

Integrity and functionality of surgical instruments in a public university hospital: prospective study

Integridade e funcionalidade dos instrumentais cirúrgicos de um hospital público universitário: estudo prospectivo

Integridad y funcionalidad de instrumentos quirúrgicos en un hospital público universitario: estudio prospectivo

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ABSTRACT: Objective: To characterize the integrity and functionality of surgical instruments in a public university hospital. **Method:** This is an exploratory, cross-sectional research, carried out in a large university hospital in the Northeast of Brazil, from May to July 2022. 384 instruments were evaluated regarding their integrity and functionality, divided into twelve classes, each containing 32 items. The inspection mechanisms used followed national and international standards. **Results:** Approximately half of the equipment evaluated showed non-compliance in at least one integrity and one functionality test. **Conclusion:** There was a high rate of non-compliance of instruments representing the hospital's layette. The data reflects the pressing need for the institution to invest in screening, periodic evaluation, and maintenance of instruments.

Keywords: Surgicenters. Materials management, hospital. Perioperative nursing.

RESUMO: Objetivo: Caracterizar a integridade e a funcionalidade dos instrumentais cirúrgicos de um hospital público universitário. **Método:** Trata-se de uma pesquisa exploratória, transversal, realizada num hospital universitário de grande porte do Nordeste do Brasil, de maio a julho de 2022. Foram avaliados 384 instrumentais quanto à sua integridade e funcionalidade, divididos em doze classes, cada uma contendo 32 itens. Os mecanismos de inspeção utilizados seguiram normas nacionais e internacionais. **Resultados:** Aproximadamente metade dos equipamentos avaliados apresentaram não conformidade em pelo menos um teste de integridade e um de funcionalidade. **Conclusão:** Houve alto índice de não conformidade dos instrumentais representativos do enxoval do hospital. Os dados refletem a necessidade premente de a instituição investir em rastreio, avaliação periódica e manutenção de instrumentais. **Palavras-chave:** Centros cirúrgicos. Administração de materiais no hospital. Enfermagem perioperatória.

RESUMEN: Objetivo: Caracterizar la integridad y funcionalidad del instrumental quirúrgico en un hospital público universitario. **Método:** Se trata de una investigación exploratoria, transversal, realizada en un gran hospital universitario del Nordeste de Brasil entre los meses de mayo y julio de 2022. Se evaluaron 384 instrumentos, divididos en doce clases de 32 instrumentos cada una, según las normas nacionales y internacionales para evaluar integridad y funcionalidad. **Resultados:** Aproximadamente la mitad de los instrumentos evaluados no cumplieron al menos una prueba de integridad y una de funcionalidad. **Conclusión:** Hubo un alto índice de incumplimiento entre los instrumentos que representan la canastilla del hospital. Los datos reflejan la urgente necesidad de la institución de invertir en el área de *screening*, evaluación periódica y mantenimiento de instrumentos.

Palabras clave: Centros quirúrgicos. Administración de materiales de hospital. Enfermería perioperatoria.

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INTRODUCTION

Surgical instruments are made by metal alloys (mainly stainless steel) and polymers (rubbers), with specific surgical applications. A successful surgical process is related to quality, handling, and durability of the instruments. Failures related to these tools, especially during surgery, can cause inconvenience to the surgical team, unmeasurable damage to the patient and, ultimately, material losses to the hospital and legal implications for team members and managers¹.

The international quality standards of the American Society for Testing and Materials (ASTM) F 899-09², F 1026-86 (2008)³ and the International Organization for Standardization (ISO) 7751/88⁴ and 7741/86⁵, as well as the national standards of the Brazilian Association of Technical Standards (*Associação Brasileira de Normas Técnicas* – ABNT) NRB 14.059⁶ and NRB 14.058⁷ determine, among many items, functions, performances, and acceptance standards that ensure the effectiveness of the instruments.

