

## Videoregistration of Surgery Should be Used as a Quality Control

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**ABSTRACT** Quality control of medical treatment is strictly organized and supervised. Efficacy and safety have to be proven in large randomized controlled trials, which need ethical review board approval. Content and quality of marketed drugs is controlled by industry and government. After market introduction, postmarketing surveillance is organized. This quality control is necessary to obtain reliable and predictable results and to detect even rare adverse events. Quality control of surgical treatments is close to nonexistent for individual surgical procedures and, therefore, rare adverse events cannot be detected by the sheer number of interventions analyzed. An ethical review board is rarely consulted before a new procedure is attempted or introduced. Although the outcome of surgery is surgeon and environment dependent, the only estimation of quality is results and complication rates. These, however, reflect publications by dedicated groups or data from surveys that do not necessarily reflect reality accurately. Complications are known to be under-reported whereas surveys reflect mean quality only. For most complication rates, it remains unknown which were preventable mistakes and which were unavoidable, random accidents. This huge discrepancy in quality control of medical and surgical therapies can be understood by specifics of each type of therapy. Strict quality control in surgery is, moreover, difficult to organize given that the outcome varies with the surgeon and surgical environment. Systematic videotaping of entire interventions has the potential of providing a quality control of surgery. This, moreover, has become technically feasible at low cost. In conclusion, we need to reflect and organize quality control in surgery. Systematic videotaping of entire procedures seems to be an inexpensive and easy way to organize this control. *Journal of Minimally Invasive Gynecology* (2008) 15, 248–253 © 2008 AAGL. All rights reserved.

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In 1899, Eugène Louis Doyen wrote in “The Cinema and the Teaching of Surgery,” “When I saw for the first time, on the screen of the cinema, one of my operations, I realized how much I ignored myself. . . . I corrected, I improved, I simplified; so that the cinema allowed me to improve my surgical technique. . . . I was happy to be able to criticize myself and my own operations of the previous days.” [1] His films, which have recently been recovered, are a testimony to this [2,3].

For drug therapy, efficacy and absence of side effects have to be shown in large randomized controlled trials before market introduction [4–8]. To ascertain absence of even rare side effects, sufficiently large numbers are re-

quired that permit detection of these rare events [9]. Development of promising drugs with liver toxicity in as little as 0.1% of patients have been promptly arrested [10]. The chemical content of drugs is quantitatively and qualitatively strictly controlled and the tolerated deviation is very small. After market introduction the chemical content of each drug is strictly controlled and postmarketing surveillance is organized [11–22]. History is full of examples where efficacious drugs were withdrawn because of rare side effects that had not been previously detected [23,24] and recently blockbuster drugs have been withdrawn because of very rare side effects. A typical example of postmarketing surveillance in gynecology is the large-scale trials on hormone replacement therapy that permitted detection of rare events as an increase in deep venous thrombosis in as few as 2/10 000 women [25–29].

For surgical therapy, quality control is very different. Because sham surgery is unethical and blinding is close to impossible, the outcome is generally evaluated in rather small observational studies or in comparative trials describ-

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ing results and complications [30]. Surgical therapy differs strikingly from medical therapy for each aspect of quality. Drug trials require strict institutional ethical review board authorization, in contrast with the loose introduction of new surgical techniques, which generally are based on individual conviction. Product control (i.e., quality control) of individual surgical procedures is nonexistent, and postmarketing surveillance is restricted to surveys with known under-reporting of complications. The largest difference in quality control of surgical therapy in comparison with medical therapy is the rather small numbers of patients in surgical trials that, therefore, cannot detect rare adverse effects.

### **Surgical Therapy Quality Control is Very Different and Often Absent**

Quality control of medical therapy is based on qualitative and quantitative control of the chemical content of each pill or injection. The drug content of each pill can vary within narrow limits only. For surgery this quality control of individual surgical intervention is simply absent. Because outcome will vary with the surgeon's techniques, skills, and environment, differences in outcome of trials may reflect as much difference in the surgeon as in the technique. This variability in outcome of surgical procedures has, to our knowledge, never been addressed adequately and it remains unknown what part of the variability in outcome is inherently associated with technique and what part is a result of variability between surgeons or environment.

