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Research Paper

Mechanic and surface properties of central-venous port catheters after removal: A comparison of polyurethane and silicon rubber materials

Ulrike Braun[a,*], *Edelgard Lorenz*[a], *Christiane Weimann*[a], *Heinz Sturm*[a], *Ilham Karimov*[b], *Johannes Ettl*[c], *Reinhard Meier*[d], *Walter A. Wohlgemuth*[e], *Hermann Berger*[b], *Moritz Wildgruber*[b,f]

[a]*BAM Federal Institute for Materials Research and Testing, Unter den Eichen 87, 12200 Berlin, Germany*
[b]*Department of Diagnostic and Interventional Radiology, Klinikum rechts der Isar, TU, München, Germany*
[c]*Department of Obstetrics and Gynecology, Klinikum rechts der Isar, TU, München, Germany*
[d]*Department of Radiology, Universitätsklinikum, Ulm, Germany*
[e]*Department of Radiology, Universitätsklinikum, Regensburg, Germany*
[f]*Department of Clinical Radiology, Universitätsklinikum, Münster, Germany*

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ABSTRACT

Central venous port devices made of two different polymeric materials, thermoplastic polyurethane (TPU) and silicone rubber (SiR), were compared due their material properties. Both naïve catheters as well as catheters after removal from patients were investigated. In lab experiments the influence of various chemo-therapeutic solutions on material properties was investigated, whereas the samples after removal were compared according to the implanted time in patient. The macroscopic, mechanical performance was assessed with dynamic, specially adapted tests for elasticity. The degradation status of the materials was determined with common tools of polymer characterisation, such as infrared spectroscopy, molecular weight measurements and various methods of thermal analysis. The surface morphology was analysed using scanning electron microscopy.

A correlation between material properties and clinical performance was proposed. The surface morphology and chemical composition of the polyurethane catheter materials can potentially result in increased susceptibility of the catheter to bloodstream infections and thrombotic complications. The higher mechanic failure, especially with increasing implantation time of the silicone catheters is related to the lower mechanical performance compared to the polyurethane material as well as loss of barium sulphate filler particles near the surface of the catheter. This results in preformed microscopic notches, which act as predetermined sites of fracture.

*Corresponding author. Fax: +49 30 8104 1627.
E-mail address: ulrike.braun@bam.de (U. Braun).

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1. Introduction

The use of artificial elastic, polymeric materials in medical application is a wide field ranging from short time applications, such as cardiac or urinal catheters, up to long time implants (spines, ventricles) or complex components, such as defibrillator or pacemaker leads (Wintermantel and Ha, 2009). It is a major challenge to guarantee the functionality and stability as well as the biocompatibility of these materials (dependent on their use and application) at simultaneous patient comfort (ISO 10993). Due these complex requirements for materials and components, only interdisciplinary research can reveal failure mechanisms and offer solutions for improvement of materials.

For patients with chronic illness central venous catheters (CVCs) enable easy and safe venous access for laboratory testing, drug delivery and parenteral nutrition (Baskin et al., 2009). Depending on the duration of implant as well as various patient-specific factors, various catheter-related complications such as thrombosis, catheter associated infection or catheter leakage/rupture limit their use. Central venous port catheters, which remain implanted from months to years, pose special requirements to the used material in terms of stability, anti-thrombogenic and anti-infectious properties (Walser, 2012). Catheter related thrombosis and infection are the most frequent complications that require emergent removal of a central venous port catheter (Wildgruber et al., 2015). The ideal catheter is highly flexibly, yet stable and chemically inert over a long time period, and is not prone to thombosis or infection. Up to now, no rubber material fulfils all these requirements. Nowadays catheter materials frequently consist of polyurethane or silicon rubber materials. A comparison of 698 implanted venous-access ports of both materials implanted at the forearm (Wildgruber et al., 2016) observed that catheter-related bloodstream infections as well as thrombotic complications occurred significant more frequently with polyurethane catheters. In contrast to this the silicon trend to exhibit increased mechanic failure, such as disconnection or catheter rupture. Of note, this observation was limited to brachial port devices and catheters, which experience different mechanical forces compared to chest port placement. However the fact that significant differences were noted with respect to the used catheter material shows a potential impact of rubber material on catheter related complications.

