Endoscopic Surgery— A Fascinating Idea Requires Responsibility in Evaluation and Handling

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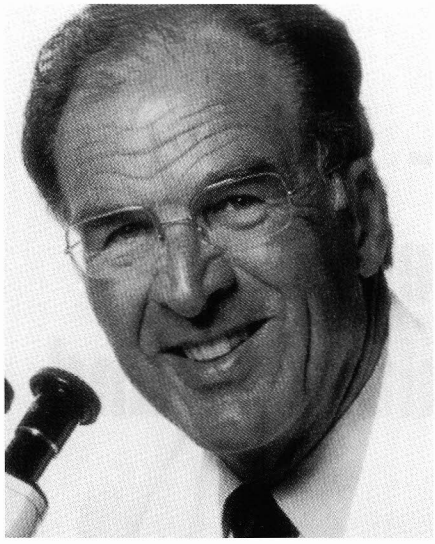
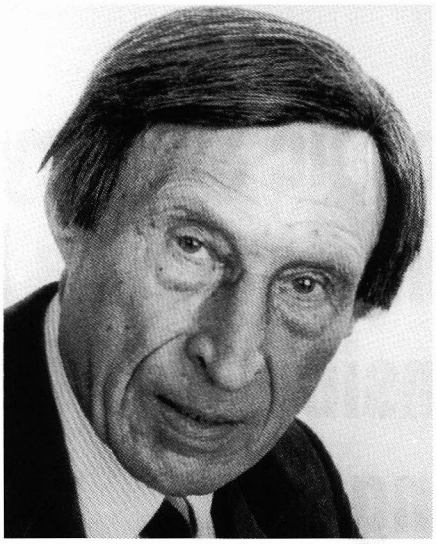
When we think of the pioneers of endoscopic surgery, we think of people like Wittmoser, Semm, Mühe, Wickham, Mouret, Perissat and Buess as well as industrialists like Karl Storz and Leon C. Hirsch (Figure 1).[1,2,3,4,5] Despite differences in personalities, these pioneers had an impact on endoscopic surgery because of important, common denominators they shared, such as curiosity, eccentricity, and, according to De Bono and Böcher,[6,7] "lateral thinking." Of course, these pioneers were ignored at the beginning and even called crazy. They saw controlled clinical trials as irrelevant to their work. They were open minded, innovative and recognized the revolutionary potential of seeing their ideas come to fruition.[8] And it was from these risk-takers that endoscopic surgery—this fascinating alternative in general surgery—was born.

In contrast to these pioneers, other "experts" had been endoscopically looking into the abdomen for more than 20 years. They were publishing books with nice pictures, but never came up with the simple, but important idea of removing the gall bladder. These people can be called "vertical" thinkers.[8]

In time, the climate changed and the pioneers' new ideas were accepted with almost complete enthusiasm. Interest was ignited and spread out to cover new applications and indications. But now, as with other new surgical ideas, prudence and caution are called for. Feasibility and general acceptance, after all, are

