Operational Application of Instruments and Infection Prevention – the Surgeon’s View

Th. Fengler, E. Kraas

Design of Surgical Instruments:
Thursday, 22.11. 2007 at 9.40-10.15
Radboud University Nijmegen, Medical Centre
The Netherlands

Cleanical Investigation & Application
Chirurgie-Instrumenten-Arbeitsgruppe (CLEANICAL®) Berlin

Chirurgie-Instrumenten-AG (CLEANICAL®) Berlin - Clinical Investigation & Application
www.cleanical.eu
1993 Foundation of the „Chirurgie-Instrumenten-AG (CIA)“ in the hospital Moabit Berlin
Secretary Dr. med. Dipl.-Ing. Thomas W. Fengler, Member of the following Scientific Organisations:
German Society of Surgery, German Society of Abdominal Surgery, the European Association of
Endoscopic Surgery (E.A.E.S.), German Society of Sterile Processing (DGSV) e.V.
Technical Consultant Helmut Pahlke, Member of the DGSV e.V.

1994 Quality of instruments for laparoscopy – Retro- and prospective Clinical studies on medical devices for abdominal surgery in the hospital Moabit Berlin

1998 Projects with different manufacturers (BODE, KARL STORZ Endoscopes, Miele PROFESSIONAL, ebro Electronic, Olympus, Stryker) on residual contamination and process control during the steps of processing, and optimisation of medical devices

1999 Organisation of the worldwide first multicentric study on remaining contamination after automated cleaning and before thermal disinfection for different instrument design in 6 CSSD of German hospitals
1st International FORUM Medical Devices & Processes in the Congress Center, MEDICA Düsseldorf.

2000 Foundation of the SMP GmbH in Tübingen – Validating, testing, investigating
CEO Klaus Roth

2001 New Company ZEHNACKER CLEANICAL® GmbH for processing services

2002 3rd International FORUM comes to Berlin

2005 International Business Support – “FORUM on Tour” Armenia, China, Georgia, Ireland, Mexico, Noruay, Russia

2007 New Companies CMP GmbH (Validation) and CLEANICAL® GmbH (Coaching Hospitals and manufacturers)

Intelligent medical devices lead to new approaches in surgery .... ....and dentistry as well.
Complex interacting devices need skilled staff and „training on the job“ - not only for the surgeon.....

There has been a tremendous Development since the 80’s in Surgery.

- What happens to the instruments?
- What happens to process control?
What about dentistry?

We see the dentist perhaps more often than any other doctor. Implantology urges the need for process control in this field of surgical treatments as well.

German Hygiene Recommendations distinguish for tissue between Non critical, semi-critical, critical (Spaulding) and for the design aspect in A, B, C with respect to the easiness of access to all surfaces and the resistance to heating up the medical device.

Considering operational application....

• Medical devices become finer and more complexe in design which makes them prone to damage (Ophthalmology, ENT, microsurgery, neurosurgery, traumatology, robotic surgery)
• Processing has to be executed following the “state of the art” requiring skills and knowledge of the regulatory affairs.
• Process control is verification and validation of available parameters on a „reasonable value“
• Documentation results and reassures the process
• Cleaning is still a complexe parameter and automated cleaning is recommended but not in every case (possible)
• Good processing preserves the investment for them medical devices
A broad Field of Applications ...

Reprocessing needs time

Chirurgie-Instrumenten-AG (CLEANICAL®) Berlin – Clinical Investigation & Application
www.cleanical.eu
In Surgery, there is no time left, but Processing has its Steps

Everybody knows what to do? Clear description of the „operations“?
Any manual Precleaning?

How?
Take care of Your work and of Yourself!

Under pressure ... it does not work!
Adequate Devices at the State of the Art?

Small Parts Showing up
No messing around ...

Typical Faults with Ultrasound
Fine instruments need fine Treatment

Complemento apto para posicionar, enjuagar de todos lados con suficiente presión

Validated Processing needs Verification

Chirurgie-Instrumenten-AG (CLEANICAL®) Berlin – Clinical Investigation & Application
www.cleanical.eu
Basket Call

Chirurgie-Instrumenten-AG (CLEANICAL®) Berlin – Clinical Investigation & Application
www.cleanical.eu

Foggy

Chirurgie-Instrumenten-AG (CLEANICAL®) Berlin – Clinical Investigation & Application
www.cleanical.eu
Textiles are the Contrary of Instruments

Intended Use?
EN ISO 17664: The manufacturer provides the user of the re-processible medical device with information on its intended use (function, handling) including an information for manual and (preference) automated reprocessing.

Complete Manual

Klinik setzte 47 Patienten falsches Gelenk ein

Durch einen Übersetzungsfehler wurden im St. Hedwig-Krankenhaus Prothesen verwechselt

....understood?
Messing around?

Right Instrument - wrong Place
I have a dream:
„One touch“ from Operating Theatre to Central Sterile Supply Department ...

