Effect of E-Beam Sterilization on Optical and Rheological Properties of Some Viscoelastic Products

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Introduction: Electron beam (E-beam) irradiation utilizes high energy electrons to treat an object for a variety of purposes, such as sterilization or cross-linking of polymers. Electron beam processing can break chains of DNA in living organisms, such as bacteria, resulting in microbial death and rendering the space they inhabit sterile. E-beam processing has been used for the sterilization of medical products and production of aseptic packaging materials for foods.

Healon, a brand name by AMO, describes a *cohesive* viscoelastic containing 1% of a high molecular weight sodium hyaluronate. Healon EndoCoat OVD is a *dispersive* viscoelastic containing 3% of low molecular weight sodium hyaluronate. Both products are widely used in cataract surgery. These products are sterilized either through steam (Healon OVD) or ethylene oxide (EtO) (Healon EndoCoat OVD). High temperature is required for steam sterilization, while EtO sterilization requires additional tests for determining EtO residuals. On the other hand, the E-beam process is relatively fast, with no chemical residues. These advantages make it an attractive potential alternative sterilization technique for Healon viscoelastic products. UV-Vis-NIR absorption and rheological properties of these products before and after E-beam sterilization are presented here.

Material and Methods: Treated and untreated samples of Healon EndoCoat OVD and Healon OVD were assessed for UV-Vis spectral and dynamic viscosity attributes. Each sample group consisted of 4 E-beam treatment levels and two controls (with no treatment). UV-Vis-NIR percent transmission (%T) were recorded, using a Beckman DU800 spectrophotometer over the region 200 – 1100 nm and referenced versus water at the blank.

Viscosity measurement was made using AR2000EX Rheometer from TA instruments. A Cannon® certified viscosity standard N30000 was used as a reference. The viscosity of various samples were measured at shear rates from 0.1 sec^{-1} to 100 sec^{-1} and extrapolate to the zero shear rate to have zero rate viscosity.

Results: Figure 1 shows the UV-Vis-NIR spectra of Healon OVD before and after E-beam treatments at different doses. An absorption peak around 255 nm was observed for control samples. This peak became masked by high absorption out to >300 nm induced by the E-beam treatment, even with the lowest dose of 10 kGy. The generation of the high UV-Vis absorption, which increased with dose of treatment, is of interest regarding the overall assessment of the outcome. The spectral analysis was consistent with our observation of increasing coloration of samples with the dose level.

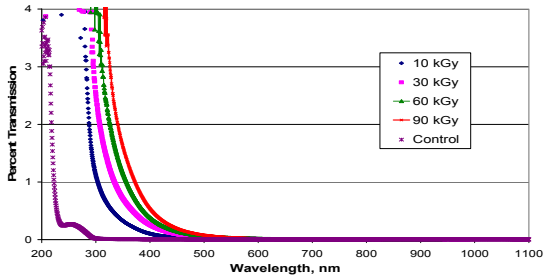

Figure 1. UV-Vis-NIR spectra of Healon OVD at different doses of E-beam treatment; and the results were similar for the Healon Endocoat OVD.

Zero-rate viscosities of Healon and Healon EndoCoat OVDs, before and after E-beam treatment at various levels, are summarized in the Table 1. As shown in the table, viscosity dropped significantly after E-beam treatment. There was no relationship between the viscosity drop and the dose of treatment, since even the lowest level of treatment completely eliminated measurable viscosity.

Healon OVD		Healon EndoCoat OVD	
E-Beam dose (k-Gy)	Zero rate viscosity (Pa.s)	E-Beam dose (k-Gy)	Zero rate viscosity (Pa.s)
0 kGy	151.0	0 kGy	78.0
10 kGy	0.2	10 kGy	0.2
30 kGy	0.2	30 kGy	0.2
60 kGy	0.1	60 kGy	0.2
90 kGy	0.6	90 kGy	0.1

Table 1 Viscosity of Healon and Healon EndoCoat OVDs at different E-beam Doses

Conclusions: The test E-beam treatments caused unacceptable color changes in the viscolelastic products after (or during) E-beam processing. Also, the viscosities of Healon and Healon EndoCoat OVDs dropped precipitously, with no viscosity remaining at even the lowest dose. Therefore, the data suggest that sterilization of the current Healon and Healon EndoCoat products by E-beam process may not be feasible without some change to the packaging configuration, such as by using a higher grade of glass to prevent the discoloration and loss of viscosity due to degradation of the HA. Whether there is a connection between the leaching of colored substance from the glass into the product and the degradation of the HA (and thus loss of viscosity) is unknown.

Reference:

1. Zou Z, Wang Q, Deng G, Fan B, Li S etc. Chinese Journal of Biochemistry and Molecular Biology, 2012, 28(1), P 71-78.

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