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Investigation into the Lubrication Regime for Lumbar Total Disc Replacement of the Spine

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Abstract: - The lubrication regime of articulating surfaces plays an important role for the understanding of the tribological conditions and the resulting wear performance of total disc replacement (TDR) of the spine.
In the present study the lubrication regime for lumbar TDRs with ball and socket design have been assessed by applying the Hamrock-Dawson elasto-hydrodynamic lubrication theory. The effect of varying articulation *radii* and different material combinations on the lubrication regime have been investigated considering load and motion cycles for a representative *in vivo* situation as well as for *in vitro* wear testing situations.
Independent of geometry or bearing material combinations, the formation of a stable lubrication film is very unlikely for lumbar TDR. The study also reveals that *in vitro* testing conditions must be carefully selected in order to correlate with the lubrication regime for corresponding *in vivo* situations.

Keywords: *ball-in-socket joint, elasto-hydrodynamic lubrication, load and motion cycle, lumbar total disc replacement, spine, biotribology*.

I. INTRODUCTION

Spinal fusion is the gold standard for treating degenerative conditions of the aging spine by encouraging adjacent vertebra to grow together. Since the development of the SB Charité I artificial disc in the early 1980ies [1], total disc replacement (TDR) has evolved as a promising alternative to spinal fusion. Its aim is to preserve spinal motion at the treated levels, and possibly to reduce adjacent-level degeneration [2,3].

During the last 15 years a variety of lumbar TDR designs have been developed and introduced for clinical use [4]. The majority of the current approaches to arthroplasty in the lumbar spine use principles similar to those used in hip arthroplasty with spherical shaped articulating surfaces. The material combinations used include UHMWPE, CoCrMo alloys, and high performance ceramics to mention the most common.

TDRs must resist harsh operating conditions over their entire service life: The corrosive environment, high mechanical stress, and cyclic loading must be considered when developing and validating new implant designs. Besides the geometrical factors and the material selection for articulating implant surfaces, the type of lubrication regime is an important element for the understanding of the tribological conditions and the resulting wear mechanisms for artificial joints.

Analogous to published work for artificial hips [5], or wrist implants [6] the lubrication regimes for lumbar TDRs with ball and socket design have been estimated in previous studies [7, 8]. In [9] the lubrication regime for cervical TDR was analyzed. All these studies applied the Hamrock-Dawson elasto-hydrodynamic lubrication theory in order to calculate the lubrication film thickness for different material combinations. However, these studies are of limited practical relevance as they do not consider the kinematics and the load conditions for typical daily activities in an *in vivo* situation.

The aim of this study is to close this gap by considering the kinematics and loads in the lumbar spine for a typical daily activity. Based on this information the likely lubrication regimes for lumbar TDRs with different bearing material combinations are calculated. In addition these lubrication regimes are compared with the expected lubrication regimes during *in vitro* wear testing of lumbar TDRs as proposed by the ISO 18192 standard. This is of high importance as *in vitro* testing shall mimic the tribological conditions of an *in vivo* situation.

II. METHODS

2.1. Lubrication model

For the calculation of the lubrication regime a lumbar TDR with a ball and socket design was considered. For the calculation of the minimum lubrication thickness h_{min} the Hamrock-Dawson elasto-hydrodynamic lubrication theory was applied, assuming circular contacts between the articulating surfaces (1). For further details refer to *e.g.* [7] or [10].

$$\frac{h_{\min}}{r'} = 2.80\left(\frac{\eta\, u}{E'r'}\right)^{0.65}\left(\frac{F}{E'r'^2}\right)^{-0.21} \tag{1}$$

In (1) F denotes the axial force and η the lubricant's viscosity. As discussed in [7] the lubricant in a TDR is assumed to be interstitial fluid with a viscosity η of 1.24mPas which is approximately 8 times less viscous compared to the synovial fluid of a diarthrosis. In the case of *in vitro* wear tests of TDRs the viscosity of the test medium containing 20% bovine serum is 1.0mPas [11]. Fortunately this is very close to the viscosity assumed for interstitial fluid for the in vivo case. Please note that in both cases (*in vivo* & *in vitro*) the fluid was assumed to be Newtonian and possible shear thinning effects were neglected.

