Polymeric Materials for Articulating Motion Preservation Devices

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Introduction

Material selection for total disc replacement has initially utilised the materials employed successfully in total joint replacement. However polyethylene components from artificial discs have demonstrated adhesive/abrasive wear at the dome and rim[1]. There has also been evidence of microscopic rim damage, including radial and transverse cracking, fracture, plastic deformation and third body damage[2]. Polyethylene based devices have also been shown to experience large increases in wear when tested under curvilinear or limited cross shear motion profiles[3-5]. Engineers continue to search for new materials to prolong the lives of implantable devices by reducing wear and the potential for mechanical failure.

PEEK-OPTIMA® materials have been used extensively in spinal fusion. In response to the growing interest in the wear performance of these materials for total disc replacement multi-directional pin-on-plate testing has been carried out to provide guidance on the potential of these materials for self-mating articulating spinal devices.

Materials and Methods

Four different material combinations were tested on a four station device that applied both reciprocation and rotational motion (Figure 1). The bearing materials studied included PEEK-OPTIMA , PEEK-OPTIMA LT1CA30 containing polyacrylonitrile (PAN) based carbon fibres and two development materials, PEK and pitch carbon fibre reinforced PEEK-OPTIMA (PEEK-OPTIMA LT1CP30).

All pin and plate samples were machined from injection moulded shapes. A 40N load was applied to each station which resulted in a contact stress of approximately 2MPa. Rotating and reciprocating speeds of 1Hz were chosen. The lubricant used was 24.5% bovine serum (protein content $15gl^{-1}$) which was heated to 37ºC. The wear was assessed gravimetrically and the tests each completed a minimum of 2 million cycles. Control pins were included to take account of weight change due to lubricant uptake.

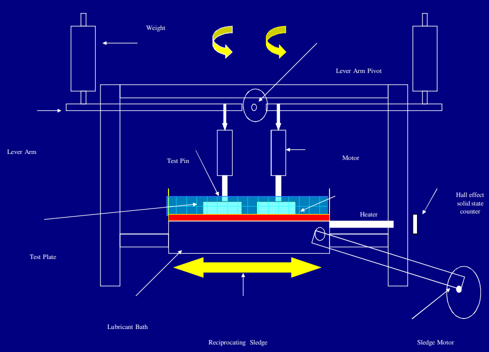

Figure 1 Multi-Directional Pin on Plate Machine

Results

All materials were subjected to mechanical testing. All tests were carried out on injection moulded test samples and the results shown in Table 1.

Table 1 Mechanical Properties of Test Materials

Test	Self-Mating Polymer Wear Couple			
	PEEK–OPTIMA	PEEK-OPTIMA LT1CA30	PEEK-OPTIMA LT1CP30	PEK
Tensile Strength ISO 527 (MPa)	100	228	160	94
Tensile Elongation ISO 527 (MPa)	34	1.7	5.6	66
Flexural Strength ISO 178 (MPa)	163	324	250	146
Flexural Modulus ISO 178 (GPa)	4	19.4	13.3	3.85
Notched Izod Impact Strength ISO 180 (kJ/m^2)	7.5	9.5	5.8	10.6

Wear Results

It is essential that wear screening tests correctly estimate the wear performance of materials. Prior to these tests, the mean wear factors for PTFE, acetal and UHMWPE bearings against metal have been calculated and compared with clinical wear factors[6]. This demonstrated that clinically relevant values of wear could be achieved by this screening method and would provide a useful comparison for this study. Identical test conditions were used for the tests on PEEK-OPTIMA materials. The results are shown in Figure 2.

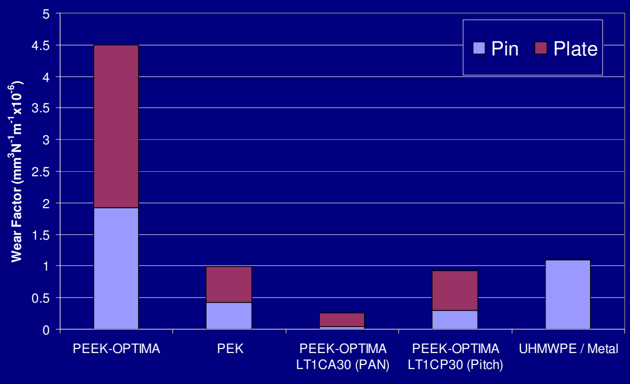

Figure 2 Wear Factors for Self-Mating Wear Couples

Discussion

It should be noted that these conditions are intended as screening for biomaterials for hip prostheses (ASTM F732-000) and therefore should be used as guidance only.

In general the PEEK-OPTIMA material wear couples demonstrated a short running in period before exhibiting a steady weight loss. The samples became highly polished throughout the wear test with average surface roughness changing from around 1 micron to 0.1-0.2 microns within the first 1 million cycles of testing.

The self-mating PEEK-OPTIMA wear couple produced the highest wear factor in our tests with a value higher than that of UHMWPE/CoCrMo which was comparable with PEK.

However recently a PEEK-OPTIMA based nucleus replacement device was tested under conditions incorporating a cross shear motion profile using modified ISO/DIS 18192 parameters. These implants demonstrated a constant average wear rate of 0.45±0.01 mg/million cycles over 10 million cycles, indicating that self-mating PEEK-OPTIMA is relatively insensitive to changes in motion profiles[7] and may serve as a better material than traditional metal on polyethylene disc arthroplasty devices.

The addition of carbon fibres provides a significant reduction in wear compared with UHMWPE / Metal. It is interesting to note that PEEK-OPTIMA LT1CA30 provides lower wear than the pitch fibre reinforced material which has proved to be a low wear couple in combination with alumina in hip prostheses studies[8].

Conclusion

A number of candidate materials for spinal arthroplasty devices have been identified through pin-on-plate testing. PEEK-OPTIMA and LT1CA30 PEEK-OPTIMA materials have a successful clinical history in load bearing applications and evaluation of the biological response to particles of PEEK and carbon fibre reinforced PEEK are encouraging [9,10].

Preliminary indications from nucleus replacement device testing suggests further investigation of these materials in spine arthroplasty wear simulator testing would be merited[7]. These materials could potentially offer lower wear devices with greater radiolucency, no metal ion exposure and greater design and manufacturing flexibility.

References

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