CHARACTERIZATION OF PARTIALLY COVERED SELF-EXPANDABLE METALLIC STENTS FOR ESOPHAGEAL CANCER TREATMENT: IN VIVO DEGRADATION

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Introduction

Squamous cell carcinoma of the esophagus is the fourth cause of death in males and seventeenth in females. There is no change or a slight decrease in incidence over the last three decades [1]. More than 50% of patients present with an unresectable tumor, progressive weight loss and dysphagia, require palliative treatment. Among the many available methods of palliation, stenting is the method of choice. This is because of technical simplicity, wide availability and immediate alleviation of dysphagia. Patients requiring stenting are usually diagnosed with III and IV grade dysphagia and significant weight loss. The stents that are currently used, despite relatively good tolerance, are not free from side-effects and complications. One of the most common problems associated with stenting is granulation tissue overgrowth and stent obstruction. Coverage with a polyurethane or silicone membrane protects from tumor ingrowth, but overgrowth beyond ends of the stent and granulation tissue formation remains an issue.
The study aimed to investigate the impact of long-term usage in the body on the physicochemical properties of the partially covered esophageal stents.

Materials and Methods

For the investigations, 16 partially-covered self-expandable metallic stents (SEMS) 7–12 cm long and a diameter of 18 mm (Ultraflex Boston Scientific, USA) were used. For the physicochemical investigation as the obtained stents were cut into 1x1 cm coupons. The morphology of the NiTi stent and polyurethane covered surfaces were evaluated by SEM. The properties of polymeric samples were analyzed using DSC. The measurements were carried out in a temperature range of 25–600°C with a heating rate of 10°C min^{-1} in Ar flow of 50 cm^3 min^{-1} [2]. The changes within the surface of polyurethane were followed by contact angle measurements (CA) [3]. ATR-FTIR analyses of the polymeric films were performed in order to analyze the structural changes of polyurethane, the spectra were recorded in the range 4000–650 cm−1. DMTA was used to determine the glass transition temperature (Tg), taken as the maximum of tan δ and the maximum of loss modulus, E". The relaxation spectrum was scanned from –70 to 150°C, at a frequency of 1 Hz, and a heating rate of 3°C/min

Results and Discussion

Partially covered self-expandable metallic esophageal stent (SEMS) placement is the most frequently applied palliative treatment in esophageal cancer. Structural characterization of explanted 16 Nitinol-polyurethane SEMS (the group of 3 females, 13 males, age 40-80) was performed after their removal due to dysfunction. The adverse bulk changes in the polymer structure were visualized with the SEM (FIG. 1), analyzed with the use of TGA, DMTA, and ATR-IR and discussed in terms of melting point shift (9ºC), glass transition shift (4ºC), differences in viscoelastic behavior and systematic decrease of peaks intensities corresponding to C–H, C=O, and C–N polyurethane structural bonds. The scanning electron microscopy observations revealed all major types of surface degradation, i.e. surface cracks, peeling off the polymer material, and surface etching. The changes in the hydrophobic polyurethane surfaces were also revealed by a significant decrease in wettability (74º) and the corresponding increase of the surface free energy (31 mJ/m^2). It is worth emphasizing that substantial differences were observed between the proximal (esophagus) and distal ends (stomach) of the stents which were discussed in terms of interaction with specific body fluids.

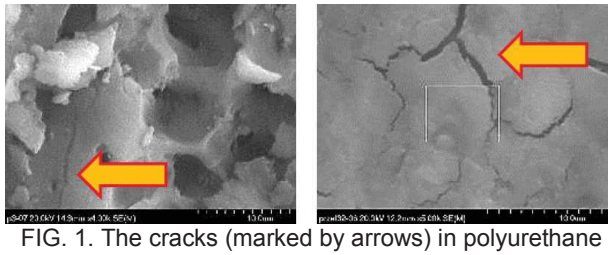

FIG. 1. The cracks (marked by arrows) in polyurethane surface resulting from exposure to the human body environment revealed by SEM images.

Conclusions

The obtained results also show that the contact angle and the polymer melting temperature can be considered as suitable parameters for analyzing the extent of the stent degradation processes. To our best knowledge, this work is the only report in the literature that shows the influence of chemo- and radiotherapy and the role of the microenvironment of the esophagus and stomach on the structure of the polyurethane/nitinol stents.

References

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