty with both tumor dissection and renorrhaphy with traditional laparoscopic instrumentation.¹ After the Da Vinci Surgical System (Intuitive Surgical, Sunnyvale CA) was approved by the Food and Drug Administration (FDA) in 2000, there has been increased utilization of minimally invasive PN. By 2010, approximately one-third of PNs performed utilized a minimally invasive approach with 24% of patients receiving robotic assisted laparoscopic PN (RALPN) while 9% of patients underwent LPN.¹⁴

Previously it has been demonstrated that the learning curve associated with minimally invasive PN may be improved with robotic surgery as well as the benefits of improved perioperative outcomes including complete resection of margins, shorter warm ischemia time, and fewer conversions to open surgery.^{13,14} However, there

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are concerns regarding the costs associated with robotic platforms and these systems may not be economically feasible for low volume hospitals.^{15,16}

The FlexDex Surgical needle driver (FlexDex Inc., Brighton MI) is a novel articulated laparoscopic instrument which mimics the 7° of motion afforded by robotic instrumentation. This system has previously been described for use in foregut and thoracic procedure.^{17,18} We sought to compare our initial outcomes for LPN performed with the FlexDex instrument to those from RALPN from a single surgeon to determine if the FlexDex instrument provides equivalent operative and clinical outcomes in the performance of minimally invasive PN.

METHODS

After obtaining Institutional Review Board approval for the use of the FlexDex instrument and this study, patients were consecutively enrolled between August 2017 and October 2018 from 2 hospitals in Chicago, Illinois; Mount Sinai Hospital (MSH), and University of Illinois at Chicago (UIC) Medical Center. Patients were prospectively selected following radiographic evidence (with computerized tomography or magnetic resonance imaging) of a solid renal mass concerning for a renal tumor which was amenable to a PN approach as determined by the discretion of the attending surgeon (SC). For this study, a goal enrollment of 10 patients was selected following Idea, Development, Evaluation, Assessment and Long term study (IDEAL) framework recommendations for implementation of new surgical technology.¹⁹ Patients were excluded if they were younger than 18 years old, pregnant women, currently detained by federal or state institution for criminal activity and were unable to provide informed consent to undergo a surgical operation.

MSH is a community hospital with limited resources and without a robotic surgical system, therefore surgical options for PN included an open or laparoscopic technique, while UIC is an academic hospital equipped with the Da Vinci Xi and Si surgical systems offering open, laparoscopic, and robotic PN approaches. After counseling of risks and benefits prior to surgical intervention, no patients with masses amenable to PN elected to undergo

open surgery and when offered robotic surgery, no patient elected to undergo LPN during this study period. As such, patients for the LPN arm were from MSH while patients in the RALPN arm were from UIC. All surgeries were performed by a single attending surgeon (SC).

The FlexDex needle driver was used for all patients undergoing LPN at MSH during the tumor extirpation as well as the renorrhaphy. The FlexDex needle driver was initially described in 2010 and was approved by the FDA in 2016.²⁰ This instrument utilizes a decoupled forearm to wrist motion when transmitting motion to the instrument tip. This instrument allows for 2 additional degrees of rotation including pitch and yaw that are manipulated using the mechanical mechanism. An example of this articulation is shown in Figure 1.

Patient age, sex, and basic demographic information was retrospectively recorded. Preoperative Charlson Comorbidity Index (CCI) was calculated to predict 10-year survival. Preoperative radiographic imaging was reviewed, largest dimension of the renal mass was evaluated with the R.E.N.A.L. nephrometry system as previously described.² Intraoperative variables including warm ischemia time, estimated blood loss, and total surgical operative time as well as postoperative data including length of hospitalization stay and 90-day complications Clavien-Dindo classification grade 2 or greater were recorded.²¹ The pathologic assessment was performed using the 2009 Tumor, Node, Metastasis (TNM) staging system.²² Pathological data included tumor histology, size of greatest dimension, and surgical margin status.

Statistical analyses were performed using Kruskal-Wallis for continuous variables, chi-squared analysis for categorical variables and Mann Whitney *U* test for nephrometry scores, and CCI. All values were tested against the null hypothesis with a significance level a priori of an alpha = .05 and 2-tailed tests were used when applicable. SPSS (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY IBM Corp.) was used for all analysis.