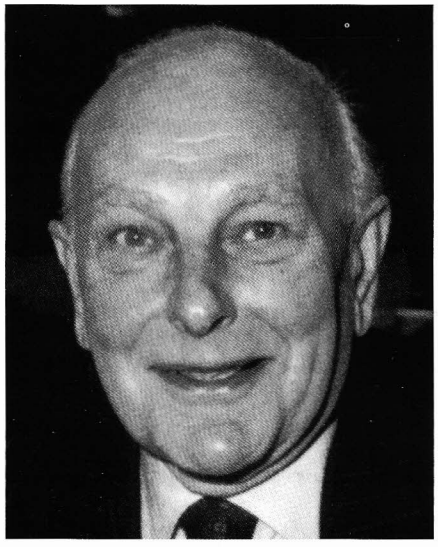


K. Semm.

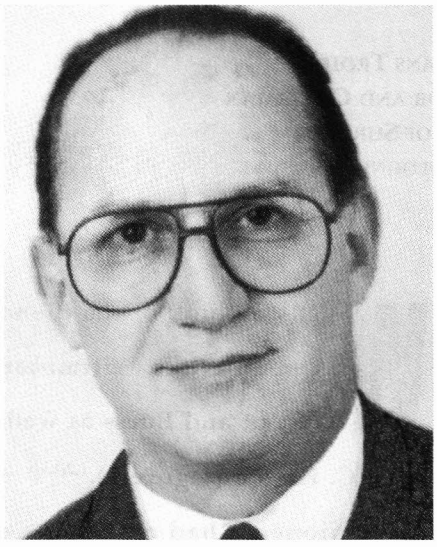


R. Wittmoser.

E. Mühe.

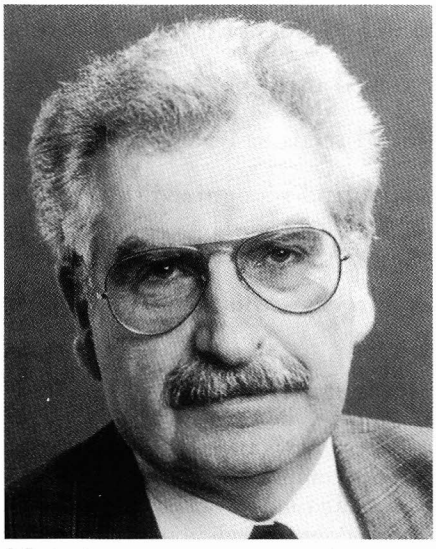


J.E.A. Wickham.

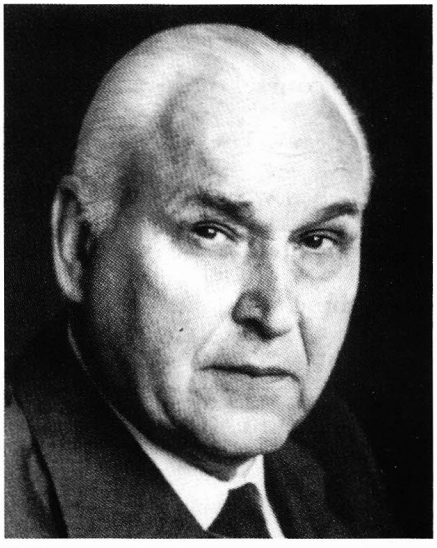


P. Mouret.

F. Dubois.



J. Perissat.



K. Storz.

L.C. Hirsch.

Figure 1: Pioneers of surgery especially endoscopic surgery. Different personalities having common denominators such as having an idea, realizing the idea, being open minded, curious and taking the risk, where/are lateral thinkers according to De Bono.

not always a guarantee of suitability (Table 1).

The Need for Testing

While the first step is to think of a "fascinating" idea, the second, much harder step is to evaluate and test that idea. After all, if results were reported with the same intensity as new techniques, modification or even removal of numerous surgical interventions would become apparent. And sometimes in today's environment, evaluations are based on meager results, such that "experience" means one case, "series" means two cases, and "a trial" means three.

In addition, in clinical medicine we rarely test for truth because, generally, we are only testing for statistical differences. For example, when we are interested in testing differences between open and endoscopic cholecystectomy, we are unaware that both methodologies may be inappropriate.

In line with this thinking, my hypothesis of endoscopic surgery is as follows: endoscopic surgery equals greater comfort, less trauma, same or equal safety, and better outcome (Figure 2). Endoscopic surgery also requires less impairment of the patient during preoperative evaluation, surgical procedure and postoperative care. (In this case, it is important that "comfort" is defined from the patient's perspective.) In addition, performing endoscopic surgery should minimize the use of tubes/drainage procedures in the form of nasogastric tubes and I.V. lines. It should also reduce the amount of dressing changes, and avoid or reduce acute postoperative pain and fatigue.

In summary: endoscopic surgery is only justified when it can improve a patient's comfort with the same or increased level of safety found in conventional procedures.

