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Does Hair Strand Cause Failure of Sterilization? A Controlled Experimental Study

Steril Paket İçinden Kıl Çıkması Sterilizasyonu Bozar Mı? Kontrollü Deneysel Çalışma

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ABSTRACT

Objective: Besides the standard applications of surgical aseptic techniques, it is known that different teams display different approaches in the presence of a hair strand in sterile packs. Few of the teams prefer not to use the instruments and postpone the surgery, whereas others may decide to remove the hair and the instruments in contact and continue using the remaining part. Evidence is required to determine a standard approach in such practices, which leads to negative consequences.

Methods: Overall, 108 surgical clamps were sterilised using autoclave (n=36), hydrogen peroxide (n=36), and ethylene oxide (n=36). One third of the instruments in each group were packed along with a free hair strand, another third with a strangulated hair strand, and the last third were packed alone as the control group. Microbiological specimens of the instruments were collected with swabs. Hair samples were inoculated on thioglycolate broth. Growth was evaluated after 24 and 48 hours.

Results: No growth was observed among the groups after 24 and 48 hours. Thus, all the instruments were considered sterile.

Conclusion: Hair was shown to have no significant effect as a biological burden on bacterial contamination risk.

Keywords: Infection, sterilization, disinfection, hair, asepsis

ÖZ

Amaç: Cerrahi aseptik tekniklerin standart uygulamalarının yanı sıra, farklı ekiplerin steril paketler içinde bir saç teli varlığında farklı yaklaşımlar sergilediği bilinmektedir. Ekiplerin bir kısmı alet kullanmamayı ve ameliyatı ertelemeyi tercih ederken, bir kısmı da temas halindeki saç ve aletlerin alınmasına ve kalan kısmı kullanmaya devam etmeye karar verebilir. Bu tür uygulamalarda olumsuz sonuçlara yol açan standart bir yaklaşım belirlemek için kanıta ihtiyaç vardır.

Yöntemler: Yüz sekiz cerrahi enstrüman, otoklav (n=36), hidrojen peroksit (n=36) ve etilen oksit (n=36) kullanılarak sterilize edildi. Her gruptaki aletlerin üçte biri pakete serbest bir saç teli ile, diğer üçte biri cerrahi enstrümanın eklem yerine sıkıştırılmış bir saç teli ile ve son üçte biri kontrol grubu olarak tek başına paketlendi. Aletlerin mikrobiyolojik örnekleri swablar ile toplandı. Saç örnekleri, tiyoglikolat ortamı üzerine ekildi. Üreme 24. ve 48. saatlerde değerlendirildi.

Bulgular: Grupların hiçbirinde 24. ve 48. saatlerde üreme olmadı. Böylece tüm gruplardaki aletler steril olarak kabul edildi.

Conclusion: Saçın bakteriyel kontaminasyon riski üzerinde biyolojik bir yük olarak önemli bir etkisinin olmadığı gösterilmiştir.

Anahtar kelimeler: Enfeksiyon, sterilizasyon, dezenfeksiyon, saç, asepsi

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INTRODUCTION

Despite advances in diagnosis, treatment and surgical intervention methods in surgical diseases, surgical infections remain to be the most common surgical complication. In addition to preoperative patient preparation, full and complete application of sterilization and surgical aseptic technical principles is the most significant basic element in preventing surgical infections (1-4).

Creating and maintaining the surgical aseptic area throughout the procedure is crucial in patient safety in the operating room. Surgical instruments to be used in the operation should be decontaminated, washed and disinfected with the correct methods before sterilization. In the presence of macroscopic remnants or inappropriate results, the processes should be repeated. Packaging should be done with appropriate materials. Appropriate sterilization, transfer and storage of the sterile materials should be used to provide the sterilization cycle (1,5-7).

Following the arrival of the surgical instruments and equipment to the operation room after a complete application of the sterilization cycle, it is crucial for the scrub and circulating nurse to create and maintain the aseptic area according to patient safety practices (8). Besides standard applications of surgical aseptic techniques, different teams exhibit different approaches in the presence of a hair strand in sterile packs, sets or bundles, a problem faced primarily by operating room nurses.

This situation might be a result of the incompatibility of working conditions during the packaging stage; however, the most significant issue to be sure about before making a decision is to determine whether the hair falls after opening of the package or not. In case of doubt, in accordance with the surgical aseptic technical standards, any suspicious occurrence should be considered as an impairment of sterilization (9,10).

