HARVARD | BUSINESS | SCHOOL

Case Histories of Significant Medical Advances: Laparoscopy

Amar Bhidé
Caitlin N. Bowler
Srikant Datar

Working Paper 20-008

Case Histories of Significant Medical Advances: Laparoscopy

Amar Bhidé
Tufts University

Caitlin N. Bowler
Harvard Business School

Srikant Datar
Harvard Business School

Working Paper 20-008

Laparoscopy

Amar Bhidé, Tufts University

Caitlin Bowler, Harvard Business School

Srikant Datar, Harvard Business School

Abstract: We describe how operations through laparoscopes – tubular instruments inserted into abdominal cavities – revolutionized gynecological and other surgeries inside the abdomen such as gall bladder removal. Specifically we chronicle the: 1) foundational contributions of gynecologists in France and Germany in the 1960; 2) development of female sterilization and infertility treatments (that used laparoscopes) in Britain in the 1970s; 3) transformation of gall bladder removal surgery in the US in the late 1980s, which set the stage for other "minimally invasive" surgical procedures and, 4) geographic dissemination of these procedures.

Note: This case history, like the others in this series, is included in a list compiled by Victor Fuchs and Harold Sox (2001) of technologies produced (or significantly advanced) between 1975 and 2000 that internists in the United States said had had a major impact on patient care. The case histories focus on advances in the 20th century (i.e. before this millennium) in the United States, Europe, and Japan -- to the degree information was available to the researchers. Limitations of space and information severely limit coverage of developments in emerging economies.

Acknowledgments: We would like to thank Katherine Stebbins for helpful information and suggestions.

Laparoscopy

Laparoscopy has revolutionized gynecological and other surgeries inside the abdomen such as gall bladder removal which once required cutting open the abdomen. Surgeons now routinely use "laparoscopes"—tubular instruments inserted through small incisions—to perform "minimally invasive" operations that have significantly reduced infections, hospital stays, and, recovery periods.[a]

However, as this case history shows, the "revolutionary" change has followed an extended process undertaken by innovative surgeons and medical equipment companies over decades, spurred on by patient demand. Specifically, we will describe the:

1. Technological foundations laid by the French gynecologist, Raoul Palmer, in the 1940s and 1950s, and further developed by German gynecologist Karl Semm from the 1960s through the late 1970s.
2. Adoption in gynecological procedures, namely sterilization and infertility treatments in the 1970s.
3. Transformation of gall bladder removal surgery in the U.S. in the late 1980s, which set the stage for revolutionizing other surgical procedures from the 1990s to the present.
4. Dissemination and adoption outside the U.S. from the 1990s to the present.
5. Equipment producers from the 1980s to the present.

1: Technological Foundations

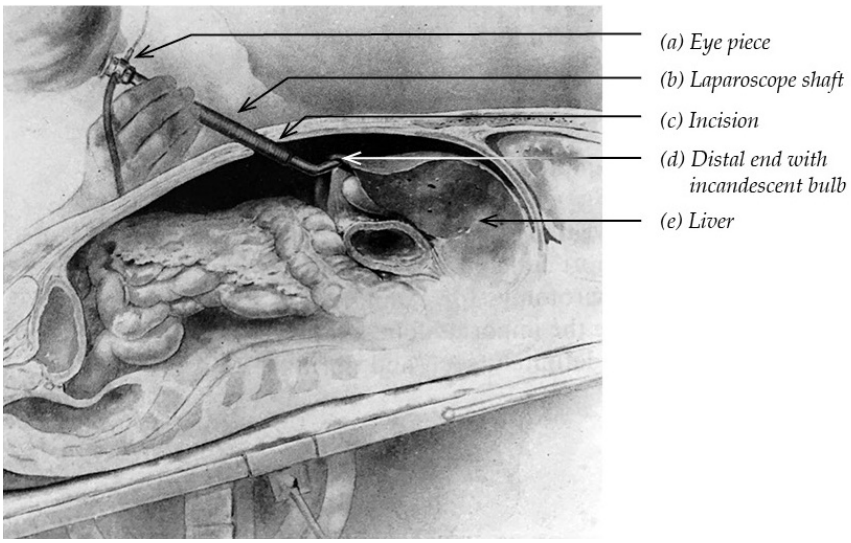
From endoscope to laparoscope

Since the 1870s European physicians had used endoscopes—rigid tubes with lenses—to examine the insides of patients' stomachs by inserting them through the mouth.[1] Around 1912 physicians started inserting endoscopes through small incisions in the abdomen (rather than the mouth) to view organs such as the liver and, in women, ovaries and fallopian tubes. Eventually, tubes inserted through incisions came to be called laparoscopes.

Figure 1 (c. 1927) shows a physician examining a patient's liver through a laparoscope. The physician peers into the laparoscope through the eyepiece (a). The laparoscope's shaft (b) enters the abdominal cavity through a small incision (c). An incandescent bulb at the end of the laparoscope inside the patient (d) illuminates the liver (e), thereby allowing the physician to see within the otherwise lightless cavity.[2]

[a] Throughout the case we refer to the traditional surgical technique of cutting open the abdomen as *open surgery*.

Figure 1 A sectional view of a patient's abdominal cavity



Source: Image from Nadeau and Kampmeier in the Color Atlas of Laparoscopy.

Note: The physician views the liver through a laparoscope.

Between 1912 and 1930 several innovations improved the diagnostic capabilities of laparoscopes. New tools inserted through a second abdominal incision were then developed to perform simple liver and spleen biopsies.[b,3] Physicians improved these early instruments for use in the abdomen by, for instance, shortening tube lengths. However, even though their diagnostic capabilities improved laparoscopes did not catch on with surgeons because they had no direct therapeutic use.[4,5] [c]

Diagnosis to Treatment

In the 1930s French gynecologist Raoul Palmer started developing rudimentary instruments that would eventually transform laparoscopy into a viable therapeutic technique. He continued to improve the instruments in the early 1940s, despite the difficulties of wartime. By the late 1940s he had standardized laparoscopy for diagnostic use in his practice and published detailed descriptions of these procedures.[6] By 1951 he was also using laparoscopy to perform sterilizations, the first instance of therapeutic use.[7]

Palmer's work inspired German gynecologist Karl Semm to learn Palmer's technique and build on those efforts. Semm's experience as an instrument maker before medical school made him uniquely suited to what became a life-long project of refining laparoscopic tools; he started this work in the late 1960s and continued into the 1980s.[8] As he envisioned new applications for laparoscopy, for example laparoscopic hysterectomy (in which the surgeon removes a patient's uterus and cervix), he developed the instruments required to perform them. Through this process he created tools for cutting, cauterizing (burning tissue with a heated instrument to stop bleeding), and resewing or suturing cut tissue.

---

[b] During a biopsy a physician removes tissue from a patient to determine the presence, kind, and extent of disease.