Current Methods for Evaluation in Clinical Research

Currently, the golden standard is the "controlled clinical trial," which uses relevant endpoints for testing and evaluation. In endoscopic surgery, the relevant endpoints have already been stated: safety, comfort, less pain, less fatigue, less fear and an early recovery. Using incorrect criteria to choose endpoints has to be avoided, and in medicine, there are all kinds of examples of incorrect criteria, for instance, the "response rates" in oncology.

In gall-bladder surgery, patients are not interested in diminishing the stone size within the gall bladder by lithotripsy to sizes of less than 3 mm. Rather, they want to get rid of colics, come home safely and eat foods they like. Enthusiasm, feasibility, traditions, and opinions are: grade 0 for accumulating knowledge. Research videos produced in the last 4 to 6 years reach the same grading. Even retrospective analysis with historical controls are to some extent worthwhile, because they take a different kind of bias into account.

As mentioned above, the best evidence is a controlled clinical trial, but only ones with *relevant endpoints and conducted with common sense.* Still, even controlled clinical trials can have inappropriate study designs, illegitimate statistics, and insufficient patient numbers. In this respect the famous sentence of Chalmers, "the first patient has to be in a trial," is absolutely nonsense![8,9]

On the other hand, an interesting and helpful evaluation is the 6-step approach to technology assessment, as modified to the ideas of Bryan Jennett[8,10] (Table 2). Interestingly, surgeons are mainly concerned with feasibility, complications and lethality. But *the most important step,* not only in endoscopic surgery, is the second step, *which describes the benefit to the patient.* Other important steps are cost evaluation as well as ethics.[11]

We have to realize that the old, famous saying "research is absolutely independent" is no longer acceptable. After Hiroshima, says philosopher Jonas H. Technik,[11] "scientists have been coming into contact with sin." And according to Nobel Prize–winner Konrad Lorenz,[12] we have to recognize that the acceptance of "new techniques" is not the same as the establishment of "new values."

• Operation by atypical localization of organs (Ptosis)	1880-1928	48	Y.
• Endocrine surgery due to fatigue	1895-1942	47	Y.
• Ligation of the mammaria interna to increase blood flow by stenocardia	1939-1960	21	Y.
• Sympathectomy to regulate blood pressure	1888-1942	54	Y.
• Gastric Freezing for treatment of peptic ulcer	1959-1969	10	Y.
• radicale, "multimodale" surgery for cancer treatment	1950- until today		

Table 1: Examples of errors in surgery and the time span during which they where performed.

