WEAR EVALUATION OF A PEEK ON PEEK DISC ARTHROPLASTY DEVICE

Tim Brown, Tom Kilpela, Qi-Bin (Chip) Bao
Pioneer Surgical Technology, Marquette, MI, USA

Background Context

Articulating disc arthroplasty devices need to exhibit high wear resistance for long term durability, which is highly dependent upon material selection. Current devices in clinical use mainly include metal on UHWMPE and metal on metal material combinations based upon the clinical success of total joint arthroplasty. PEEK-OPTIMA (PEEK) is widely used in the spine for fusion applications due to its mechanical strength, biostability, biocompatibility and radiolucency[1]. PEEK may therefore present itself as a candidate material for disc arthroplasty. NUBAC is a PEEK on PEEK disc arthroplasty device with a ball and socket articulation (**Fig.1**). An evaluation of the wear resistance of NUBAC is needed to further confirm the use of PEEK on PEEK in disc arthroplasty.

Purpose

To determine the wear rate of NUBAC and compare with other disc arthroplasty devices in clinical use.

Materials and Methods

Protocol

- ❑ 2 groups of 6 NUBAC disc arthroplasty devices (**Fig. 1**)
- ❑ Pre-soaking in saline solution at 37 ± 2° C for approximately 5 weeks
- ❑ Dynamic compressive load of 0.23….1.02 kN
- ❑ Group motion profiles:
  - NUBAC-Unidirectional: 10 Mc ±7.5° F/E followed by 10 Mc ±7.5° LB alternated to 40 Mc
  - NUBAC-Frequency Shift: ISO 18192-1 with frequency shifting - 2 Hz F/E, 1.9 Hz LB, 2.11 Hz AR and 2.84 Hz for load to 10 Mc (**Fig. 2**)
- ❑ Cleaning and weighing every 0.5 Mc (per ASTM 2025-06)
- ❑ NUBAC wear rates determined via linear regression
- ❑ Wear rates of other disc arthroplasty devices determined from the literature

Fig.1: *NUBAC.*

Simulator input parameters for the Frequency Shift group were modified from ISO 18192-1 (**Fig. 2**). For both groups, the magnitude of the compressive load represented the physiological load sharing mechanism between the annulus and nucleus in the lumbar intervertebral disc[2, 3].

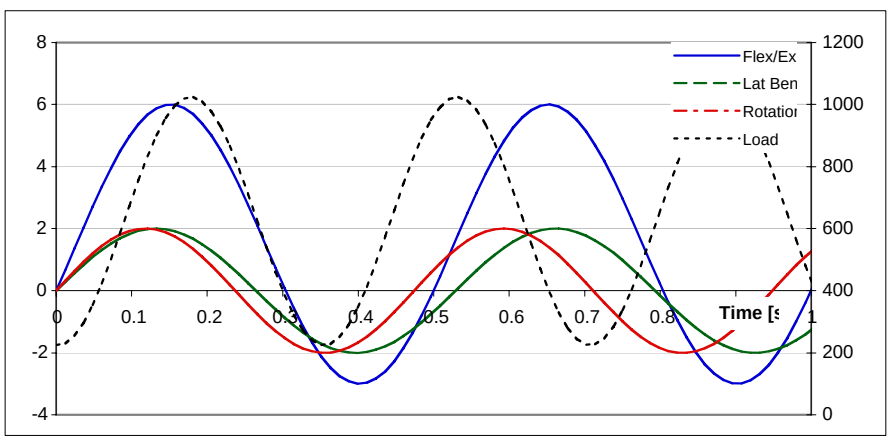

Fig.2: *Simulator input profile for the Frequency Shift group. Frequency shifting was adapted from Nechtow et al [5] and scaled from 2 Hz F/E.*

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Simulator (Fig. 4)

- 6 station spine simulator (Endolab GmbH, Germany)
- 4 DOF load/motion application with a servo-hydraulic system
- Chambers: fully sealed, temperature controlled at 37 ± 2°C
- Test fluid: newborn calf serum, phosphate buffered saline and 20 mM of EDTA with a final protein content of 20 g/L

Fig.4: *6 station spine simulator.*

Results

The NUBAC-Unidirectional group wear rate was 0.22±0.01 mm^3/Mc to 40 Mc and the NUBAC-Frequency Shift group wear rate was 0.38±0.02 mm^3/Mc to 10 Mc (**Fig. 5**). All implants maintained full functionality with no evidence of adhesion, delamination or fatigue cracks.

The literature review revealed a metal on metal wear rate of 4.91 mm^3/Mc and for metal on UHMWPE 9.78 mm^3/Mc[4]. In addition, for metal on UHMWPE frequency shifting results in a high wear rate of 17.5 mm^3/Mc to 20.3 mm^3/Mc[5] (**Fig. 5**).