Important differences in outcome and complications are well known between surgeons and procedures. Marked decreases in duration of surgery, bleeding episodes, complications, and errors in judgment are well-established during the learning curves of surgeons [31–47]. Although published reviews are not available, simple observation shows that after the learning curve, marked differences persist between surgeons [35,48]. The exact relationship between these differences in surgeons and outcome of surgery has not been established. In addition, for procedures, marked differences are well known. For endometriosis surgery, it has been shown that recognition of lesions varies with expertise [49]. The quality of cystic ovarian endometriosis surgery varies from center to center as reflected by a normal [50] to a severely reduced ovarian reserve after surgery. For deep endometriosis, completeness and radicality of treatment vary from incomplete debulking, to discoid resection, to segmental bowel resection. The large differences among groups, some performing less than 5% [51], compared with others who do more than 85% bowel resections, reflect more on surgical attitude or skill, rather than differences in disease.

### **The Human Factor in Quality Control**

Surveys of complication rates and outcome are a poor substitute for quality control. For the complications re-

ported, it is impossible to know which complications are real complications (i.e., inherent to surgery and unavoidable) and which are a consequence of a mistake or an error in judgment. For any new procedure the initially reported results and complications are those of dedicated groups and, thus, probably better than the overall results after wide introduction. These reported results and complications may vary considerably but the reasons for this variability are rarely clearly identified. In addition, the overall results in large surveys only partially reflect reality. First, under-reporting of complications is well known. Second, surveys reflect mean results and complications of all gynecologists reviewed (i.e., experienced and less experienced), those working in ideal circumstances with perfect equipment, and those for whom circumstances are more difficult. It can be expected that the results of surgeons at the beginning of their learning curve and working in less favorable conditions will be inferior. Therefore, results and complications of an intervention are poorly defined, and vary from optimal outcome in ideal circumstances, to median performance by the whole group of gynecologists in a given area. Surgery remains artisanal, manual work with quality that will vary from person to person and from day to day (i.e., surgery is a discipline where the human factor is unavoidable).

This inherent variability in quality introduced by the human factor, and the absence of quality control of individual surgical interventions, probably is the key reason for an overall loose quality control. First, after accreditation, surgical competence is generally not reassessed at regular intervals. This contrasts with regular controls of other professionals such as airline pilots and airline traffic controllers along with other groups in which mistakes or inability can also have dramatic consequences. Second, whereas institutional ethical review board authorization is strictly required for a drug trial, the introduction of small alterations or improvements of surgical techniques, even the introduction of new techniques or materials, is rather loose and rarely based on a written protocol with the expected advantages and risks available for peer review. Generally, the driving force is personal conviction. It, therefore, is not surprising that for most interventions a large number of technologic differences exist, both in materials and in techniques used. In the absence of any proved differences in outcome or complications, all modifications of techniques and materials are erroneously considered equal because they are based on observations with an important and uncontrolled variability in outcome, preventing detection of statistical significance. Moreover, these studies only exceptionally have the power to detect differences in outcome and, thus, the conclusion that there are no differences in outcome is unsubstantiated. For rare events such as complications the situation is even more dramatic, because to detect events that occur in a small percentage of cases large series are necessary. To detect differences in complication rates even larger comparative trials are necessary. Occasionally meta-analyses reach tentative conclusions [52,53].

## **Quality Control of Surgery Can Be Performed by Systematic Videorecording of Entire Interventions**

The systematic videorecording of entire interventions is a simple and inexpensive method of quality control of each intervention. It could become for surgery what the black box of airplanes is for aviation. In this comparison, it is important to stress that this black box should not be viewed as a repressive tool to judge the individual surgeon, but as a research tool aimed to evaluate the causes of differences in quality and accidents, to design methods to enhance quality, and prevent accidents.

