

Bioburden levels of spools of surgical tape in different healthcare settings

Analyses show that the contamination levels of spools and snap rings of medical tape, which have frequent contact with healthcare providers, are a source of bioburden in the healthcare setting.

INTRODUCTION

Healthcare-associated infections (HCAI) remain a major cause of patient morbidity and mortality. In European countries, an average prevalence of 7.1% has been reported with approximately 4,544,100 episodes of HCAI every year.¹ The impact of HCAI includes prolonged hospital stays, long-term disability, increased resistance of microorganisms to antimicrobials, massive financial burden for health systems, high costs for patients and their family, and unnecessary deaths.¹ The burden of disease is also reflected in annual financial losses estimated at approximately 7 billion, including direct costs only.¹

Contamination of inanimate surfaces has often been described as a source for outbreaks of nosocomial infections. Inanimate surfaces and objects, such as high-touch (or frequently touched) surfaces in the immediate vicinity of a patient, are often reservoirs for nosocomial pathogens and may play a role in the transmission of these pathogens², especially for microorganisms that are able to survive on surfaces for long periods of time. Studies indicate that nosocomial pathogens can persist in the environment for several days to several months. For example, *Staphylococcus aureus* (including MRSA) can persist between 7 days and 7 months, providing a continuous source of transmission if regular preventative measures are not taken.⁶ Additionally, hand contact with contaminated surfaces results in different degrees of transmission depending on the organism. *Escherichia coli*, *Salmonella* spp., and *Staphylococcus aureus* have 100% transmission rates, while *Candida albicans* has a 90% transmission rate and rotavirus has a 16% transmission rate.⁶ Examples

of high-touch surfaces include doorknobs, bed rails, light switches, and surfaces in and around toilets in patients' rooms²; however, often-overlooked high-touch surfaces include frequently used medical equipment items and objects, such as spools and snap rings of medical tape. Thus, a major addition to current infection control strategies is the identification of high-contact surfaces prone to contamination.⁷

Contamination may occur by transfer of microorganisms via healthcare workers' hands or direct patient shedding of microorganisms in the immediate environment of a patient's bed.² A large percentage of HAI are preventable through effective infection prevention and control measures.⁵ As hands are the most common vehicle for transmission of organisms, "hand hygiene" is a core element of all infection prevention bundles; however, studies have shown that average compliance with hand hygiene practices is unacceptably low.³ In a sample of 40 hospitals in the United States, Larson and colleagues found that even after the implementation of new guideline recommendations, hand hygiene rates remained low at a mean of 56.6% compliance, and in 42.2% of the hospitals, there was no evidence of a multidisciplinary program to improve compliance.^{4,5} Additionally, antimicrobial surfaces can serve as a useful adjunct to effective infection control protocols by providing a surface that continuously reduces bioburden counts.

In this study, we analysed the contamination levels of spools and snap rings of medical tape, as these



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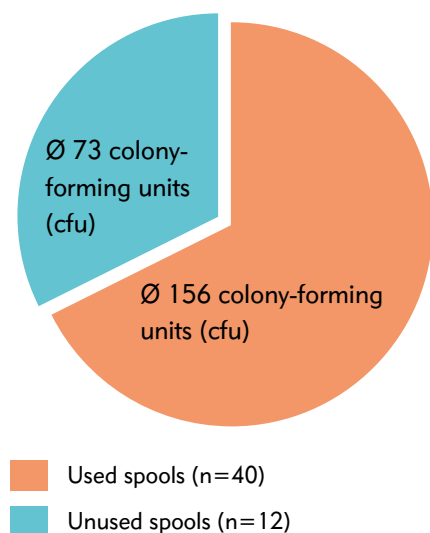
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Figure 1:
Average (\bar{x}) total bioburden
of used and unused spools.



objects have frequent contact with healthcare providers, and sought to define these objects as a source of bioburden in the healthcare setting. Secondly, we discuss the introduction of an antimicrobial surface for the spools and snap rings as a potential solution and useful adjunct to infection prevention protocols in medical settings.

