

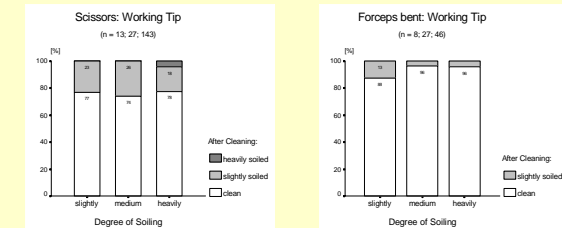
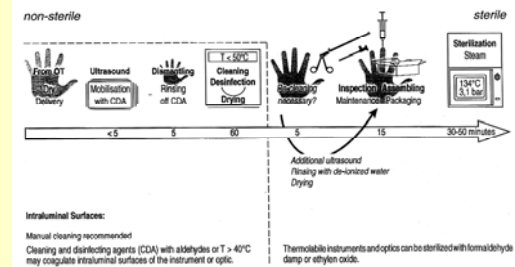
Abstract:

Laparoscopic tracer instruments on 3 test trays were processed 100 times each after operation. At 4 per 100 laparoscopies the repair index lay below that of the previously documented retrospective investigation period from 1990-96 after 6000 laparoscopies. Wear became less important compared to loss of parts. Grading of visual cleanliness showed significant differences for handle, working tip and tube, for design, ultrasound, and pump pressure of the cleaning device. Decontamination after 100 clinical cycles showed traces of proteinaceous material in the eluate on every fourth instrument inspected. Similar residual contamination has been found on instruments used in conventional open surgery, actually without sign of clinical relevance. Costs were at least 10 times cheaper for reusable scissors, forceps, trocars than disposables.

Objectives:

The rapid spread of laparoscopic methods of surgery since the end of the Eighties calls for a reappraisal of process stages in the preparation of sterile supplies with a view both to decontamination and instrument wear properties. 3 test trays with new dismantable laparoscopic instruments (Karl Storz, Tuttlingen) were made up for 100 cycles each: straight scissors, straight traumatic (insulated) and atraumatic grasping forceps, monopolar hook and bipolar forceps (Fig. 1). Each instrument bore indelible markings, no transfer of instruments between trays was admitted enabling to document individual signs of wear and tear on each instrument („mileage“). The postoperative degree of visible soiling (1-3) and the visible cleaning results (1-3) achieved with every cycle were distinguished. After 100 cycles the instrument surfaces were eluted with sodium-dodecyl-sulfate (SDS) and analysed photometrically for protein residues with the OPA-method (o-Phthalaldehyde), parallel to this with standard erythrocyte sticks. Additionally a cost comparison between reusable and disposable instruments was performed.

Sterile Supply Processing



Instrument's Wear, Repair, and Contamination - a prospective clinical trial 10/95 - 9/96

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Results:

The majority of repairs related to the sharpness of scissors' blades and to a lesser extent to fractures on working tips or hinges where the risk of parts breaking off and falling into the peritoneal cavity may exist. The occurrence rate was below 4 per 100 cycles performed. Wear is most clearly evident on the insulation after several uses. Burnt insulated electro-mechanical components represent a second source of defects and are an indication of improper use. Losses and damaged parts play an increasingly significant role since the advent of dismantable instruments which have to be reassembled during preparation for sterilisation [Fengler ThW, Pahlke H, Kraas E: Sterile and economic instrumentation in laparoscopic surgery - experiences with 6000 laparoscopic cholecystomies 1990-96. Surg Endosc (12): 1275-1279 (1998)].

	OP - Cycles	Repair	Working Tip	Tube	Handle	Contamination
Instrument Tray 1						
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	-	-	-	-	-
Instrument Tray 2						
Scissors straight	59	1	1	-	-	-
Forceps sharp isolated	78	2	-	1	1	Tube
Forceps blunt	68	1	1	-	-	Tube
Forceps bent and blunt	27	-	-	-	-	-
Instrument Tray 3						
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

Interestingly, pairs of scissors were used in only 185 (62%) of the 300 laparoscopic operations. Traumatic insulated grasping forceps were used in a total of 235 operations (78%), straight atraumatic grasping forceps were chosen 228 times (76%). The curved atraumatic grasping forceps were used relative infrequently - on all 81 times (27%). Bipolar forceps were used 238 times (79%), and the monopolar hook was used in the other surgical laparoscopies (Tab. 1).

The visible postoperative contamination after 100 cycles was documented after operation (heavily soiled, medium soiled, slightly soiled) and after the cleaning step (heavily soiled, slightly soiled, clean). Significant differences could be ascribed for the instrument section examined, its design, the use of ultrasound mobilisation, and the pump pressure of the automated cleaning device (Fig. 2-5).

Residual contamination after 100 cycles was measured from the SDS-eluate photometrically by means of the OPA method. It occurred in 25% of the examined parts (90% of all clinically used) in the range of µl albumin equivalent per ml eluate.

Disposables are at least 10 times more expensive for comparable items (scissors, forceps, trocars) as we stated detailed in our retrospective analysis [FENGLER 1998].

Conclusions:

- Dismantable instruments were easier to clean, but the option of thermal coagulation makes it difficult to judge the cleanliness of surfaces visually which actually is the only form of quality control for the cleaning step.
- Ultrasound baths can mobilise soils and enable subsequent transport of the detritus if eluted. Pump pressure may influence the result if applicable to all surfaces.
- Residual proteinaceous material (soil/debris) was detected in 25% of the examined sterile instruments which was comparable to instruments of open surgery.
- More clinical data must be available to know what is clean for sterilisation purposes.
- A test kit for quality management is required.
- Reusable instruments remain the economic choice for surgical procedures, although the cleaning efficacy as the most important step of decontamination and preparation for sterilisation is not predictable.
- Residuals may be found easier on complex instruments which concerns arthroscopic meniscus forceps as well as bone drills and is no specific problem of minimally invasive surgery.