

HIGH-RESOLUTION TWEEZERS FOR CUTTING AND COAGULATION REPROCESSING

Reprocessamento de pinças de alta resolução para corte e coagulação

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ABSTRACT - Introduction: Several studies have demonstrated the clinical benefits of the use of high resolution instruments in surgery, with reduction in the operative time, easy handling and effectiveness in the incisions, as well as lower smoke generation and thermal tissue damage. **Aim:** To demonstrate the technical feasibility of reusing devices of high resolution for cutting and coagulation, theoretically recommended for single use. **Method:** Was evaluated the efficacy of cleaning, sterilization process and functional quality of the material. The process was applied in four tweezers brand Ligasure - Valleylab. Each was identified with ribbons of different colors autoclavable for tracking. Two were submitted directly to the cleaning after the first use and from the other two were collected samples of this cleaning for the first culture. All tweezers passed through the cleaning process prior to sterilization. Then were sterilized in hydrogen peroxide. After the sterilization process, was taken material from the devices and put it on saline solution for culture. After, the tweezers were tested by a surgeon to analyze its performance in a sample of beef. Randomly at each test the researcher contaminated tweezers with strains of *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*. This process was repeated four times. The material was sent to the laboratory and seeded in culture medium capable of microbiological identification. For quality control tests all biological, chemical and quality certification of products used in the process were attached. **Results:** The results of all cultures were negative, and functionality was preserved in the four reuses. **Conclusion:** As to the functionality, the tweezers may be used at least four times, the number of times tested in this experiment. Therefore, it can be used for five times, the first coming from the factory and four more after reprocessing.

HEADINGS - Reprocessing. Surgical instruments.

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RESUMO – Introdução: Diversos estudos demonstraram as vantagens clínicas da utilização dos instrumentos de alta resolução em cirurgia, com a redução do tempo operatório, fácil manuseio e efetividade nas incisões, assim como menor geração de fumaça e danos térmicos teciduais. **Objetivo:** Demonstrar a viabilidade técnica de reutilização das pinças de alta resolução para corte e coagulação teoricamente recomendadas para uso único. **Método:** Foi avaliada a eficácia da limpeza, garantia do processo de esterilização e qualidade funcional do material. O processo foi aplicado em quatro pinças da marca Ligasure- Valleylab. Cada uma foi identificada com fitas autoclaváveis de cores diferentes para rastreamento. Duas foram submetidas diretamente à limpeza após a primeira utilização e nas outras duas foi coletado, antes desta limpeza, material para a primeira cultura. Todas as pinças passaram por processo de limpeza antes da esterilização. Em seguida foram esterilizadas em peróxido de hidrogênio. Após o processo de esterilização foi colhida, de cada pinça, cultura em meio de solução fisiológica. Após esta coleta todas as pinças foram testadas por um cirurgião quanto à sua atuação em uma amostra de carne bovina. Randomicamente, a cada teste o pesquisador contaminava uma pinça com cepas de *Pseudomonas aeruginosa*, *Staphylococcus aureus* e *Candida albicans*. Este processo foi repetido por quatro vezes. O material foi encaminhado ao laboratório e semeado em meio de cultura passível de identificação microbiológica. Para controle de qualidade todos os testes biológicos, químicos e certificados de qualidade dos produtos utilizados no processo foram anexados. **Resultados:** Os resultados de todas as culturas foram negativos e a funcionalidade preservada nas quatro reutilizações. **Conclusão:** Quanto à funcionalidade, as pinças podem ser utilizadas por no mínimo até quatro vezes, que foi o número de vezes testado neste experimento. Portanto, ela pode ser utilizada por cinco vezes, sendo a primeira vinda de fábrica e mais quatro após reprocessamento.

DESCRITORES - Reprocessamento. Instrumentos cirúrgicos.

INTRODUCTION

In videolaparoscopic surgery, it is necessary to use tweezers with high precision cutting and coagulation. Clinical studies have demonstrated the instruments high-resolution's advantages in surgery, with the reduction of the operatory time, easy handling and effectiveness in smaller incisions, as well as lower smoke generation and tissue thermal damage⁴.