Most of these surgical materials are classified as health products (HP) subject to processing, that is, reusable on several clients during their lifespan. These HP are subjected to many cycles of cleaning, inspection, sterilization, displacement, and packaging, until their effectiveness is compromised⁸.

Some of the benefits of having this type of HP (reusable) is the reduction in costs and waste produced by health services compared to single-use products. Surgical HP are critical products, as they break the skin barrier and/or penetrate sterile tissues, making safe and effective sterilization crucial⁸.

The evolution and complexity of surgical techniques, promoted by the rise of technology, required improvement in the treatment of instruments and qualification of professionals involved in this process, with the aim of ensuring the efficiency of the intervention and patient safety throughout the perioperative period⁹.

In this constant search for patient safety, nurses in surgical centers and the material and sterilization centers have gained prominence, both for their roles in coordinating teams and continuing education and for their evaluation and participation in the processing stages of surgical instruments, as well as by standardizing tests that characterize the integrity and functionality of these materials, aiming to control infections and provide safe care to users¹⁰.

Instrument evaluation research can provide information to health managers about the current situation of the institution's surgical instrument set and point out the challenges to preserving the physical conditions of these tools. This kind of research is important given the relevance of the benefits of institutional protocols for periodic evaluation of instruments, which are often ignored by managers, who consider them to be innocuous or non-priority costs.

OBJECTIVE

The main objective of this study was to characterize the integrity and functionality of surgical instruments in a public university hospital.

METHOD

Type of study

This is an exploratory, field, cross-sectional research with a quantitative approach.

Study location

The study was carried out in the surgical unit of a large university hospital, which serves exclusively the public health system. The unit has two surgicenters, an outpatient one, with four rooms, and a central one, with ten large rooms, which supports fifteen surgical specialties, traditional or via laparoscopy, from outpatient cases to major ones (cardiac, neurological, and oncological surgeries and transplants). Data was collected from May to July 2022.

Population and sample

To determine sample size, the sample calculation equation for the study of proportion in a finite population was used. Considering significance level of 95%, margin of error in the estimate of 5%, lack of identification of other research on the topic in Brazilian hospitals, and lack of an estimate from the service itself, the hypothetically adopted prevalence was 50% for the number of instruments that showed non-compliance.

Sample size was estimated at 384 pieces, given that the total number of instruments belonging to the institution totaled 7,452 in the previous year's inventory. Also considering that no other research on the topic was identified in Brazilian hospitals and that there is no estimate for the service itself, the hypothetically adopted prevalence was 50% for the number of instruments that present non-compliance. Sample size was estimated at 384 pieces. Collect was stratified, according to the types of equipment. Twelve classes of instrumentals were included, with 32 observations for each one.

Surgical instruments with less than a month of sterilization and those belonging to the hospital were included (private instruments from professionals and companies were not evaluated). 12 classes of instruments used most frequently in the institution and covering the four surgical stages were selected: Mayo scissors, Metzenbaum scissors, anatomical forceps with and without teeth, Halstead forceps (mosquito), Crile/Kelly, Allis, Mixter, Collin, Foerster, Rochester Pean, and Mayo Hegar needle holders. Loose materials were excluded, considering that the control of the evaluated items was done by box and the separate units made this control difficult, nor as contaminated instruments (post-use).

Study protocol

Instruments from the arsenal of sterile material in the central surgical unit were tested by the main researcher, a surgical nursing resident, and by a surgical center professional with experience in instrumentation and trained in the management of surgical instruments by *Associação Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização* (SOBECC).

The parts were identified by boxes to guarantee accuracy and avoid repetition of instruments, as in the service there is no identification by part. Equipment with image intensifying lenses (magnifying glass with LED lighting capable of magnifying up to eight times) was used to inspect the instruments for adequate cleaning and physical condition (stains, cracks, and signs of corrosion). Subsequently, specific tests were carried out by class of instruments: scissors, needle holders, and anatomical and gripping forceps.

