

The clinical suitability of laparoscopic instrumentation

A prospective clinical study of function and hygiene

T. W. Fengler, H. Pahlke, S. Bisson, E. Kraas

Department of Surgery, Krankenhaus Moabit, Lehrkrankenhaus der Humboldt Universität zu Berlin, Turmstrasse 21, D-10559 Berlin, Germany

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Abstract. On the basis of experience gained from 6,000 laparoscopies (73% cholecystectomies) at the Moabit Hospital in Berlin, we carried out a cohort study to analyze the failure rate and decontamination of labeled “tracer” instruments processed in three test trays that were each subjected to 100 cycles. The majority of repairs focused on the functional parts of separable scissors and damaged or lost components. At 4%, the repair index after laparoscopic use was less than that of a previously documented investigation period covering 1990 to 1996. A comparison of the costs of disposable and reusable instruments showed that reusable instruments were more cost-effective by a factor of ≥ 10 , indicating that the price gap reported in our previous calculation for 1992 and 1994 has closed only slightly. After 100 cycles, we found traces of proteinaceous material in the eluate on every fourth instrument inspected (eight of 32); half of them (four) gave a positive reading when tested with a hemoglobin pseudoperoxidase test stick. It must be said, however, that similar residual contamination has been found on instruments used in conventional open surgery, with no indication of clinical relevance. This study was designed to examine the clinical suitability of laparoscopic instruments in terms of function and hygiene. Improvements in instrument design and cleanability must focus in particular on the reproducibility of cleaning results, because cleaning is the most important step in processing sterile supplies. As the number of minimally invasive operations has risen considerably, a mere visual check no longer meets the requirements prescribed by modern quality assurance. A multi-center study of residual proteins found on tracer instruments in all surgical fields is now in progress.

Key words: Cleaning — Complications — Instruments — Laparoscopy — Sterilization

The objective of sterilization is to kill or irreversibly deactivate all microorganisms and viruses—in particular, bacterial spores—in or on the surfaces of an object [3]. To achieve this level of hygiene, thousands of surgical instruments and parts are regularly transported, disassembled, checked, and—in so far as they are able to withstand heat—sterilized with the aid of saturated steam. Legal considerations have led to a strict interpretation of the term “sterilization,” even in the absence of a standardized approach dictating the means by which this objective might be met through disinfection and sterilization [1, 4, 7, 10, 11, 12, 16, 23]. Adequate cleaning of all surfaces, including lumens, is a prerequisite to ensure that any residual contamination will be permeable to steam or disinfectants, since there is a critical thickness of biofilms [25, 28].

The rapid spread of laparoscopic methods of surgery since the late 1980s has necessitated a reappraisal of the process of preparing sterile supplies in terms of both decontamination and instrument wear. By now, minimally invasive techniques are widely applied in most advanced societies. In 1996, two-thirds of all cholecystectomies and one-third of all appendectomies performed in Germany were done using minimally invasive methods [9]. Of the 1.8 million cholecystectomies performed annually in the United States, ~80–90% are now done laparoscopically. In addition, minimally invasive techniques are used in 30–40% of the 200,000 thoracic procedures performed annually, 10–15% of the 1.5 million appendectomies, 10–15% of the 2.0 million hernia repairs, and 5–10% of the 1.8 million hysterectomies. According to Malchesky et al., “the cleaning process itself may involve many processes, but the most important outcome is the removal of protein material” [15].

The intensive use of tubular instruments in this type of surgery requires a more systematic appraisal of their surgical and hygienic properties. Videoscopic surgery is highly dependent on technical reliability, and a switch to conventional methods of surgery due to technical failure can never be ruled out. So far, only a limited number of clinical studies have dealt with technical failure or examined the hygienic reuse of sterile instruments [2, 7, 14]. These reports