METHODS

Fifty-two surgical tape spools, both used and unused (Table 1), from different manufacturers were collected from a total of six test centres throughout Hamburg, Germany for analysis. Spools from different manufacturers were collected to illustrate use of surgical tape under routine clinical conditions. Unused spools were taken directly out of the original packaging and tested. Used spools were collected after use and transported separately in a sterile bag to the laboratory. The test centres included two hospitals, two doctors' offices, one outpatient clinic, and one blood transfusion clinic. Testing of the bioburden of all surfaces was performed in accord with ISO 11737-1/ SGS SOP M 943*. Using aseptic techniques to minimize risk of secondary contamination, the collected spools were rinsed with 100 ml of a rinsing liquid for 10 min on a shaking platform. The liquid was then divided and analysed as follows:

- 30 ml for total aerobic colony count by membrane filtration;
- 30 ml for yeasts and moulds by membrane filtration;
- 10 ml for *S. aureus*, *E. coli*, *P. aeruginosa*, and enterococci by enrichment methods; and
- 10 ml for *C. albicans* by an enrichment method.

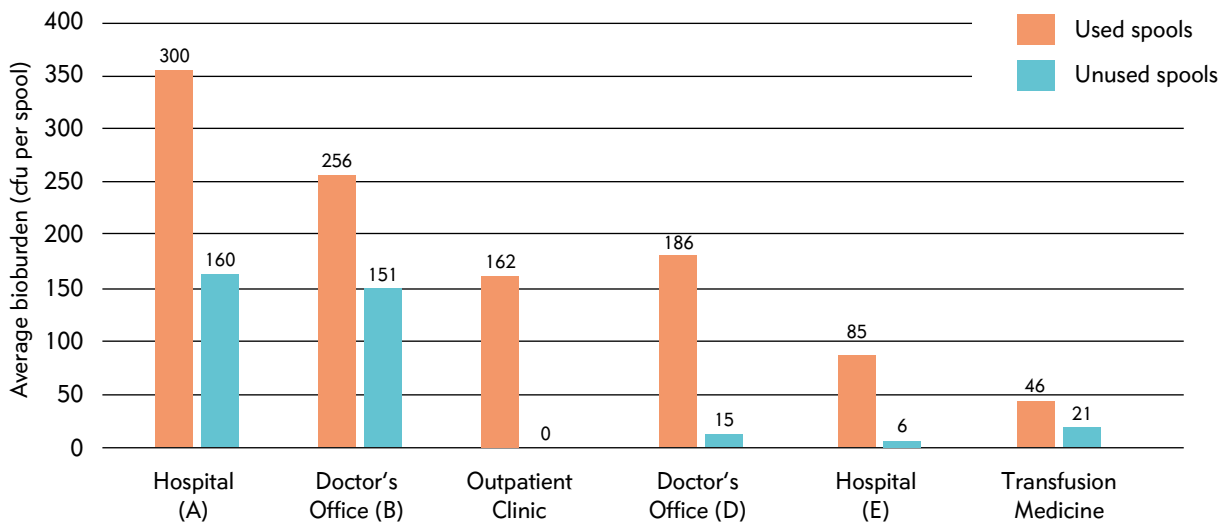
After isolation of specific microorganisms, the total bioburden (colony-forming units cfu/mL) was measured. The bioburden of a product was determined in order to assess the number of viable microorganisms present on the device as an indicator of the hygienic standard in a clinical setting. Manufacturers must ensure a low bioburden in finished products through the implementation of the current guidelines of Good Manufacturing Practice during the manufacture, storage, and distribution of pharmaceutical preparations.¹³ Thus, unused spools served as the control in this experiment and to provide a baseline for comparison of used spools. A bioburden threshold of 50 cfu/g (or mL) was set for used spools according to the suggested threshold for assessment of surface hygiene of 5 cfu/cm², proposed as a microbiologic standard for safer hospital environments⁸, and using an average surface area of 10 cm² for the spools.¹² In support of this threshold, Dancer⁸ suggested that identification of ≥ 5 cfu/cm² on a high-contact surface indicates the potential for increased risk of infection for the patient in that environment.

RESULTS

The number of cfu per spool differed between the six test centres. However, in general, used spools had a higher bacterial load than unused spools with an average of 156 cfu per used spool (n=40) and an average of 73 cfu per unused spool (n=12; Fig. 1). The numbers of contaminated spools from each test centre and the identified microorganisms are presented in Table 3. However, as growth of contaminants is dependent on the growth media selected (Table 2), microorganisms other than those presented in Table 3 may have been present on the spool.

The highest bioburden was found in the hospital (site A) with 853 cfu and an average of 353 cfu for used spools, respectively. The second highest bioburden was found at the doctor's office (site B) with the highest values at 643 cfu and an average of 256 cfu for used spools, respectively. Only one of six test centres (17%), transfusion clinic (site F), had contamination levels below the threshold value of 50 cfu per spool (Fig. 2).

