The Impact of Technology on Surgery: The Future Is Unwritten

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The relationship between surgery and technology represents a major issue for the future of our profession. Several new technologies are proposed to surgeons and introduced into the clinical practice every year, in many cases after a very limited evaluation. The clinical and economical consequences of this phenomenon and the role of surgeons in managing it represent one of the major challenges we are facing.

TECHNOLOGY AND SURGERY IN THE LAST CENTURY

For decades, general surgery was performed with a limited use of technology. General surgeons till the 1980s were reluctant to embrace new technologies, such as flexible endoscopy or laparoscopy, and underestimated their potential.

The first laparoscopic appendectomy performed by a German gynecologist, Kurt Semm, on May 30, 1980 was considered an attempt to the holiness of abdominal surgery at such a point that the surgeon was suspended by the German board of surgeons.1 A few years later, when Eric Muhe performed the first laparoscopic cholecystectomy, times were not yet sufficiently mature to accept and develop the concept of minimal invasive surgery (MIS): when the first postoperative complications occurred the technique was abandoned.2

However, the advent of Charge-Coupled Devices (CCD) cameras added to the laparoscope, radically changed the perception of laparoscopic surgery. In a few years, between 1987 and 1992, surgery changed forever. In 1987, Philippe Mouret performed a cholecystectomy by videolaparoscopy and, together with Jacques Perissat and François Dubois, standardized the technique.3 The first presentation of a video showing a laparoscopic cholecystectomy in the US by Jacques Perissat in April 1989 during the Louisville Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Meeting was defined by Ken Forde, the SAGES president, as "…a singular event that changed the course of SAGES and surgery, perhaps for all time." The so called laparoscopic "second French revolution" had started and had its epitome during the 1992 world congress of the International Federation of Societies of Endoscopic Surgeons (IFSES) in Bordeaux. In the 5 years after the first videolaparoscopic cholecystectomy by Mouret, the vast majority of procedures in general surgery have been performed using the laparoscope: from colectomies to gastrectomies, from adrenalectomies to pancreatic resections, from bariatric to oncologic surgery.4

The possibility of making completely visible the act of surgery changed everything: the era of video-assisted surgery had just begun. This revolution in surgery was essentially driven by a few pioneers in laparoscopy and by the growing patients' demand for small scars and a better cosmesis. Industries have been taken by surprise. In fact in the early nineties laparoscopic instruments were sold out and manufacturers were unable to keep pace with the requests for new equipments.

All of a sudden, after decades of low technological profile, surgeons started to believe that technology per se was going to revolutionize surgery, leading to the equation "more technology = better surgery."

Is this true nowadays? Has this been true for the last decades?

NEW MILLENNIUM: THE FIRST DECADE

The most disruptive technological achievement in the era of MIS was the so called Lindbergh procedure, a transatlantic laparoscopic cholecystectomy performed by Jacques Marescaux and his team from New York on a patient in Strasbourg. The paper reporting this extraordinary procedure was published in Nature few weeks after the performance.5 Although in his article Marescaux discussed the advantages of this technique and its role in the future of surgery, the concept of remote surgery was abandoned. Nevertheless, this project, financed by Telecom France, improved significantly the speed of telecommunication and radically changed the quality of long distance phone calls. But it had no impact on surgery.

The advent of laparoscopy represented also a huge opportunity for the surgical companies. In the 1990s, the companies producing laparoscopic equipment and instruments had a huge commercial success.

Companies like Ethicon Endosurgery and Autosuture were among the main driving forces behind the diffusion of MIS: they organized courses, created facilities for dry and wet lab surgery, financed research projects, and influenced surgical careers.

All of a sudden, the relationship between companies, surgeons, medical associations, and institutions became more complex. Till then, general surgeons were not used to deal with the concept of conflict of interest, while this issue was well known in the pharmaceutical industry.

In the 1990s, the growth of many companies acting in the field of MIS was very consistent. To keep up with these financial results they needed new technologies, new “revolutions.” Companies and surgeons were looking forward to reproducing a new laparoscopic revolution: Single Incision Laparoscopic Surgery (SILS)? Natural Orifices Transluminal Endoscopic Surgery (NOTES)? Robotic surgery?

THE INFLUENCE OF ECONOMY ON THE FUTURE OF SURGERY

Different authors have proposed different models to evaluate the factors that drive to the adoption of a new technology into clinical practice. In my opinion, one of the most interesting theories was proposed by Wilson,6 who identifies 3 factors: patients’ demand for technology, low cost to surgeons for learning and using the procedure and manufacturers’ aggressive promotion of the technology. This last point will prove to be by far the most important driving force, strictly dependent on the potential economical impact of the considered technology. A low cost technology applicable to a limited number of patients will determine a different level of promotion by a company compared to a highly expensive technology potentially applicable in very frequent pathologies.