nonsterile

sterile

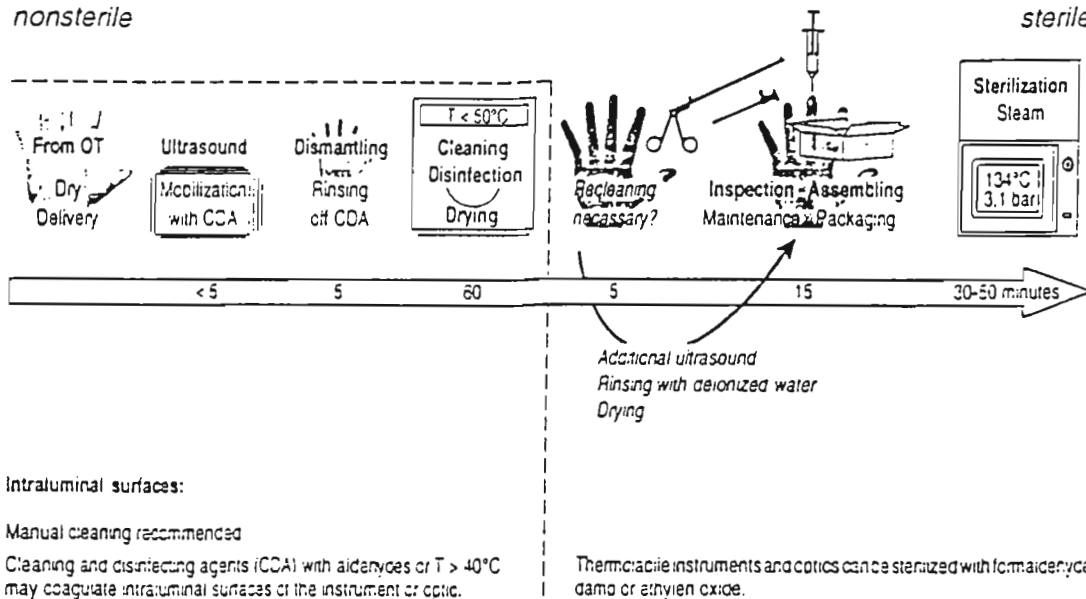


Fig. 1. Sterile supply processing (see [8]): manual and automated steps from dismantling to cleaning to sterilization.

have generally focused on surgical complications, such as the accidental puncture of blood vessels when introducing the trocar and intestinal bleeding [5, 6, 11, 20, 21, 24].

In the past, hospitals did not routinely examine instruments for wear and tear and residual contamination according to quality assurance criteria. When instruments are steam-sterilized, technical parameters can be checked using biological, chemical, and physical indicators (test spores, Bowie-Dick test, temperature, pressure); however, there are no indicators available to monitor cleaning, which represents the single most important decontamination stage. Therefore, hospitals had to rely solely on visual checks. The physical and chemical documentation and evaluation of cleaning parameters in the processing of sterile supplies is an area that has been ignored largely; at best, it has been a spinoff of test systems created by the food industries [18, 22, 23, 27]. Furthermore, it is important for any evaluation of surgical functionality and hygienic suitability to be quantifiable. A test protocol that yields clinical data on medical products should be devised to establish manufacturer liability, as suggested by the Medical Devices Directive (MDD 1998), which differentiates only between the liability of manufacturers and operators [17].

In recent years selected laparoscopic instruments were examined for quality control reasons at the Moabit Hospital to determine their functional and hygienic suitability for the entire cycle, from the operating table to the Central Sterile Supplies Department (CSSD) [8]. Experience gained from 6,000 surgical laparoscopies performed during the period 1990–96 enabled the CSSD and the first surgical ward to carry out practical experiments in conjunction with the Free University of Berlin and a number of companies involved in the manufacture of medical products (Surgical Instruments Working Group). The objective of this work was to collate the results of a clinical cohort study involving three test trays subjected to 100 cycles each and evaluate the results in terms of instrument suitability (handling, functionality, economy, reusability).

Materials and methods

After use in an operation, the instruments requiring sterilization were sorted into suitable dry containers that were then sealed. No manual pre-cleaning by the theater staff was allowed either during or after the operation. In the case of tubular laparoscopic instruments, although early rinsing of lumens would be beneficial to the cleaning process, disinfection, in particular with aldehydes, was avoided so as not to complicate intramural cleaning. Aldehydes promote the fixation of proteinaceous material, the removal of which is the main part of the cleaning process. The water-tight containers were then transported on trolley to the CSSD several times a day using elevators and road vehicles.