Few teams prefer not to use the instruments, sets or bundles and even postpone cases that have no set alternative even though they know the hair was placed in the packaging stage. Some other teams may choose to continue using the set after removal of the hair strand. In cases with no set alternatives (e.g. the orthopaedic kit supplied by the company), evidence is required in determining a standard approach in such practices, which leads to significant consequences with adverse effects on the patient, the workflows of the teams and corporate functioning. This study aimed to evaluate the effect of a hair strand on sterilization of surgical instruments sterilised with autoclave, hydrogen peroxide and ethylene oxide techniques.

METHODS

The experimental protocol for the study was approved by the İstanbul Yeni Yüzyıl University, Local Ethics Committee (approval number: 2020/06-453, approval date: 08.06.2020). This non-randomised post-test-controlled study was designed to provide evidence in the case of presence of a hair strand in packages sterilised in autoclave, hydrogen peroxide and ethylene oxide. There was no contact with the patient within the scope of the study; hence, patient consent was waived.

Cleaning of Surgical Instruments

Overall, 108 surgical instruments (surgical clamps) were cleaned by washing and rinsing at 60 °C (LK/QX-500, Laoken Medical Technology Co., Ltd.). No additional treatment such as prewash, drying, or disinfection was applied.

Classifying of Surgical Instruments Into Groups and Subgroups

The instruments were divided into three groups (n=36 each) and were to be sterilised using autoclave, hydrogen peroxide and ethylene oxide. Each group was divided into three subgroups (n=12 each). Twelve instruments in each group were packed separately to create the control groups. Twelve instruments in each group were packed with a free hair strand to create experimental group 1, and 12 in each group were packed with a strangulated hair strand on them to create experimental group 2. All packs were assigned a descriptive number (Figure 1).

Packing of Surgical Instruments

All instruments were packed separately in double layers, using paper-film packaging (Sterintech, SP Medikal Co., Ltd.) of 75x250 mm in size as the inner layer and 100x300 mm in size as the outer layer. Chemical indicators suitable for sterilization method were placed on the first layer of the packages (Attest Rapid Readout 1292, 3M; Attest Rapid Readout 1295, 3M; Attest 1264, 3M); all packages were sealed using the same device at 80 °C (Rebi Evo, Gandus Saldatrici Srl).

Sterilisation of Surgical Instruments

Thirty-six of the packs were sterilised in autoclave at 134 °C and press steamed for 7 minutes (V-1263, Steris), 36 in hydrogen peroxide at 55 °C for 70 minutes (HRF3000, Teknomar) and 36 in ethylene oxide at 55 °C for 180 minutes (ETO C 1445, Teknomar), all at the same stage and without any delay. Device performances were followed by daily rapid test biological markers and weekly applied air leak test packs. All instruments were unpacked 12 hours after sterilization in sterile conditions.

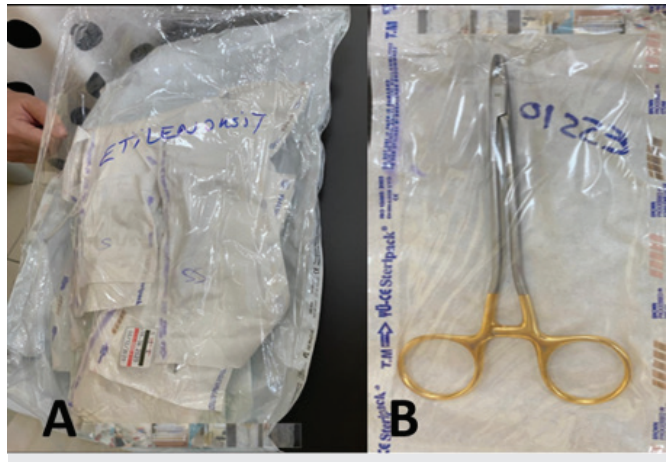

Figure 1. A) Stack of surgical instruments sterilised in ethylene oxide. B) A pack of instrument with the descriptive number

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Microbiological Cultivation

The instruments were unpacked one by one in sterile conditions placed close to the spirit stove. Swab samples of the instruments were taken using cotton swab sticks dampened with saline solution. Microbiological swab cultivation was performed on 5% sheep blood agar (GBL/Gül Biology Laboratory Industry and Trade Limited Company, rrf. no: 0854), which is suitable for the growth of several microorganisms with rich nutrient content and ensures that hemolysis is evident (Figure 2). Incubation was performed for 24-48 hours at 37 °C.