[c] During this period several Japanese physicians were applying endoscopic principles to examine the knee joint. In 1918 Professor Kenji Takagi used a narrow gauge endoscope to examine a patient's painful knee. With a view of the joint's interior he diagnosed the problem (a tubercular infection) and was inspired to design instruments specifically to view joints. These came to be called *arthroscopes*. Between 1920 and 1931 he continued to reduce the diameter of the viewing tube, from 7.3 mm to 3.5 mm. In the 1930s and 40s several physicians in Europe and Japan also reported using narrow gauge endoscopes to examine joints. In 1955 Japanese surgeon Dr. Masaki Watanabe performed the first arthroscopic surgery on a knee, to remove a small tumor. Source: Masaki Watanabe, Robert C. Bechtol, and Wesley M. Nottage, "History of Arthroscopic Surgery," in *O'Connor's Textbook of Arthroscopic Surgery*, J.B. Lippincott Co, Philadelphia, 1-2.

Concerns about the effectiveness and safety of Palmer's and Semm's innovations, however, limited their adoption by other physicians. Skeptics characterized the laparoscopic approach as "blind" because physicians could not directly see what they were operating on inside the abdominal cavity.[9,10] Further, it did not allow surgeons to physically touch ("palpate") organs to feel irregularities they could not see. Surgeons who tried to replicate Palmer's techniques from his publications encountered problems and complications. For instance, the incandescent bulbs used to illuminate the abdominal cavity could burn tissue on contact. And in female sterilizations (in which the surgeon closed off the patient's fallopian tubes), the surgeon risked puncturing bowels. Consequently, many gynecology clinics in Germany banned the technique until 1966.[11] To overcome the reputational damage that these complications had caused within the surgical and patient communities, Semm even changed the name of the procedure to "pelviscopy."[d]

Semm and Palmer did however find allies in two German endoscope manufacturers, Karl Storz (est. 1945) and Richard Wolf (re-established 1947). Semm initially collaborated with Storz, then founded his own company, WISAP, in 1959 to develop and commercialize his inventions. In the same period Palmer worked with Wolf to develop "cold light" laparoscopes in which a long, quartz rod channeled light from an external source into the patient, thus eliminating risk of internal burns.[12] (These devices first sold in 1960.) In 1966 Storz released a laparoscope that pushed illumination further by integrating new fiber optic technology for even better illumination.[13]

The new laparoscopic equipment did not, however, significantly increase adoption of the technique until the 1970s when gynecologists adopted laparoscopy for female sterilization and fertility treatments, as we will now see.

2: Adoption in gynecological procedures

Sterilization

British gynecologist Patrick Steptoe brought laparoscopy into the mainstream by codifying and popularizing its use in female sterilization. In 1959 Steptoe had traveled to Paris to receive training from Palmer with the hypothesis that laparoscopy would be a less risky alternative to diagnostic procedures which required physicians (especially gynecologists) to make a large abdominal incision.[e] Palmer had then also persuaded Steptoe to capitalize on England's more liberal attitudes toward family planning and use laparoscopy to perform female sterilizations.[f] Traditional sterilizations required cutting open the abdomen and having women stay in hospital for three days after the procedure. Laparoscopic sterilizations could be performed through three small incisions as "out-patient" procedures, which did not require hospitals stays.[14] Women also recovered more quickly because there was no large wound to heal. But in many countries, including France, attitudes and rules that restricted female sterilization made the advantages of the minimally invasive laparoscopic procedure irrelevant.

In 1967 Steptoe authored a textbook that provided detailed instruction for laparoscopic sterilization. The book's appearance coincided with the start of a movement to eliminate restrictions on female sterilization in the United States. Previously, state and local government rules had required hospital committees to approve every female sterilization. Legislation passed in 1967 (the year Steptoe's book was published) by the state of Virginia led to a repeal of these requirements throughout the United States and

---

[d] In France, Raoul Palmer had called the procedure "ceolioscopy." Many clinicians living in regions formerly under French colonial control know the technique by this alternate term.

[e] The practice of incising a patient's abdomen to make diagnostic assessments was called *laparotomy*. John Ruddock was an American cardiologist and internist practicing in Los Angeles who had the same concerns about the risks of laparotomy as Steptoe. He adopted laparoscopy as an alternative to laparotomy in the early 1930s. As Ruddock explained, "the internist must share the responsibility for fruitless laparotomies performed for diagnostic purposes; and should use all the ancillary procedures at his disposal before he recommends a diagnostic laparotomy, in order to make, or corroborate, an intra-abdominal diagnosis" Source: Leon Morgenstern, "From Cardiology to Laparoscopy: John Carroll Ruddock, MD," *Surgical Innovation,* 12(3), 185-6.

[f] Both France and Germany were largely Catholic countries where family planning, including sterilization, was discouraged.

a surge in demand from women for sterilizations followed. Between 1970 and 1975 female sterilizations nearly tripled—from 185,000 to 670,000 per year—catching up with male sterilizations, which had never required hospital committee approvals.[15]

Many women asked for laparoscopic sterilization as it did not require hospital stays, and minimized recovery time.[16] Detailed instructions in Steptoe's textbook provided a crucial resource to gynecologists learning the technique, because at the time no other training was available.[17] By 1977 at least 4,000 physicians were performing laparoscopic sterilizations at the rate of about one per week.[18] Growing demand in turn prompted residency programs in gynecology to teach laparoscopic sterilization.

In vitro Fertilization

Fertility treatments provided an even higher profile (but not immediately as common application) for laparoscopic techniques. Steptoe again played a leading role. Besides standardizing laparoscopic sterilization, the gynecologist had also published several articles in medical journals in the mid-1960s The articles caught the attention of Robert Edwards, an animal biologist who in 1958 had joined the National Institute of Medical Research in London to study human fertilization.[g]

Edwards recruited Steptoe to extract eggs laparoscopically from the ovaries of women who had been unable to naturally conceive and between 1968 and the mid-1970s Edwards and Steptoe used those eggs to develop the techniques of *in vitro* fertilization (IVF). Their first article on this technique, published in 1969, attracted worldwide media attention. [19] Then, after nearly ten more years of research, Steptoe and Edwards announced the birth of the first "test tube baby," Louise Brown in 1978.

Although Brown's birth brought Edwards and Steptoe global recognition, they could not secure funds from public agencies for follow-on clinical or research work. In 1980 they turned to private sources to establish the world's first IVF center, Bourn Hall Clinic, near Cambridge, England. Soon after teams established IVF clinics around the world, all using laparoscopy to extract eggs. [h]

3: Transformation of gallbladder removal

Appendectomies set the stage

Although gallbladder removals would later become the leading application of laparoscopy in general surgery, laparoscopic appendectomies performed in the 1970s came first. And, it was a gynecologist, the German laparoscopy pioneer Karl Semm, not a general surgeon, who led the way.