Consider 4 examples of technologies in the field of MIS: SILS, NOTES, Transanal Endoscopic Microsurgery (TEM), and Robotic Surgery.

SILS included the development of special access ports and a few dedicated instruments. The technique is very complex for surgeons, the demand from patients for a reduction in scars is limited, the economical impact for companies is also limited. After a decade of practice the interest in SILS is fading away.

NOTES was proposed in the early years of the new century, but the need for a specific technology was not met by the industry in the last 15 years. Transoral, transgastric, or transvaginal cholecystectomies did not appeal to patients nor to surgeons and eventually the project has declined. Nevertheless, new techniques, such as Transanal Total Mesorectal Excision (TaTME), are increasingly performed thanks to the application of the concept of NOTES.

TEM was developed by Gerhard Buess in 1983,7 it was used only in a few European centers in the 1990s and finally reached the deserved success in the new millennium for local excision and for a new access to rectal cancer radical surgery, the TaTME. Why was TEM underestimated and had such a delayed diffusion? Indications surely were limited, but mainly the technique was perceived as difficult at the time, requiring a long training not easily supported by a business model and the instrumentation is reusable therefore limiting the interest for the company to push its diffusion. The delayed diffusion of TEM represents the perfect example of the overwhelming importance of manufacturer promotion in respect to the other 2 driving forces for the diffusion of the technology as described by Wilson.6

ROBOTIC SURGERY offers the best example of the power and efficacy of a well-conducted aggressive promotion of a technology by a company.

At the dawn of the new millennium, there were a few companies developing different concepts of robotic surgery, but later on, one company succeeded in conquering the market. Intuitive Surgical Inc (Sunny Vale, CA) did manage to become the only manufacturer in the field of robotic surgery. Moreover, Intuitive Surgical Inc blocked the development and marketing of different technologies in the field by owning so far almost 3500 patents, preventing this way any competition that is the fuel of progress.

From this monopolistic situation, the company designed a marketing strategy that led to a very large diffusion of the Da Vinci technology, even in the absence of good clinical evidence of its efficacy.8 Although in clinical use for almost 20 years, with thousands of published articles, there are no randomized controlled trials (RCTs) demonstrating the superiority of robotic surgery over standard laparoscopy.9 This is of no surprise. The way robotic technology is conceived overlaps the characteristics of standard laparoscopy, so that any advantage could be limited to a reduced need for training or an increased confort of the operator, both difficult to translate into a real clinical benefit for the patient. Different it would be if robotic technology were used to overcome the current limitations of laparoscopy or to allow to perform surgery through flexible endoscopy taking advantage from automation, miniaturization, and flexibility to access upper or lower GI pathologies through natural orifices.

On the contrary, while a sophisticated technological tool such as the Da Vinci could represent a step forward in the management of complex cases in limited indications, the economical issues related to the development of a billion dollars technology, push the industry to extend clinical application to more diffuse pathologies including very basic procedures such as inguinal hernias.10

INDUSTRY–PHYSICIAN RELATIONSHIP

The analysis of the penetration and diffusion of the 4 techniques and technologies discussed above shows that the role of the industry is at present the main driving force that determines the adoption of innovations in surgery. Only once in a while, a disruptive innovation changes the history of surgery and in that case the change is driven by physicians and patients. This was the case of laparoscopic surgery after the advent of CCD cameras or of organ transplantation after the development of effective immunosuppressive drugs. Otherwise, in the vast majority of cases, a technological innovation modifies

only partially a given surgical procedure needing hundreds or thousands of patients to prove its efficacy Nevertheless, it is of the utmost importance to submit a new technology to a carefully structured validation process before introducing it into the routine clinical practice.

One of the main challenges for the surgical community in the coming years will be to improve EBM evaluation of any given new technology before its widespread clinical application.

In this scenario the relationship among industry, physicians, and professional medical associations plays a crucial role.11 In a recent article, Patel et al12 assessed the conflict of interest (COI) in robotic surgical studies, validating author's declarations with the open payments database reported to the Centers for Medicare and Medicaid Services. The results were unexpected and worrying: only 21% of studies with a COI declared it in a COI statement, and only 18% of the authors who received payments declared it. Moreover, studies that had undeclared payments from Intuitive Surgical Inc were more likely to recommend robotic surgery compared with those that declared funding (odds ratio 4.29, 95% confidence interval 2.55–7.21).