Free or strangulated hair samples were plated in the thioglycolate broth (GBL/Gül Biology Laboratory Industry and Trade Limited Company, rrf. no: 0658) which is a general-purpose medium used for the cultivation of anaerobes and microaerophiles and recommended for tests of biologic materials. This process was performed in a laminar flow cabinet (Figure 3). Incubation was performed for 24-48 hours at 37 °C in aerobic incubator. The growth in all mediums was evaluated after 24 and 48 hours (Figure 4) (11).

Statistical Analysis

Statistical analysis was not required as no growth was detected in all sterilization methods and packages.

RESULTS

Evaluations of the cultivation of the swab cultures in the experimental groups and control group on the blood agar medium after 24 and 48 hours revealed no growth. Moreover, observations after 24 and 48 hours of thioglycolate broth cultivation of the hair strands in the experimental groups 1 and 2 showed no growth (Table 1).

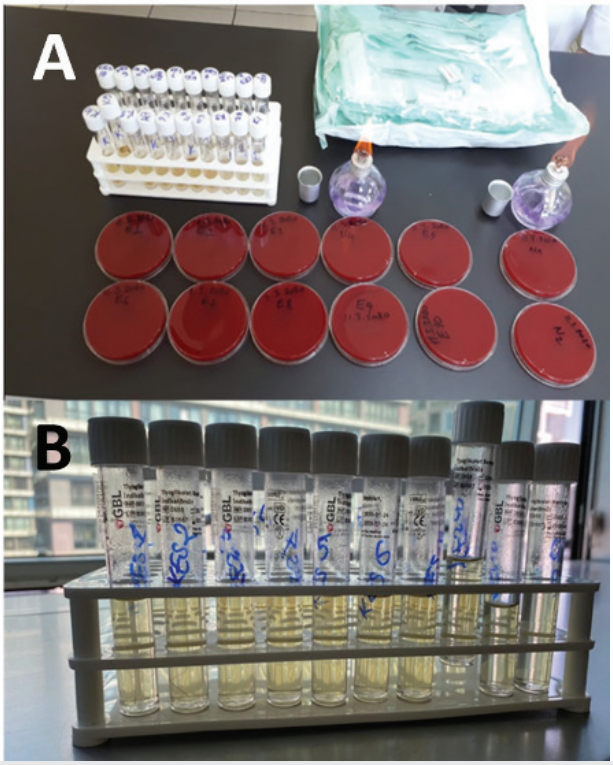

Figure 2. A) Cultivated blood agar mediums. B) Cultivated thioglycolate mediums

DISCUSSION

Presence of a hair strand in the sterile set is considered to ruin the sterilization by increasing the biological load (9,10). Surgical instruments are considered crucial materials since they penetrate the sterile tissue. Critical materials should be sterile while in use to prevent the risk of infection (12).

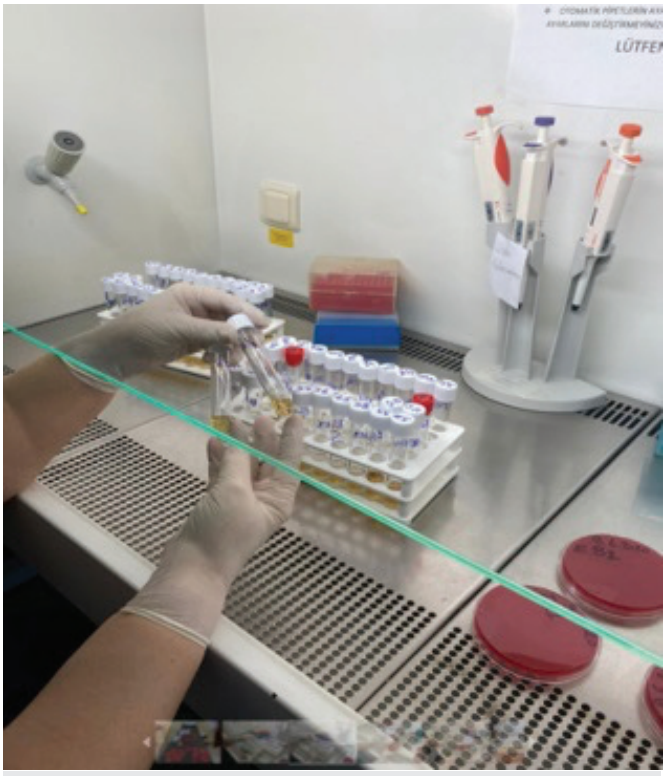

Figure 3. Plating of the hair samples to the blood agar and thioglycolate media in the laminar flow cabinet

