



Exploration of robotic-assisted surgical techniques in vascular surgery

Kyle Miller¹ · Dale Bergman¹ · Glenn Stante¹ · Chandu Vemuri²

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Abstract

Robotic-assisted surgical approaches for vascular surgery are feasible regarding minimally invasive exposure, dissection, ligation and skeletonization for varicose vein ligation, anterior spine exposure, femoral-popliteal bypass, femoral vein harvest and aortic aneurysm repair. The authors performed a cadaveric exploration to demonstrate proof of concept and feasibility for a robotic-assisted approach. Surgeon autonomy over endoscopic vision, robotic instrumentation and retraction were noted as key benefits over existing open vascular approaches. Robotic-assisted approaches for vascular surgery enable innovative minimally invasive approaches to disease states not amenable to endovascular repair. Potential reductions in paresthesia through nerve identification were noted during a cadaveric exploration for varicose vein ligation in the setting of chronic venous insufficiency. Minimally invasive femoral artery exposure via a retroperitoneal approach could potentially reduce the morbidity associated with the traditional groin incision. Further exploration and procedure refinement are warranted.

Keywords Robotic-assisted surgery · Vascular surgery · Proof of concept · Procedure exploration

Introduction

Vascular surgery has embraced innovative, minimally invasive techniques as the field has progressed toward endovascular approaches for venous disease, arterial occlusive disease and aneurysm. However, there remains a large opportunity for innovation in a number of vascular clinical applications where disease states are not amenable to endovascular interventions and existing approaches are technically challenging and result in inferior patient outcomes. Our cross-functional team composed of physicians, a biomedical engineer and medical device expert sought to explore unmet clinical procedure opportunities that would be enabled with robotic-assisted approaches by performing a broad analysis of the vascular surgery landscape. We analyzed vascular surgery opportunities with the following criteria for each respective procedure from a clinical and

market perspective: clinical needs, surgeon value for robotic-assisted approaches, and clinical outcome data for existing and emerging approaches, current complication rates, current technology market offerings and market trends.

This whiteboard analysis ultimately allowed us to de-prioritize two potential applications including carotid endarterectomy (CEA) and thoracic outlet syndrome (TOS) repair. We avoided exploring CEA given the low complication rates with a shift toward stenting [carotid artery stenting (CAS)] in light of equivalency and non-inferiority with comparison to open CEA repairs. Further, we elected to not explore an ideal application for a robotic-assisted approach in TOS given the low procedure volume. We found it difficult to justify exploring a robotic-assisted approach given the low volumes which would ultimately impact the necessary learning curves for adoption and procedure refinement.

Stadler and colleagues (Na Homolce Hospital, Czech Republic) have reported on an extensive case series of 310 robot-assisted vascular procedures including 61 procedures for abdominal aortic aneurysm repair [1]. This group has already demonstrated feasibility for robotic-assisted vascular techniques for occlusive disease and aneurysms. For our exploration, we merely sought to replicate their utilization of the da Vinci system for a femoral vein harvest that can potentially compliment robotic-assisted techniques for abdominal aortic aneurysm repair. The evaluation we

✉ Kyle Miller
kyle.miller@intusurg.com
Chandu Vemuri
cvemuri@med.umich.edu

¹ Medical Research, Intuitive Surgical, Inc., 1266 Kifer Road, Sunnyvale, CA 94086, USA

² Department of Vascular and Endovascular Surgery, University of Michigan, Ann Arbor, MI 48109, USA

performed supported exploration of vascular procedures where there were large disease burden and high volume of procedures while tabling less promising applications for future investigation. We sought to identify lower complexity procedures where robotic-assisted approaches could ultimately provide a beachhead or anchor procedure for vascular surgeon learning curves and training. We elected to explore the following applications: varicose vein ligation, anterior spine exposure, femoral-popliteal bypass and femoral vein harvest.

Varicose vein ligation

24% of US adults suffer from varicose veins putting the current prevalence at more than 60 million. Further, 6% of US adults have advanced chronic venous disease [2]. Despite a number of existing treatment modalities relying on endoluminal radiofrequency ablation, endovenous laser ablation, and chemical scleropathy, the literature we evaluated demonstrated that surgery was associated with the most favorable outcomes regarding the need for additional treatment and evidence of post-intervention claims for symptomatic varicose veins [1]. Vascular surgeons we talked to through customer discovery relayed that patients were often subjected to 20–30 stab incisions with a ligation or phlebectomy technique while emerging trans-illuminated powered phlebectomy techniques suffer from paresthesia and nerve injury given the morcellation mechanism. We found there to be an unmet need for a definitive, minimally invasive surgical modality for varicose veins.

