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Alternative bearing materials for intervertebral disc arthroplasty

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ABSTRACT

The objective of our study was to test alternative polymer-on-polymer articulations for cervical total disc arthroplasty with favourable biotribological properties and the benefit of radiolucency in comparison to the clinically well established metal-on-polyethylene coupling. In vitro wear simulation was performed according to ISO 18192-1:2008 (*E*) with the clinically introduced activ® C cervical artificial disc (Aesculap AG Tuttlingen, Germany) made of UHMWPE/CoCr29Mo6 in a direct comparison to experimental disc articulations made of PEEK, CFR–PEEK and PEK. Each material combination was tested for 10 million cycles with a customised 6 station spinal wear simulator (EndoLab Thansau, Germany). Gravimetric and geometric wear assessment, optical surface characterisation and an estimation of particle size and morphology were performed.

The gravimetric wear rate of the clinical reference polyethylene-on-cobalt–chromium was 1.0 ± 0.1 mg/million cycles, compared to 1.4 ± 0.4 mg/million cycles for PEEK, to 0.02 ± 0.02 mg/million cycles for CFR–PEEK and 0.8 ± 0.1 mg/million cycles for PEK.

In conclusion, a number of different candidate materials for total cervical disc arthroplasty were compared using the same disc design. Whereas the polymer-on-polymer articulation of PEK showed no substantial benefit in comparison to polyethylene-on-cobalt–chromium and whereas natural PEEK tends towards pitting and delamination, the carbon fibre reinforced PEEK demonstrated an excellent wear behaviour with a reduction in order of a magnitude. Therefore, the CFR–PEEK based polymer-on-polymer articulations may be an alternative to polyethylene-on-metal and have a high potential for next generation disc replacements.

1. Introduction

Over the last decades, anterior cervical discectomy and fusion (ACDF) has been established as the gold standard for treatment of degenerative disc disease in the cervical spine [1,2]. However, spinal fusion of the segment may, in the long term, result in progressive degeneration of the adjacent levels (ALD) [3,4]. These clinical findings were supported by in vitro-flexibility studies demonstrating increased motion and intradiscal pressure in the cervical spine segments adjacent to fusion [5,6]. Hence, motion preservation procedures like artificial disc arthroplasty (TDA-C) have been introduced with promising early clinical results [7–9].

Short- or midterm complications after TDA-C include device dislocation, substantial rates of heterotopic ossification or spontaneous fusion [10]. Among other factors they might be attributed to minimum available disc height of some devices resulting in overdistraction of the intervertebral space and excessive bone preparation of the vertebral endplates. Apart from increased risk of migration, this may induce heterotopic ossifications and subsequent fusion [11].

The clinical outcome of patients after lumbar TDA indicates that aseptic loosening may not be a dominant source of implant failure as in hip replacements [12,13]. However, the clinical significance of polyethylene wear debris and subsequent osteolysis was reported in total disc arthroplasty [14–16].

Most of the current TDA-C implants are ball-in-socket designs using the material combinations of metal-on-polyethylene and metal-on-metal or with a flexible polymer core between titanium alloy endplates.

At present, due to the limited clinical experience with TDA-C, inadequate knowledge exists about the wear behaviour of these

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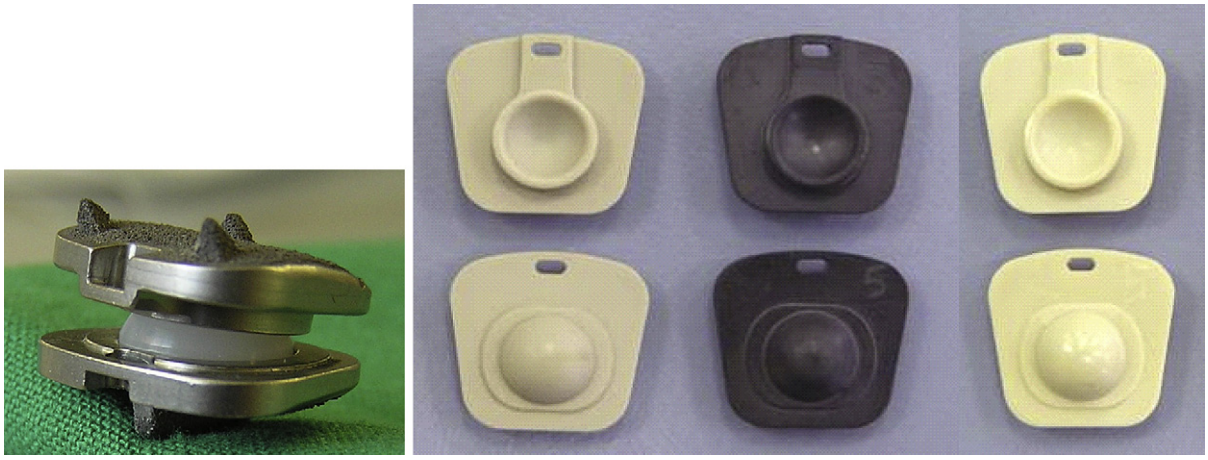

Fig. 1. Total disc arthroplasty device for the cervical spine (activ® C) with superior endplate made out of a CoCr29Mo6 alloy and an inlay made out of UHMWPE (left) and the prototypes of the experimental polymer-on-polymer articulations out of PEEK, CFR–PEEK and PEK.

devices. But particulate debris and ion release resulting from in vivo degradation of TDA-C implant components may be recognized as a factor limiting the longevity of the procedure. Degeneration of a polyurethane core [17] as well as significant concentrations of chromium and cobalt due to the release of ions after metal-on-metal total disc arthroplasty [18] were described in the literature. Particulate wear and metal ion release were suspected to trigger a local biologic response leading to osteolysis, periprosthetic bone loss and aseptic loosening of joint replacement implants [19,20]. Despite of these inadequacies of some first-generation TDA-C implant designs, cervical disc arthroplasty remains a topic of ongoing high interest in view of its potential to prevent adjacent level degeneration [4,6,21]. To a significant extend, the long term clinical outcome of TDA-C procedures may depend on the ability to minimize debris generation of artificial disc materials in mostly young and active patients.