In this study, we focus on the material-related differences of both polymeric materials to explain a possible structure-property relationship. Two different rubber materials commonly used as central venous port catheters in predominantly oncologic patient populations were investigated with respect to mechanic stability, physico-chemical degradation and surface properties of the rubber material. Catheter material was investigated in its' native state and after incubation in a lab experiment in various chemotherapeutic solutions. Additionally, catheters explanted from patients after various duration of intravenous placement were investigated.

2. Materials and methods

2.1. Catheter rubber material

Two different types of port catheter materials were investigated. Silicon port catheters were purchased from Cook Medical, Bjaeverskov, Denmark (SiR catheters) and polyurethane catheters were obtained from PFM Medical, La Chaux-de-Fonds, Switzerland (TPU catheters). Both catheters are established for use as central venous port catheters, implanted either pectorally or at the forearm. Catheters investigated were of similar diameter (SiR:5.0 French=5/3 mm, TPU:4.8 French=1,6 mm). Identification of these catheter materials was performed by ATR-FTIR measurements.

The investigated TPU catheter was identified as polyurethane based on hexamethylendiisocyanate/butanol (hard segment) and polycarbonate glycol (soft segment (Christenson et al., 2004; Dempsey et al., 2014; McCarthy et al., 1997; Tanzi et al., 1997)). Characteristic signals of urethane group can be observed at 3380 and 3300 cm^{-1} (free and bonded N–H ν_{as}), ~1716 cm^{-1} and 1690 cm^{-1} (free and bonded C=O ν_{as}), 1520 and 1305 cm^{-1} (Amide II ν(C–N)+δ(C–N–H)) and Amide III δ(NH+δ(OCN)) as well as 1085 and 1040 cm^{-1} (C–O–C). For the carbonate group characteristic signals are identified at 1743 and ~1716 cm^{-1} (free and bonded C=O ν_{as}), 1250 cm^{-1} (C–O–C), 960 cm^{-1} (O–C–O) and 790 cm^{-1} (C(O)–O) and for aliphatic chains at 2924, 2854, 1460, 1450 and 1400 cm^{-1}.

The SiR rubber material is mainly based on poly(dimethylsiloxane). The major signals in ATR-FTIR of the catheter material are the stretching vibration of methyl groups at 2964 cm^{-1} (ν_{as}) and 2907 cm^{-1} (ν_s), at 1260 cm^{-1} (δ_s) the bending and at 800 cm^{-1} (γ) the deformation vibration of Si–CH_3 groups. Between 1100 cm^{-1} and 1000 cm^{-1} the stretching vibration of Si–O–Si backbone can be detected (Launer, 1987).

Both of the investigated materials, the TPU and the SiR catheters contain barium sulphate ($BaSO_4$). This was identified by ATR-FTIR signals at 1187, 1123, 1078, 987 (sulphate group) and 638 as well as 611 cm^{-1} (ν) and EDX-SEM investigations. According to our investigation the amount of $BaSO_4$ added to both TPU as well as SiR catheters is around 2–5 wt%.

2.2. Durability tests in chemotherapeutic solution

To assess potential effects of chemotherapy agents on the catheter material, ~10 cm long catheter pieces were incubated with various antineoplastic agents ex-vivo for 3d and 21d. Port catheter pieces were placed in 6-well plates, incubated with the chemotherapy agents and placed into a cell culture incubator at 37 °C and 5% CO_2 atmosphere with 80% humidity. The following chemotherapy solutions were prepared: Paclitaxel 6 mg/ml, nab-Paclitaxel (albumin-bound Paclitaxel) 5 mg/ml, Cisplatin 1 mg/ml, Trastuzumab 2 mg/ml and Epirubicin 2 mg/ml. Additional samples were similarly incubated with 1000 IU/ml of Heparin. Catheters incubated with 0.9% saline served as control. After the incubation period catheters were rinsed with saline and processed further for mechanical and chemical assessment.