ASSESSMENT OF DAMAGES IN FLEXIBLE NASO-FIBROSCOPE DISINFECTED WITH PERACETIC ACID

Avaliação de danos em nasofibroscópio flexível desinfetado com ácido peracético Evaluación de daños en nasofibroscopio flexible desinfectado con ácido peracético

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ABSTRACT: Objective: To evaluate possible damages in naso-fiberscopes caused by disinfection with peracetic acid. **Method:** Applied research. Three new naso-fiberscopes subjected to disinfection with peracetic acid were monitored and photographed under stereoscopic microscope, for 18 months, to evaluate the behavior of the polymer and fiber naso-fiberscopes, related to the use of this disinfectant. Nurses and medical team were trained with emphasis on the correct handling and safe processing of the fibers. **Results:** Fibers were regularly analyzed and photographed during the study period, totaling 3,979 uses. In all fibers, cracking of the excess adhesive material around the fiber sealing area was observed, without functional impairment. After more than 2,000 uses, a flexible naso-fiberscope (FNF) developed surface cracks at the distal tip of the fiber cover, without however compromising the sealing test. **Conclusion:** The peracetic acid did not cause functional damage or oxidation in the FNFs, in the formulation used and during the study period, although the manufacturer recommends aldehydes solution to disinfect. **Keywords:** Disinfection. Fiber optic technology. Endoscopes. Damage assessment.

RESUMO: Objetivo: Avaliar a ocorrência de possíveis danos em nasofibroscópios causados pela desinfecção em ácido peracético. Método: Pesquisa aplicada. Três nasofibroscópios novos, submetidos à desinfecção com ácido peracético, foram acompanhados e fotografados em microscópio esteroscópio, ao longo de 18 meses, para avaliar o comportamento do polímero e da fibra do nasofibroscópio, relacionado ao uso desse desinfetante. Houve capacitação das equipes de enfermagem e médica com ênfase no manuseio correto e no processamento seguro das fibras. **Resultados:** As fibras foram analisadas e fotografadas regularmente, durante o período do estudo, totalizando 3.979 usos. Foi observado, em todas as fibras, craquelamento do excedente de material adesivo em torno da área de vedação das fibras, sem comprometimento funcional. Um nasofibroscópio flexível (NFF), após mais de 2.000 usos, apresentou fissuras superficiais na cobertura da ponta distal da fibra, sem, contudo, comprometer o teste de vedação. **Conclusão:** O ácido peracético, na formulação utilizada e no período estudado, não causou danos funcionais ou oxidação nos NFFs, apesar de o fabricante recomendar a desinfecção por solução de aldeídos. Palavras-chave: Desinfecção. Tecnologia de fibra óptica. Endoscópios. Avaliação de danos.

RESUMEN: Objetivo: Evaluar la ocurrencia de posibles daños en nasofibroscopios causados por la desinfección en ácido peracético. Método: Estudio aplicado. Tres nasofibroscopios nuevos, sometidos a la desinfección con ácido peracético, fueron acompañados y fotografiados en microscopio esteroscopio, a lo largo de 18 meses, para evaluar el comportamiento del polímero y de la fibra del nasofibroscopio, relacionado al uso de ese desinfectante. Hubo capacitación de los equipos de enfermería y médica con énfasis en el manejo correcto y en el procesamiento seguro de las fibras. **Resultados:** Las fibras fueron analizadas y fotografiadas regularmente, durante el período del estudio, totalizando 3.979 usos. Fue observado, en todas las fibras, craquelado del excedente de material adhesivo alrededor del área de sellado de las fibras, sin comprometimiento funcional. Un nasofibroscopio flexible (NFF), tras más de 2.000 usos, presentó fisuras superficiales en la cobertura de la punta distal de la fibra, sin, con todo, comprometer el test de sellado. **Conclusión:** El ácido peracético, en la formulación utilizada y en el período estudiado, no causó daños funcionales u oxidación en los NFFs, a pesar del fabricante recomendar la desinfección por solución de aldehídos. Palabras clave: Desinfección. Tecnología de fibra óptica. Endoscopios. Evaluación de daños.