Semm began performing appendectomies after noticing during his laparoscopic gynecological examinations that some women had inflamed, but not yet infected, appendices. Semm would then preemptively remove these appendices—laparoscopically—before they became infected and required emergency surgery.[20]

However, laparoscopic appendectomies did not immediately enter mainstream surgical practice. Mild-to-moderately inflamed appendices often do not produce any symptoms, so patients do not seek treatment. When an appendix becomes highly inflamed it tends to burst, infecting the abdominal cavity, which can then trigger a life-threatening immune response (called sepsis). Therefore, physicians tried to remove appendices as soon as patients feel the pain produced by advanced inflammation and believed that

---

[g] Steptoe's initial publications in British medical journals described his process for extracting eggs (oocytes) from ovarian follicles under direct vision through the laparoscope (1970). The technique made it possible to collect patients' eggs regularly, which was needed to carry out the research into *in vitro* sterilization Edwards imagined (Brinsden, 2009). Steptoe's facility with laparoscopy, clinical practice, and genuine concern – at that time unusual – for the plight of infertile women made him an ideal collaborator. Source: [Robert Edwards: The Path to IVF].

[h] Edwards won the Nobel Prize in Physiology or Medicine for this work in 2010. Steptoe had died in 1988 so Edwards accepted on their behalf. https://www.nobelprize.org/nobel_prizes/medicine/laureates/2010/edwards-facts.html.

traditional "open" procedures were faster and safer for immediate removal because it allowed them directly view, excise, and suture the appendix.[21] Further, the size of the scar an open appendectomy left behind was small so the benefits of laparoscopy, which requires three incisions were less compelling.

In contrast, gall-bladder removals, which also treat a painful, age-old condition, are planned "elective" procedures rather than emergency operations.[i,22] While traditional open methods were effective and safe, patients required as many as six weeks to recuperate and[23] were left with large visible scars. There was, surgeons soon discovered, latent patient demand for a less-invasive surgical technique to remove gall bladders that could reduce recovery time and scarring. Additionally, arthroscopic knee surgeries that also reduced recovery times and trauma had already become popular after they were introduced in the 1960s. Here too orthopedic surgeons operated through narrow tubes inserted through small incisions. But, surgeons operating on knees did not rely on palpation to uncover problems they could not see (either directly or through a tube). The rapid spread of *minimally invasive* arthroscopic surgery likely increased the acceptance of patients, and at least some general surgeons, of the laparoscopic removals of gall bladders).

The first laparoscopic gallbladder removal

French surgeon Phillipe Mouret performed the first laparoscopic gallbladder removal in the summer of 1987 in Lyon, France,[24] but did not attempt to promote the technique further. Two U.S. surgeons from Georgia, J. Barry McKernan and William B. Saye, followed less than a year later. McKernan and Saye had attended a presentation by Karl Semm on his experience performing a laparoscopic appendectomy. They left the presentation with the question: If Semm has removed the appendix laparoscopically, why not the gallbladder? (The Georgia surgeons were unaware of the previous gallbladder removal in France.) To prepare for a laparoscopic gall bladder removal, McKernan and Saye performed a laparoscopic appendectomy in May, 1988.

Saye then found a willing patient for laparoscopic gall bladder removal by accident, in a barber shop: The surgeon was waiting for a haircut when, through casual conversation, another customer discovered he was a doctor and complained to him about her gall stones and the operation that would be necessary to remove her gallbladder. Specifically she was afraid of the large post-operative scar the surgery would leave. Saye described the new laparoscopic approach he and McKernan wanted to try to the woman and she was eager: "I want to have it now!" On June 22, 1988 they performed their first laparoscopic gall bladder removal on her.[25] There were no complications, recovery was swift, and as expected, scarring was minimal.

Improving and Promoting the procedure

The Georgia surgeons, like Mouret in France, did not promote laparoscopic gall bladder removal in the U.S. Rather two surgeons, Eddie J. Reddick and Douglas O. Olsen, and colleagues in a Nashville, Tennessee hospital, improved and popularized the procedure. Reddick was an expert in laser-assisted surgery in which surgeons used lasers, instead of scissors and scalpels, to more precisely cut tissue; this minimized tissue damage and shortened recovery time. Lasers, initially used by dermatologists in the early 1960s had spread to gynecology, gastro-enterology, and general surgery by the late 1970s. Widening use attracted surgeons to workshops on laser-assisted surgery that Reddick conducted around the country in the 1980s.[26]

In May or June of 1988, the Georgia surgeon McKernan attended a Reddick workshop during which he shared the experience of performing the laparoscopic appendectomy with the instructor. In the conversation McKernan also described his plan to perform a laparoscopic gallbladder removal procedure.

---

[i] At the time laparoscopic gallbladder removal emerged as an alternative, two other alternatives were years into development: shock-wave lithotripsy and bile acid therapy. The shock-wave approach was effective at breaking up the stones with targeted acoustic waves so the body could naturally flush them out, but the frequent recurrence of stones mitigated its viability as a long term therapy. Bile acid therapy sought to increase the gall bladder's ability to break down stones through oral administration of biliary compounds, but concerning side effects limited its use. The arrival of laparoscopic gallbladder removal eliminated need for continued research into these alternatives. Source: Charles K. McSherry, "Cholecystectomy: The gold standard," *American Journal of Surgery*, 158(3) (1989), 174-8.

Reddick immediately saw how laparoscopic gallbladder removal would appeal to patients and believed that laparoscopy could naturally extend his expertise in surgical lasers.

Reddick then recruited Olsen to perform five laparoscopic gallbladder operations in which they incorporated laser surgery techniques and two other tools: video imaging and surgical clips.

Video imaging, adapted from arthroscopic surgery of the joints. As mentioned orthopedic surgeons performing arthroscopic knee operations did not worry about palpation. Rather they relied on seeing ligaments and other structures inside knee joints. But directly viewing the insides knees through a tube was difficult.

In the mid-1970s miniaturized video cameras were attached to the end of arthroscopes to transmit images displayed on several TV screens in operating rooms. With this change surgeons did not have to peer down through the eyepiece of arthroscopes and could therefore more easily use both hands to operate. Further, the other TV screens provided visual guidance to nurses and residents assisting the procedure. Without it they would have had to rely entirely on the instruction provided by the surgeon who would be the only one looking through eyepiece. Reddick and Olsen attached these cameras to laparoscopes for use in their operating room.[27] [28] (See **Figure 2**.)

Surgical clips allowed surgeons to suture cut tissue in about half the time as manual re-sewing. These clips, however, had been optimized for open surgery. Reddick and Olsen adapted them for use laparoscopically in an improvised way. This adaptation attracted the interest and support of U.S. Surgical, the country's largest supplier of surgical clips, whose engineers helped redesign the clips Reddick and Olsen had adapted for laparoscopy to enable low-cost high-volume production. The company's sales network would subsequently promote laparoscopy's rapid adoption. (See **Exhibit 2**: U.S. Surgical's Sales force).

