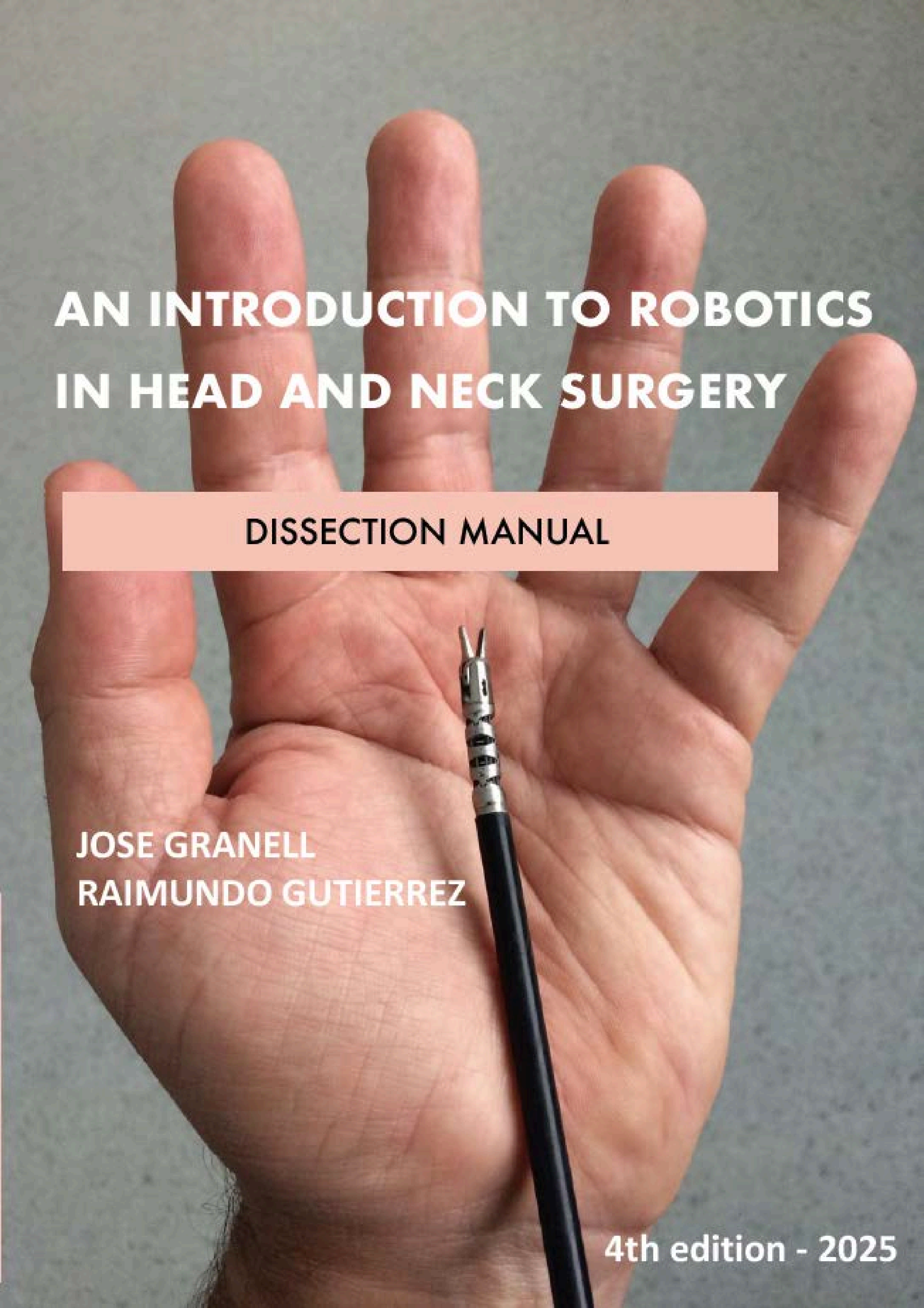
AN INTRODUCTION TO ROBOTICS IN HEAD AND NECK SURGERY

DISSECTION MANUAL



JOSE GRANELL
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4th edition - 2025

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4th edition. March 2025.

With profound reverence and heartfelt gratitude, we extend our sincerest appreciation to the countless individuals who, in anonymity, generously contribute their bodies to the advancement of scientific knowledge.