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INTRODUCTION

The flexible naso-fiberscope (FNF) is an optical thermosensitive fiber, polymer coated medical device, without internal channel, which has a handle to the distal end direction. FNF provides larger image and aims at examining pathological and normal conditions of the nose, larynx, and pharynx. During its use, FNFs may be contaminated with blood, body fluids, organic waste, and potentially pathogenic microorganisms¹. Therefore, an appropriate processing of such equipment is crucial to prevent cross contamination between uses. It is considered a semicritical instrument and requires, at least, high-level disinfection for contacting mucous membranes, according to the recommendations from the Centers for Disease Control and Prevention (CDC), from the United States of America², and the *Agência Nacional de Vigilância Sanitária* (ANVISA)³.

The high-level chemical disinfectants recommended by manufacturers of optical fiber generally contain aldehyde formulations as their active ingredient, once they are highly compatible with polymers, rubbers, and metals. Among the aldehydes, the most often employed one is 2% glutaraldehyde (GL), due to their low cost. However, the disadvantage of this formulation is the toxic potential, which may affect especially the professionals who handle it, causing severe eye, nose, throat, and lungs irritations, accompanied by headache, sleepiness, and dizziness, if not properly handled. Another disadvantage is that it may impregnate organic material on surfaces^{2,4}. The second option of disinfectant solution would be 0.55% ortho-phthalaldehyde (OPA); however, it may cause eye irritation and spots on the skin, on mucous membranes, on clothing and on environmental surfaces, as well as cause hypersensitivity in patients with repeated exposure. Cases of anaphylactic reaction in patients undergoing cystoscopy have been registered^{2,4}.

At the *Hospital de Clínicas da Universidade Estadual de Campinas* (HC-Unicamp), the use of disinfectants based on aldehydes was questioned by occupational health associations and by the Unicamp servers' union, due to their potential occupational hazard. The risks to the patient were also weighted, in particular the possibility of anaphylactic postcystoscopy reaction by OPA. As a result, the hospital abolished the use of aldehydes, replacing them with disinfectant based on peracetic acid (PA), which is similarly suitable for high-level disinfection of endoscopes.

The PA has fast action for all vegetative microorganisms. The mechanism of action is poorly understood, but it is believed to act by denaturing proteins and committing cellular metabolism by oxidation of their structures such as other oxidizing agents. Its main disadvantage is the possibility of rusting metals, noting that this feature depends on the formula^{2,4}. In Brazil, PA formulations differ as to the presentation form (liquid or powder) of both the solution and the activating agent. They also vary as to the presence and effectiveness of antioxidants in the formulation components.

In our health service, the solution adopted for disinfection of all endoscopic equipment is the PA solution (Anioxide 1000[®]) whose presentation is liquid, with neutral pH, and liquid activator. This product is applicable to all types of endoscopes and fibers available in the hospital^{5,6}.

In August 2013, the HC acquired two naso-fiberscopes for adult patients (Pentax[®]) and a pediatric one (Olympus[®]) to be used by Otorhinolaryngology professionals, especially in the outpatient unit, with average daily use of 15 naso-fiberscopic procedures.

The FNFs manufacturers recommend only using GL or OPA for disinfection^{7,8}. They warn that there might be a risk of oxidation and loss of useful life of the fibers by using PA, which would result in the cancellation of equipment warranty if this solution is used. Although there is no consistent content in the literature⁴ to confirm damages to endoscopes related to the use of PA, there is a concern among professionals on this issue.

Given the institutional policy of non-use of aldehydes, despite the shortcomings and risks referred by the manufacturer, as well as the cancellation of the consequent guarantee, the option was to use PA for disinfecting FNFs. The central question of the study was: what would be the damages in the newly acquired FNFs resulting from disinfection by PA, in HC, over 18 months? Therefore, we planned to implement a methodology to monitor any damage to such equipments.