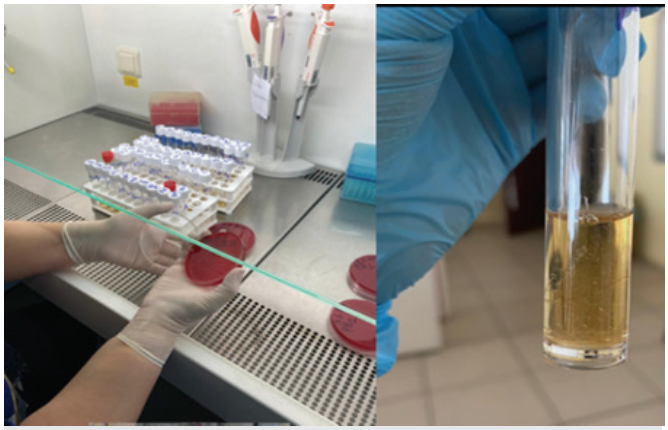

Figure 4. Growth evaluation of plated samples on the blood agar and thioglycolate media in the laminar flow cabinet

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Table 1. Surgical instrument microbiological swab and hair cultivation results

Pack No.	Autoclave sterilization						Hydrogen peroxide sterilization						Ethylene oxide sterilization					
	Control group		Experimental group 1		Experimental group 2		Control group		Experimental group 1		Experimental group 2		Control group		Experimental group 1		Experimental group 2	
	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48
IO 1	N	N					N	N					N	N				
IO 2	N	N					N	N					N	N				
IO 3	N	N					N	N					N	N				
IO 4	N	N					N	N					N	N				
IO 5	N	N					N	N					N	N				
IO 6	N	N					N	N					N	N				
IO 7	N	N					N	N					N	N				
IO 8	N	N					N	N					N	N				
IO 9	N	N					N	N					N	N				
IO 10	N	N					N	N					N	N				
IO 11	N	N					N	N					N	N				
IO 12	N	N					N	N					N	N				
FH 1	N	N	N	N			N	N	N	N			N	N	N	N		
FH 2	N	N	N	N			N	N	N	N			N	N	N	N		
FH 3	N	N	N	N			N	N	N	N			N	N	N	N		
FH 4	N	N	N	N			N	N	N	N			N	N	N	N		
FH 5	N	N	N	N			N	N	N	N			N	N	N	N		
FH 6	N	N	N	N			N	N	N	N			N	N	N	N		
FH 7	N	N	N	N			N	N	N	N			N	N	N	N		
FH 8	N	N	N	N			N	N	N	N			N	N	N	N		
FH 9	N	N	N	N			N	N	N	N			N	N	N	N		
FH 10	N	N	N	N			N	N	N	N			N	N	N	N		
FH 11	N	N	N	N			N	N	N	N			N	N	N	N		
FH 12	N	N	N	N			N	N	N	N			N	N	N	N		
SH 1	N	N			N	N	N	N			N	N	N	N			N	N
SH 2	N	N			N	N	N	N			N	N	N	N			N	N
SH 3	N	N			N	N	N	N			N	N	N	N			N	N
SH 4	N	N			N	N	N	N			N	N	N	N			N	N
SH 5	N	N			N	N	N	N			N	N	N	N			N	N
SH 6	N	N			N	N	N	N			N	N	N	N			N	N
SH 7	N	N			N	N	N	N			N	N	N	N			N	N
SH 8	N	N			N	N	N	N			N	N	N	N			N	N
SH 9	N	N			N	N	N	N			N	N	N	N			N	N
SH 10	N	N			N	N	N	N			N	N	N	N			N	N
SH 11	N	N			N	N	N	N			N	N	N	N			N	N
SH 12	N	N			N	N	N	N			N	N	N	N			N	N

IO: packages including instruments only without a hair strand, FH: packages including a free hair strand, SH: packages including a hair strand strangulated to the instrument, N: negative