In the CSSD, the instruments were manually sorted, disassembled wherever possible, and processed in an ultrasonic bath (except for laparoscopes and other fragile components) before subsequently being arranged in or connected to the inserts of a washer-disinfector using the necessary adapters. During cleaning, the instruments, which are generally made from chromium-nickel steel, are in contact with water, electrolytes, and chemical detergents. For the subsequent sterilization process, temperatures of $\leq 134^{\circ}\text{C}$ and pressures of up to 3.1 bar are reached (Fig. 1).

In compiling the criteria for instrument suitability, the instrument circuit should be documented in its entirety, with all its properties and on a continuing basis, including any irregularities that may occur. First, the instrument stock and any instances of failure of the laparoscopic instruments were recorded. This log contained information regarding the type of instruments, time of use, and parameters of the cleaning process (tray contents, machine identification, cleaning program, trolley code, type of detergents).

The selection of instruments was restricted to steam-sterilizable mechanical and electromechanical components that are typical for the surgical techniques required for laparoscopic cholecystectomy and regularly used at the sterile surgeon/patient interface. The criteria of interest were as follows:

- Instrument design (functionality and handling at the operating table and in the CSSD, disassembly, cleaning, maintenance, mounting)
- Frequency of failure (fragility, separable instruments)
- Reusability (susceptibility to soiling, cleanability, ability to withstand wear and tear)
- Economic aspects (as compared with those of disposable instruments with identical function)

Three test trays with new laparoscopic tracer instruments (Karl Storz, Tuttlingen, Germany) were made up for 100 cycles; the instruments included straight scissors, straight traumatic (insulated) and atraumatic grasping forceps, monopolar hooks, and grasping forceps. Each instrument was indelibly marked, and no transfer of instruments between trays was allowed. These precautions allowed us to document any individual signs of wear and tear on each instrument or section ("mileage"). A repair index

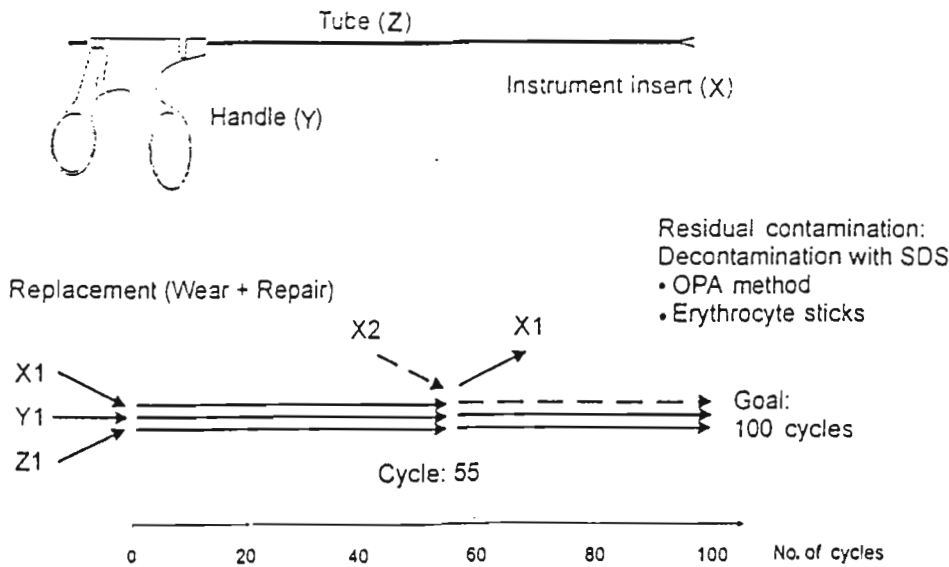


Fig. 2. Flow chart for the individual instruments in the three test trays during 100 clinical cycles from laparoscopic operating theater to CSSD: prospective instrument study 1995-96.

was then assigned to the assembled instrument of which the repaired components were a part (Fig. 2).

