Synthetic Synovial Fluid as a Lubricant for Wear Tests on Total Knee Endoprostheses

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INTRODUCTION: Synovial fluid is considered to be an excellent lubricant that greases and thus maintains the function of a natural joint throughout its lifetime [1]. However, its rheological and tribological properties vary greatly from patient to patient and it is almost impossible to develop a synthetic lubricant that displays all properties. For better comparability, bovine serum is recommended as a lubricant for preclinical wear studies of artificial knee joints. However, it presents other rheological properties than human synovial fluid [2]. In addition, the production of bovine serum from animals is controversially discussed [3]. Hence, the development and testing of synthetic synovial fluid is of interest. Some studies have investigated a substitute medium for cell biological and biomechanical studies, but long-term tests in wear simulators have not yet been performed [4–6]. It is unclear whether synthetic synovial fluid can create reproducible and physiological wear conditions and is suitable for long-term wear testing. The aim of this study was therefore to evaluate the suitability of synthetic synovial fluid as a lubricant for wear tests of total knee endoprostheses.

METHODS: Bicondylar metallic femoral components made of cobalt-chromium and polyethylene inserts made of conventional UHMWPE (Multigen Plus Knee System) were tested according to ISO 14243-1 and 2 standards in synthetic synovial fluid, composed of hyaluronic acid, bovine serum albumin and phospholipid lecithin filled with Ringer's solution, over 2.5 million cycles in a standard knee wear simulator. Every 0.5 million cycles, the medium was changed, and gravimetric wear measurements of the inserts were performed. At the end of the test, a surface analysis of the inserts and an analysis of the isolated wear particles were conducted. The data were compared with the results of a previous study [7] using an identical total knee design under the same test conditions and bovine serum (protein content of 30 g/l) as lubricant. In addition, the bearing couples were repeatedly tested according to ISO 14243-3 in both media with regard to its dynamic behavior in the 6-degree-of-freedom VIVO^{TM} simulator for 2,000 load cycles.

RESULTS: In synthetic synovial fluid, the mean wear rate was 19.69 ± 1.52 mg per million cycles. The wear rate of the UHMWPE inserts increased linearly with increasing number of cycles. Macroscopic and microscopic observations revealed typical wear marks and mechanisms on the UHMWPE inserts as seen in retrievals [8]. The wear particles detected were predominantly fibrillar and partially granular in shape. Shape and size distribution of the particles remained constant throughout the test. The wear test using bovine serum showed a significantly lower wear rate of 11.89 ± 1.09 mg per million cycles ($p = 0.0019$, unpaired t-test). For the dynamic analysis with VIVO^{TM} simulator significant differences between both lubricants were found for anterior-posterior force, internal-external moment and flexion-extension moment.

DISCUSSION: The reproducible wear rates and similar wear patterns of UHMWPE inserts in comparison to retrievals confirm the suitability of the synthetic synovial fluid as an alternative lubricating medium for wear tests. Furthermore, the choice of lubricant had a significant effect on the resulting joint dynamics, particularly at the reversal points of the motion with zero entrainment speed, as suggested in the literature [9]. A limitation of our present study is that due to the high variability in the composition of human synovial fluid, synthetic synovial fluid can only represent a part of the human variety. In addition, the composition was based on the data of healthy human synovia. However, the synovial fluid in the joint is altered after joint replacement. Several studies aim at the replacement of bovine serum albumin with a plant-based substitute [10,11] in order to completely eliminate animal products in the production of synthetic synovial fluid. Future studies should compare the rheological properties of synthetic synovial fluid with those of bovine serum and synovial fluid of patients with total joint replacement.

SIGNIFICANCE/CLINICAL RELEVANCE: Tribologically loaded endoprosthetic implants are currently tested with lubricating medium based on bovine serum that cannot fully represent the lubricating properties of human synovial fluid. Since the synthetic synovial fluid better represented these properties, this may be step forward in the preclinical, tribological testing for articulating surfaces of total knee endoprostheses.

REFERENCES:

[1] Shen G, Zhang J-F, Fang F-Z. In vitro evaluation of artificial joints: a comprehensive review. Adv Manuf 2019;7:1–14. https://doi.org/10.1007/s40436-018-00244-z.
[2] Klein J. Molecular mechanisms of synovial joint lubrication. Proc Inst Mech Eng Part J J Eng Tribol 2006;220:691–710. https://doi.org/10.1243/13506501JET143.
[3] Jochems CEA, van der Valk JBF, Stafleu FR, Baumans V. The use of fetal bovine serum: ethical or scientific problem? Altern Lab Anim ATLA 2002;30:219–27.
[4] Bortel EL, Charbonnier B, Heuberger R. Development of a Synthetic Synovial Fluid for Tribological Testing. Lubricants 2015;3:664–86. https://doi.org/10.3390/lubricants3040664.
[5] Nečas D, Vrbka M, Marian M, Rothammer B, Tremmel S, Wartzack S, et al. Towards the understanding of lubrication mechanisms in total knee replacements – Part I: Experimental investigations. Tribol Int 2021;156:106874. https://doi.org/10.1016/j.triboint.2021.106874.
[6] de Vries EG, van Minnen BS, Wu Y, Matthews DTA, van der Heide E. Tribological behaviour of a synthetic synovial fluid and polyurethane in biomedical implants. Biotribology 2023;33–34:100242. https://doi.org/10.1016/j.biotri.2023.100242.
[7] Schubert R, Zietz C, Bergschmidt P, Fabry C, Bader R. Wear Simulator Study Of Malaligned TiN-Coated Versus Uncoated Metallic Femoral Components Of A Bicondylar Knee Endoprosthesis. vol. EFORT14-1388, UK, London: 2014.
[8] Wimmer MA, Andriacchi TP, Natarajan RN, Loos J, Karlhuber M, Petermann J, et al. A striated pattern of wear in ultrahigh-molecular-weight polyethylene components of Miller-Galante total knee arthroplasty. J Arthroplasty 1998;13:8–16. https://doi.org/10.1016/S0883-5403(98)90069-9.
[9] Marian M, Orgeldinger C, Rothammer B, Nečas D, Vrbka M, Křupka I, et al. Towards the understanding of lubrication mechanisms in total knee replacements – Part II: Numerical modeling. Tribol Int 2021;156:106809. https://doi.org/10.1016/j.triboint.2020.106809.
[10] Kobayashi K. Summary of recombinant human serum albumin development. Biologicals 2006;34:55–9. https://doi.org/10.1016/j.biologicals.2005.08.021.
[11] Sijmons PC, Dekker BMM, Schrammeijer B, Verwoerd TC, van den Elzen PJM, Hoekema A. Production of Correctly Processed Human Serum Albumin in Transgenic Plants. Bio/Technology 1990;8:217–21. https://doi.org/10.1038/nbt0390-217.

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