

## Serum protein content used for simulator tests

The current versions of ISO 14242-1: 2002-03 (Hip simulator) and ISO 14243-1: 2002-03 (Knee simulator) recommend a dilution of the serum to 25% as well as a protein content not less than 17 g/l.

Following this straight forward process, the protein level used for the tests will depend on the initial protein concentration of the serum. It therefore seems to be appropriate to define the protein content rather than defining the dilution.

According to data given by Dumbleton [1], the in-vivo protein content ranges between 20 and 40 g/l. Noordin [2] determined the protein content of synovial fluid taken from patients with prosthetic joint arthroplasty to be 27.9 g/l (mean) within a range of 21 to 43 g/l.

The impact of the protein concentration on the wear of total joint replacements has been determined by Wang [3] as well as by Clark [4] and others. Testing metal hip balls against polyethylene cups did result in low wear rates at low and high protein concentrations. The wear maximum has been found to be within the physiological range of the synovia fluid.

Summarizing the data given by different researchers, it can be concluded that:

**The physiological protein level is about 30 g/l**  
**The maximum wear will be measured at about 30 g/l**

It has to be noted that wear will be influenced by multiple parameters, like the serum composition, the amount of serum within the test chamber, the serum temperature and others. Up to now, there is very little knowledge about impact of the parameters mentioned above.

Based on the investigations described herein, EndoLab decided in 2000 to run all wear tests at a defined protein level of 30 g/l. Nevertheless this will contradict the procedure defined by the ISO standards (both of them being currently under revision) and requires approval by the customer.

### Literature:

1. Dumbleton JH. Tribology of natural and artificial joints. London: Elsevier, 1981.
2. Noordin S, Schmalzried TP, Campbell P, Amstutz HC: Synovial fluid from patients with prosthetic joint arthroplasty: Protein concentration and in-vivo wear of polyethylene. 43 ORS, San Francisco, CA.
3. Wang A, Essner A, Polineni K, Startk C, Dumbleton JH: Lubrication and wear of ultrahigh molecular weight polyethylene in total joint replacements. Tribology International, Vol 31, pp 17-33, 1998.
4. Clarke IC: Wear studies of ceramic on poly. Alternative bearing surfaces in total joint replacement. Philadelphia, Pennsylvania, 2000.