Working Paper 20-008

Case Histories of Transformational Advances

Laparoscopy – Minimally Invasive Surgery

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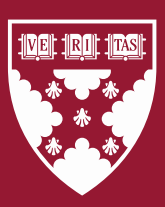

Harvard Business School

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Activate Care

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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 1960s; 2) the development of female sterilization and infertility treatments (that used laparoscopes) in Britain in the 1970s; 3) the 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: Like the other histories in this series, this advance 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 significant 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 thank Katherine Stebbins for helpful information and suggestions.

Laparoscopy —Minimally Invasive Surgery

Laparoscopy has revolutionized gynecological and other surgeries inside the abdomen, such as gallbladder 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.

The following sections describe: 1) foundational technologies and procedures for laparoscopy developed by gynecologists from the 1940s through the 1970s. 2) extension of laparoscopy to gallbladder removal in the late 1980s, 3) adoption of the technique in the 1990s.

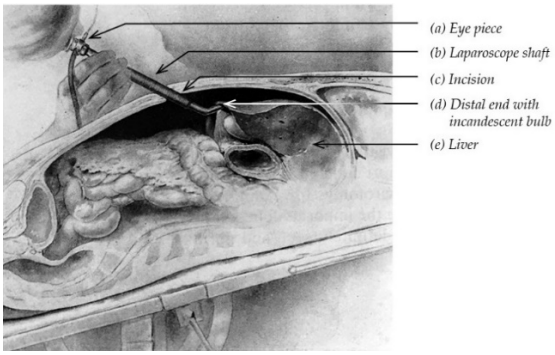
1. Foundational Technologies and Procedures (1940s-1970s)

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.

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 biopsies to remove tissue from livers and spleens.[2] 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 known therapeutic use.[3,4]

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.[5]

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



This case history does not present original research or new thesis. Instead, it summarizes historical developments and includes questions to stimulate reflection and discussion.

Meanwhile, Japanese physicians were adapting endoscopes to examine the interiors of knee joints. In 1918, Professor Kenji Takagi used a narrow-gauge endoscope to diagnose the cause of a patient's painful knee tubercular infection. Takagi then designed instruments to view joints (that came to be called *arthroscopes)* and, between 1920 and 1931, progressively reduced the diameter of their viewing tubes 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.[6] Then, in the 1960s, 'minimally invasive' arthroscopic repairs of knees and other joints became routine.

Diagnosis to Treatment. In the 1930s, French gynecologist Raoul Palmer started developing instruments that would eventually transform laparoscopy into a practical therapeutic technique. He continued to improve the instruments in the early 1940s despite wartime difficulties. By the late 1940s, he had standardized laparoscopy for diagnostic use in his practice and published detailed descriptions of these procedures.[7] By 1951, he was also using laparoscopy to perform sterilizations, the first instance of interventional use.[8]

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.[9] 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.

However, concerns about the effectiveness and safety of Palmer's and Semm's innovations limited their adoption by other gynecologists. Skeptics characterized the laparoscopic approach as "blind" because they could not directly see what they were operating on inside the abdominal cavity.[10,11] Nor could they physically touch ("palpate") organs as they had traditionally done. (Later, in the 1990s, the inability to palpate would also discourage some general surgeons from using laparoscopy to remove gallbladders. It did not, however, discourage arthroscopic knee operations where orthopedic surgeons, operating mainly by sight, had not relied on palpation.)

Gynecologists who did try to replicate Palmer's techniques from his publications faced problems and complications. For instance, the incandescent bulbs illuminating 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.[12] 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."[13]

However, Semm and Palmer found support from 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 the risk of internal burns.[14] (These devices were first sold in 1960.) In 1966, Storz released a laparoscope that pushed illumination further by integrating new fiber optic technology for even better illumination.[15]

Sterilization. The new equipment did not, however, significantly increase the adoption of laparoscopy until the 1970s, when British gynecologist Patrick Steptoe codified and popularized it for

female sterilization. In 1959, Steptoe 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.[a] Palmer had then also persuaded Steptoe to capitalize on England's more liberal attitudes toward family planning and use laparoscopy to perform female sterilizations. 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 hospital stays.[16] Women also recovered more quickly because there were no large wounds to heal. However, in many countries, including France, religious 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 instructions for laparoscopic sterilization. The book's appearance coincided with the start of a movement to end 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 Commonwealth (state) of Virginia led to a repeal of these requirements throughout the United States, and 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.[17]

Many women asked for laparoscopic sterilization as it did not require hospital stays and minimized recovery time.[18] Detailed instructions in Steptoe's textbook provided a crucial resource to gynecologists learning the technique because, at the time, no other training was available.[19] By 1977, at least 4,000 physicians were performing laparoscopic sterilizations at the rate of about one per week.[20] 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 common) application for laparoscopic techniques. Steptoe again played a leading role. Besides standardizing laparoscopic sterilization, the gynecologist published several articles in medical journals in the mid-1960s.[21] 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.

