

Ultrasound scissors: new single-use instruments vs. resterilised single-use instruments – a prospective randomised study

Ultraschallscheren zum Einmalgebrauch: Vergleich von Zuverlässigkeit und Bedienungskomfort einmal resterilisierter Ultraschallscheren mit Neugeräten

Abstract

Background: The aim of this study was to compare reliability in handling and function of resterilised and single-use disposable ultrasonic scissors.

Methods: In a prospective randomized study, the surgeon blindly tested new and resterilised ultrasonic scissors. The parameters were force of activation, cutting effect, coagulation effect, error messages and disturbing generator noise.

Results: 51 new and 49 resterilised instruments in 94 operations were evaluated. The differences in force of activation, cutting effect and coagulation were not significant. Error messages and disturbing noises were rare in both groups. 6 new instruments and 2 resterilised instruments had to be exchanged because of problems during surgery.

Conclusion: This study demonstrates comparable reliability in function and handling of resterilised and new ultrasonic scissors. The use of resterilised instruments leads to distinctly reduced costs and could contribute to efficiency in laparoscopic surgery.

Keywords: laparoscopy, disposable instruments, costs, efficiency, reprocessing

Zusammenfassung

Hintergrund: In einer internen Qualitätsstudie sollte die Zuverlässigkeit in der Funktion sowie der Bedienungskomfort von einmal resterilisierten Ultraschallscheren und Neugeräten aus Sicht des Operateurs vergleichend überprüft werden.

Material und Methoden: In einer prospektiv randomisierten Studie wurden von einem laparoskopisch erfahrenen Operateur die verwendeten Ultraschallscheren (neu oder resterilisiert) in Bezug auf die Parameter Betätigungskräfte, Schneidwirkung, Koagulationswirkung, Fehlermeldungen und störende Geräusche des Generators beurteilt.

Ergebnisse: 51 neue Instrumente und 49 resterilisierte wurden bewertet. Die Beurteilung der Betätigungskräfte sowie der Schneid- und Koagulationswirkung war nicht signifikant unterschiedlich. Fehlermeldungen und störende Geräusche traten ebenfalls in vergleichbarer geringer Anzahl auf. 6 neue und 2 resterilisierte Scheren mussten wegen Problemen während der Operation ausgetauscht werden.

Schlussfolgerung: Unsere Studie zeigt, dass einmal resterilisierte Ultraschallscheren in vergleichbarem Maße zuverlässig funktionieren und nicht weniger Bedienungskomfort bieten als Neugeräte. Die Verwendung resterilisierter Instrumente kann zur Steigerung der Effizienz laparoskopischer Eingriffe beitragen.

Schlüsselwörter: Laparoskopie, Einmalinstrumente, Wiederaufbereitung, Kosten, Effizienz

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Table 1: Post-operative parameters evaluated by the surgeon

Force of activation	optimal	too strong	too weak
Coagulation effect	optimal	acceptable	unacceptable
Cutting effect	optimal	acceptable	unacceptable
Generator error messages	none	acceptable	unacceptable
Disturbing noises	none	acceptable	unacceptable

Table 2: The various operations in both groups

Laparoscopic Operation	New Instruments n=49	Resterilised Instruments n=45	Total n=94
Colon resections	22	18	40
Fundoplicatio	19	15	34
Gastric band	2	3	5
Gastric bypass	2	1	3
Liver resection	1	2	3
Gastrocystostomy	0	1	1
Pancreatic resection	0	1	1
Stomach wall tumour	0	2	2
Oesophageal diverticulum	1	0	1
Extended adhesiolysis	1	0	1
Adrenal adenoma removal	0	1	1
Splenectomy	0	1	1
Removal of splenic cyst	1	0	1

Background and objective

Laparoscopy has in the meantime become established as a standard method in visceral surgery, gynaecology and urology. Alongside the many advantages of this method, the cost factor is often cited as a disadvantage. Therapy costs are playing an increasingly important role in the healthcare system due to the growing scarcity of resources. In addition to surgery times that are often slightly longer, a considerable proportion of the higher operation costs involved in laparoscopy are incurred through the costs for instruments. Here, one can mention above all expensive single-use instruments, which lead to higher costs in comparison to conventional operations. The aim of this study was to compare the function and ease of handling of new single-use ultracision scissors with instruments that had been resterilised.