The hypothesis of our study was that there are alternative polymer-on-polymer articulations for cervical total disc arthroplasty with favourable biotribological properties in comparison to the clinically well introduced metal-on-polyethylene coupling.

2. Materials and methods

An in vitro wear simulation was performed with the clinically introduced activ® C cervical artificial disc (Aesculap AG Tuttlingen, Germany) in metal–polyethylene coupling as a reference in comparison to three different polymer-on-polymer articulations. The activ® C disc design consists of an inferior metallic endplate with a fixed convex-shaped inlay made out of polyethylene which articulates with a superior metallic endplate in form of a spherical joint. The spherical radius of the inlay is 5 mm; for the wear test, the largest XXL size disc was used in the nominal total disc height of 7 mm. Taking the study's basic research character into account, the articulation of the activ® C design was retained unchanged, two-piece prototypes being fabricated out of the investigational polymer material combinations.

For the metal-on-polyethylene articulation, the UHMWPE core was machined from GUR 1020 and the superior endplate of the disc out of a CoCr29Mo6 alloy with a highly polished bearing surface. For the polymer-on-polymer articulations, three different groups of prototypes were machined from polyaryletheretherketone (PEEK-Optima LT1, Invibio Ltd. Thornton-Cleveleys, UK), a carbon fibre reinforced PEEK version containing 30% polyacrylonitrile (PAN) based carbon fibres (CFR–PEEK LT1 CA 30) and from polyaryletherketone (PEK) (Fig. 1). The polyethylene inlay and all prototype polymer components were packed under nitrogen atmosphere and sterilized by γ-irradiation (30 ± 2 kGy).

In vitro wear simulation was performed according to ISO 18192-1:2008 (*E*) in a direct comparison of the disc articulations CoCr29Mo6/UHMWPE, PEEK/PEEK, CFR–PEEK/CFR–PEEK and PEK/PEK. The ISO protocol requires all movements to be realized in a sinusoidal waveform with a frequency of 1 Hz and a kinematic pattern with a rotational displacement of ±7.5° in flexion/extension, ±6° in lateral bending and ±4° in axial rotation. The corresponding axial force (F_{axial}) is applied in a dynamic sinusoidal loading mode with 150 N in flexion and 50 N in extension in a frequency of 1 Hz (Fig. 2).

The inferior endplates of the specimen were aligned on the simulator with an inclination of 0° in the sagittal and coronal plane in accordance with the anatomy of the cervical spine. The axial load was applied to the superior endplate with 0° offset

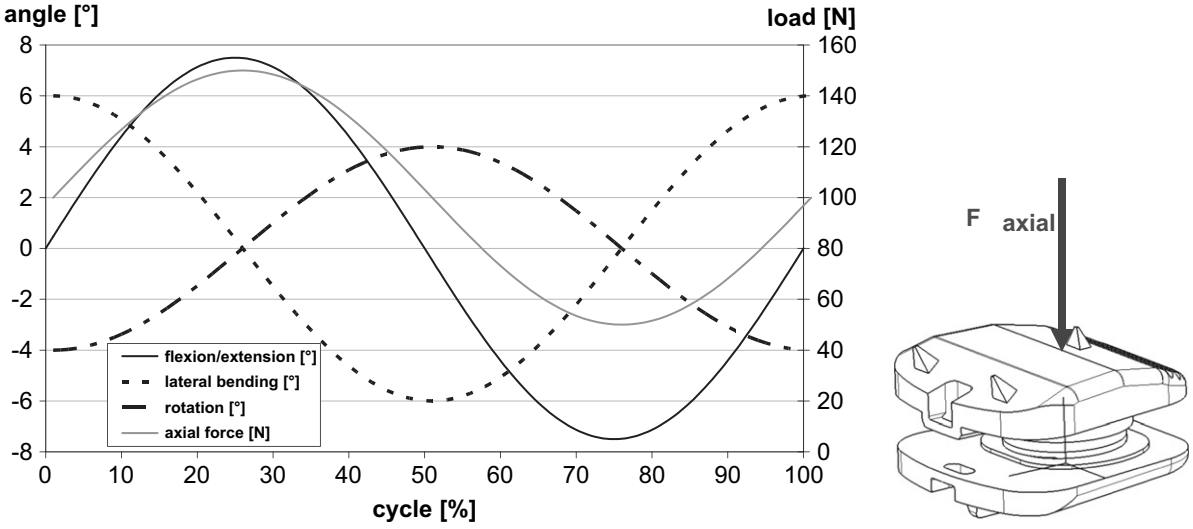

Fig. 2. Load and displacement parameters for the wear test according to ISO 18192-1:2008 (*E*) and positioning of the artificial disc in relation to the direction of the axial load.