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INTRODUCTION

The field of robotic surgery in head and neck applications continues to evolve at an unprecedented pace. Since the publication of the third edition of this manual in 2020, significant advancements have emerged in both technology and surgical techniques for robotic-assisted procedures. These innovations have not only expanded the capabilities of surgeons but have also enhanced patient outcomes.

Robotic surgery now occupies a pivotal role in minimally invasive approaches to complex anatomical regions. The integration of advanced imaging modalities and improved surgical tools are driving this transformation. These technologies facilitate superior visualization, precision, and accessibility, overcoming challenges previously deemed insurmountable. But most important, the advent of artificial intelligence is going to change everything. We need to be prepared.

This expanded new edition reflects the latest progress in soft-tissue robotic surgery systems, including updates on new devices and a fore view on those to come. The manual also incorporates insights from cutting-edge training methodologies, emphasizing hands-on learning through virtual reality simulators and other innovations.

Furthermore, this edition delves deeper into experimental and clinical applications of robotic systems, offering comprehensive guidance on dissection techniques in human models. By addressing emerging trends and practices, it aims to serve as a definitive resource for trainees and experienced surgeons alike. This document is meant to serve as a comprehensive, step-by-step instructional guide; that is why we call it a "manual".

Why present it in the form of a traditional "book"? Certainly, the current world demands a constantly updated source of information. We made it possible after the previous edition of the manual, in a webpage. In headneckroboticsurgery.com you will likely find anything you are looking for on the topic. All medical information provided is uploaded and reviewed by a qualified medical doctor with the utmost care and in good faith. The content is accurate, up-to-date, and intended to offer valuable insights for both health professionals and patients. Specific update dates are noted to ensure transparency and relevance.

But sometimes it is just ok to start with a traditional book that contains all the basics in an organized manner. This is what the manual is made for. To be a starting point. The content of this manual is updated as March 2025, and everything is moving forward fast. We have tried to have a glimpse on the next future at every critical topic. But, for now, this is what it is. It will guide your dissection to learn the techniques. And in a few years, when outdated, it will still tell you the story.

The manual is divided into five sections, starting with an overview of robotic systems and other required materials, progressing through the training and credentialing process, and the specific training modules, first on inert modes and particularly on virtual training, and then animal and human dissection. Notable updates on the previous edition include an expanded coverage of robotic platforms, including comparisons of their capabilities and applications, and a detailed description of training methodologies and the credentialing process. Also, updated techniques for transoral and remote-access procedures, reflecting the latest surgical developments.

Lastly, we acknowledge the global community of researchers, clinicians, and trainees whose contributions have shaped this rapidly advancing field. We trust that this manual will continue to provide valuable support in your surgical journey.

JG, RG
March 2025

INTRODUCTION TO 2020 THE EDITION

We conducted our first TransOral Robotic Surgery (TORS) dissection course on cadaveric models in February 2015. For the second edition in December 2016 we wrote a short dissection manual as a guide for the course. But a lot of practical information was lacking related to the application of robotic surgery in the head and neck, including that related to training in an experimental environment. Therefore, we decided to edit a proper book entitled "*Introducción a la cirugía robótica en cabeza y cuello. Manual de disección*" (in Spanish). It was published in January 2017 before the third edition of the course in March 2017. As we move forward it is evident that very quickly many of the previous "facts" became outdated. In the introduction to the previous version of the manual, we stated that "this manual is likely to require prompt updates" given the accelerated pace of the technical and surgical evolution. We needed to set to work and release a new edition. We decided that it would be an English edition so that, hopefully, it could be useful for a wider number of surgeons. Here it is.

Surgery with robotic instrumentation, like any other surgical technique, depends upon a learning and training process. This learning must start from previous knowledge and experience. To perform robotic surgery in the head and neck, prior training in head and neck surgery is required. The experience in minimally invasive surgical approaches, and the skills with endoscopes and endoscopic instruments will make the learning process expeditious. But certainly, things are changing fast, and for some surgical specialties robotic surgery is replacing endoscopic surgery as a standard, so that even the initial learning is becoming robotic. This is not so at this moment for robotic surgery in the head and neck. Therefore, the training curve will strongly depend upon previous experience. For many procedures, particularly for TORS, the robotic versions might be considered "easier" than the non-robotic alternatives (for example with laser instrumentation). Accordingly, the experienced surgeon will find him/herself performing a similar technique alas with a new friendly and intuitive tool. Transition to robotics shall be smooth.

