

DIMENSIONAL STABILITY OF UHMW-PE PARTS: INFLUENCE OF AGING AND CROSSLINKING

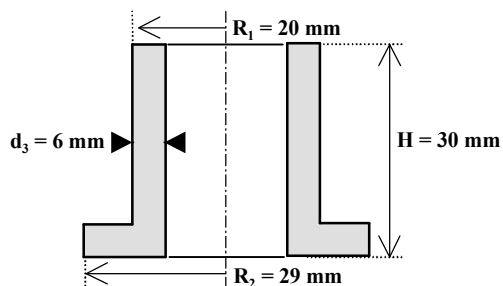
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INTRODUCTION: Ultra high molecular weight polyethylene is the main material used as a bearing surface in total hip or knee replacements due to its high toughness and wear resistance. However, as a result of the extremely high ($> 10^6$ gr/mol) molecular weight and thus high melt viscosity, UHMW-PE powders cannot be processed using screw extruders. Instead, sheet compression molding or ram extrusion techniques are used to sinter the particles into a preform. This preform is machined into the desired implant, packaged, sterilized and after a shelflife period implanted. Additionally, highly crosslinked polyethylenes have been developed by irradiating (γ or e-beam) the preforms in the solid or molten state, followed by a thermal treatment to enhance the cross-linking process. The long term dimensional stability of polyethylene part is important for the bearing surface and, due to the modularity of many hip and knee systems, also for the connectors which snap into a metal backing. Here, the influence of the processing steps on the dimensional stability of machined UHMW-PE parts is investigated. The dimensional changes during shelflife or clinical use are mimicked using accelerated aging tests which corresponds with 5-10 yr. Shelflife¹ or 4yr. clinical use²

METHODS: Sheet compression molded material (GUR 1020) was purchased at PolyHiSolidur, Vreden Germany. Test specimens as shown in Fig 1, were produced from untreated and crosslinked UHMW-PE and tested according to the matrix shown in Table 1.

Figure 1: Cross section of test cylinders



Crosslinking: The UHMW-PE was preheated at 125°C, irradiated with e-beam (7 Mrad) and

subsequently remelted before it was slowly cooled down

Sterilization: The samples were packaged under nitrogen atmosphere and sterilized using 3 Mrad γ radiation.

Aging was done according to ASTM F2003-00, method B. The cylinders were inserted for 14 days in a vessel at 5 atm. oxygen pressure and 70°C.

The **Dimensions** of the cylinders were measured on the inside and outside at a height of 12, 18 and 24 mm using a 3-D coordinate measuring machine (Mitutoyo Euro C9106, accuracy 3 μ m). Samples were thermostated at $20 \pm 1.0^\circ\text{C}$. The roundness is defined as the difference between the maximum and minimum radius³. Data presented here are averaged over at least 8 cylinders. Cross comparison of the data was done using the T-test (sigmastat software).

Table 1: Test matrix for cylindrical specimens

X-linked	Sterilized	Aged	Code
No	No	No	Gur
No	No	Oxygen	Gur Aged-O ₂
No	Yes	No	Gur St
No	Yes	Oxygen	Gur St +Aged O ₂
No	Yes	Nitrogen	Gur St +Aged N ₂
Yes	No	No	X-linked
Yes	No	Oxygen	X-linked+Aged O ₂

RESULTS: During aging, all cylinders slightly deformed into an ellipsoid as could be observed on all height levels. As an example, the dimensions of crosslinked polyethylene before and after aging in oxygen are shown in Figure 2. (pls. note the scale!). The roundness values are shown in Figure 3. The highest deviation from roundness is observed for the sterilized and oxygen aged material (Gur St+Aged O₂). There is no statistical difference between the UHMW-PE as-machined (GUR), the aged PE (GUR Aged O₂), the sterilized PE (GUR St) and the sterilized PE aged in nitrogen (Gur St+Aged N₂). However there is a statistical difference ($P < 0.05$) between the sterilized and oxygen aged UHMW-PE (Gur St+Aged O₂) and all the other materials. Finally, aging of crosslinked PE results in a significant ($P < 0.001$) increase in roundness.

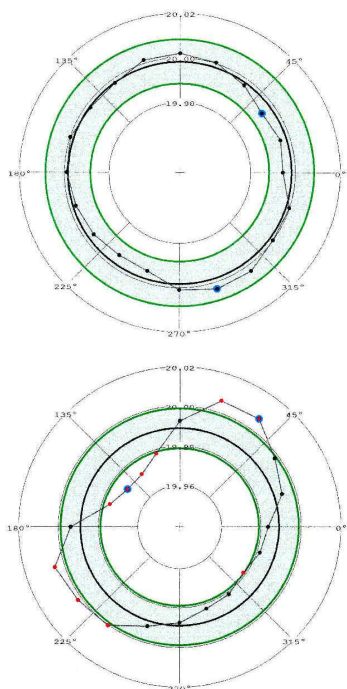


Figure 2: Top view of outer dimensions at 24 mm height for X-linked UHMW-PE as machined (top) and after aging in oxygen (bottom).

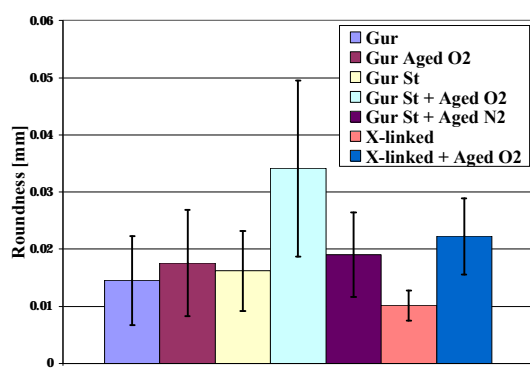


Figure 3: Roundness for the test cylinders, outer diameter at $H = 24$ mm.

DISCUSSION & CONCLUSIONS: During the sheet molding process, the UHMW-PE is subjected to thermal/mechanical cycles which influences the density, homogeneity and amount of residual stresses in the material, which are also present in the cylinders. Release of these stresses results in a small deformation into an ellipsoid (Figure 2). The highest deviation from a perfect cylinder is observed for the UHMW-PE that has been sterilized and aged in oxygen at 70°C. There is no difference between the as-machined (GUR), the aged (Gur Aged O₂) and the sterilized part (Gur St), i.e., the combination of γ -sterilization and thermal activation in an oxygen environment causes the dimensional change. During the γ -sterilization,

chain scission in PE occurs resulting not only in a small amount of crosslinks, but also free radicals that are trapped into the material⁴. These radicals are reactive towards oxygen at elevated temperature leading to a cascade of oxidative reactions⁵. Consequently the molecular weight decreases enabling a release of the internal stresses. These degradative reactions can not occur in an inert nitrogen atmosphere (Gur St+Aged N₂). For the production of the highly cross-linked polyethylene, a large amount of chain scission and free radicals has been generated on purpose. Afterwards the preform is remelted and slowly cooled down. Consequently, the free radicals are eliminated and the residual stresses are reduced. Therefore, the dimensional change after aging in oxygen is lower compared to the sterilized and aged Gur materials. To summarize, accelerated aging in oxygen of sterilized UHMW-PE leads to a dimensional change twice the deviation from roundness after machining.

REFERENCES:

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