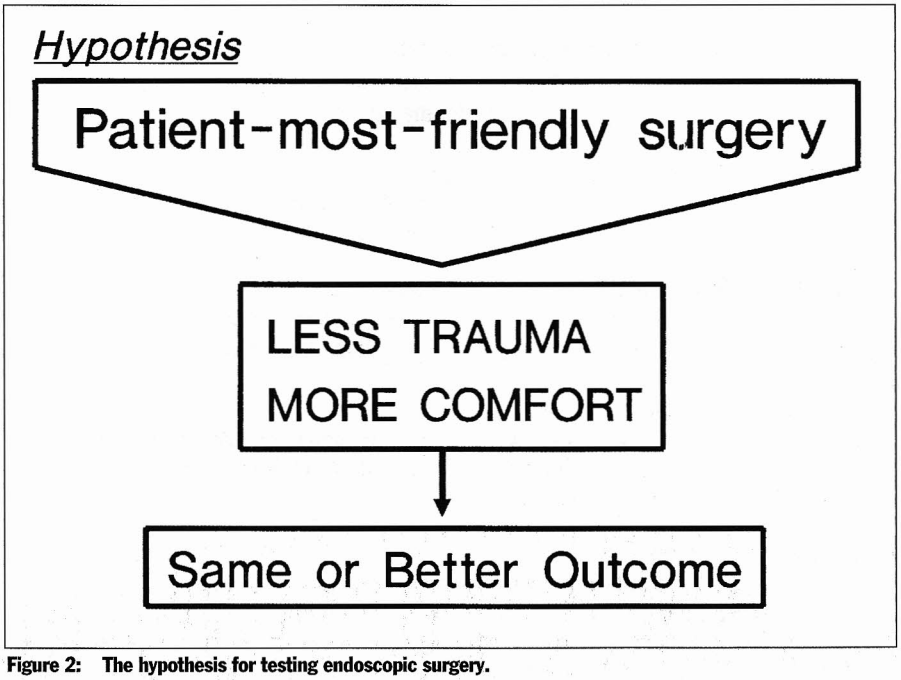


Figure 2: The hypothesis for testing endoscopic surgery.

Evaluation of Endoscopic Surgery—the Reality

Even with today's appropriate study designs and relevant endpoints, it seems impossible to perform "clean" controlled clinical trials. The reasons[13] for this include insufficient definitions in measuring short- and long-term outcomes. Until now, there has been no unified definition for "overall complications," "local complications," or "overall postoperative complications," all of which has caused confusion in comparative clinical investigations.

For this reason, *a new classification of positive and negative events in endoscopic surgery* (Table 3) has been prepared based on a patient-friendly surgery. The term "patient friendly" refers to the patient's, not the caretaker's, perspective. This new classification enables the surgeon to plan an operation with the outcome of the patient in mind. It is also "neutral" in a legal sense, is easily understood and is organized for short-term outcomes.

More Reality

In 1994, 5 years after endoscopic surgery was enthusiastically accepted, many procedures are practiced, although only a small number are sufficiently established and are considered standard procedures. According to my understanding, laparoscopic cholecystectomy is the golden standard for symptomatic gallstone disease. The only contraindication is the incompetence of a surgeon. The treatment is safe and effective in remedying pain and dietary restrictions and, most importantly, produces less discomfort when performed.

Although originally met with much enthusiasm, endoscopic appendectomy is not as convincing as laparoscopic cholecystectomy, despite 5 published, controlled clinical trials.[14,15,16,17,18]

The trials have many deficiencies such as the number of patients included and the diagnosis of "acute" appendicitis. And, of course, the placebo effect (prognostic selection bias) has to be considered. I am reasonably convinced, however, that endoscopic appendectomy under trial condition is, at the very least, not worse than open procedures. Even more convincing is the effectiveness of endoscopic techniques for reflux procedures, even though this is a very rare disease.

The other procedures that are reported, published or *shown in video demonstrations are still experimental.* But this is not to suggest that we are seeing the end of experimentation. Like the period after Christian Bernard's first heart transplantation, we have only reached a plateau.

Criteria	Element (Examples)
1. "Feasibility:	→ Technical applicability Complications Mortality
2. "Efficacy"	→ Benefit to the patient
3. "Effectiveness"	→ Safety, applicability, suitable for everyday use
4. Benefit to the surgeon	→ Simplification of operation
5. Costs	→ Cost analysis influence to: • cost-effectiveness • cost-benefit • cost-utility
6. Ethics	→ "Primum non nocere" "Primum utilis esse"

Table 2: Methodic accesses to the assessment of new technologies (endoscopic surgery) regarding singular - absolutely necessary - steps. (Technology assessment; according to B. Jennett, modified by H. Troidl.)

Class I.	**Incident-free surgery - no incidents:** no surgical technical problems and no negative outcome for the patient
Class II.	**Inconsequential incident surgery:** one or more surgical technical problems, but no negative outcome for the patient (intrabdom. stone loss, bleeding)
Class III.	**Consequential non-incident surgery:** no surgical technical problems, but one or more negative outcomes for the patient (hematoma, wound infection)
Class IV.	**Incidents:** one or more surgical technical problems with corresponding negative outcomes for the patient (changing op.-method intra-op., re-laparotomy)
Class V.	**Incidents:** death in any relation to operation

Table 3: A possible classification of incidents most influence by the view of the patients. Measuring positive and negative events in the short outcome.