Anterior spine exposure

We found there to be more than 250,000 lumbar fusions performed annually for degenerative disk disease [3, 4]. Overall, spine and vascular surgeons we interviewed discussed the opportunity for minimally invasive exposures and the need for co-surgeons to protect critical vascular structures in the process. Given that anterior spine exposure assistance is a bread-and-butter core vascular procedure, we sought to better understand the technical challenges of utilizing a robotic-assisted approach.

Femoral-popliteal bypass

There are an estimated 150,000 open lower extremity revascularization procedures annually in the US [5]. Surgical wound infections associated with vascular interventions are multifactorial, a known risk and a major culprit given the vascular access needed via groin incision for

femoral-popliteal bypasses. It is known that graft placement in the subcutaneous location instead of the subfascial location increases risk of SWI with a relative risk of 11.6 in infrainguinal bypass surgery. Regardless of technique for groin incisions with vertical crossing or oblique sparing approaches, SWI for infrainguinal femoral vessel exposure remains problematic with SWI rates ranging from 6 to 30% in prospective and retrospective analyses [6]. We sought to move this traditional groin incision to the abdomen and explore a paramedian-retroperitoneal exposure of the distal iliac and proximal femoral artery.

Femoral vein harvest

The femoral-popliteal vein is known to vascular surgeons as an agile conduit that can be utilized for reconstruction of infected aortic grafts and a multitude of bypasses. However, the harvest and exposure are technically difficult [7]. Our goal was to explore a minimally invasive technique for robotic-assisted exposure, dissection and harvest.

Materials and methods

The da Vinci Xi[®] surgical system was utilized in a cadaveric exploration. The procedure explorations were led by the senior author following an extensive discussion on the various merits and potential applications for robotic-assisted surgery within the domain of vascular surgery. Vessel exposure, dissection, ligation and anastomoses were performed entirely with the robotic system.

Results

Iliac artery, proximal femoral artery and anterior spine exposure

The female cadaveric specimen was placed in a supine position with the feet supported in modified lithotomy positioning to enable optimal lower extremity dissection following the initial retroperitoneal (RP) great vessel dissection. Access to the great vessels was performed via a robotic-assisted minimally invasive retroperitoneal approach utilizing a 5-cm lower left paramedian incision (Fig. 1). This was followed by a careful manual dissection with blunt dissection, Metzenaum scissors and a Weitlaner retractor to expose the plane between the transversalis fascia and the peritoneum. The space creation was followed by placement of a GelPOINT wound retractor Advanced Access Platform (Applied Medical Resources Corporation; Rancho Santa Margarita, CA). The GelPOINT cover was then attached



Fig. 1 Lower left paramedian incision for retroperitoneal access



Fig. 2 GelPOINT with direct cannula insertion and pneumo-insufflation for space creation

followed by staggered introduction of three 8-mm da Vinci cannulas. The da Vinci Xi[®] patient side cart was then docked (Fig. 2). Pneumo-insufflation was then established to aid with space creation. A careful dissection was extended laterally utilizing the Fenestrated Bipolar Forceps (FBF) and Hot Shears[™] [monopolar curved shears (MCS)] rolling the peritoneum medially to expose the distal aorta and iliac bifurcation (Fig. 3). In addition, the distal lumbar spine and sacrum were exposed. The common iliac vessels were skeletonized caudally to expose the bifurcation into the external and internal iliac branches at the pelvic brim. The minimally invasive approach allowed for dissection and direct visualization of the external iliac diving below the inguinal ligament with its transition to the femoral artery. Further, this demonstrated the ability to effectively move the traditional groin exposure of the femoral artery in a femoral artery bypass to a

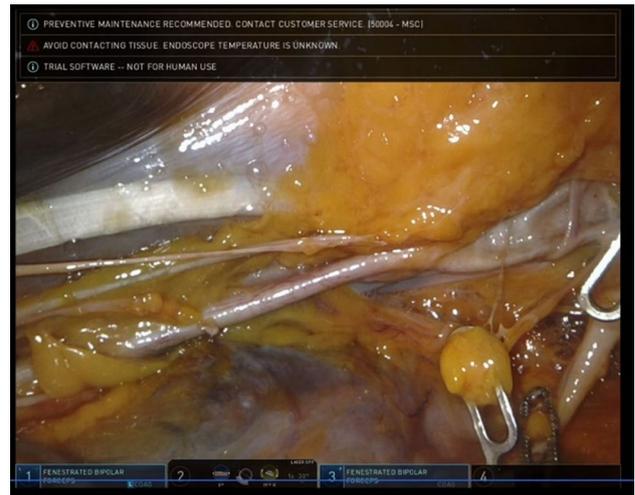


Fig. 3 Great vessel and iliac vessel exposure via a robotic-assisted retroperitoneal approach



Fig. 4 Direct cannula insertion into subcutaneous pocket along medial distal thigh for lower extremity access

paramedian-retroperitoneal approach which has the potential to reduce surgical site infection rates and wound breakdown given the morbidity associated with that incisional approach.

