TIME-DEPENDENT STRUCTURE CHANGES OF POLYMERS FOR MEDICAL APPLICATION DURIMG THEIR LIFE CYCLE

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As for all polymers, polymers in medical applications must fulfil demanding safety requirements and withstand various influences, such as mechanical, biological or chemical stress. The demands with regard to durability are highly dependent on the specific application. Beyond this, performance with respect to durability is not only determined by the practical application, but is also influenced by the life-cycle history. The oxidative attack at increased temperatures during processing and storage must be considered, as well as irradiation during the sterilisation process and the influence of humidity during the use in vivo [1].

The goal of the work is to evaluate the different aging-relevant parameters for individual polymeric products for medical application. Catheter tubes and syringes based on poly (urethane ether) (TPU) and poly (propylene) (PP) were analysed for their durability against aqueous solutions (TPU) and against oxidation processes (PP) at various temperatures. The changes were characterised by macroscopic and molecular tests methods, such as, mechanical tests, chemical composition analysis (FTIR, TG-FTIR, EDX), changes in morphology (DSC) and oxidation behaviour (ICOT, OIT).

TPU exposure in the autoclave tests under wet and dry conditions does not affect the chemical structure of the material significantly (hydrolysis, oxidation etc.). Beside the continuous loss of processing morphology (short to long-range ordering of hard segments) after 1 d of immersion in a wet environment the material morphology changes significantly. TPU probably incorporates water during immersion, resulting in changed flexibility of the polymer chains. Consequently the microstructure of hard and soft segments transforms to higher-ordered phases or structures [2].

PP syringes exposure to high oxygen concentration in the autoclave result in a significant degradation of antioxidants (Irganox 1010, Irganox

1076, Irgafos 168) (Figure 1). It could be shown that independent on the temperature the major part of the antioxidant is consumed during the first 10 days of immersion. After this time the presence of Irganox 1076 plays the major role in the stabilisation of the polymer due to mechanic stability and carbonyl formation. Under the used aging conditions in autoclave ICOT and OIT measurements detect the major decomposition of antioxidant at the beginning of tests, but both methods alone are not functional to predict the life time of the polymer product.

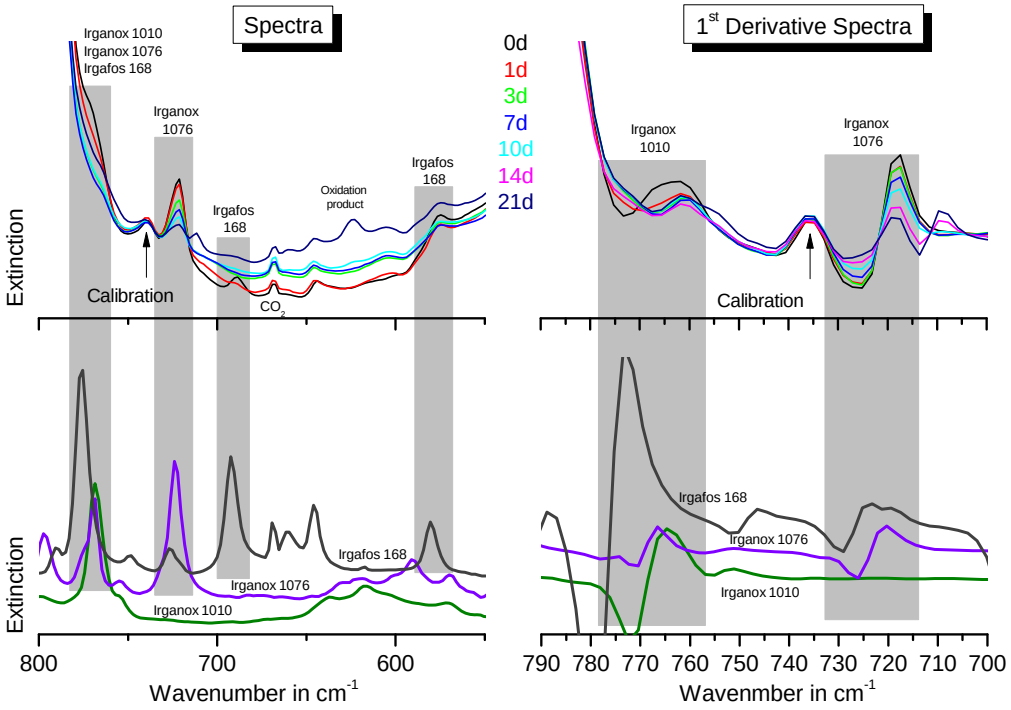

Figure 1 Details of FTIR spectra and derivatives of FTIR spectra of PP syringe and reference spectra in transmission mode at various aging times in autoclave (80°C, 50 bar).

1. ISO 10993 Biological evaluation of medical devices.
2. Braun U., Lorenz E., Maskos M. Inter. J. Art. Org. 34(2): 129, 2011.