WEAR TESTING OF TOTAL HIP JOINTS ACCORDING TO ISO AND DEVELOPMENT OF A NEW HIP JOINT SIMULATOR ACCORDING TO ISO

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INTRODUCTION
The development of new, highly sophisticated materials for the articulating surfaces of total hip endoprostheses has led to an increasing demand for testing and verification. This includes tests and research regarding bio-compatibility, static load bearing capacity of the prostheses as well as tribological investigations. Since it has been found that wear debris play a dominant role in the osteolytic loosening of implants, wear testing becomes especially important with new materials being developed to prolong the service life of an endoprostheses. The wear resistance of materials utilized for endoprostheses has been tested by the use of wear simulators for decades at laboratories throughout the world [1].

As a consequence of widely diverging test methods being in use, the technical committee TC150 'Implants for Surgery' of the ISO (International Organization for Standardization) has aimed to develop an International Standard, ISO/FDIS 14242: Implants for surgery - wear of total hip joint prostheses on the basis of kinematics and kinetic data from gait-analysis and a method of assessment of wear. This new standard will constitute a base for the comparability of scientific data resulting from tribological testing of total hip endoprostheses. The first experiences with the newly developed hip simulator E-SIM using common material pairings in total hip arthroplasty give promising results both in the characteristics of wear and the amount of removed material. A inter-laboratory validation of wear simulation with the E-SIM Hip Simulator is currently performed.

SETUP AND MEASUREMENT
The specimen are to be mounted in an upright physiological position with an inclination angle of 45° and submerged to a lubrication fluid (25 % calf serum and 75 % deionized water) during the test. The fluid is to be replaced every 500,000 cycles and wear measurement either gravimetric or with the dimensional method is to be carried out subsequently. The displacement and load cycles are repeated with a frequency of 1 Hz for a total duration of 5*10^6 cycles. Gravimetric measurement determines the volume of the removed material from the articulating zones by dividing the weight loss with the density of the material. The dimensional method uses co-ordinate measuring machines (CMM) to evaluate the amount of material removed from the surface.

DISPLACEMENT AND LOAD
The displacement curves published in the standard describe a three axial relative movement between the two articulating surfaces (the femoral ball head and the acetabular cup) and the forces applied. The movement angles stated are based upon the recommendation of the ISB [2] using an orthogonal co-ordinate system with a rotation order flexion/extension (FE) before inward-outward rotation (IOR) before adduction/abduction (AA). The ISO/FDIS 14242-1 sets the direction of the load into the vertical axis of the acetabular component (and fixes it there). The temporal amount of the load follows a double peak "Paul-curve" [3].

MECHANICAL SETUP
The newly developed hip simulator, E-SIM, is a single-station simulator that can be integrated modularly to a maximum number of 12 individual test stations, all directed by a single control Personal Computer (PC). The center of the femoral ball head stays in the point of cross-section of the three rotational axes of the simulator throughout the test. The femoral device centers in the u-shaped bow, which conducts adduction/abduction. The bow itself is attached to disk-like ring applying flexion/extension with the FE-axis horizontally to the fundamentals of the simulator. The AA-axis is perpendicular to the FE-axis and oscillates with the FE-motion around it (fig. 1). The inward/outward rotation is introduced by the acetabular component vertically to the base line of the simulator. The motion is applied through heavy-duty, wear-resistant, linear motors (two-phase synchronous motors with permanent magnet-excitation). The load is supplied pneumatically by a proportional pressure regulating valve using piezo-technique driving a membrane cylinder that submits the load without moment to the acetabular component. The test specimen can be subjected to a maximum load of 5 kN. The simulator is equipped with all necessary sensor controls to guarantee a continuous monitoring of the wear simulation. A special software developed for the E-SIM Hip Simulator allows integration into a local area network (LAN) or to the internet.

REFERENCES