From here, the basic scheme is the same as in any surgical training. The first step is the basic learning, which in the case of robotic surgery includes the knowledge of the robotic platform itself. Robotic surgery requires some technical skills that are completely different from any other surgical technique and that require specific focus. Also, trainees should learn about the application of robotic surgery in the head and neck, the indications (consolidated or in development) and the results already published by the different groups working in robotic surgery applied in the head and neck. Then, training in an experimental environment is necessary. It is likely that the virtual training systems based on software will largely replace this experimental work. This is certainly a field which is particularly developed in robotics, to a point that largely overcomes the limits of robotic surgery itself. In the authors´ view in a few years robotic surgery will completely change the way we learn surgery. Nevertheless, today the training in the experimental operating room is irreplaceable. It is a necessary preliminary step before beginning supervised clinical activity.

The experimental surgical training is usually performed with two types of biological models: animal models and anatomic human models. Both are useful. The animal model allows an *in vivo* surgery; certainly, in a different anatomy, but models are chosen to provide enough analogies. We must understand that the surgery done on the experimental animal is the only surgery we will do in a living being before our first surgery on a patient, and therefore we must value it and take proper advantage. In the human cadaver, we will become familiar with the surgical anatomy; but we shall learn about tissue dissection, haemostasis and management of possible *in vivo* complications on the animal. For anatomical human models, we will use fresh frozen cadavers, or cadavers subject to any other preparation method with which the tissues are in adequate condition for the use of the energy systems we use in robotic surgery. Both the management of the experimental animal and that of the human models must be done in accordance with the corresponding regulations and with the due respect that emanates from adequate medical ethics.

The experimental training in robotic surgery has the peculiarity that it requires the availability of a robotic surgery system for training. Even the availability of clinical equipment is still limited in many areas of the world, which makes the training offer in robotic surgery still relatively scarce. The application in head and neck is also in minority within the clinical indications of robotic surgery. However, both these indications and the clinical use itself are increasing very fast. Therefore, we feel that the demand for training is also growing accordingly.

We are confident that the present text will be useful as a guide for dissection for experimental training in robotic surgery. We have included all the basic contents of the regular training path, as well as the two current main applications in the head and neck: TORS and remote access to the neck.

We have found the physical format of the book, printed in B5, to be practical to be carried to the dissection lab. We have included some blank pages at the end to allow the trainees to take notes. We hope it will become a valuable tool in the fascinating process of learning robotic surgery.

JG, RG. Madrid, May 2020

Disclosure

Since February 2017, J Granell acts as a proctor for Transoral Robotic Surgery (TORS) for *Abex*, with a collaboration and advice contract.

PD. We feel that the "preface" written by Bert W O'Malley Jr and Gregory S Weinstein to our previous 2016 book might be informative as an historical introduction, so we transcribe it bellow.

PREFACE TO 2016 THE EDITION

Plato, one of the world's great philosophers, stated that "a true creator is necessity, which is the mother of our invention". For head and neck cancer, the serious consequences and quality of life damaging effects of radical radiation and chemotherapy was that definite need that spurred our journey into robotic surgery. This personal odyssey began in 2004 at the University of Pennsylvania, where we initiated novel cadaver and animal experimentation to devise TransOral Robotic Surgery (TORS) procedures that could solve that important need of both quantity and quality of life for our head and neck cancer patients. While we were filled with enthusiasm and dreams of changing our specialty, we found that many of our colleagues across the world not only said that "It could not be done", but also that "It should not be done!" Why should there be doubt concerning the utility of robotics in head and neck surgery?

Why should there be such a strong resistance to change within our specialty? We believe this sentiment and growing resistance began in the 1990´s when a significant number of senior medical and radiation oncologists as well as head and neck surgeons proclaimed that chemoradiation would entirely replace surgery as the primary treatment of head and neck malignancies. We recall a specific encounter in 1999 with a renowned head and neck surgeon, who at a national meeting approached us independently and prophesized that in a few years head and neck surgeons will be looking for work and would be relegated to performing post chemoradiation salvage surgery. Naturally we will not divulge who this individual was but given the large numbers of head and neck surgeons that at the time shared those similar sentiments, we presume you will have difficulty determining who made that proclamation. Fortunately, we were not dissuaded in our effort to create TORS, and frankly we did not believe that head and neck surgery was a thing of the past.

