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Progressive Endolaparoscopic Vascular Training in a Computerized Enhanced Instrumentation Based on Outcome Measurements

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1. Introduction

Our commitment in minimally invasive vascular surgery began in 1982, when we designed our endoscope, attached to a micro video camera to make the Endoscopic transaxillary first rib and cervical bands resection safer.

During the next decade we evolved with the rapid technological development of minimally invasive surgery.

In 1996, the French Canadian Dr. Ives Dion was the first to create a solid animate Laboratory training toward the approach of full laparoscopic human aortic reconstruction.

In 1997 we modified Dr. Dion's animate model into the following aspects:

- Create the Transperitoneal approach.
- Aortic graft with two anastomosis.
- Introduction of computerized enhanced instrumentation or Robotic technology.

During the next five years, 1997-2001 few Centers around the world were divided among "robotic" vs. "Non Robotic" in pursuing the tremendous technical effort to conquer the human aortic reconstruction.

In 2002 a Dutch-American team effort (Dr. Wisselink-Dr. Gracia) conquered for the first time the Robotic Full Laparoscopic Aortic Reconstruction using the Zeus Robotic System (Computer Motion). Our first Full Laparoscopic Aortic Graft was done in 2005, and our first Robotic Assisted Aortic Graft was done in 2007.

The objective in this chapter is to describe our own training methods, not only for a vascular surgeon interested in robotic technology, but also to other specialties; this is a very friendly and cost effective approach to solve the dilemma of "steep learning curve" for vascular surgeons. In addition, resolves the credential institutional process for every specialty involved in robotic surgery.

2. Modular robotic training program

This program was created in 2004 based upon our own self training and training other individuals of different specialties since 1997.

3. Basic concept

The Robotic Surgeon, regardless of his/her specialty needs to perform three basic tasks:

1. Tissue manipulation or dissection
2. To cut tissue
3. To suture tissue or graft materials

These tasks change in intensity depending upon the surgical procedure. Specialties like vascular surgery, cardiac surgery in which the suturing task is critically important for the functional outcome of the procedure. Not only the quality, but the speed is very important. It literally separates vascular surgery from other specialties in which there is less suturing demand. We worked with Dr. James Rosser (2000-2002) adopting his own exercises of "Top Gun" Laparoscopic School of training to the robotic technology.