RESULTS

During our study period between August 2017 and October 2018 ten patients underwent LPN using the FlexDex laparoscopic

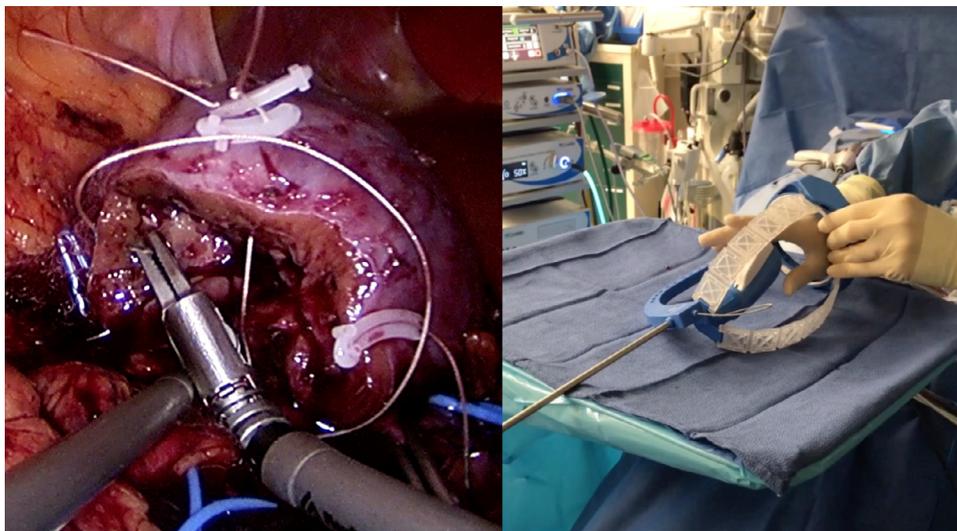


Figure 1. Depiction of the articulating laparoscopic FlexDex needle driver during the renorrhaphy after a partial nephrectomy and the interface with the wrist of the surgeon controlling articulation. (Color version available online.)

needle driver and standard laparoscopic instruments at MSH. Ten consecutive patients at UIC were selected who underwent a RALPN which served as our comparison arm. One patient from the FlexDex cohort was excluded from the final analysis due to operating room equipment failure unrelated to the FlexDex device with loss of pneumoperitoneum due to insufficient CO₂. This is listed as [supplementary Table 1](#) and [Table 2](#) for full patient characteristics.

Comparisons of the LPN and RALPN are shown in [Table 1](#). Median CCI was determined for both cohorts with the LPN cohort having slightly more complex patients in terms of comorbidity at a median index of 3.5 compared to the RALPN cohort of 2.5, this however was not statistically significant ($U = 38.5$, $z = .83$, $P = .41$). The median preoperative renal mass seen on radiographic imaging using either computerized tomography or magnetic resonance imaging for patients undergoing LPN and RALPN was 3.7 cm and 2.3 cm respectively ($P = .29$). The median R.E.N.A.L. nephrometry score assigned to tumors resected by LPN and RALPN was 7 and 6 respectively ($U = 36$, $z = 1.02$, $P = .51$). The median warm ischemia time for patients undergoing LPN and RALPN was 25.5 minutes and 18.5 minutes respectively ($P = .36$). The median estimated blood loss for patient undergoing LPN and RALPN was 200 mL and 50 mL ($P = .03$). The median operative time for patients undergoing LPN and RALPN was 203 minutes and 194 minutes respectively ($P = .76$). No patients in either the LPN or RALPN groups required conversion to an open surgical approach. The median length of stay in terms of number of nights hospitalized for LPN and RALPN was similar (3.0 and 2.5 nights respectively, $P = .26$). In the LPN cohort, 3 Clavien-Dindo Classification grade ≥ 2 complications were noted as compared to 2 within the RALPN cohort, this was not statistically significant ($P = .61$). Following LPN, 3 patients required blood transfusion as compared to 2 patients in the RALPN cohort ($P = .61$). In the LPN cohort, 2 patients were sent to interventional radiology for embolization of segmental arteries due to ongoing postoperative bleeding. No patients in the RALPN cohort required an interventional radiology procedure.