Figure 2 Surgeons perform a laparoscopic procedure

A: *Surgeon & Surgeon's monitor*
B: *Assistant & Assistant's monitor*
C: *Nurse*

Source: Modified from Renee C. Minjarez and Blair A. Jobe, "Surgical therapy for gastroesophageal reflux disease, GI Motility online, 2006, https://www.nature.com/gimo/contents/pt1/fig_tab/gimo56_F3.html, accessed May 2017.

Note: The team views the patient's abdominal cavity on monitors. Multiple monitors allow team members to position themselves optimally around the patient, to assist the primary surgeon.

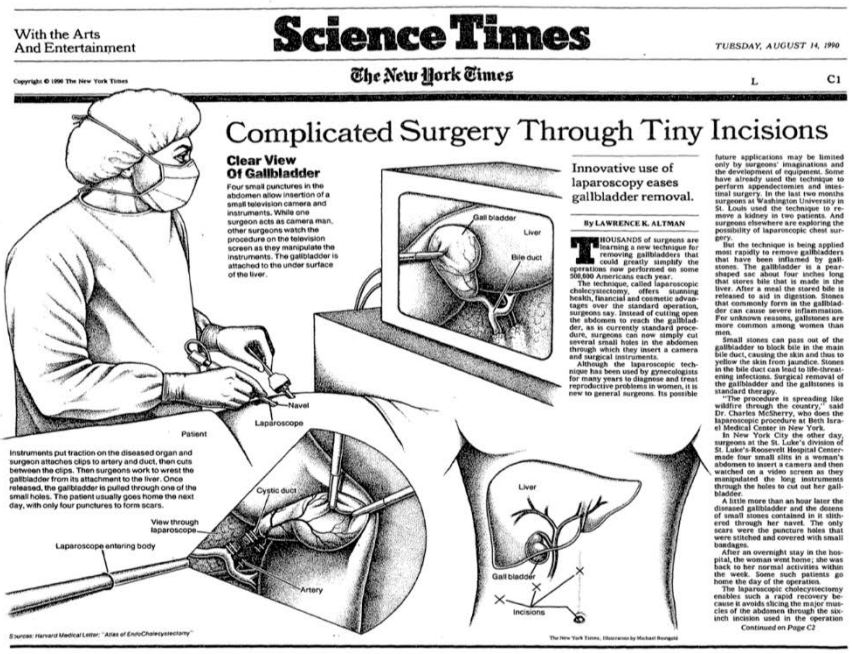
Popularizing the Procedure

Reddick and Olsen first disseminated their new technique for laparoscopic gallbladder removal through Reddick's three-day laser workshops. Then they made a splash at the October 1989 meeting of the American College of Surgeons.[29] U.S. Surgical and Karl Storz had information booths on the main floor of the conference hall, as leading instrument manufacturers commonly did at conferences. Rather than share

their work in a traditional paper presentation, Reddick and Olsen showcased their technique through a video that played throughout the day in those booths.[30] The video immediately captured the attention of surgeons and reporters. Articles about the event published in the Wall Street Journal and New York Times garnered nationwide public attention.[31] (See **Figure 3**.)

Media coverage spurred patient demand for the procedure.[32] "Without mass media," commented Reddick, "we would still be back doing a few cases here and there. The news media made all the difference in the world. The U.S. media is so prevalent and they jump on every story and play crazy."[33]

Figure 3 A New York Times article, published August 14, 1990



With the Arts And Entertainment

Science Times

TUESDAY, AUGUST 14, 1990

The New York Times

L C1

Copyright © 1990 The New York Times

Complicated Surgery Through Tiny Incisions

Clear View Of Gallbladder

Four small punctures in the abdomen allow insertion of a small television camera and instruments. While one surgeon acts as camera man, other surgeons watch the procedure on the television screen as they manipulate the instruments. The gallbladder is attached to the under surface of the liver.

Navel

Laparoscope

Patient

Instruments put traction on the diseased organ and surgeon attaches clips to artery and duct, then cuts between the clips. Then surgeons work to wrest the gallbladder from its attachment to the liver. Once released, the gallbladder is pulled through one of the small holes. The patient usually goes home the next day, with only four punctures to form scars.

Cystic duct

View through laparoscope

Laparoscope entering body

Artery

Gall bladder

Liver

Bile duct

Liver

Gall bladder

Incisions

Innovative use of laparoscopy eases gallbladder removal.

By LAWRENCE K. ALTMAN

THOUSANDS of surgeons are learning a new technique for removing gallbladders that could greatly simplify the operations now performed on some 500,000 Americans each year.

The technique, called laparoscopic cholecystectomy, offers stunning health, financial and cosmetic advantages over the standard operation, surgeons say. Instead of cutting open the abdomen to reach the gallbladder, as is currently standard procedure, surgeons can now simply cut several small holes in the abdomen through which they insert a camera and surgical instruments.

Although the laparoscopic technique has been used by gynecologists for many years to diagnose and treat reproductive problems in women, it is new to general surgeons. Its possible future applications may be limited only by surgeons' imaginations and the development of equipment. Some have already used the technique to perform appendectomies and intestinal surgery. In the last two months surgeons at Washington University in St. Louis used the technique to remove a kidney in two patients. And surgeons elsewhere are exploring the possibility of laparoscopic chest surgery.

But the technique is being applied most rapidly to remove gallbladders that have been inflamed by gallstones. The gallbladder is a pear-shaped sac about four inches long that stores bile that is made in the liver. After a meal the stored bile is released to aid in digestion. Stones that commonly form in the gallbladder can cause severe inflammation. For unknown reasons, gallstones are more common among women than men.

Small stones can pass out of the gallbladder to block bile in the main bile duct, causing the skin and thus to yellow the skin from jaundice. Stones in the bile duct can lead to life-threatening infections. Surgical removal of the gallbladder and the gallstones is standard therapy.

"The procedure is spreading like wildfire through the country," said Dr. Charles McSherry, who does the laparoscopic procedure at Beth Israel Medical Center in New York.

In New York City the other day, surgeons at the St. Luke's division of St. Luke's-Roosevelt Hospital Center made four small slits in a woman's abdomen to insert a camera and then watched on a video screen as they manipulated the long instruments through the holes to cut out her gallbladder.

A little more than an hour later the diseased gallbladder and the dozens of small stones contained in it slithered through her navel. The only scars were the puncture holes that were stitched and covered with small bandages.

After an overnight stay in the hospital, the woman went home; she was back to her normal activities within the week. Some such patients go home the day of the operation.

The laparoscopic cholecystectomy enables such a rapid recovery because it avoids slicing the major muscles of the abdomen through the six-inch incision used in the operation

Continued on Page C2

Source: Harvard Medical Letter: "Atlas of EndoCholecystectomy"

The New York Times. Illustration by Michael Rompotti

Source: Lawrence K. Altman, "Complicated Surgery Through Tiny Incisions," The New York Times.