„One touch“:
Transport ... Cleaning ... Packaging ... Sterilisation
Transport in Baskets without Complications

Plastic Baskets are prone to Wetness
The Art of Packaging

Sources of Infection:
Remaining wetness attract microorganisms to swim...
Trauma is a Trauma

In those plastic Containers You can see typical Condensation
Baskets and wrapping Paper is the State of the Art

Alternatives to Steam Sterilisation

Peróxido de hidrógeno-
Esterilización a baja temperatura

Formaldehído

Chirurgie-Instrumenten-AG (CLEANICAL®) Berlin – Clinical Investigation & Application
www.cleanical.eu
Documentation is always possible

The Description of the Working Place has to be in Place
Data Logger –
to replace chemical and biological Indicators

What do we care? We are Surgeons, we want:

• Form follows function – Function enables therapy!
• Surgeons want to take the instrument in their hand feeling familiar with it.
• They need to have confidence in function.
• Confidence means for hygiene reproducible quality of processing for sterile use.
Quality in Surgery

How to measure quality generally and with special regard to instruments? It depends strongly on the surgeon’s skills. Wound infection, pain scale, scarring, general recovery time are quite soft parameters in relation to the instruments used. Obviously the mortality rate is a highly relevant indicator of the success of a (surgical) therapy. According to internationally published data the mortality lies between 0,04% and 0,09% for laparoscopic cholecystectomy (Hölbling et al. 1995, Ludwig et al. 2001, Shea et al. 1996). Laparoscopic cholecystectomy is a safe, effective, and cost-efficient alternative to open cholecystectomy.

<table>
<thead>
<tr>
<th>Single-use vs. Multiple-use Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>In a survey of 10 studies we could resume:</td>
</tr>
<tr>
<td>• Reusable medical devices (instruments) are far superior to single-use instruments from an economic point of view (7-27 times less expensive).</td>
</tr>
<tr>
<td>• Considering the economic arguments single-use devices are only recommended in case of better performance in specific surgical tasks. Some instruments are available exclusively in a single-use variety.</td>
</tr>
<tr>
<td>Note: For medical devices manufacturing, transportation and ecological considerations (waste, water, detergents) are still a debatable field of calculation.</td>
</tr>
</tbody>
</table>
What the Surgeon needs ...

As far as reliability of the instrument is concerned, no significant differences between single-use and multiple-use instruments could be observed.

Repair data and quality of specific complex instruments are difficult to examine.

Occurrences of malfunction of reprocessed instruments was mentioned once.


Note: We have studied the performance of laparoscopic instruments in the Surgical Work Group Berlin (1998):

Fengler TW, Pahlke H, Kraas E.

What the Patient needs ...

As far as safety of the patient is concerned, no significant differences between single-use and multiple-use instruments could be detected in this analysis.

Note:

Patient safety mainly depends still on the skills of the surgeon and the organisation of the whole surgical procedure. The choice of medical devices, processing modalities, equipment and staff is just a part of it.
Re-use of Single-use Medical Devices

Re-using single-use medical devices results in a transfer of liability from the manufacturer to the processor (external or CSSD, one day surgery) for all relevant features e.g. function, material alterations, hygienic deficits.

The practice of re-use for economic reason is commonly performed, but cannot be generally recommended.

The manufacturer’s reasons for declaring an instrument „single-use only“ must be known if re-processing is considered e.g. thermolability.


Criteria for Staplers

Stapler in their different forms (hernia stapler, Endo-GIA, EEA) must be safely applying clips. It is useful to have magazins for recharging (separate sterile package).

Re-processing with the different steps of transportation and cleaning is critical for the safe function of the stapler.

These single-use devices offer a high safety, are saving time especially for anastomosis and broaden the possibilities for the operation.
Criteria for Dissectors

Even blunt dissection causes bleeding. To stop bloodloss and to keep a clear view on the field of operation multiple techniques are used. Most time consuming is sewing with the needle. A safe and time-saving alternative for the closure of vessels is dissection with the support of heat (electrocoagulation) or ultrasound (cavitation). Cleaning of these instruments is very difficult and remanents lead to a reduced function and hygiene seems to be a problem. A separately packed inlet in case of a dismantable instrument might bring the solution – no single-use, no reprocessing of the whole instrument.

Criteria for Scissors

Scissors must be sharp for dissection. For mechanical reasons, but also with the use of monopolar current laparoscopic scissors become easily blunt. The advantage of single-use scissors is a guaranteed sharpness (If not so You can return it to the manufacturer). An alternative is an extra packed inlet for reusable instrument shaft and grip.
Criteria for Trocars

There seem to be few arguments to choose single-way trocars. The silicon closure valve of certain trocars that are claimed to be „disposable“ offer features for intraabdominal sewing and external application of the knot thus avoiding gas leakage. There are no „safety shield“ trocars that used to be frequently one way medical devices. Most severe accidents of aorta perforation happened, because surgeons were not aware of the fact that during penetration there still is a certain moment when the obturator can penetrate deeply.

Criteria for Accessories like ...

The function (sharpness, cleanliness) of the Veress-needle could be a reason to offer it as a disposable. Balloons for preperitoneal hernia repair, mesh, liposuction cannulas the endobag are certainly disposables. Note: It is advised to compare different alternatives (vary or even change the technique of operation).
Resumée

• The surgeon has high confidence in his co-workers and in the medical devices.

• The surgeon is aware that remanents on external and internal surfaces of instruments might reduce the function and can cause hygienical problems harm to the patient.

• Sterilisation means cleaning in the first place. Reusable instruments are without any doubt the most economical choice.

• Where cleaning is not possible or where the complexity of the function is obvious, single-use instruments are preferrable.

• Adequate documentation is an obligation.

Friday, 29th of February 2008

Vorankündigung
5. Instruments
FORUM 2008
Medizinprodukte & Prozesse
24 February 2008 Berlin