Study design and research methods

Since 2004, Ultracision® instruments (Ethicon®) have been resterilised once (Vanguard®, Berlin) by way of a certified procedure, and offered again at a reduced price. Function and ease of handling were compared in a prospective randomised study. All laparoscopic procedures from April 2004 to August 2005 in which an experienced

laparoscopic surgeon used Ultrasound scissors were included in the study.

The instruments (new instrument or resterilised instrument) were selected according to a random list without the surgeon's knowledge. Following the procedure, the surgeon evaluated the instruments in a questionnaire. The study includes a series of 100 pairs of scissors, which met the inclusion criteria. The data was collated in an Excel® table and analysed using the statistics programme Sigma-Stat 2.0. Relative frequencies were analysed using the Exact-Fisher-Test. The significance level was set at $p < 0.05$.

Approval was obtained from the Ethics Committee of the University of Tübingen.

Table 1 shows the post-operative parameters evaluated by the surgeon.

Results

51 new instruments and 49 resterilised instruments were evaluated in a total of 94 procedures. Table 2 provides an overview of the various laparoscopic operations.

Figure 1 shows the evaluation of the force of activation, which was optimal in 95.9% of the resterilised Ultrasound scissors and in 94.1% of the new Ultracision® scissors. This difference was not statistically significant ($p = 1.000$).