Warning—Two Sides of the Coin

It is well known that new techniques or surgical concepts, such as endoscopic surgery, have at least two sides. The **positive side** is characterized by a scrutinizing look at old dogmas, a questioning or neglecting of old endpoints, and a search for new and better solutions to old problems. The **negative side** is characterized by some colleagues neglecting proven facts, creating new and inappropriate indications, and even creating new diseases for their new techniques, resulting in new, unknown complications and serious disasters.

One important example of this negative side is the laparoscopic technique for hernia repair. About every 3 months in the last 4 years, a different technique using endoscopic instruments has been enthusiastically reported and recommended as the treatment of choice.

(Table 4) The most simple rules and regulations for clinical research, however, have been neglected.

The situation can be summarized by Konrad Lorenz's statement, "Darüber hinaus wird im technomorphen Denken auf beinahe zwangsneurotische Weise das bloe Bestehen der Möglichkeit, einen bestimmten Vorgang technisch zu realisieren, mit der Verpflichtung verwechselt, dies tatsächlich zu tun." ("Moreover, in technomorphous thinking, the pure existence of the possibility to put a certain procedure into practice is confused with the obligation to really do so in an almost obsessive neurotic manner.")[12] In addition, in this situation, even the most important, traditional ethics in medicine are neglected: "primum nihil nocere" (first of all no harm) and "primum utilis esse" (the benefit to the patient).

This scenario reminds me of Nietzsche's famous and important comparison between modern science and the Middle Ages: "It is not the victory of science which is characteristic of the 19th century but the victory of the scientific method over science itself." In other words, we now have methods (i.e., endoscopic surgery) and are looking for applications. No longer do we have the problem of looking for the hammer to pound the nail; rather, we have a new hammer and are actively looking for something to pound.[19]

This presents a different set of problems. On the one hand, we have to recognize the importance of adequately defining "complication." We also have to report complications so that important comparison/research work can be done.[20] On the other hand, extensive complications or disasters are usually not reported in highly sophisticated journals or scientific papers, only in weeklies or on television or expanded before a trial (Figure 3).

The world of publications does not reflect reality.

To make matters even more complicated, more than 80 percent of surgeons do not publish. The world of publications is dominated by "academic surgeons" who often are better writers than performers. In addition, positive results dominate the published material, because winning is more popular than losing in the "championship" game of surgery. And honesty, often times, is not the driving force.

What we often don't hear about are disasters in endoscopic surgery, disasters such as damaging various organs and big vessels (for example, the aorta or even aorta and vena cava, and iliaca communis, both sides). Certain disasters, like small bowel ischemia following inflation of the abdomen with CO_2, are know only through rumors!

Failure Analysis: A Neglected Method

To overcome these disasters, which luckily are rare, we must not only report them, but also *avoid* them. The method of choice for avoiding compli-

"Nails for the New Hammer"

	Technique	Promoter
1.	Simple Clip	Ger
2.	Plug + Clip	Corbitt, Schulz
3.	Plug + Patch	Katkhouda
4.	Trans-abdominal Pre-peritoneal Patch (TAPP)	Arregui, Popp
5.	Intra-abdominal Only Patch (IPOM)	Fitzgibbons
6.	Totally Pre-peritoneal Repair (TPP)	McKernan, Dulucq

Table 4: Current methods of endoscopic inguinal hernia repair and their promoters. "Moreover, in technomorphous thinking the pure existence of the possibility to put a certain procedure into practice, is confused with the obligation to really do so in the almost obsessional neurotic manner" [12]