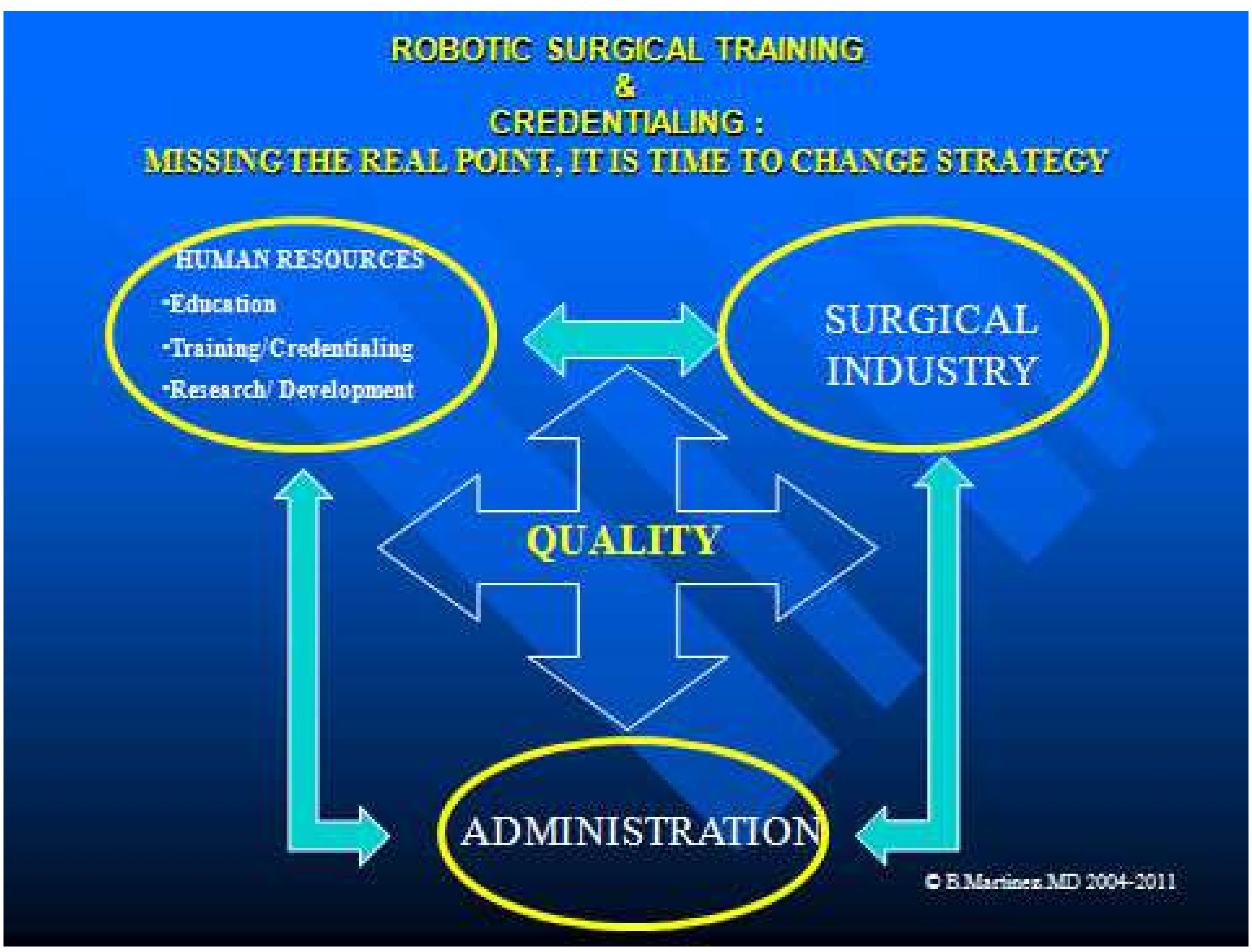

Fig. 1. Robotic Surgical Training & Credential

4. Delivery quality

The robotic trainee is not going to deliver good quality, unless there is clear support from the Institutional Administration. Full commitment for a dedicated space and human resources to support the execution of this program. Delivering quality in surgical procedures is saving economic resources for the Institution. **(Fig. 1)**

5. Learning new set of skills

The trainee (student-resident-junior or senior surgeon) is facing a real dilemma in terms of selecting the time, the opportunities, the cost and most importantly, how to put this package together in a very difficult economic era.

The individual has to learn a new set of motor sensory skills involving BRAIN-EYES-HAND-FEET functional coordination, including the function of the voice. This learning process falls into these four areas. **(Fig. 2)**

Fig. 2. Progressive Endolaparoscopic Vascular Training

1. Console: the trainee must spend time performing the exercises and measuring his/her performance.
2. Stand-By: the surgeon at the side of the patient is very important, sometimes more than the console surgeon in the execution of certain portion of the procedure.

3. Robotic System: The full potential of the equipment and its limitation must be know.
4. Classroom Debriefing: very similar to Aerial Combat, classroom didactic discussions are required in order to improve the performance of the Team. And avoidance of potential mistakes.

We took the “Rosser Cobra Rope” and the “Rosser Intracorporial suturing” to simulate tissue manipulation and tissue reconstruction functions designing our own “Cutting Exercise” technique. These are the “keys” of the entire learning process. We teach and demonstrate these exercises in individual and group sessions. When we see the immediate learning process, we then teach suturing anastomosis. **(Fig. 3)**

Fig. 3. Suture Anastomosis

As friendly and competitive as these exercises would be we bring the trainee slowly into a new area of measuring outcome performance for the training and credentialing process.