Edwards recruited Steptoe to extract eggs laparoscopically from the ovaries of women who had been unable to conceive naturally. Steptoe's facility with laparoscopy and – at that time unusual – concern for the plight of infertile women made him an ideal collaborator.[22] Between 1968 and the mid-1970s, Edwards and Steptoe used the laparoscopically extracted eggs to develop *in vitro* fertilization (IVF). Their first article on this technique, published in 1969, attracted worldwide media attention. [23] 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 set

[a] John Ruddock, a Los Angeles physician who had the same concerns about the risks as Steptoe adopted laparoscopy as an alternative in the early 1930s. As Ruddock explained, "the internist must share the responsibility for fruitless [incisions] performed for diagnostic purposes; and should use all the ancillary procedures at his disposal before he recommends a [large incision], 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.

up the world's first IVF center, Bourn Hall Clinic, near Cambridge, England. Soon after, teams set up IVF clinics around the world, all using laparoscopy to extract eggs. [b]

Questions (for reflection and discussion):

Before reading further, please write down (in less than ten words) which innovation, event, or condition you found to be the most foundational. (Be prepared to explain why.)

- _____

2. Laparoscopic Gallbladder Removal (1980s)

Removing Appendices. 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.[24]

However, unlike 'minimally invasive' arthroscopic knee surgery, which had quickly become popular in the 1960s, laparoscopic appendectomies were slow to enter mainstream 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 felt the pain produced by advanced inflammation and believed that traditional "open" procedures were faster and safer for immediate removal because they allowed them to view, excise, and suture the appendix directly.[25] Further, the size of the scar an open appendectomy left behind was small, so the benefits of laparoscopy were less compelling.

First Gallbladder Removal. Gallbladder removals were surgical treatments for a painful, age-old condition, typically the formation of gallstones in the gallbladder and bile duct. But gallstones were typically not life-threatening. Therefore, unlike emergency appendectomies, gallbladder removals were planned, "elective" procedures.[26] And traditional open gallbladder removals left large visible scars, which laparoscopic procedures would avoid.[27]

French surgeon Phillipe Mouret performed the first laparoscopic gallbladder removal in the summer of 1987 in Lyon, France,[28] but did not try to promote the technique further. Two US 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 had removed the appendix laparoscopically, why not the gallbladder? (The Georgia surgeons were unaware of the earlier gallbladder removal in France.)

To prepare for laparoscopic gallbladder removal, McKernan and Saye performed a laparoscopic appendectomy in May 1988. Saye then found a willing patient for laparoscopic gallbladder removal by

[b] 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.

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 gallstones and the operation that would be necessary to remove her gallbladder. Specifically, she was afraid of the large postoperative 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 gallbladder removal on her.[29] There were no complications, recovery was swift, and, as expected, scarring was minimal.

Advancing the Procedure. The Georgia surgeons, like Mouret in France, did not actively promote laparoscopic gallbladder removal in the U.S. Rather, two surgeons, Eddie J. Reddick and Douglas O. Olsen, and colleagues in a Nashville, Tennessee hospital, developed and popularized the procedure. Reddick was an expert in laser-assisted surgery in which surgeons used lasers, instead of scissors and scalpels, to cut tissue more precisely. This minimized tissue damage and shortened recovery time. Initially used by dermatologists in the early 1960s, Lasers had spread to gynecology, gastroenterology, and general surgery by the late 1970s. Widening use attracted surgeons to workshops on laser-assisted surgery that Reddick conducted nationwide in the 1980s.[30]

In May or June of 1988, the Georgia surgeon McKernan attended a Reddick workshop where 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. Reddick at once 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.

One was video imaging, adapted from arthroscopic knee surgery. As mentioned, orthopedic surgeons performing knee operations did not worry about palpation. Instead, they relied on seeing ligaments and other structures inside knee joints. But, viewing the insides of a knee through a tube while performing a 'minimally invasive' arthroscopic procedure was difficult.

In the mid-1970s, miniaturized video cameras were attached to the ends of arthroscopes to transmit images displayed on several TV screens in operating rooms. This allowed surgeons, who no longer had to peer down through an eyepiece, to use both their hands more easily. The TV screens also guided nurses and residents assisting the procedure. Previously, they had to rely entirely on the instruction provided by the surgeon, who would be the only one looking through the eyepiece. Reddick and Olsen attached these cameras to laparoscopes for use in their operating room.[31] (See **Figure 2**.)

