Retrospective Study on Long Term Storage Effects on UHMWPE in an Inert Environment

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INTRODUCTION:

Packaging of conventional UHMWPE has been a controversial topic since the 1990's. Most orthopedic manufacturers have converted from gamma irradiating in an air environment to gamma irradiating in an inert environment. The change was introduced after extensive experimentation by industrial and academic researchers showed increased oxidation after long term storage in air.[1] In this study, the level of oxidation of the UHMWPE component was compared to the percent residual oxygen concentration inside the package.

MATERIALS AND METHODS:

For this study, GUR 1050 UHMWPE components packaged in an inert atmosphere were analyzed after long term storage. The inner cavity package material is Barex®, which is an oxygen barrier material. A vacuum is pulled to purge the ambient atmosphere and then nitrogen is back-flushed into the cavity and heat sealed with an aluminum foil lid. The packaged components were stored under normal storage conditions. The percent residual oxygen level was measured using a PBI Dansensor oxygen analyzer which has a lower measurement range of 10 ppm. The percent oxygen was determined by extracting the inert atmosphere through a needle adapter with continuously flow through an oxygen sensor. Surface Oxidation Index (SOI) measurements were performed using a FTIR microscope spectrometer on microtomed thin films per ASTM Standard F2102-01. The degree of oxidation is expressed as the ratio of the peak area of the oxidative functional groups centered near 1720 cm^{-1} and the peak area of the non-oxidized polyethylene centered near 1370 cm^{-1}. IR measurements were obtained by scanning cross-sectionally through the part from the articulating surface to the backside.

RESULTS AND DISCUSSION:

Graph 1 represents the oxygen concentration measured inside the package. The scale on the graph is 0 - 20% to show the data in relation to ambient air which contains 20.9% oxygen. Table 1 is the data graphically represented in Graph 1. The oxygen concentration starts at 0.0% after irradiation. The oxygen levels increased from 0.0% to <0.75% after almost nine years of long term storage. This indicates the package construction efficiently limits oxygen permeation. SOI measurements were taken immediately after the package was opened. No surface oxidation (OI < 0.01) was detected on any of the components after long term storage in an inert atmosphere as shown in Figure 1. This indicates again, that the oxygen has been successfully removed from the package and measurable oxidation has not occurred.

CONCLUSION:

Low oxygen concentrations are maintained after long term shelf storage in this nitrogen flushed cavity design. The percent of residual oxygen remains low which minimizes the risk of premature onset of oxidation. This was confirmed with no surface oxidation being detected after approximately nine years of storage.

Graph 1
Percent Residual Oxygen Concentration

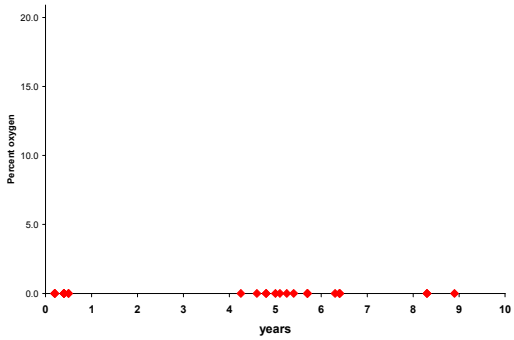
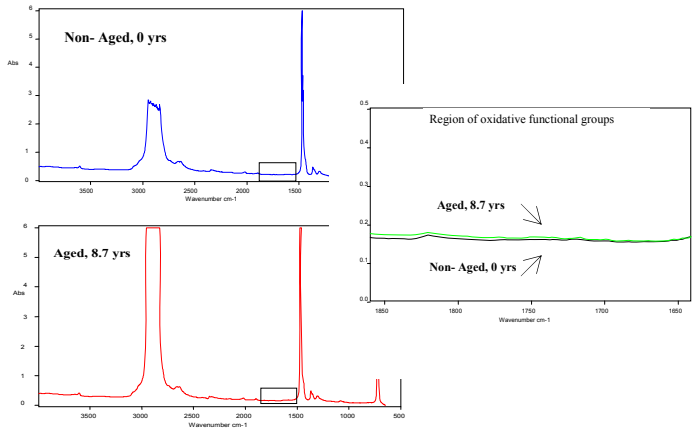


Table 1

Yrs on Shelf	Product Family	No. of samples	Avg. % Oxygen
0.2	MG II	3	0.00%
0.4	Nex Gen CR	4	0.00%
0.5	Nex Gen PS	2	0.00%
4.2	Trilogy	1	0.00%
4.6	Trilogy	1	0.00%
4.7	Nex Gen CR	1	0.04%
4.8	Trilogy	1	0.01%
5.0	Trilogy	1	0.02%
5.1	Trilogy	1	0.46%
5.2	Trilogy	1	0.10%
5.4	Trilogy	1	0.75%
5.7	Nex Gen PS	3	0.10%
6.3	Nex Gen PS	1	0.12%
6.4	Nex Gen CR	3	0.18%
8.2	MG II	2	0.15%
8.7	MG II	1	0.19%

Figure 1
FTIR Comparison of Non-Aged v. Aged Polyethylene Packaged in Nitrogen



References:[1]Kurtz, S.M., 2004. The UHMWPE Handbook