OBJECTIVE

To evaluate possible damage in naso-fiberscopes caused by PA disinfection.

METHOD

This is an applied research of systematic follow-up of the integrity of 3 new FNFs submitted to PA disinfection, over 18 months, in HC-Unicamp.

Before the use of FNFs, a training was conducted in partnership with the technician of the Biomedical Engineering Center (acronym in Portuguese – CEB) at Unicamp, who is responsible for the maintenance of hospital equipment. The training was directed to both medical and nursing staffs, emphasizing the correct handling and safe processing of FNFs.

A processing protocol was described, step by step, with photographic illustration and included the following procedures:

- Sealing test after each use. It can be accomplished with a manual or electronic system connected to a specific route of FNF. Blowing is carried out between 100 and 200 mmHg and the pressure loss inside the equipment is measured to detect any holes. If the pressure remains stable, the FNF is intact and can be processed and used. If the pressure drops within 30 seconds, there may be a leakage and the FNF should be sent for repairing. The presence of holes can compromise the fiber, once that liquids are infiltrated in the equipment, damaging it, in addition to compromising their cleaning and disinfection;
- Soaking the entire fiber, including the command area, in an enzymatic detergent solution, with contact time and dilution recommended by the manufacturer; then, carry out mechanical cleaning with soft nonwoven fabric throughout the length of the fiber and the command area;
- Rinsing in clean water. Drying with disposable absorbent nonwoven fabric;
- Full immersing in PA for the time recommended by the disinfectant manufacturer (10 minutes);
- Abundant rinsing in potable water for complete removal of disinfectant residues;
- Drying with disposable absorbent nonwoven fabric; and
- Making it available for immediate use or packaging.

The FNFs are kept suspended, in appropriate devices, to packaging during the day. At the end of the work shift, after the last processing, the equipment are dried out and stored in sealed containers, previously disinfected with 70% alcohol, followed by sealing. The breaking of the seal implies new processing.

To ensure traceability, the systematic documentation of processing (date, time, process time, person executing it) and

controlled uses is instituted, in which the name and hospital registration number of the patient, as well as the equipment's usage time to perform the exam are recorded.

A procedure for evaluating the fiber structures by stereoscopic microscope ($Zeiss^{(0)}$) is also established. This stereoscopic microscope is an optical instrument, associated with an incident and transmitted lighting system, which enables enlarged three-dimensional view of objects. This instrument enables the image to be enlarged by 80 times, without cutting or prior preparation of the object. The equipment can be attached to the camera or the monitor for image registration. The naso-fiberscopes' assessment was performed before their first use and, monthly, during the first six months of use. After this period, assessments were performed quarterly. The medical team was instructed to report any loss of functionality in the analyzed FNFs.

RESULTS

The fibers were observed and photographed regularly, from September 2013 to February 2015.

At first observation, prior to use, white spots, resulted from the manufacturing process, were observed in fiber body 1 (Figure 1), just above the bonding area of the seal test structure. Stains intensified with use and were characterized just as cosmetic changes; no changes were observed in the polymer structure.

After six months of use, a cracking was observed in the surplus of a product around the lens. This was considered by the CEB technician as loss of excess adhesive and did not compromise the fiber (Figure 2). Throughout the

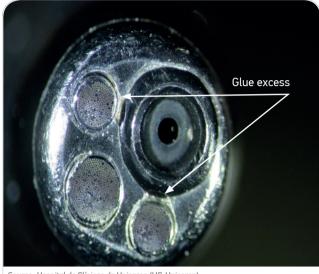


Source: Hospital de Clínicas da Unicamp (HC-Unicamp).

Figure 1. Stains in the naso-fiberscope's body displaying before the first use. Date: September 2013.

observation period, a reduction in this excess was observed. After 18 months of use (Figure 3), the excess was fully eliminated.