Systematic videorecording of entire interventions has been used by individual surgeons for the past few years because it only recently has become technically realistic. Videorecording of sequences of surgery on videotape and later on CD/DVD has been performed for many years but the massive amount of data associated with systematic and continuous videorecording made storage and retrieval close to impossible. Recently, advances in computer technology have made systematic videorecording, storage, and retrieval of entire procedures a valid option at a reasonable cost. Key factors were the reduction of the cost/byte of permanent storage [54] and the exponential increase in computing power [55] needed to run complex videocompression algorithms in real time.

Videorecording and storage of surgical interventions can, moreover, be enhanced by visual and electronic watermarking that can link a videorecording to a patient and intervention, and prove that the videorecording is original and has not been tampered with. Confidentiality and patient anonymity can be maintained by encryption that prevents unauthorized people from viewing the videorecordings or enabling them to make the link between a videorecording and a patient, surgeon, or hospital.

## **Systematic Videorecording of Entire Interventions Has Advantages for the Surgeon**

First, experience has shown that videorecording, just like live surgery, increases the accuracy and precision of surgery. This is a consequence of the human factor, where alertness is increased and speed of intervention is slowed down a little bit by the mere knowledge that every mistake will be recorded. Second, whenever a complication occurs, reviewing the videorecording can be helpful in making an early diagnosis and subsequent early intervention. Third, in case of medicolegal problems, a videorecording allows the surgeon to show that performance was accurate, meticulous, and precise and that the complication was not the consequence of inadequate surgery. This aspect is becoming of increasing importance because lately there has been a tendency to reverse who has to give evidence. Previously the patient had to prove that the surgeon made a mistake, but today the surgeon increasingly has to prove that a mistake was not made. Without a videorecording, this is difficult or

impossible. Therefore, not videorecording is becoming increasingly unwise because it puts the surgeon in a difficult position if it must be shown that surgery was performed adequately.

## **Systematic Videorecording of Entire Interventions is Expected to Increase the Quality of Surgery While Decreasing Costs**

Over time, systematic videorecording used like a black box in aviation will allow scientific investigation of the mechanisms of accidents and their prevention.

Autoregulation is expected to lead immediately to increased quality and decreased complication rates. The knowledge that someone might have a look at the videorecording later will enhance awareness, prudence, and thus quality, just as cameras do for speed control of cars by their mere presence even without being active. Similarly by autoregulation, the probability that a surgeon who does not feel 100% confident will seek help before he embarks on difficult surgery will increase.

## **Systematic Videorecording Will Have Side Effects and Will Raise Concern**

Systematic videorecording of entire procedures may be met with strong psychologic resistance because of the thought that big brother is watching us. It may also raise concerns that the videorecordings might be used against the surgeon. Mistakes and errors will indeed be registered, and could be used against the surgeon during medicolegal action. The concern indeed is real that the medicolegal system and judges will not always be able to distinguish accurately between unavoidable accidents and real mistakes and that the surgeon, therefore, could erroneously be condemned. One solution to this might be to use technology to restrict the use of a videorecording. If restricted to the surgeon, the surgeon then could use the videorecording exclusively to his or her favor. Another concern is that systematic videorecording could be used to evaluate the skills of an individual surgeon, where instead it should be seen as a useful tool for credentialing after training. Videotapes might, moreover, be used for intermittent recredentialing of surgeons similar to the procedures for airline pilots who have to undergo physical and practical tests on a regular basis. This concept is not new, having been considered for implementation for several years by the AAGL and accreditation bodies, including the Accreditation Council for Gynecologic Endoscopy (ACGE).

Today, however, there are no data nor agreements on what the minimal skill levels of a surgeon should be.

## Discussion

Quality control of surgical therapy is largely absent and loosely organized. It also is very different from the strict quality control of medical therapy. The key difference is that for medical therapy all pills can be guaranteed within narrow limits to be similar, whereas for surgical therapy each individual intervention will vary with the expertise and skill of the surgeon and with that surgeon's equipment and environment. Large randomized controlled trials, thus, are difficult to perform. Drug therapy is largely based on patented innovation, and quality control is financed by the expected or actual return on investment, which can be huge in comparison with surgery. Because surgical interventions are excluded from patentability, investment incentive is limited and, therefore, this field lacks funds. These considerations can explain and make understandable why quality control in surgery is so poorly organized in comparison with medical therapy. It should, however, not be used as an excuse to ignore the overall absence of organized and efficient quality control in surgery.