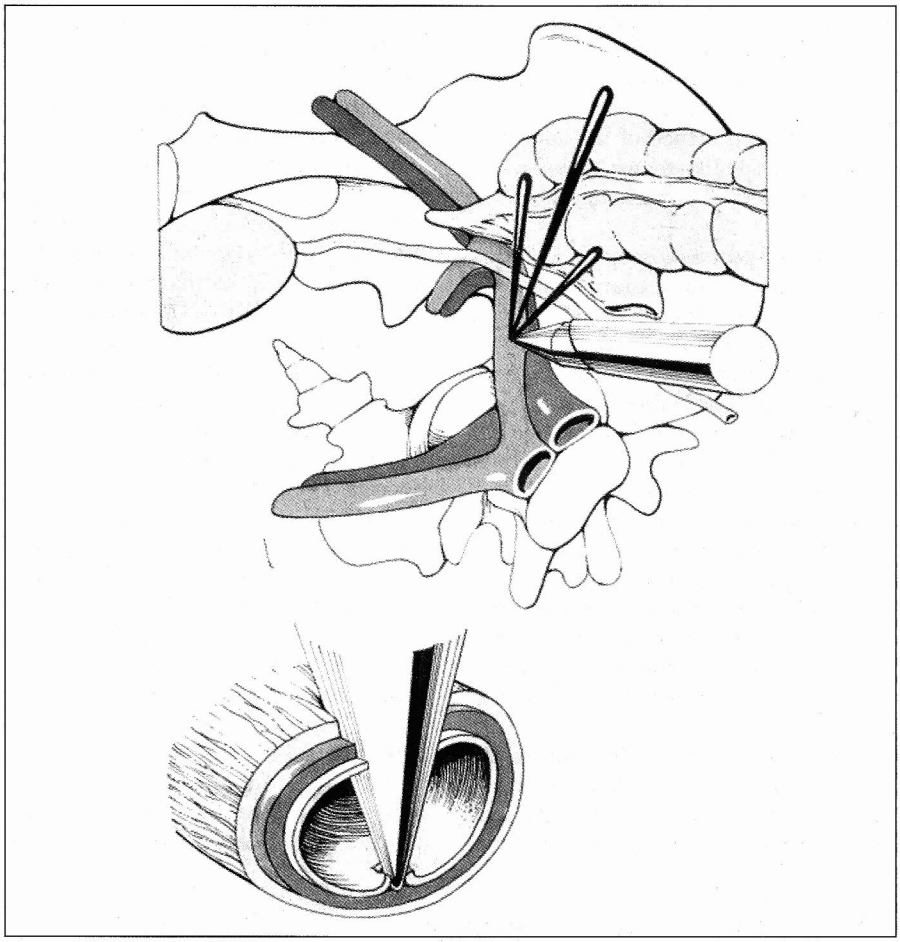


Figure 3: New complications, disasters of a new technique.

Failure analysis:	
Clinical setting:	**Young, slim girl with strong abdominal wall, appendicitis.**
What happened?	**Puncture with trocar of the right iliaca communis, endangering the posterial wall (intima), re-thrombosis, ischemia of the right leg, nerve damages, amputation**
Why did it happen?	**• Unawareness of the possible disaster • Using a sharp trocar, not realizing the damage of the posterial wall**
How to avoid it?	**• Never use sharp trocars at all • Always check posterial wall**

cations and disasters is failure analysis,[21] which is already common practice in the industry (Table 5). The concept of failure analysis has three steps. The first step is counting/scrutinizing the complications, which is often already done. The second step is analyzing—also usually done. *The third and most important step, however, is devising ways to avoid complications, especially disasters.*[22] (This is not always easy since there are many books on treating complications but none on avoiding them.)

Warning—Industrial Driven Medicine

In an important editorial, A.S. Relman, the retired editor-in-chief of the New England Journal of Medicine, stated that "medicine is no more a profession but a business".[23] Samuel Sarmiento, a well-known, academic, orthopedic surgeon, echoed this attitude in an exiting editorial: "Industry has assumed the role of a major underwriter of graduate and postgraduate orthopedic education....."[24] Sarmiento went on to say, "Much of the education of the orthopedist seems to be structured to satisfy the marketing needs of industry."