The hemostasis, which is of great importance and is crucial in preventing postoperative complications and usually time consuming, is substantially shortened by introduction of high-resolution tweezers. Various instruments have been used in clinical practice searching for a safe and rapid hemostasis. However many of these instruments cause heating due to the lateral dispersion ("thermal diffusion"), which can cripple vital structures. In recent years researchers have developed instruments to be managed with lower thermal diffusion to reduce surgical and post-surgical complications¹¹.

The tweezers of high-resolution allows simultaneously cutting and sealing, being generally used in videolaparoscopy¹¹.

On the other hand, it is necessary to mention the infectious problems in operative sites. The surgical time greater than two hours is an important risk factor for Surgical Site Infection and this is one of the main increase in hospital costs³. The patients who develop hospital infections, beside the high risk of death, generate an increase of hospital stay, complications and high costs for the institution⁹.

The use of ultrasonic's tweezers result in reduction of 15-20% for operatory time and has excellent cost/benefit ratio compared with the conventional technique⁸. In pulmonary lobectomies for example these costs are decreased in 30.8% when considering its use⁵.

Studies of surgical time on hemorrhoidectomy showed that the operation time is significantly reduced with the use of high precision tweezers for cutting and coagulation in relation to the use of conventional knives. It can also reduce postoperative pain⁷.

Alongside the various advantages of this method, the cost factor, generated by the acquisition of tweezers, is often cited as a disadvantage. These costs at the time of purchase, although their overall benefits as mentioned, are impactful in public health system and private assistance, that generally intent to reduce the cost of medical assistance¹. The tweezers cost is the biggest disadvantage, which makes often impracticable or hinders its routine use⁶.

Despite this problem, there is no denying that the use of high precision tweezers for cutting and coagulation, represent revolutionary factor in surgical technique and tend to save considerably the suturing and reduce surgical time and complications.

In Brazil and in several other countries, the high

cost of disposable products or single use devices, the development and dissemination of technology and the limited resources for the acquisition of such material, led many hospitals to reprocess these instruments and others, like the trocars¹⁰.

The national health surveillance agency¹, published in the Official Federal Journal, in August 2006, the Resolution No. 2605, which lays down in its first article, a list of medical products, that are prohibited to be reprocessed (BRASIL, 2006)².

Ligasure tweezers are not part of this list; however, as they cannot be dismantled and the Brazilian Society of Nursing in Surgical Center and Anesthetic Recovery Material and Sterilization Center¹², in its 2007 Best Practices Manual, describes the protocol of validation and deployment of reprocessing of these materials, they are not usually reused.

This study aims to follow this protocol and to assess whether or not there is safety in reprocessing these tweezers.

TECHNIC

This study was carried out in a private hospital. It is a general hospital with an average of 330 surgeries monthly, 22% being by videolaparoscopy.

Four high-resolution tweezers for cutting and coagulation were studied, each identified with different color's steam for tracking it. The first use was always in videolaparoscopic surgeries, in patients undergoing bariatric surgery.

Material

In all the tweezers, after use, samples for microbiological assessment were collected and submitted to the mechanical cleaning process, through manual pass-through and ultrasonic washing, manual drying, packaging and a hydrogen peroxide plasma sterilization.

Cleaning and sterilization

The cleaning and sterilization process consisted in rinsing with running water only in the extension of the tweezers and articulated parts. Then this same part was immersed for five minutes in the ultrasonic washing with enzyme soap. After this, a mechanical washing was realized with a bristled toothbrush and also with the help of a 13x4.5 needle gauge, for cleaning of grooves. The tweezer was drought with compressed air in high-pressure for about five minutes. Professional inspection with 5x magnifying glass increase was realized for evaluation of cleaning. To undergo a sterilization process, the tweezers were packed in cellophane suitable Tyvec brand with a sealing to 90°C, and submitted to sterilization by hydrogen peroxide plasma sterilization process.

Then, the packaging were opened and harvested

cultures of joints, tip tweezers and interior plastic cage was performed. The tweezers were identified with white, red, blue and green steam.