Saphenous/superficial lower extremity vein, distal femoral artery and distal femoral vein exposure

Following proximal vessel exposure, attention was then turn to the left lower extremity and distal femoral artery exposure. Three 8-mm incisions were made in a three finger breadths off of the medial portion of the patient's patella (Fig. 4). A subcutaneous pocket was created to connect the three incisions so that pneumo-insufflation could be established and an endoscopic view could be established within



Fig. 5 Subcutaneous dissection and superficial vein exposure



Fig. 6 Femoral artery and vein exposure with tunnel connecting to prior RP dissection

the newly created subcutaneous space. Three 8-mm da Vinci cannulas were then introduced and secured with purse-string sutures. Pneumo-insufflation was then utilized to aid with initial dissection of the space. Again, the FBF and MCS were utilized to create a subcutaneous dissection plane to show feasibility for dissection and ligation of varicose veins in the setting of chronic venous stasis (Fig. 5). The saphenous vein was identified during the course of the superficial dissection. A deeper dissection was then performed with exposure of the sartorius muscle followed by identification and skeletonization of the femoral artery and femoral vein (Fig. 6) proximally to their take off under the inguinal ligament completing a connection to the initial RP dissection. Small branches of the femoral vein were then ligated with both bipolar energy and medium Hem-o-lok® clip

application to demonstrate feasibility for femoral vein harvest. Finally, small arteriotomy and venotomy were created distally followed by an anastomosis between the two vessels in lieu of graft insertion to demonstrate proof of concept for distal robotic-assisted vasculature anastomosis.

Discussion

Our cross-functional team led by the senior author was able to provide sufficient exposure, dissection and skeletonization for all of the procedure areas we outlined for exploration during the cadaveric study. We safely gained entry to the retroperitoneal space via a paramedian approach utilizing the GelPOINT wound protector device. Further, we were able to place the patient's leg in a modified lithotomy position to place cannulas directly into the subcutaneous space allowing for superficial vein, femoral vein and femoral artery exposure following mobilization of the sartorius muscle. Optimal patient positioning was a key contributor in setup and docking which likely contributed to the minimal amount of collisions experienced throughout the exploration in both the retroperitoneal and lower extremity dissections.

The vascular surgeon leading the exploration quickly learned the dissection techniques with robotically controlled instrumentation noting numerous advantages over open and endoscopic approaches including surgeon autonomy over vision and retraction, tremor stabilization, Endowrist architecture with instrument manipulation and enhanced vision. In particular, we noted successful proof of concept and feasibility for vessel skeletonization for all procedures explored with the ability of the surgeon to ligate side branches using clips or advanced energy (vessel sealer) with high-resolution 3D vision providing for nerve identification and preservation throughout the lower extremity. Perhaps the most promising result from the exploration was the potential to move femoral artery exposure away from the traditional groin incision toward a retroperitoneal approach. Further, we noted opportunities for robotic-assisted pillars including auto-fluorescence imaging (FireFly®) to aid vessel branching and identification along with virtual 3D reconstructions and potential endoscopic overlay to assist with planning and navigation.

The cross-functional group of collaborators fully recognizes that there are a number of rate-limiting factors for further development including the challenges that minimally invasive access imposes on vessel clamping and limb ischemia with bypasses, occlusive disease and aneurysmal disease. Stadler and colleagues have addressed the challenges for this larger issues with a hybrid approach [7]. Despite the advantages of robotic-assisted approaches for the vascular procedures outlined, we also recognize the learning curve associated with the technology and how variations in

disease pathology could potentially impact scalability and training to reproduce consistent outcomes. The group plans to continue technique refinement while also continuing customer interviews and discussion to continue to understand the value proposition for vascular surgeons for these respective applications.

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Compliance with ethical standards

Conflict of interest Authors Dr. Kyle Miller, Dale Bergman and Glenn Stante declare employment through Intuitive Surgical and each own stock in the company. Author Dr. Chandu Vemuri has received a honoraria for lab participation.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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