This computerized enhanced instrumentation training program has three different modules based upon performance. (**Fig. 4)**

1. Basic Laparoscopic, very similar to Rosser’s criteria.
2. Basic Robotics
3. Advance Robotics

There are hours of minimally dry laboratory practice that are required. At the end of each module the trainee must perform “on examination”: in order to pass and move to the next module of higher technical skills. The modules can be taken in separate periods of time or in a solid one time block.

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Computerized Enhanced Training

Stage	Objective	Inanimate (Hours)	Animate (# Animals)	Clinical Exposure	Time Period (Weeks)	Estimated Cost Per Surgeon
Basic Skills	Eye-Hand coordination	10	0	1	1	$2,404
Basic Robotics	Eye-Hand-Feet-Voice coordination	20	3	4	2	$10,005
Advanced Robotics	Anastomosis less than 30 minutes (robotic aortic graft	30	4	4	2	$13,886
Total		60	7	9		$26,295

Fig. 4. Computerized Enhanced Training

Animated laboratory exposure is critically important in the robotic learning process. These are a progression of tasks, as skills are developed for a maximum cost benefit. The progressive learning task involves:

1. Port placement.
2. Engagements and disengagements of the robotic system. Then performing Transperitoneal aortic dissection, clamping application of the aorta. Finally, it is the Aortic graft implant repeating two suture anastomosis.

The "graduation" or final examination is to perform a fully endolaparoscopic robotically assisted aortic graft implant in less than 200 minutes of total operative time and maximum of 72 minutes of aortic cross clamping time, delivering good anastomosis products .

The cost analysis shown was made in 2004. This was based upon our laboratory cost and it was compared with other models around the world. Significant variability exists among different institutions.

6. Clinical exposure

During the course of training the exposure of clinical material and surgery demonstrations are absolutely critical requirements. Our philosophy was that "safety" is the main priority. We worked with U.S. Food and Drug Administration during the clinical application of robotic technology in humans, we created our own aortic protocol. We obtained the investigational device exemption required for new technology. **(Table 1)**

Description	Robotic da Vinci®	Robotic da Vinci® Predetermined	AESOP® Assisted
Femoral grafts	4		
Iliac grafts	4		
Aortic grafts	4	2	45
Endoleaks type II	5		
Retroperitoneal	4		
Thoracic Outlet Syndrome	195		91
Sympathectomies	6		
Total	224		

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Table 1. Total robotic Clinical Exposure

Fig. 5. Porcine Infrarenal Aortic Graft

7. Results

7.1 Trainees

During 2002-2008 fifty five trainees passed through out our laboratory of training program. Twenty nine (29%) percent were local-regional surgeons. Forty nine (49%) were residents and twenty two (22%) were visitors out of state and out of USA. (**Fig. 6)**

The following conclusions were revealed:

We found that visitor surgeons were the most successful and having the least difficulties in the establishment of robotic technology in their respective geographic locations.
We felt that our dry laboratory training program was not optimized and significant potential for improvement exists.