The degree of postoperative visible soiling and the visible cleaning results achieved were entered for each cycle on an instrument tracer slip. Three degrees of postoperative soiling (heavy, medium, light) and soiling after cleaning (heavy, light, clean) were distinguished. The information included all operative parameters (e.g., ultrasound mobilization, detergent, washer-disinfector). The test to determine the extent of residual contamination was performed after 100 cycles by means of elution of the surfaces of the instrument sections (handle, working tip, lumens) for 10 min in 5 ml of the common detergent sodium dodecyl sulphate solution (SDS). The solution (eluate) underwent photometric analysis to detect protein content in the form of primary amino groups using the highly sensitive modified OPA method (reaction of tho-thalaldehyde in the presence of *N,N*-dimethyl-2,3 mercapto ethyl ammonium chloride, a thiol component with α and ϵ terminal amino groups of proteins). In a parallel test, the eluate was also checked with the standard erythrocyte quick-test sticks used in the diagnosis of microhematuria to detect erythrocytes (pseudoperoxidase reaction) [18, 19].

A comparison of the costs of disposable and reusable instruments used in similar procedures (scissors, three pairs of grasping forceps, four trocars, clip applicator) was performed for 1996. Sterile processing was disregarded as waste disposal, because laparoscopic operations accounted for <30% of all operations and disposal methods differ considerably from site to site.

Results

Most of the repairs were related to the sharpness of scissor blades and—to a lesser extent—to fractures on the blades or tongue sections that might lead to a risk of sections breaking off and falling into the peritoneal cavity. The occurrence rate was <4%. Wear was most clearly evident on the insulation after several cycles of use. Charred or open-circuited electromechanical components represented a second source of defects that indicated improper use of the instrument. The loss of components and damage to them has become more significant since the introduction of separable instruments. A similar phenomenon was previously observed with trocars. The repair index of the tracer instruments processed in the test inserts was much lower than that recorded for the retrospective survey [9].

Due to the statistically low incidence rate, we found no particular clusters of defects needing repair in the three test trays after 300 cycles; these defects can be ascribed to the frequency and nature of usage (Table 1). Interestingly, only

185 pairs of scissors (62%) were used in 300 laparoscopic operations: 61 (tray 1), 59 (tray 2), and 65 (tray 3). Traumatic grasping forceps were used in a total of 235 operations (78%): 80 (tray 1), 78 (tray 2), and 77 (tray 3). Straight atraumatic grasping forceps were used 228 times (76%): 77 (tray 1), 68 (tray 2), and 83 (tray 3). The curved atraumatic grasping forceps were used relatively infrequently; in all, they were used 81 times (27%): 28 (tray 1), 27 (tray 2), and 26 (tray 3).

Bipolar grasping forceps were used 80 times (tray 1), 77 times (tray 2), and 81 times (tray 3)—hence, in all, 238 times (79%). Due to an instrument mixup, figures on the actual frequency of use were not reliable and were therefore not evaluated. Alternatively, three ceramic monopolar hooks were used. These remained free from damage throughout the 100 test cycles and are still in circulation (62 operations during the study; 21%).

The evaluation of postoperative contamination after 100 cycles and residue visible to the human eye after cleaning in a washer-disinfector provided interesting findings for the individual components, such as working tips, tubular sections, and handle pieces (Fig. 3). There were significant differences that could be ascribed to instrument design, function (thermal coagulation), influence of ultrasound (US), and water flow of the pump (automated device). Dismantable instruments were easier to clean; thermal coagulation made it difficult to judge the surface and to clean it safely. Ultrasound mobilizes soils and enables their removal. Pump pressure influences cleaning, as compared with similar automated cleaning systems. The differences between insulated and noninsulated tubes were not significant, possibly due to differences in the type of surface (metallic vs black).

Residual contamination detected via SDS elution and the chemical-photometric OPA method of analysis was similar to the residue contained in fingerprints. It was recorded on eight of the 36 eluted instrument sections used in clinical operations. In five cases, the contaminated areas consisted of the inner surfaces of various instrument tubes. In four of these cases, a quick-test using sticks yielded evidence of the presence of hemoglobin.