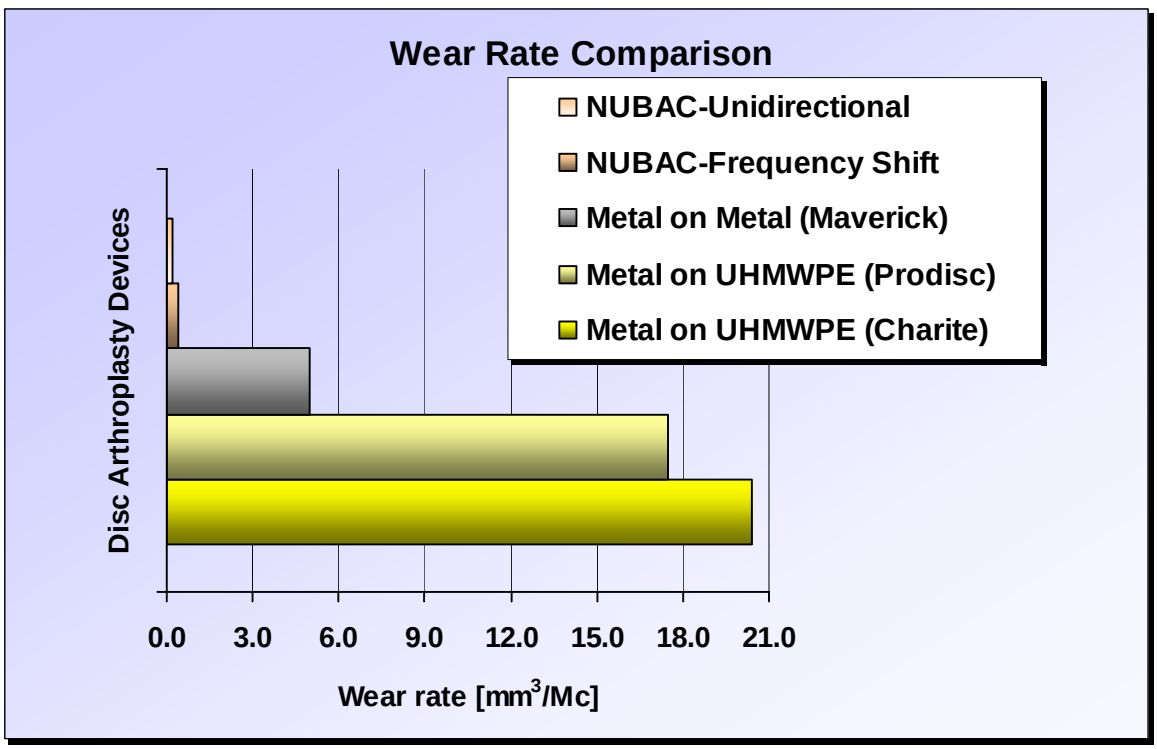

Fig.5: *Wear rate comparison of NUBAC vs. other articulating disc arthroplasty devices.*

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Discussion

Orientation softening is a known detrimental wear mechanism for UHMWPE. This occurs due to molecular orientation of the polymer chains at the wear surface. The polymer chains are preferentially aligned parallel to the predominant motion vector which coincides with the direction of the principal tensile and shear stresses. This leads to a decrease in shear strength and a significant increase in the wear rate under multidirectional wear testing or “cross shear” motion[6].

The rationale for alternating between flexion/extension and lateral bending for the Unidirectional group was to verify if self-mating PEEK underwent a similar phenomenon. If alignment of the polymer chains occurred during flexion/extension, there would be a significant increase in the wear rate during the lateral bending phase. The results of this study showed that the Unidirectional group wear rate was consistently linear to 40 Mc, suggesting that orientation softening leading to a significant increase in the wear rate during cross shear motion does not occur.

Frequency shifting assures that a non-repetitive load and motion profile is applied over the entire contact area, resulting in a worse case scenario with respect to cross shear. For metal on UHMWPE articulation, it has been shown that frequency shifting can increase the wear rate several orders of magnitude[5]. For NUBAC, there was a small increase in the wear rate for the Frequency Shift group as compared to the Unidirectional group.

Conclusion

NUBAC is the only articulating disc arthroplasty device tested to 40 Mc with maintenance of full functionality suggesting long term durability. Frequency shifting is a worst case scenario for wear testing since the load and motion profiles are non-repetitive. This did not lead to the several orders of magnitude increase in the wear rate as reported for metal on UHMWPE[5]. PEEK on PEEK, in the form of NUBAC, exhibits high wear resistance. The wear rate is at least an order of magnitude less than metal on metal or metal on UHMWPE disc arthroplasty devices, supporting its use in disc arthroplasty.

References

[1] Kurtz S, Biomaterials, 27: 4851: [2] Nachemson A, CORR, 45: 107-22, 1965; [3] Edwards T, Spine, 26(16): 1753-9, 2001; [4] Bushelow M, 22nd NASS, P32; [5] Nechtow W, Trans 52nd ORS, 0118; [6] Wang A, Wear 248: 38-47, 2001

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