Functional tests

A functional test was performed by a surgeon, utilizing the tweezers on a beef with approximately 1 cm thickness and 18 cm width. The surgeon could divide completely the tissue. This process was repeated three times in all the mentioned details.

Sterilization efficacy

All tweezers were tested for sterility four times. Each test was harvested material for culture of joints and racks.

Then, randomly, two tweezers were contaminated with strains of bacteria and fungi (*Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*). The researcher who performed the cleanup after this contamination, was unaware of which tweezers was colonized.

Steps to collect material for microbiological culture

- 1) The researcher who reaped the culture used sterile gloves.
- 2) A Mayo table was prepared with sterile field for material deposition.
- 3) One DME swab was opened from its sterile recipient.
- 4) One hundred millimeters of saline 0.9% solution was add to recipient.
- 5) The swab was dipped into the saline solution.
- 6) The gripper was opened by another researcher in sterile technique.
- 7) The researcher responsible for collection of culture opened the second tweezers pack tip, dipping their articulated part in the recipient with saline solution with movements of opening and closing the tweezers. Were taken out 20 ml of the solution with sterile syringe for lab culture.
- 8) Then the researcher responsible for the collection of cultures took the swab and passed it on the internal parts of the instruments.
- 9) For the green and blue clamps, the first gathering used the same method, but the collections were performed before the first cleaning procedure and sterilization when the clamps were contaminated with the flora of the patient that used it for the first time.
- 10) Randomly, the researcher in each test contaminated the device with known strains of *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*.
- 11) The tweezers were forwarded to the process of cleaning and sterilization.
- 12) The material harvested for culture was identified by colored tape, and also by the number of times that the procedure was being held and then forwarded to the local lab to be seeded.

Microbiological study

All samples collected were seeded in culture media for microbiological cultures and identification. The materials collected with swab were initially submitted to the enrichment process in the Merck 's BHI and after 24 hours were sown in small plates of Agar Mac Conkey, Agar Manitol e Chromagar Candida, all Probac. These same materials harvested with swab were also sown amid Anaeroinzol S and Blood Agar and put in jar with oxygen depletion CO₂ generator and incubated for 48 hours (all cards and generators were Probac).

The materials collected were also sown in Hemobac Triphase Micobacteria adult for micobacteria searching. They were seeded with 10 ml of the saline and the swab, and 10 ml was sent to the laboratory. The flasks were incubated for 30 days for the final release of the results.

After incubation at BHI, the materials were sown on boards, occurring growth of *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* only on controls, confirming that the material really was contaminated with these bacteria.

Maintenance quality of tracing process

All high-resolution tweezers were marked with tape in different colors and recorded the date of each use. When the clamp was used four times, with quality assured in the process of sterilization and functionality, it was discharged.

Quality control was attached to this process, with certification of packaging using enzymatic soap, chemical and biological tests. Technical reports were also attached showing the existence of preventive maintenance of ultrasonic washer and hydrogen peroxide autoclave. Also, were archived records of temperature changes and relative humidity of the air of the storage area.

As security in the cleaning process, randomly, on the first Monday of each month, was put a clip after reprocessing.

Ethical aspects

In this study the reprocessed tweezers were not use in humans. They were tested in beef without vitality. Therefore it was not necessary to submit the research protocol to Ethics Committee approval.

RESULTS

There was no vegetative growth in any of the devices reprocessed. Even in the ones contaminated with flora or with strain of bacteria and fungi, there was no microbiological growth.

About functionality, there wasn't any difficulty in the precision of cutting. In coagulation was observed that the tissue remained, fully fenced with no bleeding, although considering a non alive tissue.

DISCUSSION

This study showed that the high-resolution devices for cutting and coagulation can be reprocessed safely from the analysis of the results checking cultures after cleaning and sterilization.

As the instruments were not tested more than four times it is possible to consider that with five uses the tweezers already become financially viable without losing the standards of efficiency in use.

CONCLUSION

Regarding the operation, the device may be used for at least four times, which was the number of times tested in this experiment. Therefore the clamp can be used safely five times, being the first the one that comes from the factory and four more after reprocessing.

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