Note: The article introduced laparoscopy to the greater New York metropolitan region.

4: Dissemination & Adoption

Factors Favoring Adoption

Surgeons in smaller practices enthusiastically adopted the new gallbladder removal technique. The capital investment required was affordable. In 1991 a full laparoscopy system cost between $30,000 to $40,000 (or $50,000 in 2016).[34] Private and public health insurance programs supported laparoscopy because it reduced the days patients spent recuperating in hospitals (which the insurers would otherwise have had to pay for). For the first few years in use Medicare even reimbursed hospitals at rates equal to open gallbladder removal.[35]

As with other surgical innovations, surgeons were free to adopt laparoscopic procedures as long as they had the consent of patients. And, U.S. Food and Drug Administration (FDA) rules, which could have slowed the development of clips, lasers and other devices used in laparoscopy did not. The 1976 Medical Device Regulation Act had given the FDA authority to require clinical trials for new devices; previously the FDA only had such authority over new drug introductions. Devices that the FDA decided were not "substantially equivalent" to existing devices had to undergo clinical trials to demonstrate safety and effectiveness. Basic laparoscopes had entered the U.S. market prior to 1976, and as device manufacturers

introduced new features in their offerings, the FDA deemed them substantially equivalent and did not require clinical trials.[36]

Physicians did have to learn new techniques, such as inflating the abdomen to create the space needed to view the organs clearly and manipulating instruments through small incisions.[j] And as mentioned earlier, some surgeons, particularly in academic medical centers favored the traditional open procedure[37] in which they could directly feel ("palpate") and see organs inside the abdomen instead of relying just on images displayed on a TV screen. "Why look through a keyhole when you can look through an open door?" they asked.

U.S. Surgical's sales force, which provided training, as well as strong patient demand helped overcome these obstacles. More than half of all 33,000 general surgeons learned laparoscopy within 18 months of the 1989 American College of Surgeons meeting.[38] In 1992, the National Institutes of Health declared laparoscopic gallbladder removal the gold standard of care for gallstones.[39] By then, 80% of all gallbladder removals (totaling nearly 300,000) in the U.S. were already being performed laparoscopically. (See **Exhibit 3** for a timeline of the events described in this section.) And eventually, more conservative medical centers adopted the procedure.

Some skeptics did question whether the quicker procedure encouraged more people with gall stones to undergo surgery, thus increasing total costs. However, unlike other high-cost operations, such as coronary artery bypass grafting (CABG), whose cost-effectiveness attracted considerable scrutiny, no systematic review of laparoscopy's economic impact on healthcare costs in the U.S. was ever undertaken. Its overall cost-effectiveness was simply taken for granted. [k]

Adoption in Other Developed Countries

The U.S. Office of Technology Adoption (OTA) had sponsored studies of the diffusion of several new medical technologies, including laparoscopy, in ten industrialized countries. The studies, compiled into a volume published in 1980 and updated in 1994, reported that adoption of laparoscopy in Europe and other developed countries lagged, although with some variations between individual countries.

Administrators in Britain's National Health Service (NHS), who were under pressure to reduce costs, favored laparoscopy because it promised shorter hospital stays, which they assumed would be less expensive. However they did not, according to the OTA study, offer much actual support. Rather adoption started in the relatively small private health sector where it was championed by younger surgeons and eager patients.[40]

The French national health insurance scheme that provided universal coverage to the population neither hindered nor promoted dissemination. Adoption took place in those clinics already equipped for diagnostic laparoscopy where physicians were willing to extend use of this equipment for therapeutic use.[41, 42]

In Germany, the conservative culture of general surgeons (which as mentioned went back to Semm's time) and their unwillingness to learn new skills were significant obstacles. This changed only after that physicians in other disciplines, such as urology, were going to be performing more and more of the laparoscopic procedures patients demanded.[43]

---

[j] An *insufflator* inflated the abdomen by pumping CO_2 into the abdomen. A *trocar* was a very short, rigid tube inserted into a patient's abdomen. The surgeon inserted his scope or tool into the abdominal cavity *through* the trocar. The trocar created a seal around the opening to prevent air, gas, or fluids from escaping through the tube.

[k] Patients' stays in intensive care units were shorter when compared with open surgery, but the number of patients who sought out laparoscopic gallbladder removal increased significantly. The increased volume of surgeries generated more costs for health systems. Further, surgeons began to regularly do additional procedures prior to a laparoscopic surgery to gather data on the patient's anatomy and condition, which added to total costs. (OTA 126)

Sweden was exceptional in quickly following the surge in laparoscopic surgery in the US. In 1990, the Swedish Council on Health Technology Assessment commissioned a review of the potential therapeutic uses of laparoscopy. Just a year later, in 1991, the health service created a fund to support services associated with shorter post-operative recovery times, such as laparoscopy.[44]

Like many countries in Europe, Canada paid for the healthcare of citizens. But physicians had considerable choice around how to deliver care, particularly for procedures that did not require expensive capital equipment (like heart-lung machines or MRIs). This flexibility allowed Canadian physicians to quickly respond to patient demand for laparoscopic surgery. Echoing patterns in the U.S., a surgeon at a community hospital rather than a prominent teaching hospital performed Canada's first laparoscopic gallbladder removal in 1990. However, he learned of the technique on a trip to Europe. By March 1993, just two and a half years after that first gallbladder removal, nearly 70 percent of hospitals across Canada had adopted the technology for surgery.[45]

Laparoscopic gallbladder removal also arrived in Australia in 1990 and the Australian Institute of Health (AIH) assessed it immediately, found the up-front cost to hospitals acceptable, and supported adoption. It also quickly introduced instruction into teaching hospitals and smaller surgical centers.[46] Eventually the AIH developed standardized accreditation and training procedures for laparoscopic gallbladder removal in response to concerns that surgeons in smaller centers were not adequately skilled.

As in the U.S., no other developed countries systematically analyzed over-all cost effectiveness. Health authorities simply assumed that lower upfront capital costs and shorter hospital stays translated into greater cost-effectiveness. The possibility that cheaper and less invasive procedures might increase in unnecessary operations was noted but not investigated.

Adoption in Low- and Middle-Income Countries

Interviews with informed observers suggests that some hospitals in large cities that tried to keep up with technological advances and had surgeons who had trained abroad started using laparoscopy by the mid-1990s. But, outside the urban centers, factors such as the lack of training in new techniques and the relatively low cost of hospital stays (compared to other costs) favored known, open procedures. (See **Exhibit 4**.)

5: Producers

Laparoscopic surgery required three kinds of sophisticated instruments: the laparoscopes themselves; "insufflators" to inflate the abdomen (with carbon dioxide); and, short metal tubes called "trocars" to create sealed openings for inserting laparoscopes and other tools into abdomens without letting gases or fluids escape . In the 1980s and 1990s only a few large medical device companies, all based in Germany and the U.S. produced all three. The German companies, Karl Storz and Richard Wolf, had, as mentioned, collaborated with pioneering laparoscopists. The U.S. companies were Stryker (which would later become the market leader) American Cystoscope, Cabot Medical, Eder Instruments, KLI, and Reznik.