Figure 2 Surgeons perform a laparoscopic procedure guided by TV monitors.

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

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

Source: Adapted from Minjarez and Jobe (2006).

The other was surgical clips, which allowed suturing cut tissue in about half the time as manual resewing. Reddick and Olsen modified the clips, designed for traditional open surgery, for laparoscopy. Their modification attracted the interest of US Surgical, the country's largest supplier of surgical clips. US Surgical's engineers helped further redesign Reddick and Olsen's clips to enable low-cost, high-volume production. The company's sales network would later promote laparoscopy's rapid adoption.

Questions (for reflection and discussion):

Before reading any further, write down (in less than ten words) what you found most significant or surprising in the development of laparoscopic gallbladder removal operations.

•

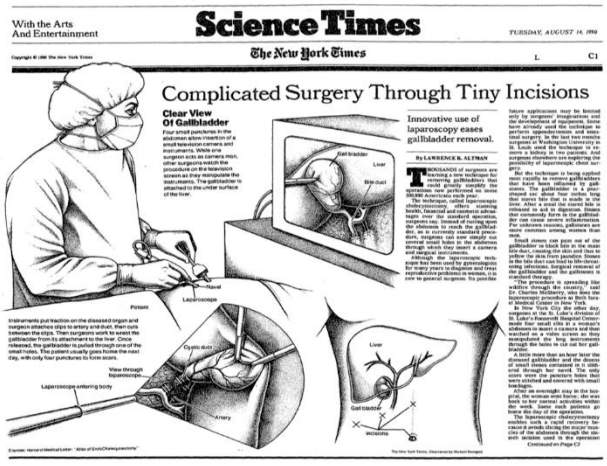
Be prepared to explain why you found this significant.
Also, think about what might have to happen for the wide dissemination of the technique.

3. Adoption (in the 1990s)

Publicizing the Procedure. Reddick and Olsen first taught their new technique for laparoscopic gallbladder removal in Reddick's three-day laser workshops. Then, they made a splash at the October 1989 meeting of the American College of Surgeons.[32] US 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 played throughout the day in those booths.[33] 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.[34] (See **Figure 3**.)

Media coverage spurred patient demand for the procedure.[35] "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 US media is so prevalent, and they jump on every story and play crazy."[36]

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



With the Arts And Entertainment

Science Times

The New York Times

TUESDAY, AUGUST 14, 1990

L C1

Complicated Surgery Through Tiny Incisions

Clear View Of Gallbladder

Innovative use of laparoscopy eases gallbladder removal.

By LAWRENCE K. ALTMAN

Source: Lawrence K. Altman, "Complicated Surgery Through Tiny Incisions," *The New York Times*. August 14, 1990.

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

Incentives and Obstacles. As with arthroscopic knee surgery in the 1960s, patients welcomed laparoscopic gallbladder removal, which reduced both scarring and recuperation times: traditional open methods could require six weeks for patients to recuperate. Meanwhile, efforts to develop non-surgical treatments for gallstones encountered problems. Shock-wave lithotripsy broke up gallstones with sound waves so the body could naturally flush them out. But the stones frequently recurred. Another alternative -- orally administered drugs to dissolve gallstones -- raised concerns about side effects.[37]

Surgeons, particularly in smaller practices, enthusiastically responded to patient demand. The capital investment required for the new technique was affordable. In 1991, a full laparoscopy system cost between $30,000 and $40,000 (or $50,000 in 2016).[38] 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, Medicare even reimbursed hospitals at rates equal to open gallbladder removal.[39]

As with other surgical innovations, surgeons were free to adopt laparoscopic procedures if they had the consent of patients. And, US 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 US 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.[40]

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.[c] Basic surgical techniques for suturing, ligation, resection, and so on had to be adapted for laparoscopy. But these could not be easily learned, as in traditional open operations, by assisting experienced surgeons.[41] And as mentioned earlier, some surgeons, particularly in academic medical centers, favored the traditional open procedure[42] in which they could directly feel ("palpate") and see organs inside the abdomen instead of relying on images displayed on a TV screen. "Why look through a keyhole when you can look through an open door?" they asked.

US Surgical's sales force (See **Exhibit 2**) and a "training dummy" (called the Pelvi-trainer) that the German laparoscopy pioneer Semm had developed in 1985[43] helped overcome the knowledge problems. More than half of all 33,000 general surgeons learned laparoscopy within 18 months of the 1989 American College of Surgeons meeting.[44] The "explosive acceptance of laparoscopic procedures [was] previously unparalleled in the history of surgery."[45] In 1992, the National Institutes of Health declared laparoscopic gallbladder removal the gold standard of care for gallstones.[46] By then, 80% of all gallbladder removals (totaling nearly 300,000) in the US 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.