In all patients undergoing PN, tumor pathology showed RCC in 18 of 20 (90%), including histological subtypes of clear cell type RCC 12 of 20 (60%), and papillary RCC 6 of 20 (30%). Final TNM staging revealed pT1a in 12 of 20 patients (60%), and pT1b in 6 of 20 of patients (30%). On microscopic pathologic analysis 1 patient from the LPN cohort had positive margins, and 2 patients from the RALPN cohort had positive surgical margins, however this was not statistically significant ($P = .39$).

Follow-up data was available for 9 of the 10 patients from the LPN cohort as 1 patient from the LPN cohort was lost to follow-

up. Over a median follow-up of 213 days (range 13-341), all patients were considered free of disease at the time of their most recent clinical appointment or postoperative imaging (retroperitoneal ultrasound or computer tomography of the abdomen and pelvis) as per our standard follow-up for RCC. No additional adjuvant treatment has been required for patients in the LPN cohort.

DISCUSSION

Within our initial cohort of patients of LPNs utilizing the FlexDex articulating needle driver, we found similar perioperative outcomes between LPN and RALPN including complication rates, operative time and hospital stay. Using this small initial cohort we have shown that LPN using an articulating needle driver is feasible, however larger sample cohorts and comparison to traditional LPN would provide further evidence in the safety and efficacy of articulating instruments.

Between our 2 groups, patients undergoing LPN were slightly more complex and had somewhat larger tumor size. LPNs utilizing FlexDex resulted in a median of 7 more minutes of warm ischemia time compared to RALPN ($P = .36$), although the median LPN warm ischemia time was generally acceptable with a median less than 30 minutes. Tumor stage and positive margin rates were comparable between the 2 arms. Thus, we found that for similarly complex tumors, the FlexDex system may allow for somewhat longer but safe amounts of warm ischemia time compared to RALPN, but similar clinical outcomes with respect to operative time, length of stay, complete resection of margins, and perioperative complications. While use of the articulating instrument subjectively improved the ease of renorrhaphy, the tumor resection still relied on a purely laparoscopic technique and during this trial we did not distinguish between the time required for resection and reconstruction as contributors to the total ischemia time. Although this series was limited by a small sample size, 1 significant finding that we did observe between the 2 groups was greater estimated median blood loss within patients undergoing LPN (200 mL) as compared to RALPN (50 mL) ($P = .03$), however rates of transfusion were no different ($P = .61$). In both cohorts, hilar occlusion was obtained by placement of a laparoscopic bulldog clamp on both the renal artery and vein.

Table 1. Laparoscopic partial nephrectomy versus robotic assisted laparoscopic partial nephrectomy

	LPN With Flexdex N = 10	Robotic Assisted LPN N = 10	P Value
Charlson comorbidity index	3.5	2.5	.41
Size (cm)	3.7	2.3	.29
Ischemia time (min)	25.5	18.5	.36
Estimated blood loss (mL)	200	50	.03
Operative time (min)	203	194	.76
Length of stay	3	2.5	.26
R.E.N.A.L. score	7	6	.31
Blood transfusions	3	2	.61
Positive margins	1	2	.39

LPN, laparoscopic partial nephrectomy.

The difference in blood loss and elevated transfusion rates noted in this series may be attributed to the initial learning curve with the articulating needle driver, somewhat larger tumors in the LPN cohort, or complexity of the patients. While longer term follow-up oncologic results will be required to fully assess the efficacy of this approach, our initial results suggest that the FlexDex instrument represents a safe and feasible option for performing LPN.