Other manufacturers focused on trocars which were the least sophisticated of the instruments used in laparoscopy and sometimes sold as disposable products. Between 1977 and 1986 seven companies had applied for the FDA's approval for new trocars. As laparoscopy boomed, trocar applicants jumped with 23 new companies seeking approvals from the FDA in 1994 alone.[1] (See **Exhibit 5**.)

---

[1] The 1976 Medical Device Regulation Act first brought the efficacy of medical devices under the FDA's purview. (Earlier legislation had covered safety). The 1976 Act required the FDA to classify devices as new products or extensions of existing products. Devices classified as new had to undergo clinical trials before they could be sold. If, however, the FDA classified a device as an extension of an existing device, no trial is necessary; companies merely have to file a "510(k)" notification with the FDA. Since devices like trocars had been used before 1976 new trocar producers all sought and secured 501 (k) exemptions.

Aside from the instrumentation, laparoscopic operations used, as mentioned, suturing clips and a variety of accessories. U.S. Surgical established itself as a leader in this market in 1989 and 1990 initially by selling laparoscopic suturing clips. It then offered single-use "kits" that included these clips, as well as other surgical accessories such as forceps and graspers. U.S. Surgical's revenues and earnings surged as hospitals across the country bought these kits in bulk to meet patient demand for laparoscopic surgery.

Increased competition for both kits and standalone laparoscopic clips, notably from Johnson & Johnson, reduced market share. Further, once physicians mastered laparoscopic procedures, many adapted traditional multiple-use surgical tools for laparoscopic use. This eliminated the need for the laparoscopy-specific disposable tools in U.S. Surgical's and others' kits. Simpler, cheaper kits would suffice. This trend among physicians toward reusable tools was encouraged by hospital and Medicare administrators hunting for opportunities to contain costs.[47] [48]

By the 2000s the frenzied growth of 1990 to 1995 gave way to a more gradual, but steady increase. As the rate of growth slowed the market consolidated and the number of entrants fell. As of 2009 two companies dominated the $1.5 billion global market: Stryker Corporation (with 47% of sales) and Karl Storz (with 34%). And less than five new companies sought approval for trocar-related devices each year from 1997 through 2016.

Epilogue: Laparoscopy as a platform technology

After adoption in gallbladder removal in the U.S., laparoscopy expanded to other abdominal operations performed by general surgeons, starting with hernia repair and colon removal. Physicians then used it to examine the extent of a cancer's spread within the abdomen and to remove malignant tissues. By 2005 the practice was firmly embedded in a variety of surgical applications performed by general surgeons, gynecologists, colorectal surgeons, and oncological surgeons. These include appendectomy, hernia repair, tumor removal, bariatric surgery, anti-reflux surgery, and many others. Even in appendectomy, where the advantages are relatively modest, laparoscopic procedures in the US increased from 20% in 1999 to 43% in 2003.[49]

Many technological advances have continued to support laparoscopic surgery. Surgeons have reduced the number and size of incisions that different procedures require. Some procedures can now be performed using a single incision in the abdomen, where three were previously required.[50] Other teams have developed robotic laparoscopic tools to provide surgeons even greater control in complex procedures.[51] Accurately visualizing the volume and contours of internal organs and tissues on two-dimensional screens posed significant challenges. Engineering teams have combined sensor technology into existing software that allows surgeons to perceive two-dimensional renderings as if they are in three dimensions. Robotics and visualization continue to be rich areas for research and development.

Exhibit 1 List of tools required for diagnostic laparoscopy c. 1930s - 40s

Tool	Purpose
Laparoscope	A rigid tube with lenses inserted through a small incision in the abdomen. Used to view inside the abdominal cavity.
Insufflator & Veress needle	The insufflator pumped CO_2 into the abdominal cavity through a rubber tube and Veress needle. The CO_2 inflated the abdomen to create the space that allowed better visualization and maneuvering of organs by physicians.
Trocar	A short, rigid tube inserted into a patient's abdomen. It allowed a tool or viewing scope to be inserted into the abdominal cavity. A seal attached to the opening prevented air, gas, or fluids from escaping through the tube.
Light source	Incandescent lamp inserted into the abdominal cavity (through a trocar) to illuminate the cavity.
Graspers	Instruments that allowed the physician to maneuver organs within the abdominal cavity. (Inserted through a trocar.)
Biopsy needle	Needle used to extract cells for diagnosis by a pathologist. (Inserted through a trocar.)

Source: R. Vecchio, B.V. Macfayden, and F. Palazzo, "History of laparoscopic surgery," *PanminervaMed*, 42 (2000), 87-90.

Note: All of these tools are still standard laparoscopic instrumentation. Manufacturers have since developed them significantly.

Exhibit 2 U.S. Surgical's Salesforce

During the 1970s U.S. Surgical's auto-clip device revolutionized wound closure in open surgery by dramatically reducing the time required to close up a patient. The founder of the company, Leon Hirsch, was a curious, scientifically-minded New Yorker who graduated from the prestigious Bronx Science in 1945. However, as a dropout of City College, he was an unlikely founder of a major medical device manufacturing company. After leaving school he sold household products and coin-op laundry machines for 17 years.

By 1964 Hirsch was looking for an opportunity to enter a higher margin business with no preference as to the particular industry. That year he noticed a bulky, club-like device on a colleague's desk that turned out to be an early version of an auto-suture device surgeons had never adopted (a Hultl stapler). Hirsch took the device home, refined the design through a series of balsawood models, and got feedback on the potential device from several surgeons at Johns Hopkins. With the surgeons' encouragement he invested his life savings ($75,000) to have a machine shop produce working models.

When Hirsch first launched U.S. Surgical in 1967 surgeons were reluctant to adopt the new technology, preferring to close wounds using traditional needles and durable thread. Hirsch realized that a knowledgeable salesforce conversant in medical terminology, instrumentation, and surgical procedures would be the key to communicating the auto-clip's benefits to surgeons. In 1972 he developed a rigorous six-week training course for potential salespeople who then visited operating rooms around the country, educating surgeons and facilitating adoption of the auto-clip. The sales force built the company's market share and reputation.

The direct lines of communication the sales force created between operating rooms and U.S. Surgical's engineers were critical to the company's ability to develop new products. They were the channel through which company representatives picked up on the experimentation in laparoscopy occurring in the U.S. between 1987 and 1989. This ground-level knowledge gave the company a significant lead over competitor Johnson & Johnson, which launched its own line three years later; in 1992 U.S. Surgical controlled 85% of the market. The laparoscopic auto-clip device the company delivered in late 1989 was a key element in the rapid adoption of laparoscopic surgery in the U.S.

