ISO 18192-2: Notes from the Tianjin ISO meeting – open issues.

30-Jan-08

1. Scope

I. The WG has proposed to reduce the scope of this ISO to fatigue testing only. This would solve some of the problems of the test for example how to distinguish between particles generated by the nucleus and the artificial annulus. Wear testing could be done using a less complex method such as Taber Abrasor testing.
My statement: This would be an attractive option to solve some of the real problems of this test. Nevertheless I refuse to abandon the "perfect solution" at this time point. Let's work on this problem a little bit more. We can reduce the scope at CD stage.

5.1 Fluid test medium

II. The WG has proposed to replace "calf" serum by "bovine".
My statement: We have seen some problems in hip simulator tests when using bovine serum. This might be related to certain material combinations and/or serum suppliers. To stay consistent with the other wear tests (ISO 14242-1, ISO 14243-2 and ISO 18192-1) I would prefer to keep it "calf" serum.

6.1 Simulated annulus

III. The WG is afraid that we are testing the annulus and not the implant. Can we avoid the annulus?
My statement: I completely agree. The development of the annulus has been pretty cost intensive and time consuming so far and unfortunately still a work in progress. I also would prefer spending this money on lets say a Mediterranean beach than on silicone materials.
My concern about testing without the annulus is that most of the nucleus devices do neither have a sufficient shear stiffness nor compression stiffness. We therefore would be forced to run this test in deflection control mode. Doing so would require an additional test in order to measure the in-vivo behaviour of the nucleus-annulus system followed by the "real" fatigue/wear test as well as continuously recording the stiffness of the implant.
Again, we might use this as an option if we do not succeed in setting up an annulus.

IV. The annulus material and dimensions should be fully specified by the standard.
My statement: Yes. This will be done as soon as we have a final solution

V. The region of the spine covered (cervical and lumbar) needs to be included in the standard.
My statement: Yes. I will generate a proposal a soon as we know the final details of the annulus.

VI. The mechanism for connecting the annulus to the test mechanism needs to be specified.
My statement: Yes. We already figured out a nice method using a Velcro strip for

fixation of the annulus silicone. I will describe this in detail as soon as the final annulus model works.

VII. The WG requests the Project Team consider a Taber test for wear simulation (separate from a fatigue test) The Taber test is specified in both ISO and ASTM standards.
My statement: Yes. We can do this if it really becomes necessary.

6.3 Lubrication system

VIII. The WG request the project team to consider if this is clinically relevant and to provide a rationale for the requirement.
My statement: I believe that this is a copy past error from part 1 of ISO 18192. For sure the annulus should be sealed to prevent contamination but do we really trust in hydrostatic test conditions for the nucleus device? Any ideas from the experts?