On balance, the results of a comparative study of the

Table 1. Wear and tear and contamination of three test trays (handle, tube, working tip) of tracer instruments each subjected to 100 cycles

Instrument tray no.	OT cycles	Repair	Working tip	Tube	Handle	Contamination*
<i>Tray 1</i>						
Scissors, straight	61	4	4	—	—	—
Forceps, sharp isolated	80	3	1	1	—	Handle after 36 cycles
Forceps, blunt	77	—	—	—	—	Tube
Forceps, bent and blunt	28	—	—	—	—	—
<i>Tray 2</i>						
Scissors, straight	59	1	1	—	—	—
Forceps, sharp isolated	78	2	—	1	1	Tube
Forceps, blunt	68	1	1	—	—	Tube
Forceps, bent and blunt	27	—	—	—	—	—
<i>Tray 3</i>						
Scissors, straight	65	5	3	1	1	Working tip after 19 cycles
Forceps, sharp isolated	77	3	1	1	1	—
Forceps, blunt	83	—	—	—	—	—
Forceps, bent and blunt	26	—	—	—	—	Tube

* Elution was executed in 37 of 56 parts of clinically used tracer instruments (66%). Six of 37 mechanical instrument parts were contaminated (16%). For methodical reasons, two contaminated parts of a bipolar forceps are not included (tube, handle)

commercial costs of disposable and reusable instruments (excluding manufacturing, processing, and disposal costs) were overwhelmingly in favor of reusable instruments. Considering the current prices and actual failure rates during 1996 for the relevant items (scissors, three grasping forceps, four trocars, Veress cannula), reusable instruments were cheaper by a factor of >10.

Discussion

During their useful life in the operating theater—CSSD—operating theater cycle, surgical instruments spend only a brief time in the hands of surgeons. Their fitness for use must therefore be measured not only in terms of operational safety and precision of handling but also safe transportation, simple disassembly, cleanability, and quality of materials. Wear and tear is unacceptable if it impairs surgical functionality. The replacement of (sterile) instruments (or parts thereof) cannot be recommended in the dim light of a laparoscopic operation. The practical requirements of the surgeon must be weighed against the need for hygienic processing. Hence, although instrument separability facilitates cleaning, it has in part resulted in impaired transmission of muscular force and reassembly errors.

Functionality and precision are paramount to the surgeon, whereas separability and durability (availability) are important in hygienic, logistical, and economic terms. Suitable instrument design and the use of composite materials still pose a challenge to instrument manufacturers, although great progress has already been made in these areas.

The results of this prospective study confirm the existing repair statistics that we collected for all instrument cycles between 1990 and 1996 (although the total population of instruments available for the former survey was unknown). A shift toward an increased loss of parts and incorrect reassembly was noticed. The influence of frequency of use on individual instruments is negligible, as has already been demonstrated [8].

Together with the pH value of detergents and disinfectants, the quality and texture of the surface (smooth, homogeneous) has a major effect on corrodibility. Experience has shown that tubular sleeves require additional cleaning with a brush (with no metal wires) because some (visible) traces of detritus remain on the walls of the shaft and on fulcrum joints and blades despite the high rate of flow of the cleaning solution (≤ 15 L/min). It seems to be important to have a turbulent, nonlaminar flow at sites that are difficult to access. HF instruments used to carry an electric current should generally be both pre- and postcleaned.

Many instances of damage testify to the improper use of delicate and fragile instruments as a result of general rough handling and as a consequence of separability. The degree of cleaning that can be achieved depends on the nature of the instrument in question—e.g., a pair of scissors is easier to clean than serrated forceps. A comparison of cleaning results for the functional section of instruments (scissors/bipolar forceps) after 100 cycles clearly shows the problems associated with composite materials (insulation sleeves), as well as the thermomechanical load to which these instruments are subjected and its effects on residual contamination. The interrelationship between soiling and thermal adhesion to insulating material makes cleaning unpredictable.

There is no justification for reverting to the use of only disposable instruments, given the vast number of successful minimally invasive operations performed over the last decades. There is no precedent for adopting such a policy for economic reasons, as we and others have already proven [8, 13]. Furthermore, the quality of disposable instruments is generally poorer than that of reusable instruments because cheap mass-production methods demand compromises in terms of materials and dimensional accuracy.