Similar data have been published in the fields of spine surgery,13 gynecology,14 and more recently ventral hernias.15

In 2015, Surgical Endoscopy published the results of an analysis conducted by SAGES on safety and effectiveness of Da Vinci. The conclusions stated that “Gastrointestinal surgery with the Da Vinci Surgical System is safe and comparable, but not superior to standard laparoscopic approaches. Although clinically acceptable, its use may be costly for selected gastrointestinal procedures.”9 The same journal published a few months later, “A response to the SAGES assessment of the Da Vinci Surgical System” by Myriam Curet, Chief Medical Officer of Intuitive Surgical (Sunny Vale, CA) stating that robotic surgery should not be compared with laparoscopic but with open surgery, and that the SAGES assessment “used a questionable methodology: relying on RCTs data is no longer necessary.”16 Accepting such a statement can be very dangerous for the surgical community. It is worthless to remind that in 1996 an editorial on the Lancet by Horton compared surgical research to “comic opera” reporting that only 7% of all surgical articles published in 1995 on the 4 main surgical journals reported results of RCTs whereas 46% described case series with low grade of evidence.17 Despite the indignation that this remark caused, “the proportion of RCTs in surgery remains low and poor quality research continues without benefit to surgeons or patients.”18

QUALITY VERSUS QUANTITY

In the first part of this editorial, I aimed at identifying the challenges related to the present and future relationship between industry and surgery. But, can we propose solutions?

Buxton19 described the investigation of a surgical innovation that is being adopted in the context of technology assessment. He identified an initial point in the life of a given technology when the adoption is low and involves only a small number of surgeons. This period would give an opportunity for a formalized assessment. However, the following step is when the uptake of the technology suddenly increases involving a large number of adopters. This marks the point beyond which it is not possible to do a formal assessment. By this time, the technology is already, rightly or wrongly, destined for adoption. This is the point that defines Buxton law, which states “it is always too early (for rigorous evaluation) until, unfortunately, it is suddenly too late.” This concept clearly underlines the crucial role of timing in the evaluation of a new technology in a society characterized by a continuous increase in the speed of communication and decision-making processes. Because the point at which a technological innovation evolves into a novel procedure

might not be obvious at the time, prospective open registration of new procedures and early ethical approval are necessary. Evolution and evaluation can then occur simultaneously.

There is no doubt that industry needs to make profit, and profit arises from quantity. On the other hand, good surgical practice is related to quality. The complex relationship between quantity and quality in surgery was brilliantly described and analyzed in a previous European Surgical Association (ESA) Presidential lecture by Henri Bismuth stating: "…if the intention is to ensure the quality of care, is quality quantifiable? How can we measure it? Should we measure it?"20

The solution, in my opinion, is to strive for quality and correctly evaluate quantity or, in other words, to quantitatively evaluate quality. In this process, there are 2 keywords: Ethics and Evidence-Based Medicine (EBM). EBM is the only paradigm that guarantees a correct quantitative evaluation of clinical results, while the respect of strict ethical standards will guarantee quality in surgery.

As stated by Patel et al13 "Much had been written about the value of industry–physician relationship in advancing innovation and improving care. Collaboration between industry and physicians may well be essential to innovation, but the extent of this relationship needs to be transparent, and easily ascertained to allow readers of these studies to assess how a COI could bias the study results and recommendations."

Nevertheless, the enclosure of a correctly completed COI declaration to a manuscript submission form is not sufficient; awareness of COI should represent a strong ethical commitment in everyday practice of every surgeon.

Therefore, to bring objective research practices into the operating theater will require changes in attitude by surgeons and by professional medical associations.

For surgeons, the culture of research and evaluation should be inculcated during training so that it becomes as embedded as the profession's emphasis on safety.19 At the same time, professional medical associations should respect the same ethical standards in their relationship with companies and sponsors.

I strongly advocate that ESA should play a leading role in this process through the natural role of leadership of its members and, in a more ambitious strategy, through the creation of a working group devoted to Health Technology Assessment (HTA) in surgery.

CONCLUSION

It is difficult to foresee the impact of new technologies on future surgical practice considering that:

- Technology does not per se improve surgery
- We should carefully and ethically evaluate new technologies
- Greater scrutiny and transparency are necessary when dealing with medical industry

Nevertheless, if on one side "the future is unwritten" (Joe Strummer, The Clash), on the other side it is our duty to push the boundaries of surgery respecting quality, cost effectiveness, excellence of results and avoiding to delegate to the industry the future of surgery, our future and the future of our patients.

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