In February 2015, the presence of surface cracks was observed (Figure 4) in the coverage area of the distal tip, which is the fiber movement region. These cracks occurred after more than 2,000 uses of the fiber n° 1 at the time of the FNF assessment in the stereoscopic



Source: Hospital de Clínicas da Unicamp (HC-Unicamp).

Figure 2. Excess of adhesive material loosening around the seal area after six months of use. Date: January 2014.



Source: Hospital de Clínicas da Unicamp (HC-Unicamp).

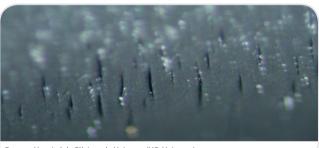
Figure 3. Visualization of the same fiber after 18 months of use without excess of adhesive. Date: January 2015.

microscope. However, fiber integrity was preserved and the sealing test was negative. These cracks are expected from wear and tear, resulting from repeated movements during the use of the FNF in the examination, and cannot be attributed to the disinfectant applied. Maintenance work was preventively executed on the fiber to replace the equipment trim.

Air leakage was detected in fiber n° 2 FNF during the sealing test. The protection was ruptured in the top, next to the command area, evidencing a failure in handling, once this damage occurs by traction or improper movement of the fiber caused by the operator. Early detection prevented infiltration and other serious damages to the FNF.

In the analyzed period, from the acquisition of FNFs up to February 2015, the fibers have been intensively used, as shown in Table1. Only slight discoloration and loss of gloss could be observed with the naked eye when the external coating with new fibers was compared with used fibers.

During the study period, the FNFs were processed 3,979 times without any report from the medical team about damages in the fiber's functionality during the exams. Nurses used 56,685 hours for processing, with an average duration of 15 minutes per processing. Examinations took 11,277 hours during the same period, with on average 3 minutes per procedure.



Source: Hospital de Clínicas da Unicamp (HC-Unicamp).

Figure 4. Surface cracks in the distal tip of the coverage area. Date: February 2015.

Table 1. Number of uses of naso-fiberscopes, from September2013 to February 2015, at the ENT Clinic of the Hospital de Clínicasda Universidade Estadual de Campinas.

Fiber	Uses number
FNF 1 for adult	2,011
FNF 2 for adult	1,897
Pediatric FNF	71
Total	3,979

FNF: flexible naso-fiberscope.

DISCUSSION

Literature is scarce concerning the evaluation of the best method for processing FNFs. Most publications are related to the processing of endoscopes for use in digestive and pulmonary systems. FNFs are classified as semicritical devices according to the Spaulding's classification of health products, and therefore should be minimally subject to high-level disinfection.

The review article published by Collins⁹, in 2009, refers to the lack of a policy adopted by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) on FNF processing in the United States. Despite the various opinions on the subject, the authors elaborated basic premises for the handling and processing of such equipment and recommend the use of high-level disinfectant solution.

In Brazil, the *Associação Brasileira de Otorrinolaringologia e Cirurgia Cérvico-Facial* (ABORL-CCF)¹⁰ published a protocol on FNF processing which has been questioned because it recommends disinfection by rubbing with 70% ethanol, after previous cleaning. The validation of this protocol is the theme of a doctoral thesis which has not been published yet, but may contribute to the safety enhancement in their application¹¹.

Liming et al.¹² conducted a study showing the efficacy of disinfection by means of various methods of decontamination, including 70% alcohol; however, only the distal portion of FNF was evaluated. Alvarado et al.¹³ conducted a study which used the sterile sheath in FNFs for the procedures, with a processing protocol using enzyme solution and also disinfection with 70% alcohol. They concluded that the use of sheaths could replace high-level disinfection in the adopted conditions. Another author, Muscarella¹, recommends using only solutions with proven microbicidal activity of high-level disinfection and contraindicates the use of 70% ethanol and quaternary ammonium, and other agents, for the disinfection of FNF.