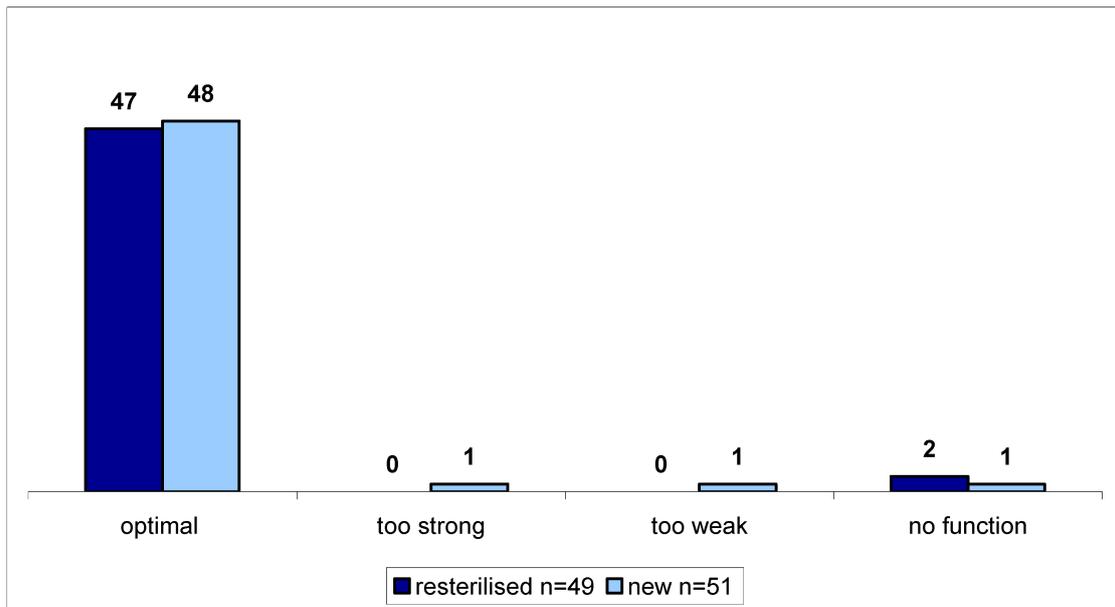


Figure 1: Comparison of the force of activation

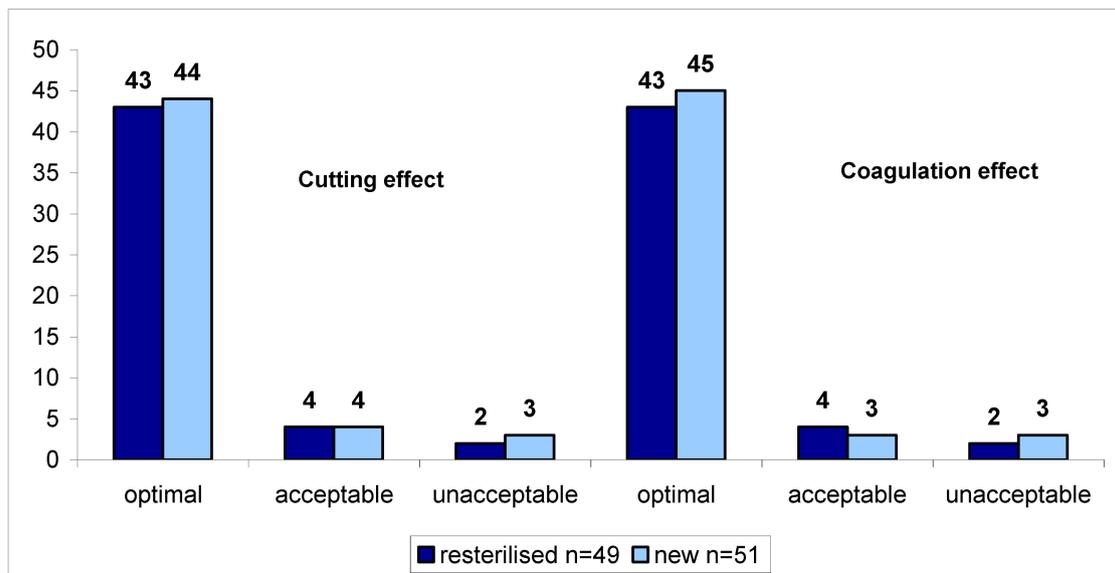


Figure 2: Cutting and coagulation effect in comparison

The cutting action was rated as optimal in 87.8% of the resterilised instruments and 86.3% of the new instruments. The evaluation of the coagulation effect was optimal in 87.8% of the resterilised scissors compared with 88.2% of the new instruments. There was no statistically significant difference for either of the parameters ($p=1.000$, $p=1.000$ respectively). See Figure 2. Comparable low occurrences of unacceptable error messages and disturbing noises were also found in both groups (4 versus 4, $p=1.000$ respectively 4 versus 3, $p=1.000$). 6 new and 2 resterilised instruments had to be replaced during the operation due to persistent problems. There was no significant difference ($p=0.269$). Table 3 shows the reasons for the replacement of scissors.

Discussion

Since the introduction of laparoscopic operating methods in cholecystectomy and appendectomy, many advantages of laparoscopic operations have been proven in studies [6], [20], [21], [23]. In the meantime, laparoscopy has become established as a standard method not only in visceral surgery, but also in gynaecology and urology. Laparoscopic surgery also plays a very important role for bariatric surgery. Extremely overweight patients profit in particular from laparoscopic operating methods [11], [17]. With increasing experience and further technical development in the area of laparoscopy, it has been possible to markedly expand the indication spectrum [9], [15]. The development of ultrasound scissors has greatly simplified the gentle laparoscopic preparation of intra-

Table 3: Reasons for the replacement of resterilised Ultracision® scissors and new Ultracision® scissors

Resterilised Ultracision® scissors	New Ultracision® scissors
2x no function despite repeated calibration	2x blade of scissors broke
	Covering came away from handle
	Singing noise, no function
	Flaking of plastic covering
	Persistent error message

abdominal tissue and made it safer. Emam and Cuschieri (among others) were also able to prove the safety of the application of ultracision dissection close to important structures in animal tests [7], [8]. Several studies have shown the clinical advantages of using ultracision instruments, such as the shortening of operating times, simple preparation and effective tissue transection, as well as less development of smoke and thermal damage [4], [8], [12], [14], [19]]. From this perspective, the ultrasound scissor is currently probably one of the most important instruments in more complex laparoscopic or laparoscopically assisted procedures. The number of instruments used in departments active in laparoscopic procedures is correspondingly high. In view of increasing numbers of laparoscopic procedures of medium and high levels of difficulty, as can currently be observed, one can assume that the number of ultracision scissors will continue to grow accordingly.