As far as the prevalence of contamination, in the hospital setting, 2 of 4 used spools (site A) and 1 of 8 used spools (site E) were identified with potential pathogens on the surface. In the doctor's office, 1 of 4 used spools (site B) harboured pathogens; whereas, 1 of 8 used spools (site C) in the outpatient clinic and 3 of 8 used spools in the blood transfusion clinic (site F) were found to have isolated microorganisms on the surface. Amongst the microorganisms isolated from the spools, hospital pathogens such as *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Enterococcus gallinarum* were identified. These are amongst the most commonly reported pathogens that

Figure 2: Average bioburden found on spools from each study site.

cause nosocomial infections. These results suggest that spools may be a potential source of health care-associated infections in daily practice and support the need to generate antimicrobial surfaces to reduce the risk of pathogen transmission and distribution in these settings.

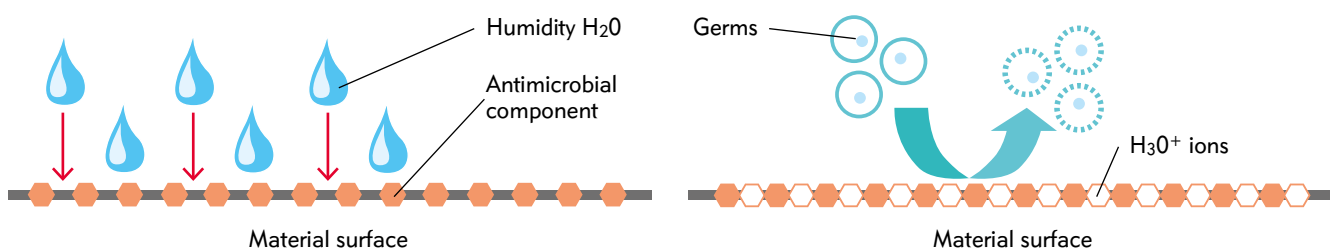
DISCUSSION

Infections, some of which may lead to serious complications, of patients in healthcare facilities are usually transmitted via high-touch surfaces of supplies or equipment that are contaminated by microorganisms (nosocomial infections). Current efforts to generate surfaces that reduce or inhibit the ability of microorganisms to grow are met by product limitations and perceived risks.⁹ Accordingly, an antimicrobial material surface that can reduce or inhibit microorganism growth without the associated risks is warranted.

As evident from this study, spools of medical tape are an easy to contaminate surface that is a potential source of pathogen transmission. This is especially true in the hospital setting, where the cfu per spool was found to be the highest. Importantly, this study represents only a snapshot

of the everyday reality in clinical settings, suggesting the potential for several limitations. For one, causal relationships are hard to establish. The study did not specifically examine the correlation between the spools and infection occurrence in the healthcare institutions. Thus, this point may be addressed in future studies. Further limitations include a small sample size and as the study aimed to show the use of spools under diverse clinical settings; the frequency of usage, exposure to pathogens and infection prevention protocols may be different across the institutions.

The results of this study highlighted the need for a material surface to aid in the reduction of pathogen transmission and distribution. The surface of the spools and snap rings of medical tapes have been modified to incorporate a special metal oxide into the polymer, as part of the packaging. The presence of the metal oxide and water from the air results in the generation of H_3O^+ ions, reducing the pH value of the spools' surface to approximately 4-5 (Fig. 3). This pH value lies within the range of that of the human skin (pH 4-6).¹¹ Such acidic surfaces are known to slow down bacterial and fungal growth and effectively kill mi-

Figure 3: Effect of a reduction in pH levels on active antimicrobial properties.

The antimicrobial component incorporated into the spool material reacts with the atmospheric moisture on the surface.

An acidic environment is formed, in which pathogens such as MRSA are destroyed.

microorganisms at pH values of 3.5-4. This mechanism is fairly non-specific and active against a broad spectrum of Gram-positive and -negative bacteria.⁹ Organisms such as Staphylococci, Streptococci, Enterococci, Legionella pneumophila, Lactobacillus acidophilus spp., Candida spp., and Aspergillus spp. are susceptible to these effects at low pH. The antimicrobial activity of these polymers is based on the formation of the acidic surface that ultimately impairs cell growth and proliferation of microbes and the formation of biofilms that lead to the elimination of infectious agents. Thus, in contrast to disinfectants and antibiotics, microbial resistance to a metalloacid material with this mode of action is unlikely to emerge,^{9,10,11} supporting its effectiveness in infection control.