Nephron sparing surgery with PN is recognized as the preferred method of extirpation of localized RCC by the American Urological Association and European Association of Urology.^{6,7} Yet, only half of all SRMs undergoing surgical treatment are excised by nephron sparing surgery, leaving many still treated by radical nephrectomy.^{9,10} With increased diffusion of robotic technology, RALPN has become increasingly popular, surpassing traditional laparoscopic PN, due in large part to the easier learning curve and associated improved clinical outcomes compared to traditional laparoscopy.¹¹⁻¹⁴ Unfortunately even though robotic surgery has enabled more urologists to offer minimally invasive PN, the associated costs are still a significant concern to many practitioners and healthcare systems.¹⁶ While there are no randomized controlled trials comparing RALPN to LPN, meta-analyses have concluded that RALPN offers shorter length of stay, lower rates of conversion to open, higher rates of complete resection of margins, shorter warm ischemia time, and fewer conversions to open surgery as compared to LPN.²³ In contrast to these studies' conclusions, our results demonstrate that an articulating laparoscopic device may allow LPN to be as efficacious as RALPN, with potentially significantly decreased costs. Minimally invasive surgery primarily decreases perioperative costs by shortening length of stay, but the costs of instrumentation and maintenance associated with RALPN represent a significant barrier for further diffusion of minimally invasive PN.^{24,25} Although, one of the advantages of RALPN from pure LPN is the shorter learning curve, during this small series it was our experience that the articulating needle driver provided a less challenging and more intuitive interface than pure LPN and as such may reduce this learning curve. Prior to this series, the attending surgeon performed 5 dry simulations lasting for approximately 1 hour each to practice suturing. Following the initial dry sessions, and after about 10 total procedures (including PN, vesicovaginal fistula repair, pyeloplasties, and ureteral reimplantation), the surgeon felt subjectively comfortable with the articulating instrument. Throughout the series, clamp time did appear to downtrend, however this finding was limited due to sample size.

One advantage of the FlexDex system besides the articulated instrument is it requires no additional consoles or equipment in addition to traditional laparoscopic equipment. The cost for the utilization of the disposable needle driver instrument is approximately \$798 to the hospital. Further iterations of the device may also lead to other instrument attachments which would include scissors, and

other dissecting instruments including cautery. This may be particularly beneficial in low resource settings or lower volume hospitals which may not support the costs associated with a robotic platform. After our initial experience, the user interface and results were positive, and this surgical team will continue to explore the feasibility of utilizing this articulating instrument in a low resource setting to improve surgical outcomes. Further studies will be needed to determine the cost considerations for use of the FlexDex needle driver.

There are several limitations of this study. Foremost, this report represents an initial experience from a single experienced laparoscopic surgeon who has performed more than 200 laparoscopic PNs, and with a small sample size of patients. Further validation of these initial outcomes will be needed with additional clinicians and with longer term follow-up to demonstrate the generalizability of these outcomes and oncologic safety. Further investigation is needed to evaluate if there is a substantial learning curve for LPN as noted with other complex laparoscopic operations including laparoscopic radical prostatectomy²⁶ and traditional LPN without articulating instrumentation.²⁷ Additionally, as the RALPN and LPN operations were performed at different clinical sites, pathological examination was performed by different pathology laboratories which may impact tumor grading and rates of positive margins and thus appropriate risk stratification.²⁸

CONCLUSION

Despite these limitations, this study represents the first clinical results for the safety and feasibility of performing LPN with this novel articulated instrumentation as well as the first study to compare these initial results to a comparable RALPN arm. This technology represents an appealing option for performing nephron sparing surgery in clinical sites without robotic technology and may be a cost-effective alternative to robotic technology for appropriately selected patients. This technology may offer a minimally invasive option for clinicians either in centers which do not have robotic technology or as an alternative to traditional laparoscopic techniques. Although this initial cohort study showed increased blood loss for the laparoscopic arm, it is unclear if this is related to the initial learning curve or some inherent characteristic of the device. Further testing of this technology in a multi-institutional analysis, ideally a randomized control trial comparing to both RALPN as well as to pure LPN, would represent a reasonable next step to determine the clinical benefits of this novel technology.

The FlexDex laparoscopic needle driver is an FDA-approved surgical device that allows the surgeon to perform laparoscopic surgery with the same 7° of motion afforded by a robotic arm and when used to perform LPN, provides comparable clinical outcomes compared to RALPN. Additional multi-center testing and larger

cohort sampling will be necessary to assess the generalizability of these initial results.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2019.05.049>.

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EDITORIAL COMMENT



This prospective study compares a novel laparoscopic needle driver to the conventional robotic platform during partial nephrectomy (PN). Robotic PN (RPN) is currently utilized in 66% of PN performed in the United States.¹ The wristed instruments and ability to recreate the movements of the hand during open surgery have allowed RPN to maintain equivalent cancer cure, while providing shorter hospital stays and decreased blood loss compared to open surgery.² However, 1 major limitation of robotic surgery is the increased cost and limited availability of this technology.³ Surgical robots come with large initial price tags, require expensive annual service contracts and costly disposables. Smaller hospitals and regions with less financial resources may not be able to afford the benefits provided by robotic surgery. However, laparoscopic PN (LPN) is more cost effective than RPN, saving \$1066 dollars per case in a study by Hyams et al.⁴ One of the main limitations of LPN is the lack of wristed instruments and the steep learning curve associated with this procedure.^{5,6} Currently only 11% of PN in the United States are performed laparoscopically.⁷ Development of a needle driver that would provide articulation to reproduce the advantages of robotic surgery at a lower cost would be a potential significant advantage.