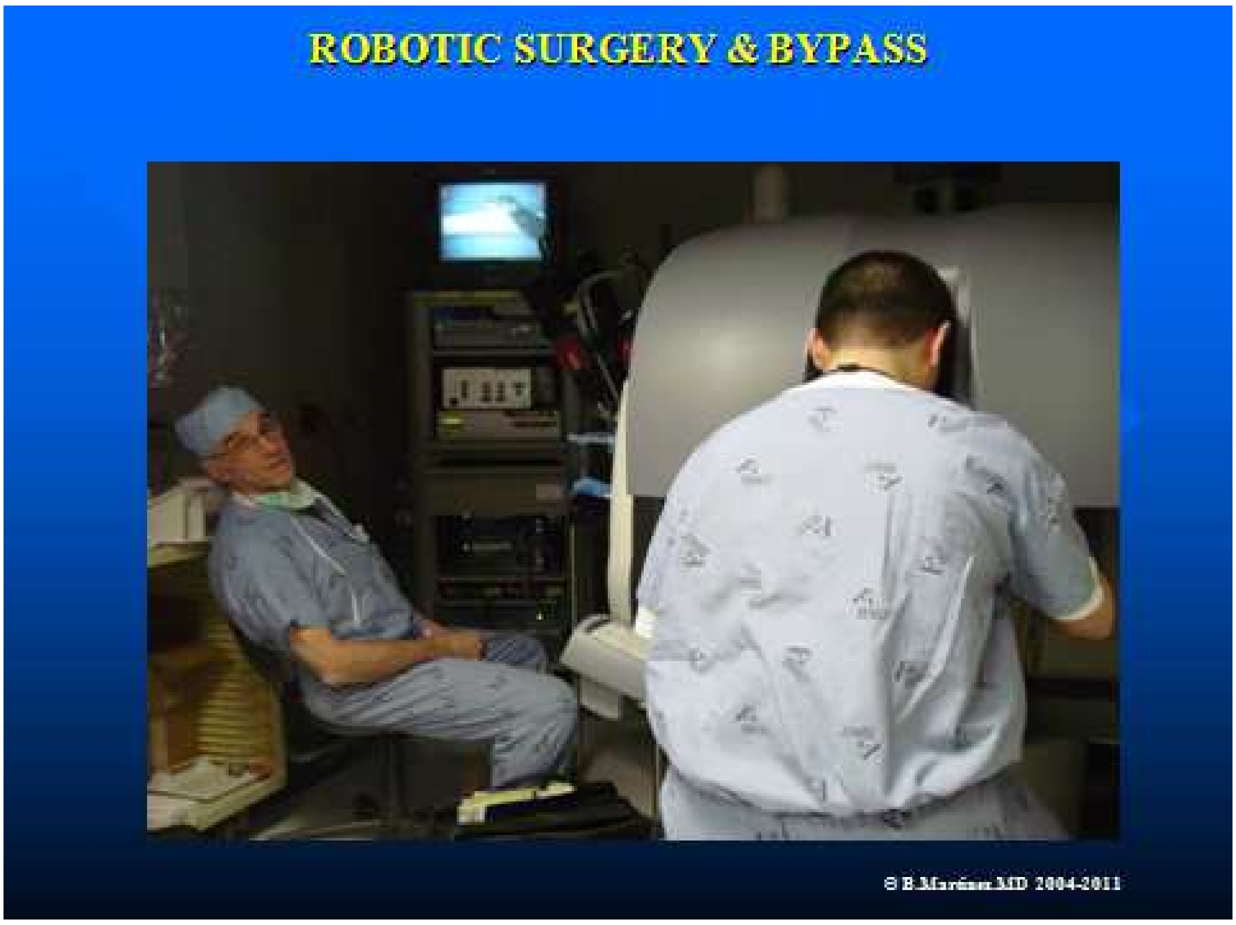

Fig. 6. Trainee in session

7.2 Laboratory model

Our laboratory training and research model has been 50 porcine models since 1997. Today we have completed 224 applications of the da Vinci® robotic in vascular surgical patients. In addition, there are 45 aortic surgical reconstruction and 91 transaxillary first rib and cervical bands resection using the first generation of robotic technology Aesop®/Hermes (1998-2002).

7.3 Aortic robotic reconstruction

Our human Aortic Robotic Reconstruction can be divided in two stages:

1. Pre da Vinci® Group (1998-2007)

Forty five patients underwent Laparoscopic Aortic Reconstruction for occlusive (29=64%) aneurysmal disease (7=16%) and combined aneurysmal and occlusive disease (9=20%).

The procedures were executed using Aesop®-Hermes robotic arm voice activated. Endoscopic Vein Harvesting instrumentation.

Thirty two patients (32/45=71%) were laparoscopic assisted (incision <9cm length) (**Fig. 7**), twelve patients (12/45=27%) were hybrid laparoscopic assisted (incision 9-16cm) (**Fig. 8**) and one patient (1/45=2.2%) full laparoscopic. **(Fig. 9)** There was one mortality (1/45=2.2%) due to non-stone cholecystitis.