While there is no certainty in building the future, and success in any experiment cannot be guaranteed, there is certainty that innovation and invention will not occur and solutions to problems will not be found if one fails to challenge the present. And then there are those who dwell on the cost and futility that may be associated with experimental failures as a rationale to stay in the present. Lewis Thomas, the former Dean of New York University and Yale School of Medicine, pointed out in his book *The Youngest Science: Notes of a Medicine-Watcher*, that Penicillin was widely known to be lethal when injected into guinea pigs. He wondered if Alexander Fleming had chosen to use the guinea pig rather than the rabbit for his revolutionary experiments on Penicillin, the resultant death of the guinea pigs may have halted the adoption of antibiotics and cost countless lives and consumed endless health care dollars over the decades to come.

Looking back into the evolution of robotic surgery in head and neck surgery, we recall the first presentation of a transoral surgery on a human patient utilizing the da Vinci surgical system. This case report from McLeod and Melder was presented at the Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery in 2003 and has been viewed by many as a failure in demonstrating the value of robotics. The problems that McLeod and Melder faced with their procedure were multiple. First, they chose as their first case the marsupialization of a simple vallecular cyst. While this may have been reasonable from the perspective of "do no harm" with a research technique, a surgeon seeing their presentation might wonder about the value of using multi-million dollar technology to perform a procedure that can easily be done with standard far less expensive laryngoscopes and hand-held instruments. Their robotic marsupialization took an hour and fifteen minutes to set up and thirty minutes to complete. In contrast, a conventional laryngoscopic approach takes perhaps 15 minutes for instrument set up and three minutes of surgical time. We see how a skeptic might see this as a bit absurd. The second problem with this 2003 report was that the surgeons utilized a "slotted laryngoscope" which only allowed the robotic camera arm and one operating arm to access the cyst and perform the procedure. One-handed surgery was not going to change the current thought and enthuse most surgeons to pursue the potential for robotics in head and neck surgery. However, we do believe that it is important to recognize the work of McLeod and Melder which was published in 2005 and coincided with our first reports of TORS in human patients. While these innovative surgeons did not invent TORS, they demonstrated important positioning options of the robotic instrument cart relative to the operating room table.

Aside from the resistance to change and prevalent skepticisms for robotics in the early 2000's, there were those who touted that robotic surgery was not a major advance over current transoral laser procedures. Transoral Laser Microsurgery (TLM) had been widely adopted for very early glottic and early to intermediate supragottic cancer. However, when the laser experts tried to popularize the use of TLM for advanced T stage laryngeal cancer, pyriform sinus, or oropharyngeal cancer these procedures never gained acceptance beyond a small cadre of surgeons and remains to this day in the early adopter phase. TLM actually works quite well for early laryngeal cancer but over the many decades since its introduction this technology had made little more than a foothold for cancers of the oropharynx.

It was in this milieu of limited primary surgical options and devastating chemoradiation that one of our Penn residents Neil Hockstein, began his senior research project with a trip to Intuitive Surgical, Inc., in Sunnyvale, California. With Department leadership and resource support for this innovative project he arrived in California with a satchel filled with various mouth retractors and a goal of determining how the multiple arms of the da Vinci system might best be passed and then manipulated transorally. Dr Hockstein's work and early publications made a major contribution to the evolution of TORS as he succeeded in showing that three arm robotic access and manipulation was possible using a common mouth retractor, such as the Crowe Davis.

This research project established the foundation for developing a series of surgical procedures in what our team at Penn coined the name TORS. It is the use of a minimum of three robotic arms inserted transorally that allowed the next level of innovation to occur. We toyed with another acronym, namely Computer Enhanced Robotic Transoral Surgery (CERTS) but we were concerned that the name may infringe upon the trademark of a popular breath mint in the United States. We also decided that TORS sounded more powerful, like the hammer wielding Norse god, Thor. We soon realized that seemingly small details such as a name or acronym could impact long-term adoption.

As we fast forward into 2016, and subsequent to the 2009 approval by the United States Food and Drug Administration for use of the da Vinci robot in transoral head and neck surgery, we are pleased and proud that TORS has maintained a rapid adoption curve world-wide. With many thousands of cases performed annually, particularly for oropharyngeal cancer and more recently for sleep apnea surgery, we reflect on what drove this rapid adoption and success of TORS. It is our opinion that the adoption of TORS stemmed from (1) the problems associated with both chemoradiation as well as the existing open and transoral approaches for oropharyngeal cancer, (2) the rapid rise of human papilloma virus (HPV) related oropharyngeal cancer worldwide, (3) our development of a comprehensive TORS training program based on clearly defined surgical steps, and (4) the relatively short learning curve associated with becoming a TORS surgeon.