Source: Reese, Jennifer. "Getting Hot Ideas from Customers." Fortune 18 May 1992: 86-87.

Note: Fleming, Cameron, Kimberly Nearing and Erik Syring. "Leon C. Hirsch and the United States Surgical Corporation." *Tales from Successful Entrepreneurs*. Boston: Harvard Business School, 15 August 1995.

Exhibit 3 U.S. timeline of laparoscopic adoption

Year	Month	Event
1987	July	In France, Philipe Mouret performs the first laparoscopy gallbladder removal.
1988	April	McKernan & Saye perform a laparoscopic appendectomy in the U.S.
	May	McKernan attends a seminar by Reddick on laser surgery. He shares his experience completing a laparoscopic appendectomy with Reddick.
	June	McKernan & Saye perform first laparoscopic gallbladder removal in U.S.
	September	Reddick & Olsen perform their first laparoscopic gallbladder removal.
	December	Reddick & Olsen publish their work on laparoscopic gallbladder removal in a journal on laser technology.
1989	January to September	Reddick & Olsen hold two- and three-day workshops on laser technology in which they teach laparoscopy to mid-career surgeons.
	October	The American College of Surgeons meeting convenes. Reddick & Olsen show video footage on the exhibition floor of a laparoscopic gallbladder removal they performed. The video gets the attention of the attendees.
	November	U.S. Surgical releases an auto-suture device adapted for laparoscopy.
1990	April	More than half of all 33,000 general surgeons are trained in laparoscopy.
1992		The National Institute of Health declares laparoscopic gallbladder removal the gold standard of care.

Exhibit 4 Challenges to adoption in Low-Middle Income Countries (LIMC)

The economics that favored laparoscopy in the West did not apply in Lower-Middle Income Countries (LMIC) of South America, Africa, and Asia, outside large urban centers. Many hospitals and health systems in these areas struggled to meet population demand for the most basic safe and affordable surgical and anesthesia services.

For those hospitals and health systems that aspired to offer laparoscopic surgery, its cost dynamics created challenges. In addition to the initial investment in reusable instruments (scopes, insufflator, etc.), hospitals had to budget for their maintenance and the disposable materials required for each. Measured just in terms of material costs, a laparoscopy procedure was more expensive than those for an open surgery. Only when accounting for systemic costs, such as length of stay, analgesics, wound complications, recovery and "cost to society"—which assumed an insurer—was laparoscopy less expensive. In countries without subsidized health insurance plans, many patients chose open surgery based on price alone.

For example, a team from the University of Toronto set out to understand why laparoscopic surgery at a major West African hospital (1,700 beds; regional general hospital and national referral hospital; teaching hospital for doctors, nurses, and midwifes) in a lower middle-income country (LMIC) was not being used to its full extent. In 2006 the hospital had acquired two sets of laparoscopic equipment, outfitted two operating rooms and trained four of its twelve surgeons in laparoscopy. However, utilization was very low.

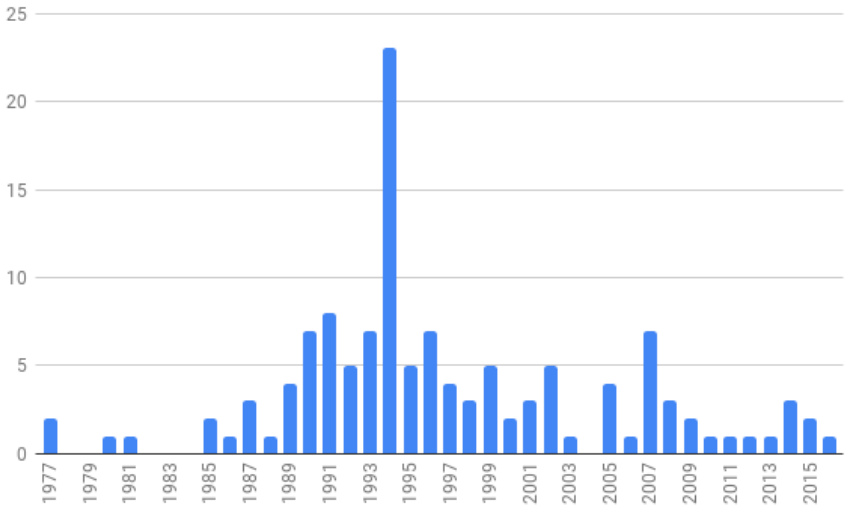
The research revealed that the pricing schemes encouraged patients to choose open surgery even though hospitals preferred laparoscopy. The low in-hospital costs for patients ($3/day) dramatically diminished the cost advantages the technology provided to payers in the U.S. or Europe. The dynamic also impacted surgeons' incentives for pursuing and maintaining laparoscopic skills.

Even health systems or hospitals that could afford laparoscopy's initial and ongoing costs sometimes found the costs of developing the human health infrastructure a challenge. In one Argentinian hospital surgeons themselves had to be motivated to learn the technique and train others, which often hinged on the question of whether there would be enough demand from patients with the ability to pay. It could be difficult to find trained surgeons to proctor the number of surgeries required to satisfy licensing boards, despite initial training abroad or in-country. Finally, nursing and anesthesiology staff in such hospitals were unlikely trained in the instruments, equipment, or surgical techniques and that burden would fall on the surgeon, making adoption an even bigger endeavor.

However, as imaging technology was also limited in these systems, public health officials recognized laparoscopy as much for its diagnostic value as its therapeutic use. Finding ways to make the tools and training more widespread for both applications remains an ongoing challenge.

Sources: Choy, Ian, et al. "Barriers to the uptake of laparoscopic surgery in a lower-middle-income country." Surgical Endoscopy 27.11 (2013): 4009-15; Tiffany Chao, et al., "Systematic review of laparoscopic surgery in low- and middle-income countries: benefits, challenges, and strategies," *Surgical Endoscopy*, April (2015); H.J. Asbun, et al., "Successfully establishing laparoscopic surgery programs in developing countries: clinical results and lessons learned," *Surgical Endoscopy*, 10 (1996), 1000-1003. See also: Meara, J. G., Leather, A. J., & Hagander, L. (2015). *Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. The Lancet*, 569-624.

Exhibit 5 Number of companies that submitted their *first* 501K to FDA for premarket approval on a trocar or trocar-related device.



Source: 501Ks.

Endnotes

[1] A.M. Kaiser and M.L. Corman, "History of Laparoscopy," *Surgical Oncology Clinics of North America* (2001): 482 - 483. See also: NIH. (2016, August). *Abdominal exploration*. Retrieved from Medline Plus: https://medlineplus.gov/ency/article/002928.htm and Ree, J. (1993). *Laparo & Endo*.

[2] P.E. Bordahl, "Tubal Sterilization: A Historical Review," *The Journal of Reproductive Medicine* 30.1 (1985): 18 - 24.