In this Pre da Vinci® group, no bleeding, non spinal cord ischemia, no thrombosis was observed. Complexity of these procedures indicates that (25/45=56%) required concomitan additional procedures like, aortic or and femoral endarterectomies and femopopliteal reconstruction.

Fig. 7. Laparoscopic Assisted for Occlusive Disease (<9cm).

2. da Vinci® Group (2007-2008)

Six patients underwent aortic reconstruction for atherosclerotic occlusive disease under the U.S. Food and Drug Administration guideline protocol. Three patients had full laparoscopic robotic reconstruction. Two patients had "pre-determined" conversion to minilaparotomy. One patient with hostile bowel and one patient had "unplanned" conversion due to hostile tunnel

All patients survived without major complications. All patients are alive, having functional grafts and one patient required aortic anastomotic covered stent to protect myointimal hyperplasia postoperative. Additionally, we have performed in eight patients' illio femoral graft robotically assisted. (**Fig. 10)**

Fig. 8. Laparoscopic Hybrid for Aneurysmal Disease (<16cm).

Fig. 9. Full Laparoscopic for Occlusive Disease.

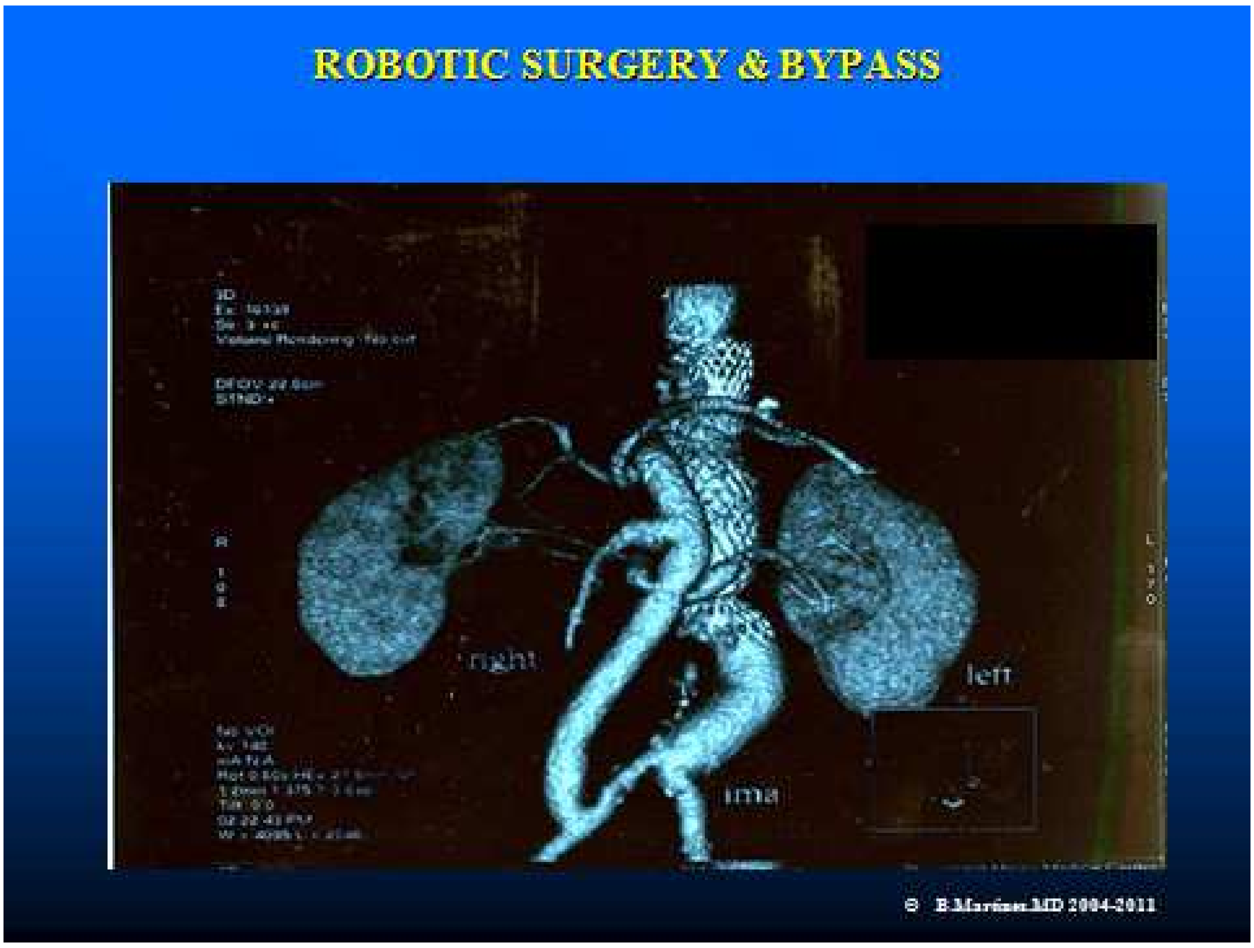

Fig. 10. Iliac to birenal-superior mesenteric and celiac graft-debranching-rebranching and aortic stenting for suprarenal aortic aneurysm. Iliac anastomosis created by full laparoscopic robotic assistance.

8. Vascular surgical approaches-new concept

Currently Vascular surgeons are most often offering to our patients, either conventional or endovascular surgical procedures- Laparoscopic Aortic Surgery is not widely accepted.

In our opinion, Laparoscopic Aortic Surgery whether it is performed using robotic technology or not, represents the “Logical Bridge” between endovascular and conventional vascular approaches.