According to [7] the entraining velocity u in equation (1) is calculated according to (2), where ω stands for the angular velocity and r_1.denotes the *radius* of the ball.

$$u = \frac{\omega\, r_1}{2} \tag{2}$$

E' in (1) denotes the equivalent elastic *modulus* which is determined according to (3), with the Young's *moduli* E_1 (ball material) and E_2 (socket material) and the respective Poisson's ratios ν_1 and ν_2. The equivalent *radius* r' is calculated using (4) where r_1 is the ball *radius*, r_2 the socket *radius*, and c_{radial} the radial clearance ($c_{radial} = r_1 - r_2$).

$$E' = \frac{2E_1E_2}{E_2\left(1-\nu_1^2\right)+E_1\left(1-\nu_2^2\right)} \tag{3}$$

$$r' = \frac{r_1 r_2}{r_2 - r_1} = \frac{r_1}{c_{radial}}\left(r_1 + c_{radial}\right) \tag{4}$$

By comparing the minimum film thickness h_{min} with the compound surface roughness $R_{a,c}$ the resulting λ-values were obtained using (5) where $R_{a,1}$ and $R_{a,2}$ denote the surface roughness of the articulating surfaces.

$$\lambda = \frac{h_{\min}}{R_{a,c}} \text{ with } R_{a,c} = \sqrt{R_{a,1}^2 + R_{a,2}^2} \tag{5}$$

Table 1: Parameters for different bearing materials

Material	E-*modulus*	Poisson's ratio	Surface roughness
CoCrMo	241GPa	0.3	0.01μm
UHMWPE	0.58GPa	0.46	0.75μm
Ceramic[1]	358GPa	0.22	0.005μm
PEEK	3.5GPa	0.4	0.25μm

[1] *Biolox Delta®, Ceramtec, Germany*

Table 2: Radial clearance for different bearing material combinations

Material combination	Radial clearance c_{radial}	Reference
UHMWPE-on-CoCrMo	100μm	[7,13,14]
CoCrMo-on-CoCrMo	30μm	[13,15]
Ceramic-on-Ceramic[1]	30μm	[13]
PEEK-on-PEEK	100μm	[16]

[1] *Biolox Delta®, Ceramtec, Germany*

The obtained λ-values allowed for prediction of the likely lubrication regimes for different configurations as expressed in the Stribeck-curve [12]. Accordingly for $\lambda > 3$ a hydrodynamic lubrication regime is expected. $\lambda < 1$ stands for boundary lubrication, and λ between 1 and 3 signifies mixed lubrication. From (1), (4), & (5) it follows that for a given bearing material combination fluid-film lubrication is encouraged by making the ball as large as practicably possible, the radial clearance as small as possible, and the bearing surface as smooth as possible.

2.2. Characteristics of bearing materials

For this study several bearing material combinations were considered. The selection was based on two factors:

(a) material combinations which are in clinical use for TDR (UHMWPE-on-CoCrMo, CoCrMo-on-CoCrMo)
(b) material combinations which have an investigational status for TDR (PEEK-on-PEEK, Ceramic-on-Ceramic).

The various input parameters needed for the lubrication model like E-*modulus*, Poisson's ratio, and typical surface roughness for the different materials are summarized in Table 1. Similar to THR, clearance values for TDR vary for different bearing material combinations. Typical values for the radial clearance c_{radial} are listed in Table 2.

2.3. Load and motion cycle (*in vivo*)

2.3.1. Range of motion (ROM)

While for hip joints there is consent on the ROM and loads during the gait cycle (ISO 14242-1 2012), a representative load and motion cycle for the lumbar spine is not readily available. In order to define such a load and motion cycle the scientific literature on kinematics and loading of the lumbar spine was consulted.

For the kinematics the full active ROM of the lumbar spine and the ROM of the individual lumbar segments was assessed by referring to various studies published in literature (*e.g.* [17]-[21]). In these studies the obtained values for the full active lumbar ROM ranged from 42° to 67° for flexion (forward bending of the spine) and from 12° to 29° for extension (bending the spine backwards). The ROM values depended on gender [18], age [18,20], and lumbar level [17,20]. A typical value for the full active ROM of a single lumbar segmentl was 12° in flexion and 5° in extension [17,20]. According to the findings in [21] the full active ROM was found to be much larger than the ROM for typical daily activities and even larger than activities with significant motion of the spine like *e.g.* changing from standing to sitting, squatting or picking up an object. Following the investigation in [21] and considering the data for bending forward (flexion maneuver), the ROM for a single lumbar segment representing a motion profile for a typical activity like picking up an object from the floor was set to 0° at the start of the flexion maneuver and to 11° for the flexed posture.