In HC-Unicamp, the recommendation of the Hospital Infection Control Committee is the use of high-level disinfectant by immersion of the whole fiber. This recommendation is supported by a work published in 2013, in which the authors Bhatt et al.¹⁴ demonstrated that there may be contaminants in the eye area and the light cables surfaces which are commonly ignored in cleaning protocols. Bhattacharyya and Kepnes¹⁵ also endorsed the flexible laryngoscopes complete immersion in disinfectant solution. With regard to possible damages resulting from the processing, only a study conducted by Statham and Willging¹⁶ was identified. The authors evaluated 60 FNFs processing cycles with OPA in automated washers and their respective repair needed. The observation time was 4 years, during which 4,336 tests were performed and there were 77 repairs. In the 2.2 mm FNFs, the average usage was 61.9 examinations before a repair; on the other hand, for the 3.6 mm FNFs, the average was 154.5 uses.

In our context, the processing is manual and no damages were found related to the use of PA in the period under review, although the greatest use has been with FNFs for adults. During this period, 3,908 tests were performed with FNF for adults, with an average of 1,954 scans/fiber.

This study also reinforces the importance of applying the sealing test in each use as key to the preservation of the fibers. The test is a preventive measure against infiltration of liquids inside the device in the event of a malfunction. Another key aspect for maintaining the integrity of the fiber, evidenced by our experience, is the need for proper handling and use in the FNFs processing. Collins⁹ recommends that all professionals who handle FNF should receive adequate training, including being familiar with the equipment, processing techniques, the products involved, and storage.

Patient safety must always be considered with the use of FNFs. FNFs or other semicritical optics can only be warranted if the entire process is carefully executed¹⁷. Since these are short procedures with a restrained demand, people tend to desire to simplify practices and ignore important processing steps. However, when the team is aware of the importance of applying the protocol, this pressure is well managed.

Although the use of PA is not recommended by the manufacturer for the FNFs purchased at HC-Unicamp, this study revealed that its use did not compromise or caused damage in the evaluated period. It is noteworthy that manufacturers recommend preventive maintenance every 200 uses; in the case of FNFs, the number of uses was reached very soon. In our context, 200 uses were reached after 3 months. Until February 2015, the FNFs for adults were used 1,954 times on average and no significant change of the polymer or structures that could be linked to use of PA were observed or detected.

A further advantage observed in the chosen PA formulation for use in the HC is related to the immersion time required for disinfection, which is 10 minutes. This time allows a greater number of tests per fiber/day, one of the criteria for selecting this PA formulation in the institution.

It should be highlighted that the processing of FNFs were carried out without the supervision of the Central Sterile Supply Department (CSSD); however, in order to comply with the recommendations established by the Collegiate Board Resolution (CBR) n^o 15 of 2012³, FNFs started to be processed by the CSSD team.

One limitation of this study is that the results cannot be generalized to other endoscopes or PA germicidal, since only one of the AP formulations available in the domestic market was used. Another limitation refers to the period of study, which is shorter than the life cycle of the FNF.

CONCLUSION

With the protocol implementation for processing and monitoring damage in the use of FNFs, it can be concluded that the PA formulation used did not cause rust or damage during the study period. The training of all staff was essential to ensure proper processing and to maintain the integrity of the fibers. The methodology adopted to evaluate the integrity of FNFs by means of the stereoscopic microscope and systematically carrying out sealing tests was effective for the monitoring of damage in this type of equipment. The magnified visual inspection also allowed early detection of changes that could not be identified with the naked eye, such as cracks occurred in the distal cover in a FNF with over 2,000 uses, due to the wear and tear of the equipment.

Although health professionals are concerned about adopting the PA for disinfection of optical materials, this study did not show (with total of 3,979 applications), damages related to that active ingredient with the formulation tested over 18 months in 3 FNFs. Future research is needed, especially to analyze different endoscopes equipment and PA formulations compared with the use of aldehydes, with longer follow-up.

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