Under the concept that we are treating the atherosclerotic occlusive and degenerative aneurysmal disease of the Infra Renal Aorta. We are at a critical evolutionary moment in which endovascular therapy is taking a primary role. However Leaders in vascular surgery, for the most part, are ignoring robotic technology as an alternative of minimally invasive vascular surgery.

Unfortunately there is a dilemma about the training and the adoption of Robotic technology.

Therefore, those vascular surgeons, without robotic training are indicating conventional surgery, whether endovascular approaches are difficult or have already failed.

Robotic Laparoscopic techniques, with their ability to "Bridge" endovascular and conventional vascular traditional surgery, are overlooked in addition to it's capability to "Rescue" endovascular procedures from complications such as "Endoleak."

9. Conclusion

Why robotics in vascular surgery? We wrote in 2004. "Because just as robotic or computer technology revolutionized "safety" in the automotive industry. This technology has the potential to revolutionize patient "safety" in surgery in the 21st century.

We have developed a very solid and comprehensive robotic training laboratory model. It allows us to demonstrate that we have delivered "safely" this technology to our patients in thoracic outlet syndrome and infrarenal aortic surgery.

The robotic vascular technology and endovascular therapy are reciprocal complementary techniques to offer minimal invasive alternatives to our patients.

The potential of robotic vascular surgery to expand in other areas (suprarenal aorta, visceral arterial reconstruction and retroperitoneal pathology) open the doors for a tremendous opportunity for training which if it is done properly as we presented, the cutting edge technology will be delivered with quality with substantial savings and economic resources for medical organizations.

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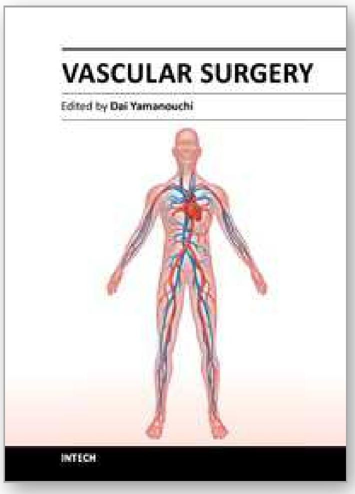
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