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EVALUATION OF THE QUALITY OF PACKAGING MATERIALS OF STORED SURGICAL STRINGS

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SUMMARY

In this study 31 sealed carton paper packages containing 12 surgical strings totally 372 samples were investigated for mould contamination. Mycological analyses were carried out on samples after a storage period of 6 months and a year time. Growth of fungi was detected on catguts and sutures that were kept at normal room temperature of 22°C to 25°C.

A large number of mould strains isolated from samples which were among the storage fungi.

We conclude that using paper as a packaging material is unsuitable, since moisture which supports fungal growth, penetrates it.

ÖZET

Key Words: Surgical strings, storage fungi, mould contamination, packaging material, sterilized surgical products.

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Bu çalışmamızda, içlerinde 12 adet cerrahi iplik bulunan, 31 adet kapalı kutu olmak üzere toplam 372 örnek küf mantarı kontaminasyonu yönünden incelenmiştir. Altı ay ve bir senelik depolama sürelerinin sonucunda örnekler mikolojik yönden analiz edilmiştir. Katgüt ve cerrahi iplikler üzerinde gelişen küf mantarlarını yakalayabilmek için örnekler 22°C ve 25°C'lik normal oda ısılarında tutulmuşlardır.

Örneklerden çok fazla sayıda ayırımı yapılan suşlar depo küfleri olarak belirlenmiştir.

Ambalaj malzemesi olarak kağıt kullanılmasının rutubeti geçirmesi ve küf gelişimini desteklemesi nedeniyle uygun olmadığı kanısına varılmıştır.

INTRODUCTION

Surgical strings are used to constrict and seal off a blood vessel, vein or artery (ligature) or to stitch together the edges of various tissues, e.g. skin, fascia, muscle, tendon, peritoneum (suture). For this purpose both absorbable and non-absorbable materials are available. Sterilized surgical catgut consists of absorbable strands of collagen derived from mamalian tissue, praticularly from the intestine of sheep. Because of its source, it is liable to bacterial contamination, and even anaerobic spores may be found in such material. Therefore, sterilization is a difficult process. Since collagen is converted to gelatin when exposed to moist heat, autoclaving cannot be used. The most suitable method is to expose the material to γ-radiation (1-10).

Catgut is packed in single threads, up to 350 cm in length, of various thicknesses related to tensile strength, packed in single-use glass or plastic containers which cannot be resealed after use. Any remaining material should be discarded (1, 12).

Sutures and ligatures are also made of various materials not absorbed by the body tissues. These consist of uniform strands of metal or organic material such as linen, nylon, silk and stainless steel which will not cause any tissue reactions and are convenient for sterilization. These are packed in single-use glass or plastic containers (1-10).

Catguts, sutures and ligatures should be stored in a cool place, and protected from light (1-13).

MATERIAL AND METHOD

Liquid Sabouraud medium and Malt extract agar medium (MAE) were used for mycological analysis (12, 14, 15). The following steps were carried out:

1. Mycological analyses were carried out directly on samples.
2. A group of samples were stored under definite conditions.
3. Mycological analyses were carried out on stored samples after a storage period of 6 months and a year time.
4. Fungi from samples were isolated and identified (15, 17-21) at the end of the storage period.

Growth of fungi was detected on catguts and sutures that were kept at normal room temperatures of 22°C to 25°C over o period of 6 to 12 months.

Each sample was transferred into a sterile jar containing 45 ml of sterile liquid Sabourraud dexrose base. These jars were gently shaked and kept for 30 minutes at 25°C in a lab line orbit Environment-Shaker/Incubator to obtain extracts of the suture contents. To suppress bacterial growth, 1 ml of antibiotic solution was added to the media to give a final concentration of 50 ppm of chloramphenicol. Two mililiters of these extracts were inoculated into malt extract agar plates by pouring. The plates were incubated at 25°C for 5 to 7 days for mould growth. At the end of the incubation period mould colonies were subcultured in duplicate on MAE medium to obtain pure cultures.