In this respect endoscopic and orthopedic surgery have many common denominators. One of my colleagues characterized this new situation by saying, "In former times we had students of Billroth and/or Halsted, and now we have students of Auto Suture Inc. and Ethicon." Today, "new ideas" are tools and instruments that can be marketed quickly and easily. The "education centers" organized by industrial companies teach surgeons surgical techniques and even indications and surgical concepts. Some companies organize public and private meetings, symposia and world conferences to promote their products.[24,8]

To counterbalance this, universities and academic societies have to try to maintain responsibility for evaluation and education. Nevertheless, the reality still remains, without industry cooperation there is no evaluation of endoscopic surgery.

Cost Analysis

Cost analysis must be considered in any technology assessment. Often, physicians, especially surgeons, understand little about the financial aspects of technology development. They are simply not educated in economics or socioeconomics. But today, this issue is becoming more important, and not only in undeveloped countries. Therefore, physicians and surgeons will have to deal with these problems.

In technological assessment, we have to first differentiate between "price" and "cost." In a nutshell, "price" means the money paid for a product and "cost" is the money needed to produce a product. (Another important related question is: "Who is asking about costs?" The patient, the surgeon, the owner of the hospital, the insurance company or the public?)

Surgeons have to understand the terms "cost effectiveness," "cost benefit," and "cost utility." In cost effectiveness, the costs of 2 different surgical procedures are calculated to determine the same outcome/endpoint. The procedure that is less costly and has the same endpoint is cost effective. In a cost-benefit analysis, different procedures are compared and the quality of the outcome is calculated in dollars. In a cost-utility analysis, quality of life (measured with such factors as the length of treatment) is calculated in dollars.

Currently, one of the "hot" topics of cost analysis in endoscopic surgery is comparing reusable versus disposable instruments. In my department, a cost-analysis study was found to be in favor of reusable instruments for laparoscopic cholecystectomy only.[25]

The Future

Talking about the future is nearly impossible. Which direction will endoscopic surgery take? Who knows![26] Skepticism and enthusiasm have to be carefully balanced. Again history is full of wisdom. Barkley Moynihan stated at a major conference in 1926 that "surgery had reached its limit and that there were no further technical developments to come." He could have not been further from the truth. Heroes like Billroth and Sauerbruch failed to estimate the value of innovations when they restricted the use of endotracheal tubes or surgical interventions on the heart. The distinguished French surgeon René Leriche stated in 1929 that "the autonomic nerve section is beneficial for different diseases, especially hypotension," which we know now to be complete nonsense.

Despite the risk of being wrong, I still favor endoscopic surgery. I am convinced that it will have a big impact on modern surgery by changing techniques, and influencing technology and teaching . Most importantly, endoscopic surgery will change endpoints, with the comfort of the patient taking precedent over all else.

Balance: Innovation Versus Evaluation

Finally, medical and especially surgical history have taught us to be aware of, and have an open mind for, new ideas. It has taught us to take risks but not at the expense of traditional ethics such as **"no harm to the patient"** and patient welfare. While this balance is sometimes difficult to maintain, it is, nevertheless, essential. After all, Nietzsche said, "The knowledge of today might be the error of tomorrow." STI

A.	1.	What was/is the clinical setting?
	2.	What happened? (events)
B.	1.	Why did it happen?
	2.	How can we avoid it?
C.	1.	Free discussion with other experts and "Normal-Thinkers" (objectivity)

Table 5: Concept of failure analysis in surgery.

REFERENCES

1. Wittmoser R. Thoraskopische Sympathicotomie bei Durchblutungsstörungen des Armes. Langenbecks Archiv und Dt Zeitschr Chir 1959; 292:318.
2. Semm K. Endoscopic appendectomy. In: Advances in pelviscopic surgery. Year Book Medical Publishers, Inc., 1982.
3. Mühe E. Die erste Cholecystektomie durch das Laparoskop. Langenbecks Arch Klin Chir 1986; 369:804.
4. Wickham JEA. Minimally invasive surgery. Br J Surg 1990; 77:721.
5. Mouret P. From the first laparoscopic cholecystectomy to the frontiers of laparoscopic surgery: The future prospectives. Dig Surg 1991; 8:124.
6. De Bono E. Laterales Denken. Der Kurs zur Erschliessung Ihrer Kreativitätsreserven ECON Taschenbuch Verlag, Düsseldorf 1992.
7. Böcher W. Natur: Wissenschaft und Ganzheit: über die Welterfahrung des

