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Editorial

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NOTES: The Media and the Science

All of the early laparoscopic pioneers suffered through the indignity of being the object of derogatory comments by the surgical academic establishment. The great surgical innovators of early era of laparoscopy like Barry McKernan and Eddie Joe Reddick (gallbladder and hernia), Joe Petelin and Maurice Arregui (common bile duct), Dennis Fowler (colon), Lee Swanstrom (esophagus), and Michel Gagner (adrenal and pancreas) all pushed the scientific envelope in busy surgical practices in smaller hospitals. Thirteen years ago, in 1994, my partner (and me by association) were less than gently chided by Nat Soper and Michael Brunt in the *New England Journal of Medicine* for doing operations that were “a triumph of technical ability over common sense”, for daring to do operations on the pancreas laparoscopically. (1)

Our next surgical technological revolution, robotics, swept the minimal invasive world at the turn of the millennium. The literature proclaimed this robotic surgery as being as “safe and effective” as laparoscopic surgery, but none actually proved it to be better. When the publications are actually analyzed, all the operations cost more and take longer (how is this effective?). While no one has actually said so, no one but the urologists are taking robotics very seriously other than for its obvious use as a marketing tool. Most of these expensive toys gather dust in the hallways of the operating room.

By 2006 most laparoscopic surgeons had seen or heard of a remarkable edited video of the removal of an appendix, albeit very normal appearing, through a gastroscope. Fully one year later no endoscopic appendectomy series has ever been published and there is only one publication in a human subject about surgery done through a NOTES technique (and that is about the rescue of a dislocated PEG, hardly something we see every day). (2) This year however, we have been treated to a plethora of animal feasibility study articles. In a recent publication from John Hopkins, the number of animals (five) is actually half the number of authors (ten) (3). At this spring's SAGES Meeting we were treated to edited videos that showed scopes introduced through the rectum, with stool affixed, used to guide surgery on gallbladders that were poorly grasped and dissected with no discernable anatomic landmarks, all often culminating in an explosion of bile. To those that state that these videos resemble the early era of laparoscopy I paraphrase the Lloyd Bentsen/Dan Quayle 1988 Vice Presidential debate; I was there and we never operated like that (and if we did, we certainly never filmed it). Obviously someone noticed and at more recent meetings like the Argentine Congress of Surgery's 78th Clinical Congress in Buenos Aires this fall, IRCAD's Jacques Marescaux treated a standing only audience to masterful video and computer graphics of a NOTES cholecystectomy. Yes we can do this operation but where is the science? Again, at the same SAGES meeting there was significant media play on the world first trans-vaginal cholecystectomy. At this writing a “Goggle” search on vaginal choleystectomies yields 35,000 hits while a PubMed search shows only 5 cases in the literature (none in North America).

The surgical community has also been treated to videos of endoscopic gastric plications in animals (what exactly was plicated to what is difficult to determine), in the guise of performing an endoluminal VBG. In 2000 Michael Sarr's group published excellent follow up data on the VBG, showing that this operation worked to sustain weight loss less than 25% of the time and required re-operation about 20% of the time. (4) American surgeons have essentially abandoned this operation. It was Karl Marx who said history repeats itself first as a tragedy and then as a farce. Why on earth would we again perform a bad operation again but now in a more technically inept way?



The current laparoscopic surgical standard is extremely high. More than one half million laparoscopic cholecystectomies are done every year, most as out patient surgery, and most of the operated patients return to work in a week. Weight loss surgeries are performed on extremely ill patients as outpatients (laparoscopic bands) and with a 2-3 day hospital stay following gastric bypass. The penetration of laparoscopy in colorectal practice is improving and well-designed patient care pathway protocols are minimizing post-operative stays. The problem is that current general surgery residency programs often provide only a low volume of advanced laparoscopic cases and interested surgeons often pursue non- accredited fellowships focused on laparoscopic surgery. There are no current clinical training programs in NOTES. In the “information age” there is significant medical attention to issues related to the quality of health care and patient safety. The public, government and payor groups are demanding specific data on patient outcome related to individual surgeons. The safe care of patients demands some form of oversight into the introduction of new procedures and technologies into surgical practice.

The idea of the NOSCAR Consortium is to develop this technology in the laboratory so that there is supportive data to present to the FDA or Institutional Review Boards so that we can advance the minimal invasive surgical battle against human disease. Perhaps this endoluminal technology even begs a marriage to robotics so that the “scaling” ability of instruments are enhanced; all of minimal invasive technology is essentially about degrees of freedom and angles to gain exposure in a restricted environment. Industry has pledged over a million dollars to the NOSCAR Consortium to support the extensive research that will be needed before introducing NOTES into clinical practice (5). We, the surgical community, need to be fully cognizant of the paradigm shift that this type of surgery entails. This is not just a new approach to do the same operations, for the first time we will deliberately violate the digestive tract to obtain access to the peritoneum. Tissue approximation methods need to be developed that will guarantee no post-operative peritoneal contamination. NOTES will require a significant learning curve to maintain spatial orientation and technological innovation is necessary to provide a stable working platform for our endoscopic instruments.

There seems to be some urgency among the surgical community to present some sort of practical applicability to these procedures and, in my opinion, an unethical competition to be the first to do something “noteworthy” (pun intended) in patients. This leads to media reporting and unrealistic patient expectations that are completely unsubstantiated by the science. Never has so much been said and written about so little of practical significance. As a profession, it behooves us to do the science first, and then do the reporting of objective findings of a definite clinical advantage of new surgical techniques in peer review literature before we extol the advantages of new, and as yet, unproven, procedures in the media.

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