Wet mount preparations with lactophenol cotton blue were prepared and investigated under low and high power dry objectives over the period of maturation cycles of fungal cultures for their identification. The taxonomic distribution of the isolates were carried out according to the literature (15, 17-21).

Thirty one packages, of each contained 12 surgical strings, totally 372 samples were analysed for mould contamination.

Types of surgical strings and their features were shown on Table 1.

Table 1: Types of surgical strings and their features

Types of surgical strings	Number of packages*	Special features
		Cordea aseptica sterile absorbable
Normal	15	Type A (from mamalian tissues)
Chromicised atraumatic	5	Type C
Chromicised	10	Type C Sterile non-capiler non-absorbable
Silk suture	1	Type B
TOTAL	31	

(*) Each package contains 12 surgical strings. Totally 372 samples were mycologically analysed.

RESULTS

Totally 335 mould strains from mycologically analysed 372 samples, were isolated and identified. After the appearance of the product on the market, during the first month we detected 32 strains from 31 samples, the following months the number of strains was increased as a result of unsuitable storage conditions. During the first 6 months the number of strains reached to 87 and at the end of the first year storage period to 216. The increase in the number of strains from the first to the last analysis was approximately five fold.

We identified 45 different species, 29 of which were belonging to Deuteeromycetes, 13 species to Ascomycetes class; 4 of them related with the perfect forms of Aspergillus genus, and 7 of them related with the perfect forms of *Pennicillium* genus which are *teleomorphic* stages of *Deuteromycetes* class. Strains isolated as species of *Talaromyces* and *Eupenicillium* belonging to Ascomycetes class are teleomorphes of *penicillium* belonging to *Fungi Imperfecti (Deuteromycetes).* In addition, *Eurotium, Emericella, Neosartorya* species are teleomorphes of *Aspergillus* species which are in the class of *Fungi Imperfecti.* Only one genus was belonging to *Zygomycetes* class. One of the isolates was deteced as coniothyrium that includes about 100 non-classified species. One strain could not be identified. The results are shown on Table 2.

Table 2: Mould strains isolated and identified from mycologically analyzed surgical strings

Isolated mould strains	Class	First month after marketting	Storage period		Total number of isolates
			6 months	1 year	
Acremonium butyri	D	–	–	1	1
Alternaria alternata	D	2	3	7	12
Aspergillus candidus	D	3	9	14	25
A. flavus	D	2	5	7	14
A. melleus	D	1	3	11	15
A. niger	D	2	5	8	15
A. ochraceus	D	1	3	6	10
A. oryzae	D	–	1	2	3
A. parasiticus	D	4	9	14	26
A. penicilloides	D	1	2	6	9
Botrytis aclada	D	–	–	1	1
Byssochlamys fulva	A	1	3	7	11
Byssochlamys nivea	A	1	2	5	8
Cladosporium cladosporoides	D	2	4	8	14
Coniothyrium sp.	D	–	–	1	1
Emericella nidulans	AA	–	2	5	7
Eupenicillium baarnense	PA	–	–	4	4
E. javanicum	PA	–	–	1	1
E. meridianum	PA	–	2	6	8
E. pinetorum	PA	–	–	2	2
Eurotium amstelodami	AA	–	–	12	12
Eurotium herbariorum	AA	–	10	17	27
Monascus ruber	A	–	–	1	1
Moniliella acetoabutens	D	–	–	2	2
M. suavealens	D	–	–	1	1
Neosartorya fischeri	AA	–	2	6	8
Paecilomyces varioti	D	–	–	1	1
Penicillium chrysogenum	D	3	7	11	21
P. echinulatum	D	2	4	10	16
P. expansum	D	2	4	8	14
P. frequentans	D	–	–	1	1
P. funiculosum	D	–	–	1	1
P. lividum	PS	–	2	8	10
P. nalgiovense	D	2	6	12	20
P. paraherquei	D	–	1	4	5
P. purpureum	D	–	1	3	4
P. variable	D	–	–	2	2
P. verrucosum var cyclopium	D	2	4	7	13
P. verr. var. verrucosum	D	1	3	5	9
Rhizopus stolonifer	Z	–	1	3	4
Scopulariopsis fusca	D	–	–	1	1
Talaromyces helicus	PA	1	3	10	14
T. wortmannii	PA	1	2	3	6
Trichothecium roseum	D	–	–	1	1
Unidentified	–	–	–	1	1
Total		34	103	247	384