According to ISO 22196, initial in vitro testing with the antimicrobial spools (BSN medical GmbH, Hamburg Germany) showed very high efficacy against *S. aureus* (MRSA) and *S. epidermis* and good efficacy against *E. coli*. In particular, the tested samples showed a bacterial pathogen reduction within 3 h with a reduction of more

than 99.9% (>log 3) of *S. aureus* (MRSA) within 6 h. Additionally, antifungal tests showed efficacy of the material within 3h against *Candida tropicalis*, *Candida glabrata*, and within 6h against *Candida albicans*. Depending on the institution setting and volume of patients, the medical tape on the spools can be used up in 1 day or last for 3 weeks, thus the antimicrobial spools are most beneficial to limit environmental contamination between consecutive cleaning procedures. It is also worth mentioning that basic standards in infection prevention should be the core of infection prevention protocols; however, in certain situations, such as in patients with a weak immune system, the proposed spool may certainly serve as a useful adjunct to the normal protocol. Based on the results of these promising in vitro tests, the continuous biocidal effect of H₃O⁺ oxides against potentially pathogenic microorganisms (including multidrug-resistant microorganisms) is a valuable addition to infection prevention protocols.¹¹

CONCLUSION

Prevention of cross-transmission of nosocomial pathogens, such as *S. aureus* and *P. aeruginosa*, is of particular interest to healthcare institutions where the transfer of these pathogens may lead to serious complications in patients with weak immune systems. The modification of spools of medical tape with antimicrobial properties has the potential to reduce the overall risk of bioburden and contamination in clinical use, thus decreasing the sources of cross-transmission. Future investigations may focus on the use of the antimicrobial spools and its role in the prevention of the transmission of nosocomial pathogens in comparison with non-antimicrobial spools commonly used in the clinical setting. ■

Table 1: Total number of spools.

Spools	Total (n = 52)
Used, n	40
Unused, n	12
Study Site	
Hospital (Site A), n	6
Doctor´s office (Site B), n	7
Outpatient´s clinic (Site C), n	8
Doctor´s office (Site D), n	10
Hospital (Site E), n	10
Transfusion medicine (Site F), n	11

Table 2: Methods used for each parameter.

Parameter	Method
Total aerobic colony count (Bioburden)	DIN EN ISO 11737-1/ TSA / 3-7d/30-35°C
Yeast (Bioburden)	DIN EN ISO 11737-1/ Sabo / 5-7d/20-25°C
Mold (Bioburden)	DIN EN ISO 11737-1/ Sabo / 5-7d/20-25°C
<i>E. coli</i> (Bioburden)	SGS SOP M 943 / McConkey-Agar / 48h/44°C
<i>Staphylococcus aureus</i> (Bioburden)	SGS SOP M 943 / BP / 48h/37°C
<i>Pseudomonas aeruginosa</i> (Bioburden)	SGS SOP M 943 / Cetrimid / 48h/37°C
Enterokokken (Bioburden)	SGS SOP M 943 / Enterococcusel-Agar / 48h/37°C
<i>Candida albicans</i> (Bioburden)	SGS SOP M 943 / Candid-Chromogen-Agar / 48h/30-35°C

Table 3: Number of contaminated spoons and identified pathogens for each test centre.

Centre (No. of Spoons)	Contaminated spoons	Identified microorganism
A: Hospital (n=6)	2 (2/4 used spoons)	Enterococcus gallinarium Staphylococcus aureus Bacteria spores Bacillus infantis Bacillus pumilus
B: Doctor's Office (n=7)	1 (1/4 used spoons)	Paracoccus yeei Bacillus infantis Kocuria rhizophila Micrococcus luteus Bacillus simplex
C: Outpatient Clinic (n=8)	1 (1/8 used spoons)	Staphylococcus epidermis Micrococcus luteus Corynebacterium sp. Staphylococcus capitis
D: Doctor's Office (n=10)	1 (1/7 used spoons)	Staphylococcus aureus Micrococcus luteus
E: Hospital (n=10)	1 (1/8 used spoons)	Staphylococcus hominis Alcaligenes faecalis Arthrobacter cummingsii
F: Transfusion Medicine (n=11)	3 (3/8 used spoons)	Staphylococcus pasteurii Staphylococcus warneri Cellulosimicrobium cellulans Micrococcus luteus Staphylococcus aureus Staphylococcus warneri

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