This feasibility study, describes a novel wristed needle driver in a series of LPN patients. Certainly, the small sample size (20 patients) and the fact that all procedures were performed by a single surgeon is a limitation. The authors found that use of the novel needle driver was associated with higher blood loss (200 mL vs 50 mL, $P = .03$) compared to robotic surgery and the transfusion rate (30%) and positive margin rates (15%) were higher than those reported in some other series.^{8,9} However, to the authors credit this was their initial experience with this technology and these outcomes will certainly improve with greater experience. A promising finding was that the warm ischemia time was similar between groups (LPN: 25.5 minutes vs RPN: 18.5 minutes, $P = .36$).

These authors should be congratulated for attempting to reduce the costs of PN. With healthcare consuming 18% of the gross domestic product in the United States, and 22% of the current budgetary expenses for 2018, devices like this experimental needle driver have the potential to lower the cost of minimally invasive PN.¹⁰ In addition, this type of device could facilitate minimally invasive PN in regions where surgical robots are not available. Certainly, larger, multicenter, prospective trials will be required to determine whether this needle driver will provide equivalent outcomes to robotic surgery but at a lower cost. In addition, comparisons between the novel needle driver and conventional LPN will be necessary to determine whether this device truly can shorten the learning curve and improve the outcomes of LPN. Technologies such as FlexDex have potential to make PN more readily available and allow for preservation of renal function to reduce risk of chronic kidney disease among this patient population.¹¹

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AUTHOR REPLY



We thank the editors for their thoughtful comments regarding our study.¹ These authors correctly note that robotic surgery has improved postoperative outcomes including shorter length of stay, decreased blood loss while sustaining curative extirpation for partial nephrectomy (PN) as compared to an open technique.^{2,3} The rapid adoption of robotic surgery since the Food and Drug Administration approval of the Intuitive Surgical platform in 2000 has accelerated the utilization of minimally invasive techniques for PN. However, this transition should not halt innovation and utilization with laparoscopic instruments in renal surgery.

As healthcare providers, it is important to be good stewards of healthcare resource utilization, balancing the potential benefits of novel innovations while also being cognizant of the costs associated with these new technologies.⁴ In this study we have proposed the use of a new technology in a resource limited hospital to perform a more minimally invasive technique for PN.

The authors point out that laparoscopic PN can be very technically challenging and is associated with a significant learning curve. Given that our study represents our initial experience with this technology, it is likely that these cases represent outcomes within the learning curve for this technology. In the prostate cancer literature, 1 study of laparoscopic radical prostatectomy demonstrated that the 5-year risk of recurrence decreased from 17% to 16% to 9% for patients treated by surgeons with 10, 250, and 750 prior laparoscopic procedures.⁵ In this study we report on the first 10 patients undergoing LPN with an articulating instrument assistance completed by 1 single surgeon. Further study to examine perioperative and postoperative outcomes with additional surgical volume will be necessary to further evaluate these initial results.

Larger and multi-institutional studies will be needed to assess the future utilization of articulating laparoscopic instruments such as this technology. We agree that a direct comparison to laparoscopic instruments would be ideal to assess the proposed benefit suggested in our study. However, in hospitals without access to a robotic surgical system there will likely remain a selection bias for patients undergoing laparoscopic PN with traditional laparoscopic instruments, in that the simple cases will undergo LPN and more complex cases will undergo open PN. Therefore, careful consideration will need to be made to match complexity parameters like RENAL Nephrometry scores used in this study to compare traditional LPN to LPN with articulating instruments.⁶

From this initial study, we have seen that warm ischemia times, operative times, and length of hospital stay are similar to robotic PN (RPN), however we do not suggest this LPN technique replace the utilization of RPN. The literature suggests that RPN is superior to LPN, and when available RPN should be performed.⁷ However, in the correct hospital setting without a robotic platform, LPN with articulating instruments may both improve LPN utilization and provide a cost-effective alternative to open nephrectomy.

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