Table 3: Summary of *in vivo* intradiscal pressure measurements for selected postures, number in brackets represent standard deviations.

Reference:	**Nachemson [22]**	**Wilke et al [23]**	**Sato et al [24]**	**Polga et al [25]**
Laying (prone/supine)	250N	0.11MPa	0.09(0.03)MPa	0.2(0.03)MPa
Standing upright	500N	0.5MPa	0.53(0.18)MPa	0.86(0.06)MPa
Standing flexed	1000N[2]	1.1MPa[3]	1.32(0.22)MPa[3]	1.09(0.05)MPa[4]
Mean body weight	70kg	70	73	73
No. of participants	1	1	28	6
Conversion factor	-	897N/MPa	833N/MPa	530N/MPa

[1] values for lower thoracic levels (T9 to T12); [2] bent forward 40°, [3] angle of inclination during bending forward not indicated, [4] bent forward 30°.

Table 4: Force values for standing upright and standing flexed, derived from of *in vivo* intradiscal pressure measurements.

Reference:	**Nachemson [22]**	**Wilke et al [23]**	**Sato et al [24]**	**Polga et al [25]**	**Mean value**
Standing upright	500N	449N	442N	456N	446N
Standing flexed	1000N	987N	1100N	578N	1007N

2.3.2. Load cycle

For defining the load of the lumbar spine in a significant maneuver like bending forward, the literature on *in vivo* intradiscal pressure measurements was consulted (see [22]-[25]). In Table 3 the measured *in vivo* intradiscal pressures for relevant postures (laying, standing, standing flexed) are listed. In addition for each study the number of participants and the mean body weight are summarized. In a first approximation the difference in pressure between standing relaxed and laying must be due to the gravity of the upper trunk including arms and head. For a person of 70 to 73 kg the acting gravity was estimated to 350 N. Considering the pressure difference between laying and standing relaxed and using the value for the acting gravity, the factor to convert pressure into force was estimated for each study (see Table 3). These conversion factors were used to transform the measured pressure values to force values. The force values of each study were weighted with the participants number in order to calculate a mean value for the force for standing upright and for standing flexed postures (Table 4).

Information on load levels for different postures is not sufficient. More importantly the time dependent progression of the loads and the resulting angular velocity during the flexion maneuver must be considered. In [26] Rohlmann et al. have reported measurements of *in vivo* loads with a telemeterized vertebral body replacement (VBR) during a flexion maneuver (refer to Fig. 1, measured data). As the affected spinal segments were additionally stabilized with a posterior pedicle screw based rod system, the measured magnitude of loads from [26] were not considered representative for our purpose. This is because only a part of the load was born by the VBR device. However the progression of loads with time and the relative change of the loads during the flexion maneuver were considered to be relevant. Based on the information on the loads from *in vivo* intradiscal pressure measurements from Table 4, the load profile from [26] was corrected by a linear factor as shown in Fig. 1.

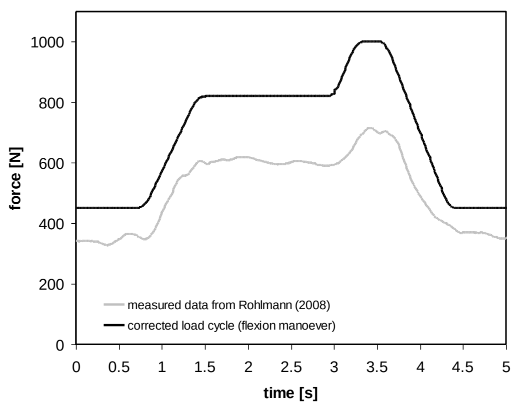

Figure 1: In vivo load cycle for flexion manoever according to Rohlmann [26] and corrected load profile to mean load values from Table 4.