Menschen. Westdt. Verlag, Opladen, 1992.
8. Troidl H. Minimal-invasive Operationsverfahren: können sie halten, was sie versprechen? Akademie der Wissenschaften, Mainz, 1993 in press.
9. Chalmers TC. Randomizing the first patient, Med Clin North Am 1975; 59:1035.
10. Jennett B. High Technology Medicine. Benefits and Burdens; Chapter: Technology assessment - a question of information. Oxford University Press, Oxford, 1986.
11. Jonas H. Technik, Medizin und Ethik. Zur Praxis des Prinzips Verantwortung, Inselverlag, 1987.
12. Lorenz K. Der Abbau des Menschlichen, Piper, München, 1988.
13. Neugebauer E, Troidl H, Spangenberger W, Dietrich A, Lefering R, the Cholecystectomy Study Group. Conventional Versus Laparoscopic Cholecystectomy and the Randomized Controlled Trial. Br J Surg 1991; 78:150–154.
14. Attwood SEA, Hill ADK, Murphy PG, Thornton J, Stephens RB. A prospective randomized trial of laparoscopic versus open appendectomy. Surgery1992; 112:497.
15. Hebebrand D, Troidl H, Spangenberger W, Neugebauer E, Schwalm T, Günther MW. Laparoskopische oder klassische Appendektomie—eine prospektiv randomisierte Studie. Chirurg 1994; 65:112.
16. Kum CK, Ngoi SS, Goh PMY, Tekant Y, Isaac JR. Randomized controlled trial comparing laparoscopic and open appendectomy. Br J Surg 1993; 80:1599.
17. McAnena OJ, Austin O, O'Connell PR, Hederman WP, Gorey TF, Fitzpatrick J. Laparoscopic versus open appendectomy: A prospective evaluation. Br J Surg 1992; 79:818.
18. Frazee RC, Roberts JW, Symmonds RE, Snyder SK, Hendricks JC, Smith RW, Custer MD, Harrison JB. A prospective randomized trial comparing open versus laparoscopic appendectomy. Ann Surg 1994; 219,6:725–731.
19. MacIntyre IMC. Laparoscopic herniorrhaphy. Br J Surg 1992; 79:1123.
20. Troidl H, Gaitzsch A, Winkler-Wilfurth A, Müller W. Fehler und Gefahren bei der laparoskopischen Appendektomie. Chirurg 1993; 64:212.
21. Troidl H, Bäcker B, Langer B, Winkler-Wilfurth A. Fehleranalyse—Evaluierung und Verhütung von Komplikationen; ihre juristische Implikation. Langenbeck Arch Chir Suppl 1993: 59–72.
22. Troidl H, Eypasch E, Spangenberger W, Langen R, Holthausen U. Schonendes Operieren. Verfahrenswahl und Strategie. Invasives versus minimal invasives Operieren. Langenbecks Arch Chir Suppl 1991: 48.
23. Relman AS. Special Article. Shattuck Lecture—The Health Care Industry: Where Is It Taking Us? N Engl J Med 1991; 325:854–859.
24. Sarmiento A. Orthopedics at a crossroad. J Bone and Joint Surg 1993; 75-A:159.
25. Lefering R, Troidl H, Ure BM. Entscheiden die Kosten? Einweg- oder wiederverwendbare Instrumente bei der laparoskopischen Cholecystektomie. Chirurg 1994; 65:317.
26. Troidl H. The philosophy of patient-friendly surgery. In: Minimal Access. The future—what next? Ed. R.D. Rosin; Radcliffe Medical Press, Oxford, 1993.