RMS

Testing • Research • Consulting

Particles and ions generated in total hip joint prostheses: *in-vitro* wear test results of UHMWPE and XLPE acetabular components

Tribology Letters 2017; 65:92

Hamoon Zohdi[1], Benjamin Andreatta[1] & Roman Heuberger[1,*]

[1] RMS Foundation, Bettlach, Switzerland *roman.heuberger@rms-foundation.ch

Introduction

Implants sometimes fail *in-vivo* due to osteolysis, aseptic loosening or hypersensitivity. These problems are associated with particle and ion release occurring in prostheses.

Thus the aim of this study was to accurately characterise wear particles and ions released from total hip joint prostheses *in-vitro*.

Shen et al., Arthritis research & therapy, 2006; 8:R70

Iwamoto *et al.*, Pseudotumor from a Metal-on-Metal Hip, J. Rheumatol. 2011; 38, 2265

Materials & Methods

Hip prostheses
provided by Mathys Ltd Bettlach, Switzerland

Acetabular components
Std. UHMWPE
cross-linked PE (XLPE, w. vitamin E, vitamys®)
- incl. artificial aging (ASTM F2003)

Heads
Stainless steel (SS, FeCrNiMnMoNbN, according to ISO 5832-9)
CoCrMo (according to ISO 5832-12)
Al_2O_3 (trade name Bionit2, according to ISO 5832-12)

Hip simulator tests according to ISO 14242-1 / -2

Test liquid Newborn calf serum, 30 g/L + EDTA, sodium azide

Particles and Ions released!

Hip simulator from EndoLab, Germany

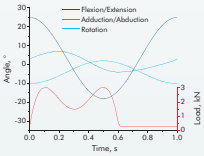


Table: Investigated test liquids[2]

Sample Identification	Acetabulum Material	Head Material & Ø	Ageing	Million Cycles	Wear
UHMWPE(0d)-SS-1MC	UHMWPE	SS 32 mm	-	1	Average
UHMWPE(0d)-SS-5MC	UHMWPE	SS 32 mm	-	5	Average
UHMWPE(14d)-SS-1MC	UHMWPE	SS 28 mm	14 days	1	High
UHMWPE(14d)-SS-5MC	UHMWPE	SS 28 mm	14 days	5	High
UHMWPE(14d)-CCM-1MC	UHMWPE	CoCrMo 28 mm	14 days	1	High
UHMWPE(14d)-CCM-3MC	UHMWPE	CoCrMo 28 mm	14 days	3	High
XLPE(0d)-SS-1MC	XLPE	SS 28 mm	-	1	Low
XLPE(0d)-SS-5MC	XLPE	SS 28 mm	-	5	Low
XLPE(0d)-CCM-1.5MC	XLPE	CoCrMo 36 mm	-	1.5	Low
XLPE(0d)-CCM-4.5MC	XLPE	CoCrMo 36 mm	-	4.5	Low
XLPE(0d)-Al_2O_3-1MC	XLPE	Al_2O_3 36 mm	-	1	Low
XLPE(0d)-Al_2O_3-5MC	XLPE	Al_2O_3 36 mm	-	5	Low
XLPE(14d)-CCM-1MC	XLPE	CoCrMo 36 mm	14 days	1	Low
XLPE(14d)-CCM-5MC	XLPE	CoCrMo 36 mm	14 days	5	Low
XLPE(60d)-Al_2O_3-1MC	XLPE	Al_2O_3 36 mm	60 days	1	Low
XLPE(60d)-Al_2O_3-5MC	XLPE	Al_2O_3 36 mm	60 days	5	Low

[2] All test liquids were used for 500,000 cycles. For example, the ones collected at 1 million cycles (MC) were in the simulator between 500,001 and 1 million cycles. The sample identification is composed of "the material of the acetabulum (accelerated ageing)-head material-no. of applied cycles". UHMWPE ultra-high-molecular-weight polyethylene, XLPE cross-linked polyethylene, SS stainless steel, CCM CoCrMo.

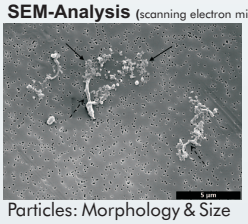
Acidic Digestion 10 mL of used test liquid

e.g. 1 h @ 50 °C

50 mL HCl (37 %)

Filtration

SEM-Analysis (scanning electron microscopy)



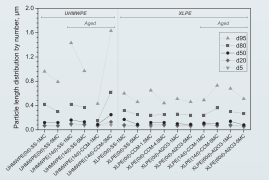
Particles: Morphology & Size

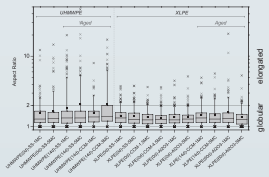
Laser diffraction
Particles: Size distribution