Mayo and Metzenbaum scissors were evaluated by tip checking, shank adjustment, blade alignment, and cutting performance tests (five-ply gauze were cut three times without interruption, with the distal two-thirds of the blades). Of the anatomical forceps, with teeth and without teeth, the integrity of the tips (bent or with broken teeth) was checked,

the uniformity of the spring junction was checked, the fit of the tips without teeth when closed (joining the two parts of the forceps), checking the tips with teeth (symmetry, perfect fit, opening without difficulty, sharp teeth).

Specific tests of needle holders and gripping forceps (Crile/Kelly, Allis, Halstead, Collin, Mixter, Foerster, and Rochester Pean) assessed the alignment of the grip rings, the closure of the racks, the tips and the fitting of the serrations, adjusting the rods and gripping. Needle holders were also evaluated for suture grip.

In addition to integrity and functionality tests regarding stains, cracks, cleaning and corrosion, for example, surgical instruments were subjected to an exclusive inspection method, developed by the researchers themselves, which consisted of classifying each item according to its characteristics and marking it with "C" (compliant) or "NC" (non-compliant). To be considered NC, the equipment must fail at least one integrity and one functionality tests. The new mechanism followed national and international standards and regulations²⁻⁷.

Data analysis

Data were recorded in a Statistical Package for the Social Sciences (SPSS) software database, version 20.0. The parameters of the evaluation script (absolute and relative frequencies) were analyzed and presented using descriptive statistics. The prevalence of non-compliance was also calculated in each test and for each instrument class. All conclusions were drawn considering a significance level of 5%.

Ethical aspects

The research was registered at the hospital's Research Support Center and released with a letter of consent. As this is administrative research, with no human beings in the sample, the hospital's flow does not require submission to the institution's Human Research Ethics Committee. The results were subsequently presented to the head of the Surgical Blocks Unit as feedback for relevant information for the service.

RESULTS

During the collection period, the calculated sampling was completed. In the integrity tests, all classes of instruments had NC parts in at least three of the four tests. The test with

the highest rate of failed instruments was stain inspection; the cleaning inspection test had the best result (Table 1).

The results of the functionality tests are presented by dividing the classes into instruments with and without racks. Scissors are the instruments in the group with the largest non-conforming sample and failed mainly in the shank adjustment test (46.9%) and in cutting performance (62.5%). Anatomical forceps with and without teeth presented few NC cases (Table 2).

Among the instruments with racks, the rack closure test had the worst performance, with 85 of the 256 instruments submitted for evaluation having failed (33.2%) (Table 3).

Scissors were the instruments with the most cases of non-compliance (78.1%; $p=0.001$ for Mayo and 75.0%;

$p=0.005$ for Metzenbaum). In a general assessment of the 384 instruments evaluated, NC rate (those that failed at least one integrity and one functionality test) was approximately half (Table 4).

DISCUSSION

In the study presented here, the non-compliance of surgical instruments of all classifications, according to their purposes, was evidenced in relation to at least three of the following indicators: cleanliness, stains, corrosion and cracks in integrity tests. Assessing the integrity of surgical instruments constitutes a nurse's management strategy, establishing a

Table 1. Distribution of non-conformities related to integrity by class of instrument assessed. Recife (PE), Brazil, 2022.

Instrument*	Integrity-related characteristics			
	Cleaning (n)	Stains (n)	Corrosion (n)	Cracks (n)
Mayo scissors	1	24	2	6
Metzenbaum scissors	1	20	3	5
Anatomical forceps with teeth	2	19	6	5
Anatomical forceps without teeth	3	19	5	5
Mayo needle holder	3	25	0	6
Crile/Kelly forceps	2	25	2	4
Allis forceps	1	17	3	6
Rochester Pean Forceps	3	27	3	0
Collin forceps	2	18	1	1
Mixter forceps	4	26	2	7
Foesrter forceps	1	21	9	6
Halstead forceps	1	17	3	4
Total (n=384)	24 (6.25%)	258 (67.20%)	55 (14.32%)	39 (10.15%)

*32 samples of each instrument type.