Technology now permits systematic videorecording of entire procedures, including archiving, retrieval, visual and electronic watermarking, and encryption limiting the use to those authorized to do so. Cost is low and not prohibitive (Figs. 1 and 2).

We know how strongly medicine has been driven by technologic innovation. Therefore, it would not be surprising that the introduction of systematic videotaping of entire procedures will become unavoidable somewhere in the future as a powerful tool to control the quality of

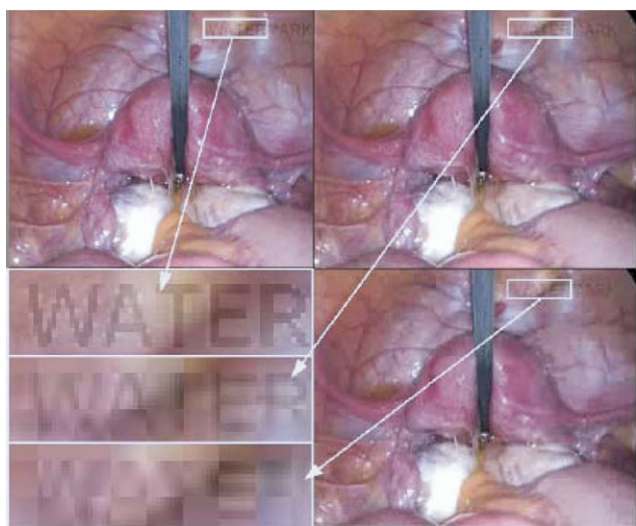


Fig. 1. Effect of video compression on image quality. The image recorded in high quality (top left, 3GB/hour) has a definition comparable to the original camera image; in archiving quality (top right, 300 MB/hour) and at 100 MB/hour (bottom right) quality is less. Quality differences are obvious after enlarging; e.g., part of the semi-transparent letters WATER-MARKING.

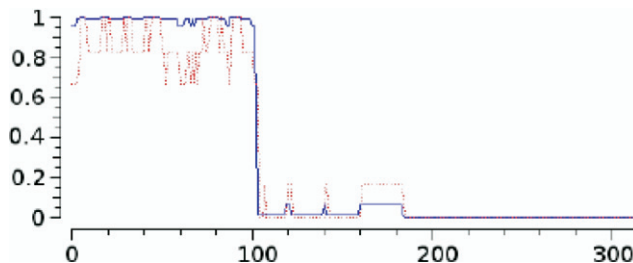


Fig. 2. Probability plot of the electronic authentication of a video with a frame by frame probability that a file has been generated by a specific surgeon or institution. In the example, the probability score (blue line) and correlation with the signature (red line) raise to almost 100% for the original video and drops to 0% for a nonoriginal clip. This can be used as an embedded copyright protection that remains traceable even after editing and applying post processing effects, or as proof that a clip is original and has not been edited.

individual interventions. It can be expected, by autoregulation, to raise the overall quality while decreasing the cost of surgery. It is useful to recognize earlier complications (unpublished data). In cases of medicolegal problems these videorecordings will permit the surgeon to prove that a flawless accurate surgery was performed, which is the reason why a series of gynecologists across the world already today systematically videorecord all their interventions for their own protection.

Systematic videorecording of entire procedures may also be seen as a threat and, thus, may meet resistance, because videorecordings might indeed be used against the surgeon in case of complications. It might be used for skill evaluation, accreditation, and intermittent recertification. It might in addition be used to control billing.

In conclusion, quality control of surgery through systematic videorecording of entire procedures has become technically feasible. It has the potential to introduce quality control in surgery and to enhance quality of surgical interventions while reducing cost of medicine. Medicolegally, it may be increasingly unwise not to videorecord. Simultaneously, videorecording meets concern and resistance. It is time, however, for reflection. Because we know by experience how strongly technologic innovation drives medicine, systematic videotaping of entire procedures could become unavoidable somewhere in the future. It will be our responsibility to organize this to the benefit of our patients and our discipline.

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