[3] R. Vecchio, R., B.V. Macfayden and F. Palazzo, "History of laparoscopic surgery," *Panminerva Med* 42 (2000): 87-90. See also: Morgenstern, L. (2008, March). "An Unlikely Pioneer in Laparoscopy: Benjamin Henry Orndoff, MD." *Surgical Innovation, 15*(1).

[4] Grzegorz S. Litynski, "Laparoscopy Between the World Wars: The Barriers to Trans-Atlantic Exchange," JSLS (1997) Apr-Jun; 1(2): 185–188. See also: Morgenstern, "An Unlikely Pioneer in Laparoscopy: Benjamin Henry Orndoff, MD."

[5] Kaiser, "History of Laparoscopy," 483 - 482. See also: Morgenstern, "An Unlikely Pioneer in Laparoscopy: Benjamin Henry Orndoff, MD."

[6] Grzegorz S. Litynski, "Raoul Palmer, World War II, and Transabdominal Coelioscopy: Laparoscopy Extends into Gynecology," *JSLS* (1997): 289-292.

[7] Bordahl, 20.

[8] Friedrich Marx and H. Moll. "A Pioneer in Laparoscopy and Pelviscopy: Kurt Semm (1927-2003)," *Journal of Endourology* 19.3 (2005): 269-71.

[9] Laurie P Cohen, "Competition, Added to Injury Reports, Depresses Hope for U.S. Surgical Rebound," *The Wall Street Journal* 26 June 1992: C1.

[10] Robert Fear, "Laparoscopy: a valuable aid in gynecologic diagnosis," *Obstet Gynecol* 31 (1968): 297-309.

[11] Kaiser and Corman.

[12] Ibid.

[13] Annetine Rosenberg and Nathan C. Gelijns, "Diagnostic Devices: An Analysis of Comparative Advantages," *Sources of Industrial Leadership: Studies of Seven Industries* (1999): 340-344.

[14] Grzegorz S. Litynski, "Patrick C. Steptoe: Laparoscopy, Sterilization, the Test-Tube Baby, and Mass Media." *JSLS* (1998): 99-101.

[15] Bruce Stokes, "Birth Control: More People are Turning to Sterilization," *The New York Times* 22 May (1977): 155. For detailed descriptions of the procedures described here and throughout, see: Marice E. Arregui, R. J. (2012). *Principles of Laparoscopic Surgery: Basic and Advanced Techniques*. Springer Science & Business Media.

[16] Bordahl, 22.

[17] Litynski, "Patrick C. Steptoe: Laparoscopy, Sterilization, the Test-Tube Baby, and Mass Media," 1998.

[18] Jaroslav F. Hulka, "Current Status of Elective Sterilization in the United States," *Fertility and Sterility* 28.5 (1977): 515-520.

[19] Litynski, "Patrick C. Steptoe: Laparoscopy, Sterilization, the Test-Tube Baby, and Mass Media," 1998.

[20] Marx and Moll, 269-71.

[21] U.S. Congress, Office of Technology Assessment, *Health Care Technology and Its Assessment in Eight Countries*, OTA-BP-H-140 (Washington, DC: U.S. Government Printing Office, February 1995): 46.

[22] G.N. Lindseth and DL Denny, "Patients' experiences with cholecystitis and a cholesystectomy," *Gastroenterol Nurs* 37.6 (2014): 407-14.

[23] Rick Dana Barlow, "New Surgical Procedure Spurs Laparoscope Purchases," *Hospital Materials Management* 16.8 (1991): 2.

[24] Fred Burbank, "Stereotactic Breast Biopsy: Its History, Its Present, and Its Future," *The American Surgeon*, 62.2 (1996): 129.

[25] Grzegorz S. Litynski, *Highlights in the History of Laparoscopy*, Frankfurt: Verlag, 1996.

[26] D.S.J. Choy, "History of Lasers in Medicine," *Thorac, cardiovasc, Surgeon* (1988): 114-117. See also: Reddick, E. J., Olsen, D. O., Daniell, J. F., Saye, W. B., McKernan, B., Miller, W., & Hoback, M. (1989, February). Laparoscopic Laser Cholecystectomy. *Laser Medicine & Surgery News and Advances*, 38-40.

[27] Kaiser & Corman.

[28] Annetine C. Gelijns and Mark Frederick, "The Dynamics of Innovation in Minimally Invasive Therapy," Health Policy, 23.1 (1993): 153-66.

[29] Walker Reynolds, Jr., "The First Laparoscopic Cholecystectomy," *JSLS* 5 (2001): 89-94.

[30] Lytsinski, *Highlights,* 276.

[31] Ibid.

[32] Raphael P. Nenner, Imperato, P.J., and Rosenberg, C., "Increased Cholecystectomy Rates Among Medicare Patients After the Introduction of Laparoscopic Cholecystectomy," *Journal of Community Health*, *19*(6), 409-415.

[33] Lytsinski, *Highlights*, 276.

[34] Rick Dana Barlow, "New Surgical Procedure Spurs Laparoscope Purchases," *Hospital Materials Management*, 16(8) (1991), 2.

[35] Gelijns & Frederick, "Dynamics," 164.

[36] Katherine McCaffrey, Amar Bhide, "MRI Scanners," Working Paper; Gelijns & Frederick, "Dynamics," 162.

[37] P.R. Brinsden, "Thirty Years of IVF: The Legacy of Patrick Steptoe and Robert Edwards," *Human Fertility, 12*(3), 137-39.

[38] *Ibid.*, 142.

[39] Kaiser, "History of Laparoscopy," 484.

[40] U.S. Congress, Health Care Technology and Its Assessment in Eight Countries, 263.

[41] U.S. Congress, Health Care Technology and Its Assessment in Eight Countries, 125.

[42] Victor G. Rodwin and Simone Sandier, "Health Care Under French National Health Insurance," *Health Affairs*, 12.3 (1993): https://www.healthaffairs.org/doi/full/10.1377/hlthaff.12.3.111, accessed February 2019.

[43] U.S. Congress, Health Care Technology and Its Assessment in Eight Countries, 159.

[44] *Ibid.,* 230.

[45] *Ibid.,* 86.

[46] *Ibid.,* 145.

[47] Ron Winslow, "U.S. Surgical Shares Plunge: Is Fall Over?" *The Wall Street Journal*, 9 April 1993: C1.

[48] *Ibid.*

[49] N.T. Nguyen, et al., "Trends in utilization and outcomes of laparoscopic versus open appendectomy," *Am J Surg*, 2004 Dec; 188(6): 813-20, https://www.ncbi.nlm.nih.gov/pubmed/15619505/, accessed May, 2019.

[50] Andrew G. Harrell, and B. Todd Heniford, "Minimally invasive abdominal surgery: lux et veritas past, present, and future," *The American Journal of Surgery* (2005): 239-43.

[51] David R. Yates, Christophe Vaessen and Morgan Roupret, "From Leonardo to da Vinci: the history of robot-assisted surgery in urology," *BJUI* (2011): 1708-13.