Rutala et al. (12), in their study to evaluate the microbial load on surgical instruments before sterilization, showed that the microbial load on surgical instruments after standard cleaning was low. It has been reported that 72% of devices had 0-10 colony-forming units (CFUs), and only 4% exceeded 425 CFUs. Furthermore, it has been reported that clean, clean contaminated, contaminated, or dirty nature of operations does not significantly affect microbial load (12). Even if the washing process is applied

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on the instruments kept without using any sterilization method, there may be microbial load; it should be regarded as non-sterile and must be subjected to a sterilization process before use. In this study, all surgical instruments were washed in a washing device at programme 1 at 60 °C for 22 minutes, passing through the stages of washing, initial rinsing 1 and second rinsing. Microbiological load assessment was not performed before sterilization; hence, all instruments were considered non-sterile.

In this study, paper + film packaging method was used and surgical instruments were placed in individual packages. The packs that contained instrument only were used as the control group and the packs containing a hair strand, free or strangulated, were the study groups that contained biologic load. Resendiz et al. (13) studied the risk of bacterial survival and contamination in surgical instruments in the presence of dried blood inoculation. Although it was not statistically significant, wrapped sets were found to be in higher risk of bacterial reproduction in presence of blood (13). Additionally, in this study, it was clearly shown that steam sterilization remains inadequate in the presence of biological debris and contaminated instruments that cause a risk for other clean instruments in the set as well. In this study, a hair strand was used as biological burden and unlike blood residue, it did not cause a higher risk of contamination.

Regardless of the sterilization method, with the presence of hair in the sterile package, especially in cases with no alternative sets, the surgery needs to be cancelled. Karahan et al. (14) reported that 14% of the delays or cancellations of surgical operations was due to operating room problems. Moreover, they found the mean continuous anxiety scores of the patients who had delayed surgery as significantly higher (45.28±5.67) (14).

In their letter, Gillespie et al. (15) reported that their operation was cancelled due to a 7 cm hair strand found in the surgical set opened in the operative table preparation at Southern Health Hospital. It was stated that this cancelled surgery caused an additional cost of 5,000 Australian Dollars and increased surgical stress for the patient, since there were no spare surgical instruments. Although the recommendations of The Australian College of Operating Room Nurses (16) were followed, an experimental study was conducted due to the material and moral damages mentioned. For this purpose, two 5 cm hair strands, two 5 cm nylon sutures, and two 5 cm silk sutures were first dipped in 0.5 McFarland (10^8 CFUs per millilitre) *Staphylococcus aureus* (ATCC 25923) solution, and each sample was inoculated in tryptic soy broth at 35 °C without sterilization as the control group. The other half of samples were left in the surgical set as the experimental group, and the sterilization of the surgical set was achieved in the pre-vacuum steam steriliser. Growth was detected within 24 hours in each of the sample cultivated in the control group. In the experimental group, all samples were cultivated in tryptic soy broth at 35 °C under aseptic conditions after sterilization, and no growth was reported in the control group after 24 and 48 hours and 1 week. The results of this study supported that the use of the surgical instruments in the presence of a hair strand may be possible in cases where cancellation of the surgery carries a high risk (e.g. when there is no spare surgical set); however, these results should be supported with comparative studies on larger sample groups. The results of our study supported the conclusion of Gillespie's study.

No growth was observed from the samples taken from the instruments or the hair in any of the groups for all of the techniques used in our study. Thus, current practices should be revised in the light of the results obtained from our study.

This study was conducted using single instruments in paper and film packages. Multiple instruments in large containers should be tested in further studies before applying the principle in daily practice. Nonetheless, the results in this study are thought to be guiding.

In our study, no statistically significant growth was observed in any of the groups sterilised with all three methods which are the most commonly used ones in our country.

Study Limitations

The limitations of the study are that surgical instruments are not packaged as a set and that a single surgical instrument is packaged in a double-layer package and subjected to sterilization.

CONCLUSION

The presence of hair, free or strangulated in the instrument, in the sterile package has no effect on bacterial contamination risk. Further experiments are warranted to explore the effect on larger surgical sets before clinical application.

Ethics Committee Approval: The experimental protocol for the study was approved by the İstanbul Yeni Yüzyıl University, Local Ethics Committee (approval number: 2020/06-453, approval date: 08.06.2020).

Informed Consent: Patient consent was waived.

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