Discussing the problems associated with chemoradiation and other surgical approaches for oropharyngeal cancer and the pandemic of HPV related oropharyngeal cancers is beyond the scope of a preface to a book. But if one searches the U.S. PUBMED database using the word "deintensification", there are thirty-seven articles currently published. Of these, twenty-nine are related to the use of chemoradiation in oropharyngeal cancer, particularly HPV related cancers. This is not a surprise since we physicians who treat oropharyngeal cancer are well aware of the introduction of high dose chemoradiation as a strategy to avoid the serious morbidity of radical open surgery of the past.

That said, we have entered an era that we are now using high dose chemoradiation that unfortunately has resulted in serious long term swallowing dysfunction, pain and stiffness, and chronic dry mouth and dental disease. In addition, chemoradiation carries both immediate mortality risk and long term mortality from late consequential effects. It was for this reason that TORS was developed and serves as the rationale for ongoing and emerging "deintensification" human clinical trials. With respect to the TORS approach, many patients avoid concurrent chemotherapy and are able to receive reduced doses and volume of radiation to no need for radiation depending on the results of their TORS and neck dissection pathology. TORS outcome data to date demonstrates an excellent quality of life profile while offering over a 90% overall survival rate, regardless of traditional risk factors such as smoking history that might otherwise portend worse oncologic outcomes with primary chemoradiation. These facts, combined with the short learning curve, have led, in our opinion, to the rapid adoption of TORS for HPV related oropharyngeal cancer across the globe.

Prior to the approval of TORS in 2009, the FDA did not allow official and corporate sponsored training of surgeons on the da Vinci robot. Nonetheless, in 2006, the two of us established the first TORS research and clinical development training program, which was held at Intuitive Surgical headquarters in Sunnyvale, CA. We brought in many of today's leaders in TORS including F. Christopher Holsinger, Eric Genden, Enver Ozer, William Carol, Christopher Rassekh, Ho-Sheng Lin, Richard Smith, Francisco Civantos and two surgeons from the Mayo Clinic system. We taught them our techniques in the cadaver lab, gave didactic lectures and distributed copies of our research protocol with the hopes that they would join us in a U.S national trial to study TORS, and requested that they proceed with research, which they did. This symposium and program, in our opinion, as much as any other, has contributed significantly to the adoption of TORS because it established a group of highly skilled, well respected and motivated early adopters of TORS. Once U.S. FDA clearance was given for TORS, we established a formal TORS training program at Penn which has trained over 400 surgeons, predominantly from the United States, but also from around the globe. The training as it was devised by us, and continues to this day includes web based learning modules, inanimate training on the da Vinci system, a full day of porcine training led by a lab proctor, and a half day of surgeon led cadaver training led by one of us. This training system has led to a remarkably safe and effective adoption and expansion of TORS procedures around the world. We both feel that the TORS Training program, created and established at the University of Pennsylvania, has been one of the most gratifying accomplishments of our careers. We have trained hundreds of surgeons and made new friends worldwide and have personally enjoyed every minute of it. As with all surgical training, indirectly we have hopefully helped many patients as well.

It was in April of 2013 that Jose Granell visited the University of Pennsylvania to learn how to develop a TORS program in Spain. He spent time with us, learning our approach, and returned back home to Madrid to develop his premiere program in TORS. This book is the first on TORS written expressly for Spanish speaking head and neck surgeons. Now for the first time over 10,000 Spanish speaking head and neck surgeons worldwide will have the opportunity learn about TORS also in their native language.

One of our favourite TED talks is by Derek Sivers called *How to Start a Movement*. This TED Talk has had well over five million views. It is under three minutes in length and we recommend you take the time to view it. Sivers states: "*Leadership is overglorified. It is really the first follower that transforms the lone nut into a leader. So as we are told that we should all be leaders, that would be really ineffective. If you really care about starting a movement, have the courage to follow and show others how to follow and when you find a lone nut doing something really great have the guts to be the first to stand up and join in*." Thanks for being among the first in the Spanish speaking world to stand up and join in and in doing so, transform two "lone nuts" into leaders. And to paraphrase our famous head and neck colleague, who harangued one of us back in 1999, lone nuts are a "dime a dozen" while leaders such as you are quite rare.

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