We believe that a number of high-quality disposable items might well be reclassified as reusable instruments. However, this is a matter for the manufacturer, since the provision of CSSD-treated instruments by a hospital is legally tantamount to placing a new medical product on the

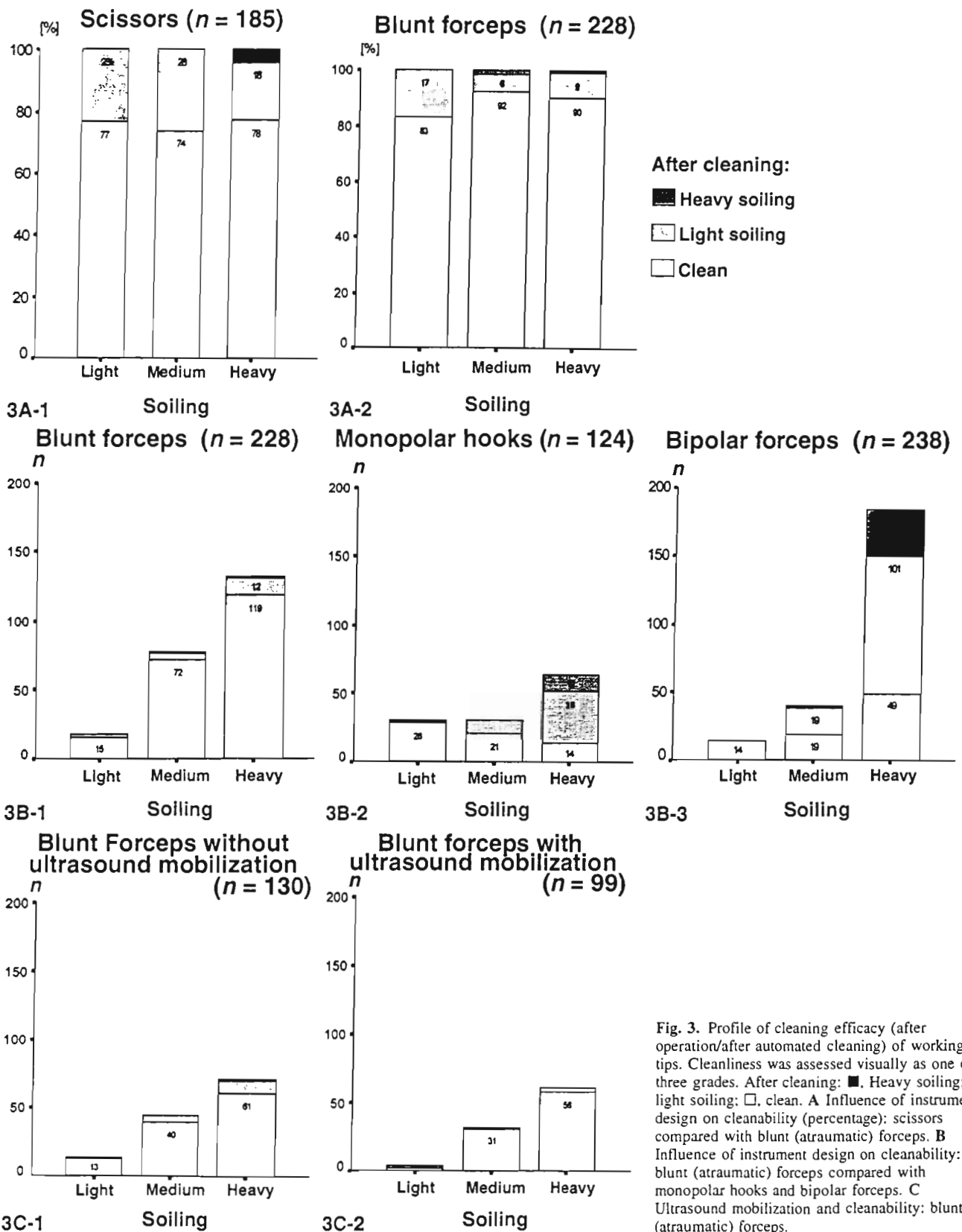


Fig. 3. Profile of cleaning efficacy (after operation/after automated cleaning) of working tips. Cleanliness was assessed visually as one of three grades. After cleaning: ■, Heavy soiling; ▨, light soiling; □, clean. A Influence of instrument design on cleanability (percentage): scissors compared with blunt (atraumatic) forceps. B Influence of instrument design on cleanability: blunt (atraumatic) forceps compared with monopolar hooks and bipolar forceps. C Ultrasound mobilization and cleanability: blunt (atraumatic) forceps.

market [4, 17]. Disposable instruments can be useful for specific tasks, such as clip stapling or as a reserve pair of sharp scissors. This point is particularly valid in view of the fact that disposable scissors were possibly used in every third operation in this prospective study.