Table 2. Results of non-compliances found in functionality tests for instruments without racks. Recife (PE), Brazil, 2022.

Instrument class*	Tip integrity (n=128)	Rod adjustment (n=64)	Alignment of the blades (n=64)	Cutting performance (n=64)	Uniformity of the spring joint (n=64)
Mayo scissors	2	16	2	20	-
Metzenbaum scissors	0	14	3	20	-
Anatomical forceps with teeth	1	-	-	-	3
Anatomical forceps without teeth	0	-	-	-	3
Total	3 (2.3%)	30 (46.9%)	5 (7.8%)	40 (62.5%)	6 (9.4%)

*32 samples of each instrument type.

Table 3. Results of non-compliances found in functionality tests for instruments with racks. Recife (PE), Brazil, 2022.

Instrument class*	Tip integrity (n=32)	Rod adjustment (n=32)	Tips/serrations fitting (n=256)	Rack closing (n=256)	Grip test (n=256)
Mayo needle holder	2	6	2	15	2
Crile/Kelly forceps	-	-	1	10	1
Allis forceps	-	-	13	10	6
Rochester Pean Forceps	-	-	4	9	3
Collin forceps	-	-	12	8	1
Mixter forceps	-	-	4	12	0
Foerster forceps	-	-	6	11	6
Halstead forceps	-	-	1	10	2
Total	2 (6.2%)	6 (18.8%)	64 (20%)	85 (33.2%)	21 (8.2%)

*32 samples of each instrument type.

Table 4. Compliance of instruments. Recife (PE), Brazil, 2022.

Instrument*	Compliant n (%)	Non-compliant n (%)	p
Mayo scissors	7 (21.9)	25 (78.1)	0.001
Metzenbaum scissors	8 (25.0)	24 (75.0)	0.005
Anatomical forceps with teeth	22 (68.8)	10 (31.2)	0.034
Anatomical forceps without teeth	14 (42.7)	18 (56.2)	0.480
Mayo needle holder	11 (34.4)	21 (65.6)	0.077
Crile/Kelly forceps	17 (53.1)	15 (46.9)	0.724
Allis forceps	15 (46.9)	17 (53.1)	0.724
Rochester Pean Forceps	17 (53.1)	15 (46.9)	0.724
Collin forceps	20 (62.5)	12 (37.5)	0.157
Mixter forceps	16 (50.0)	16 (50.0)	1.000
Foerster forceps	14 (43.8)	18 (56.2)	0.480
Halstead forceps	20 (62.5)	12 (37.5)	0.157
Total	181 (47.1)	203 (52.9)	0.262

*32 samples of each instrument type. p: χ^2 test value for proportion comparison.

measure to prevent adverse effects occurring during surgery, including the control of surgical site infections (SSI), which still account for approximately 15% of healthcare-associated infections (HAIs), resulting in prolonged hospitalizations and increased morbidity and mortality, in addition to increased hospital costs^{8,11}.

Adverse events to the patient can be linked to several factors, including the malfunction of surgical instruments caused by loss of integrity and functionality, generally due to numerous processing and, eventually, inappropriate handling. Such instruments need to have effective performance,

as they are among the mandatory items in the safe surgery checklist, in order to offer quality care, consequently reducing HAI rates, and maintaining their physical conditions¹ is a challenge.

In the inventory, a higher rate of failed instruments was found during the integrity assessment, in the inspection of stains. Stains can occur over time, after several processes, due to the accumulation of contaminants from chemical cleaning and disinfection products, ions from water and steam¹. As shown in another national study, at the site of this study, instruments are sterilized in old-fashioned steam

autoclaves¹. One of the disadvantages of the steam autoclave is its ability to damage materials, leaving them wet, risking rust and corrosion^{1,12}.