One disadvantage of laparoscopy is higher operation costs; these are compensated in part through shorter length of hospital stay or less follow-up operations e.g. through less incisional hernias [2], [5], [10]. In their study, Janson et al. found no difference between laparoscopic and open colon resections with regard to the overall costs to society within 12 weeks following the operation. The costs to the healthcare system, however, were higher [10]. In view of increasing costs pressure, economic concerns play an ever-greater role for individual hospitals, as well as for the entire healthcare system. From today's point of view, individual therapeutic procedures ultimately have to prove not only their efficacy and safety but also their cost-efficiency. Adler et al. compared single-use instruments with re-usable instruments in laparoscopic cholecystectomy and their costs analysis showed advantages for the re-usable instruments [1]. Other studies came to similar results [3], [13], [16], [18], [22].

At around € 350 each, the Ultracision® scissors constitute a not inconsiderable expense in laparoscopic surgery. Instruments that are resterilised and used more than once could contribute to a reduction in costs. An essential requirement for this is a hygienically and microbiologically acceptable condition following a correspondingly certified reprocessing procedure, as well as function and handling comfort corresponding to that of the new instruments. A reprocessing procedure certified pursuant to DIN EN ISO 13485 exists at the company Vanguard® in Berlin. The subject of our study was not hygiene or microbiological issues, but rather the function and the ease of handling of resterilised instruments from the surgeon's point of view, since there is not currently any data relating to this

from the area of clinical use. The evaluation of our data from 100 ultrasonic scissors used consecutively shows for the first time that no difference could be proven between new instruments and resterilised instruments with regard to the parameters of force of activation, cutting and coagulation effect. Error messages or disturbing noises did not occur more often in our study than with the new instruments. The high number of instruments that did not function efficiently in our study – especially in the group of new instruments – is astonishing. One would have expected this result to be more likely for the group of resterilised instruments and would then possibly have attributed this to the reprocessing procedure. Thus, it is more likely that initial production problems provide an explanation with regard to the new instruments. Instruments in perfect functioning condition appear not to be affected by a single reprocessing procedure. In our study, all surgeons had a great deal of experience in laparoscopic surgery in general and in particular with the use of ultrasonic scissors. Thus, one cannot assume any effect on the results of the study caused by the improper use of the instruments. The varying level of difficulty of the various operations was divided similarly between both groups and in our opinion did not influence the results. Our study is a simple, blind, randomised single-center-study over 17 months in a predominantly visceral surgical department. The data is based predominantly on subjective parameters relating to the function. Parameters such as post-operative bleeding, blood transfusion and operating time were not the subject of our study. Results based on subjective evaluations in clinical trials must be scrutinised more critically than objective parameters. The question as to the extent to which a possibly biased attitude of the individual surgeon with regard to the use of resterilised instruments influenced the results of the study must remain open. We are also aware that our results, which are based on relatively small groups of n=50 in each case, can only lead to an insufficient test power. This means that it is only possible to show trends, not to make statistically certain statements. With an assumed difference of e.g. 30%, 400 tests per test group would have to be carried out. Nevertheless, from our point of view, possible differences in function and handling – if they exist at all – should be seen as so low as to not appear to be of importance for the surgeon in day-to-day clinical life.

Conclusion

The present study shows a comparable reliability in function and handling of resterilised ultrasonic scissors compared with new instruments. The use of resterilised instruments leads to a clear reduction in costs (ca. € 200 per set of scissors) and thus contributes to an increase in efficiency, above all of complex laparoscopic operations. Further prospective studies are necessary to confirm these results and possibly to examine greater cost-saving effects through repeated sterilisation of one pair of scissors.

Notes

Conflict of interests

The corresponding author declares that he has connections to the following companies: Ethicon and Vanguard, but there is no conflict of interests. The presentation of the subject is independent and the description of the contents is product-neutral.

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