Skeptics did question whether the quicker procedure encouraged more people with gallstones to undergo surgery, thus increasing total costs. However, unlike other high-cost operations, such as coronary

[c] 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.

artery bypass grafting (CABG), whose cost-effectiveness attracted considerable scrutiny, no systematic review of laparoscopy's economic impact on healthcare costs in the US was ever undertaken. Its overall cost-effectiveness was taken for granted. [d]

Other Procedures. The laparoscopic approach "soon extended to essentially every aspect of abdominal surgery." Antireflux surgery and hernia repairs "underwent a major change" as quicker recoveries and fewer wound-related complications "contributed to the acceptance by surgeons and spurred patient demand." Laparoscopic extraction of abdominal organs, including the spleen, adrenal, kidney, and liver lobes, affected both removing diseased tissues and transplantation. Laparoscopy, for example, "dramatically increase[ed] the number of people willing to donate a kidney because of its decreased morbidity."[47]

Laparoscopic gastric bypass surgeries (initially introduced in the 1960s as 'open' operations) were first reported in 1994 and had contributed significantly to the popularity of this obesity treatment.[48] Similarly, gastric bands for obesity treatments, first applied in 1978 with an open procedure, were followed by laparoscopically applied adjustable bands in 1993, first in Belgium and soon after that in Italy.[49]

Diagnostic laparoscopies were developed to track the extent of the spread of cancers. Somewhat controversially, laparoscopic surgery was also used to remove malignancies from the intestine, including operations to remove all or part of the colons ("colectomy for cancer").[50]

Geographic Diffusion. A study sponsored and published by the US Office of Technology Adoption (OTA) 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, according to the OTA study, they did not offer much actual support. Instead, adoption started in the relatively small private health sector through younger surgeons and eager patients.[51]

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 the use of this equipment for therapeutic use. [52]

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 physicians in other disciplines, such as urology, began performing the laparoscopic procedures that patients demanded.[53]

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

[d] 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 more procedures prior to a laparoscopic surgery to gather data on the patient's anatomy and condition, which added to total costs (OTA 126).

uses of laparoscopy. A year later, in 1991, the health service created a fund to support services associated with shorter postoperative recovery times, such as laparoscopy.[54]

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 respond to patient demand for laparoscopic surgery quickly. Again, as in the US, a surgeon at a community 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.[55]

Laparoscopic gallbladder removal also arrived in Australia in 1990, and the Australian Institute of Health (AIH) quickly assessed it, found the up-front cost to hospitals acceptable, and supported adoption. It also quickly introduced instruction into teaching hospitals and smaller surgical centers.[56] 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 US, no other developed country systematically analyzed overall 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 unnecessary operations was noted but not investigated.

Instruments and Accessories. Laparoscopy required three kinds of 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 US) produced all three. The German companies (Karl Storz and Richard Wolf) had, as mentioned, collaborated with pioneering laparoscopists. The US companies were Stryker, American Cystoscope, Cabot Medical, Eder Instruments, KLI, and Reznik.

Other manufacturers focused on trocars, 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.[e] By 2000, new product introductions and the number of entrants had fallen. (See **Exhibit 5**.)

Aside from these instruments, laparoscopic operations used, as mentioned, suturing clips and a variety of accessories. US 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 and other surgical accessories such as forceps and graspers. US Surgical's revenues and earnings surged as hospitals across the country bought these kits in bulk to meet demand for laparoscopic surgery.

Increased competition, notably from Johnson & Johnson, reduced US Surgical's market share. Further, once physicians mastered laparoscopic procedures, many adapted traditional multiple-use surgical tools

[e] The 1976 Medical Device Regulation Act first brought the efficacy of medical devices under the FDA's purview. 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 510 (k) exemptions.

for laparoscopic use. This ended the need for laparoscopy-specific disposable tools in US 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 control costs.[57]

Questions (for reflection and discussion):

Please write (in less than ten words) what you found most significant or surprising about the adoption of laparoscopic surgery (and be prepared to explain why).

- _____

Prospects for the 2000s

A review published in 2000 concluded that "after its tumultuous debut," laparoscopic surgery was "entering a phase of slower development." Its benefits for gallbladder removal were "beyond any doubt." But the "role and cost-effectiveness" of other laparoscopic procedures, such as hernia repair or appendectomy, was "still not clear." Similarly, "enthusiasm of early reports" of laparoscopic removals of malignant parts of the colon had been "tempered" by recurrences.