(A): *Ascomycetes;* (Z): *Zygomycetes;* (D): *Deuteromycetes;* (AA): *Aspergillus* related the *Ascomycete* genus; (PA): *Penicillium* related the *Ascomycete* genus; (PS): Related *penicillium* anamorph, *sclerotial* species.

DISCUSSION

In the case of surgical strings, the risk of microbial contamination depends on the materials from which they are made (1, 13). Thus the sterilization process is quite different and controversial (4-10). Collagen structured catguts convert to gelatine when they are exposed to moist heat, so autoclaving is unsuitable (1). The most commonly employed method of sterilization for catguts is irridation by γ rays (1, 3).

A large number of mould strains isolated from samples were among the storage fungi (13, 15). Storage fungi contain a group of *Aspergillus* species, a group of *penicillium* species and unidentified strains of Fungi Imperfecti (Deuteromycetes). The members of storage fungi, *A. glaucus, A. candidus, A. ochraceus, E. nidulans, A. amstelodami* and xerophillic fungi are the major contaminants of stored products. Xerophillic fungi are usually of soil origin and resistant to dessication. The perfect forms of *Aspergillus* and *Penicillium* e.g. *Eurotium, Emericella (A. glaucus* group), *Monascus* and *Paecilomyces* are xerophillic or xerotolerant fungi. *A. glaucus, A. niger, A. ochraceus, A. penicilloides, Monilia, Monascus, P. frequentans, P. variable, Rhizopus, Scopulariopsis* species are major contaminants of xerophille products. In our study, storage fungi, soil fungi, and other mould strains which may be contaminants of sutures were isolated.

A large number of these isolated fungi are the primary causative agents of aspergilliosis, allergy and on the skin and tissues of man (22-24). When they are deposited in human tissues, they can show pre-cancerogen effect. The contamination of these products is due to erroneous production methods, and/or using unsuitable packaging materials (e.g. paper with plastic) and/or inadequate storage conditions. Using paper as a packaging material is unsuitable, as moisture which supports fungal growth, penetrates it (12, 13, 14, 16).

Determination of whether samples have a dry or low level content will be stable, and for how long, depends on a number of factors, including a_w, solutes and preservatives present, pH, and initial numbers and types of viable organisms. A detailed assessment of each of these parameters should be made for each product. If conditions of high humidity are likely to be encountered, packaging should be such that water cannot penetrate the product, and if sudden changes in temperature to occur, which can result in local condensation of water, allowance should be given. Storage tests should be conducted under condi-

tions of fluctuating temperatures before newly formulated dry or nearly dry products are marketed. Molds are the predominant spoilage flora of stored products (25, 26).

The minimum a_w for fungal growth has been observed as 0.61 to 0.62 but growth or germination at this a_w is invariably extremely slow (27, 28).

All xerotolerant fungi so far isolated belong to a few genera of *Ascomycetes* (perfect forms) or are *Deuteromycetes* imperfect forms of those genera. The majority of xerotolerant filamentous fungi belong to the genera *Penicillium* or *Aspergillus* or are perfect forms of *Aspergillus* which are called *Eurotium* and *Emericella*.

Monascus and *Paecilomyces* are reported to contain one xerotolerant species of each, have been isolated.

Temperature growth limit of fungi especially for xerotolerant mould is approximately 22°-25°C (15, 17, 18, 20, 21).

Observation of the microflora of stored samples at a_w levels above between 0.85 to 0.90 showed that less xerotolerant strains outgrew the more xerotolerant strains.

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