Recognizing the cleaning stage as fundamental in the processing of materials, the role of nurses is increasingly evident in the work processes of the hospital area, mainly due to their role in organizing processes with a view to preventing HAIs and patient safety^{1,10}.

It is worth noting that, even if cleaning does not have microbicidal action, it drastically reduces microorganisms in the materials, by up to 99.99% (4 logs) due to the removal of dirt¹³. However, in the present study, there was no microbiological assessment during cleaning inspection, considering that it is possible to identify biological action, microorganisms, and endotoxins in instruments with more accurate methods to identify contamination¹⁴.

There was a high failure rate in the inspection of instruments due to stains. Instruments are exposed numerous times to adverse situations, such as the presence of salts and the accumulation of organic material and humidity, and stains may represent changes in the instrument's metal alloy or biofilm formation. They are also subjected to aggressive sterilization methods and environments, such as exposure to chemical solutions (liquid and gaseous), high temperatures, pressures, ionizing radiation, friction, among others¹³.

This result signals the institution that all stages of the sterilization process must be revisited, with the implementation of checklists based on Resolution RDC No. 15/2012 of the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA) and international guidelines, in addition to indicating the importance of appoint a professional nurse to the position of quality/safety manager at the Central Sterile Supplies Department (CSSD).

Factors that can prevent stains and corrosion in surgical instruments are the quality of water, which must guarantee potability and purification, including periodic monitoring of hardness measurement, in addition to complete rinsing and effective drying of these materials, as detergent residues, organic material and other infectants can increase the risk of biofilms, staining instruments and causing adverse events for patients, such as SSIs¹³.

Still regarding the integrity of the instruments, corrosion and cracks were NC by 14.32 and 10.15%, respectively. One of the factors that can contribute to corrosion is the autoclave temperature, which must reach a maximum of 134°C; when exceeded, it may affect the instrument's resistance to

corrosion, stimulating the dissolution of ions with subsequent release of toxic residues in tissues and organs, causing inflammation in surgical patients.

Cracks can result from impacts and falls, increasing surface exposure to oxidation, starting the deterioration process of the material^{11,12}. It is worth mentioning that the institution has a preventive maintenance and qualification routine for autoclaves and CSSD equipment.

Regarding functionality tests, scissors are the instruments in the group with the largest non-conforming sample and were failed mainly in cutting performance (62.5%). Deformation, tension or traction on the scissors can result in misalignment of the rods, loss of cut, and inaccurate handling. Scissors deteriorate during extensive reprocessing, with the blades losing their functionality as they open and close. In this sense, repairing the cut or even replacing them should be a priority, considering that the deficit can cause surgical maneuvers with tissue damage and increased stress for the professional, negatively reflecting on the postoperative period of surgical patients¹.

Another worrying result was the rack closing test, with non-compliance (33.2%). This mechanical wear and structural damage may be related to the quality of the raw material used in manufacturing as well as to the inadequate qualification of professionals regarding the handling of instruments^{9,13}.

Furthermore, in the scenario of this research, it was found that students who enter the institution are not previously trained to handle surgical devices, which affects their functionality. Therefore, investing in periodic testing, preventive maintenance, and handling training are ways to avoid failures. In this context, nurses have a preponderant role in the management of materials and supplies in hospital environments, particularly in teaching hospitals, such as the one in this research¹⁵. With regard to surgical instruments, it is essential that managers have control and knowledge of their instrumental sets, with quality assessment preemptively, that is, routinely and before professionals' complaints are registered at the time of using the instruments.

Adopting efficient control, forecasting, and material supply systems is extremely important to avoid failures that could pose risks to patients. Nurses play a fundamental role in managing these processes, implementing the use of methodologies and tools to diagnose, evaluate, and resolve difficulties in real time, reducing institutional costs and ensuring the continuity of work safely, efficiently, and effectively in operating rooms¹⁶.