ICP-MS (inductively couples plasma - mass spectrometry)
Ion concentration

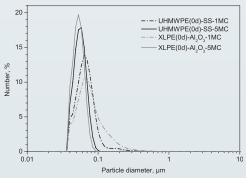
Results

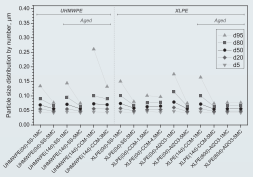
Size & Morphology by SEM

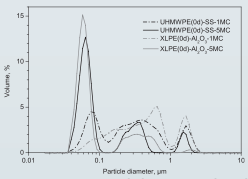


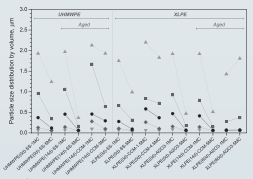


Size Distribution by Laser Diffraction









The particle size was generally larger during the running-in and decreased in the steady state regime (1 MC vs. 5 MC)

Ion Release by ICP-MS

A small amount of ions was released either from the head or the test chamber. Iron originates from red blood cells too.

Table: Ion Concentration[3] (mg/L) in the used test liquids

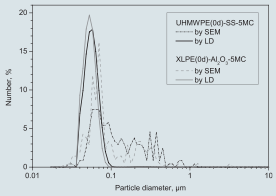
	Fe	Ni	Mn	Co	Mo	Al
Detection limit DL	0.38 - 2.56	0.06 - 0.58	0.04 - 0.33	0.005 - 0.21	0.008 - 0.05	0.16 - 1.28
Fresh test liquid	1.03 ± 0.05	< DL (0.20)	< DL (0.04)	< DL (0.08)	< LOQ (0.02)	< DL (0.25)
UHMWPE(0d)-SS-1MC	1.76 ± 0.12	< LOQ (0.20)	0.05 ± 0.01	< DL (0.08)	< LOQ (0.02)	0.74 ± 0.08
UHMWPE(0d)-SS-5MC	2.25 ± 0.12	< LOQ (0.20)	0.07 ± 0.00	< DL (0.08)	< DL (0.02)	0.38 ± 0.08
XLPE(0d)-SS-1MC	1.49 ± 0.05	< LOQ (0.20)	0.05 ± 0.01	< LOQ (0.08)	< LOQ (0.02)	0.35 ± 0.03
XLPE(0d)-SS-5MC	1.29 ± 0.01	< LOQ (0.20)	< DL (0.04)	< LOQ (0.08)	< DL (0.02)	< DL (0.25)
UHMWPE(14d)-CCM-1MC	4.14 ± 0.38	< DL (0.58)	< DL (0.33)	1.26 ± 0.04	0.07 ± 0.01	1.67 ± 0.04
UHMWPE(14d)-CCM-3MC	3.44 ± 0.02	< DL (0.58)	< DL (0.33)	0.86 ± 0.06	0.08 ± 0.02	1.42 ± 0.09
XLPE(0d)-CCM-1.5MC	1.00 ± 0.03	0.12 ± 0.01	< DL (0.04)	0.50 ± 0.01	0.03 ± 0.01	0.21 ± 0.02
XLPE(0d)-CCM-4.5MC	1.09 ± 0.02	0.15 ± 0.01	< DL (0.04)	0.63 ± 0.03	0.02 ± 0.01	0.18 ± 0.01
XLPE(0d)-Al_2O_3-1MC	1.31 ± 0.19	0.18 ± 0.01	< DL (0.04)	0.02 ± 0.01	< DL (0.01)	0.26 ± 0.02
XLPE(0d)-Al_2O_3-5MC	1.18 ± 0.08	0.13 ± 0.01	< DL (0.04)	0.02 ± 0.00	< DL (0.01)	0.19 ± 0.00

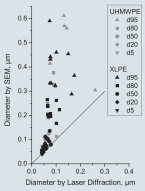
[3] Some concentrations were beyond the detection limit (<DL) or beyond the limit of quantification (LOQ: 1 or 2 of 3 repetitions beyond the DL). The uncertainty is about 10 % of the reported values for the main elements and higher for trace elements.

Discussion

Overestimation of particle diameter when examined with SEM compared to Laser Diffraction! Why?

- loss of small particles through the holes in the filter
- limited resolution, contrast and visibility of small particles on filters by SEM





Conclusions

- Combination of SEM (morphology) and laser diffraction (size distribution) is very powerful for the evaluation of wear particles.
- All wear particles were mostly globular and submicron in size.
- There were more elongated UHMWPE particles than XLPE particles while the average size was comparable.
- The size of the particles decreased by increasing the number of cycles from running-in phase (1 MC) to steady-state phase (5 MC).
- By the accelerated ageing, only the size of UHMWPE particles increased.
- Ion concentration for stainless steel heads increased with increasing head sizes.