For reusable laparoscopic instruments, the cost per operation is dictated by the absolute number of inserts and available trays (acquisition costs). Faulty but repairable instruments are typically discarded more readily when a repurchase has been announced. Careful monitoring of trays

and inserts helps to reduce the repair incidence rate, as indeed the low repair index in the test inserts (4% vs 6%) shows [8]. Reuse, however, only makes sense if the instruments in question can be cleaned reliably, since comprehensive sterilization of all instrument surfaces (including lumens) cannot be guaranteed. Plastic coating used as electric insulation material also poses a problem in terms of the cracks and crevices that generally occur after a number of sterilization cycles. If they are properly positioned and adapted to the nozzles, even trocars can be processed in a washer-disinfector.

Because cleaning is the single most important step in reducing microbial count, it must be quantifiable (separable instruments or ones with an irrigation connector, decontamination indicators). Proneness to soiling and cleanability are closely related—a fact which should be heeded by instrument development engineers.

The clinical relevance of the detection of protein residue needs to be studied in further experiments. Congealed organic surface detritus is very nearly completely dissolved by the solvent SDS (in this case, >90% recovery rate). The modified OPA method is reproducible, sensitive, and specific to amino groups typically present in proteins [18, 19]. The necessary "wet" chemical stages, including photometric extinction measurements, involve potential sources of error (preparation of the solution, dilution, transfer, batch errors), as does any other method in this field [10].

Although the exact quantity of contamination is generally unknown and its actual constituents vary, elution and detection using the OPA method is easy to perform. With this process, the instrument to be examined remains in the operating theater—CSSD—operating theater cycle. However, because of the thousands of instruments that pass through CSSD daily, the OPA method could only be performed on random samples of selected surgical instruments.

Proteinaceous material, the most important residual surface adhesion, is not confined to laparoscopic instruments [8]. In all the cases observed in this survey, only small quantities of contamination were found. The clinical relevance in terms of clusters of postoperative complications such as impaired wound closure or fever has not yet been proven. Evidence of a causal link to a contaminated instrument requires that suspicion be aroused and tests carried out. Given the praxis of antibiotic prophylaxis and the generally low infection rate associated with laparoscopic operations, we cannot conclude that the degree of instrument sterility is currently insufficient [6, 8, 14, 27]. One of the very few reports of possible cross-infections describes an outbreak of wound infection caused by contaminated bone drills used in podiatric surgery [26].

The instruments now used in minimally invasive endoscopic surgery are both modular and reusable for almost all functions and for a wide range of operations: they have an external diameter of 3 mm. There are only a few specialized functions that require the use of disposable instrument sections, which in turn requires that the instruments be separable. In these cases, greater precision in the transmission of force must also be achieved.

Discussions of the economic and environmental aspects of disposable, semidisposable, and reusable instruments are likely to be increasingly concerned with the use of individual components (for example, the blade of a pair of

scissors or a handle section); therefore, documented tests need to be done in the real-life working environment of the hospital. Test soiling and contamination that reflect field conditions must be studied under scientific laboratory conditions. In addition to laparoscopic instruments, we are seeing an increasing use in therapeutic fields of sensitive and thermally sensitive "intelligent" instruments ranging from gastroscopes and colonoscopes to dental systems and the microinstruments used in neurosurgery or in ear, nose, and throat treatment diagnostics. These instruments could also be the source of nosocomial infections [26].

A quick-test device to provide an assessment of the cleaning stage as part of the overall decontamination effort would be highly welcome but it is more difficult to develop than the chemobiological bioindicators (test spores) used in steam sterilization, since the main problem with the cleaning process is the localization of detritus and layer thickness. It is therefore necessary to run comprehensive correlation tests between clinical and laboratory contamination, such as those initiated by the Surgical Instruments Working Group, Berlin. A multicenter study is currently in progress to collect data on the amount of residual contamination on instruments after processing.

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