This "slower phase of development" would reflect, the review predicted, "a more gradual and scientific controlled adaptation of open techniques." In the meantime, "new instruments and techniques" such as very narrow incisions and instruments, cameras that could produce 3-D images, micro-robotics, and joystick-like control devices were being "processed for clinical applications." Laparoscopic surgery had "gone beyond the point of no return," and it was "impossible to predict what its "immediate and long-term future."[58]

Questions (for reflection and discussion):

Based on this case, would you expect "slower development" in the next five years? And how would this affect the market shares of the companies selling laparoscopic equipment? (Be prepared to explain why)

- Expect slower development/Do not expect slower development
- Expect significant changes in market shares/Do not expect significant change

Exhibit 1 Tools used 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	The insufflator pumped CO2 into the abdominal cavity through a rubber tube. The CO2 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: Excerpted from R. Vecchio, B.V. Macfayden, and F. Palazzo, "History of laparoscopic surgery," *PanminervaMed*, 42 (2000), 87-90.

Note: Improved versions of these tools are still standard laparoscopic instrumentation.

Exhibit 2 US Surgical

During the 1970s, US Surgical's auto-clip device revolutionized wound closure and dramatically reduced the time required to close up patients after surgery. The company's founder, Leon Hirsch, was a curious, scientifically minded New Yorker who graduated from the prestigious Bronx High School of Science in 1945. However, he dropped out of City College and sold household products and coin-operated laundry machines for 17 years.

By 1964, Hirsch was looking for a new business opportunity. 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 balsa wood models, and got feedback 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 US Surgical to sell the device in 1967, surgeons were reluctant to adopt the clip, preferring to close wounds using needles and durable thread as they had traditionally done. Hirsch realized that a 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 course to train new salespeople who then visited operating rooms, educating surgeons about using auto-clips.

The connection that the sales force created between operating rooms and US Surgical's engineers made the company a pioneer in laparoscopic auto-clip devices and its salesforce a key element in the rapid adoption of laparoscopic surgery in the US By the time Johnson & Johnson launched competing clips in 1992, US Surgical controlled 85% of the market. [59]

By 1997, the company's revenues had grown to $1.4 billion, 90% of which came from surgical staplers, sutures, disposable laparoscopic instruments, and electro-surgical products.[60] In May 1998, a conglomerate, Tyco International, which had made more than 80 acquisitions in recent years, announced it would buy US Surgical for $3.3 billion. Earlier, in January, Tyco had paid $1.7 billion for the medical products division of American Home Products. Tyco's chair and CEO, L. Dennis Kozlowski, said with the US Surgical purchase, Tyco would have "$4.5 billion in medical product sales, a solid presence in the operating room and a greatly expanded array of products for use throughout the hospital."

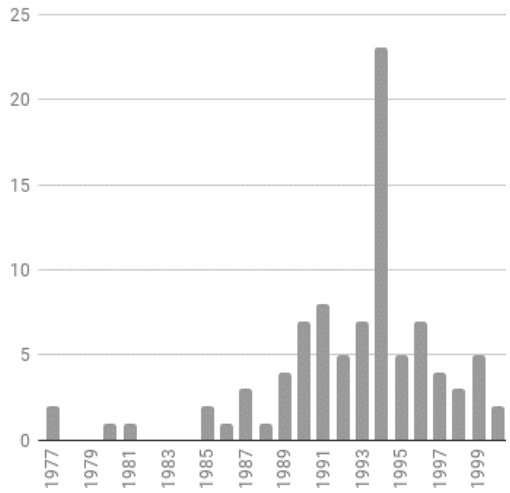
Sources: Cameron Fleming, Kimberly Nearing, and Erik Syring. "Leon C. Hirsch and the United States Surgical Corporation." *Tales from Successful Entrepreneurs*. Boston: Harvard Business School, August 15, 1995 and "Tyco cuts surgical deal" *CNN Money*, May 1998, https://money.cnn.com/1998/05/26/deals/tyco/, accessed November 2020.

Exhibit 3 Timeline of Laparoscopic Gallbladder removal in the United States 1988-1992

Year	Month	Event
1988	April	McKernan & Saye perform a laparoscopic appendectomy in the US.
	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 the US.
	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 meets. 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	US 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.

Note: As mentioned in the main text, Philippe Mouret had performed the first laparoscopic gallbladder removal in France in July 1987

Exhibit 4 Number of companies that submitted their *first* 510 K to FDA for premarket approval on a trocar or trocar-related device.



Source: FDA 510 K database.

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