In this research, the instruments considered in the evaluations are basic for the assembly of most trays and surgical kits, with a much higher turnover than special instruments and intended for a specific type of surgery. Therefore, these instruments must be tested periodically and at shorter intervals, considering wear and tear from constant use. Strategies such as identification and use of radiofrequency technologies can help track instruments and measure their use and reprocessing^{17,18}.

Of the instruments evaluated, non-conformity rate (failing at least one integrity test and one functionality test) was approximately 50%. This result must be considered as it ensures accurate information to implement administrative and managerial activities not only in the surgical center dimension, but also in the CSSD, the Hospital Infection Control Committee and the Hospital Medical Supplies Bidding Committee. In this way, essential scientific data is promoted for perioperative care committed to the safety of service users, in addition to reducing (minimizing costs, avoiding financial expenses...) financial expenses with the acquisition of instruments with a longer useful life, maintaining its integrity and functionality criteria¹⁶.

Study limitations

The limitation of the present study was the lack of validation with experts of the collection instrument, as well as the presentation of the specifications of the metallic alloys and polymers that make up the surgical instruments analyzed, according to the manufacturers' specifications. Finally, limitations could include the lack of registration and traceability that would allow estimating the time of use of the instruments, which could corroborate the findings and facilitate the understanding of the results.

Contributions to the field of nursing

Considering that the deterioration of surgical instruments, with a decrease in their functionality and integrity, can result in greater risks of adverse events, the results of this study provide information to managers and health professionals about the current situation of the institution's surgical instrument set.

In a broader observation, this research tends to promote the incorporation of material management strategies, periodic evaluation, and preventive maintenance as part of actions aimed at surgical patient safety, thus helping to develop a

standard operational protocol regarding integrity and functionality tests and to propose quality control indicators for surgical instruments, including defining criteria for removing the instrument from circulation (for example, when a non-conformity cannot be corrected).

The instruments identified in the research as NC were delivered to the head of the unit accompanied by a report produced by the researchers so that the necessary measures could be taken. Research results motivated the discussion about the hospital hiring an outsourced company to carry out periodic inventory, development of standard operating procedures for testing instruments by the CSSD team and the respective training for the operationalization of these protocols.

CONCLUSION

Approximately half of the instruments evaluated were NC, indicating shorter useful life and need for replacement to meet the required safety standard. The data reflect the urgent need for the institution to invest in systematic procedures for screening, periodic evaluation, and maintenance of instruments, as well as supporting the cost/benefit ratio in the process of acquiring surgical instruments by the institution.

It is suggested that further research be carried out in order to contribute to benchmarking and the construction of expected indicators and parameters to support the improvement of evaluation processes, which corroborate technological and managerial advances.

These results indicate the need to revisit all stages of the sterilization process in the institution, with the implementation of checklists based on ANVISA Resolution RDC No. 15/2012 and international guidelines. They also indicate the importance of appointing a professional nurse to the position of quality/safety manager at CSSD.

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None.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

AUTHORS' CONTRIBUTION

ETG: Formal analysis, Conceptualization, Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing, Supervision, Validation, Visualization. RIS: Formal analysis, Conceptualization, Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing, Supervision, Validation, Visualization. MGSL: Formal analysis, Conceptualization, Investigation, Methodology, Writing – review & editing, Supervision, Validation,

Visualization. CRAS: Formal analysis, Conceptualization, Investigation, Methodology, Writing – review & editing, Validation, Visualization. SDVNA: Formal analysis, Conceptualization, Data curation, Investigation, Methodology, Writing – original draft, Writing – review & editing, Supervision, Validation, Visualization. EMLMM: Formal analysis, Conceptualization, Investigation, Methodology, Writing – review & editing, Validation, Visualization. RLVG: Formal analysis, Conceptualization, Investigation, Methodology, Writing – review & editing, Validation, Visualization.

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