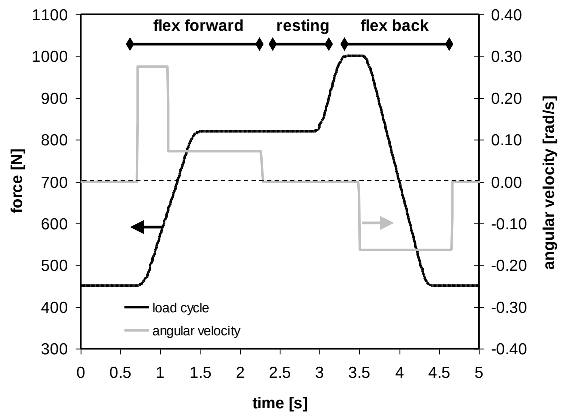

Figure 2: Proposed load and motion profile for the lumbar spine for flexing forward

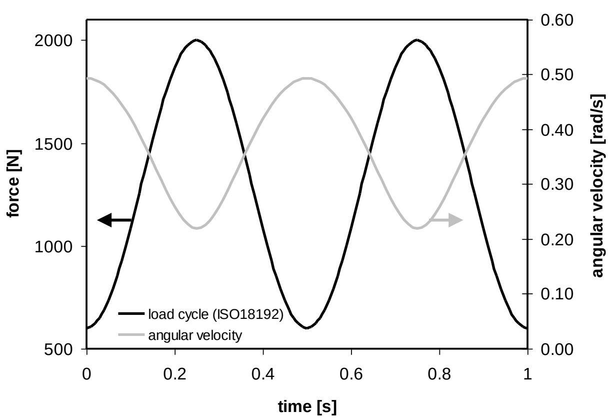

Figure 3: Load and motion profile for in vitro testing of lumbar TDRs at 1Hz, following the ISO 18192 standard.

2.3.3. Angular velocity

In the experiments performed by Rohlmann et al. [26] the test person stood relaxed for approximately 0.7s, then flexed their upper body forward as far as possible (up to 2.3s), stayed in this position until about 3.3s, flexed back (up to 4.7s), and stood relaxed again. This information was used to estimate the angular velocity of a single lumbar segment throughout the flexion maneuver by considering a maximum segmental flexion angle of 11° as described above. The data for the loads and for the angular velocity as a function of time over the entire flexion maneuver are illustrated in Figure 2.

2.4. Load and motion cycle (*in vitro* wear testing)

In vitro wear tests should mimic the wear conditions of TDRs in an *in vivo* situation. It is therefore relevant that the lubrication regimes for *in vitro* wear testing and for an *in vivo* load situation match. *In vitro* wear testing of lumbar TDRs is usually performed by applying one of the test protocols as described either in ISO 18192-1 (2011) or ASTM F2423 (2011) standards. In this study the lubrication regime has been assessed exemplarily for the standard load and displacement profile for lumbar total disc replacements of the ISO standard test protocol. For the calculation of the angular velocity the sliding distance per time increment was calculated for test frequencies of 1Hz and 2Hz following the method described by Paré [27]. The sliding velocity was calculated for various positions on the bearing ball. It was found that for the pole of the ball the sliding velocity was largest. Based on this finding the pole position of the bearing ball was taken as the reference point for subsequent assessments as it represents the position with the largest sliding velocity or entraining velocity respectively. The resulting load and angular velocity profiles throughout a wear test cycle are shown exemplarily for 1Hz in Fig. 3.

III. RESULTS

3.1. *In vivo* wear situation

Considering equation (1) and the input parameters for different bearing materials from Tables 1 & 2 the minimum lubrication thickness h_{min} and the resulting λ-values were calculated over the entire load and motion cycle representing a flexion maneuver as shown in Fig. 2. In Fig. 4 the calculated λ-values for different bearing material combinations (ball *radius* r_1 of 16.5mm which is typical for lumbar TDR) are shown.

The largest λ–values are found for an all ceramic bearing followed by the CoCrMo-on-CoCrMo set-up. PEEK-on-PEEK and the classical UHMWPE-on-CoCrMo lead to drastically reduced λ-values. In all cases the calculated λ-values are considerably smaller than unity which is the limiting value below which - following the applied model - a boundary lubrication regime is predicted. In addition to the different material combinations of the bearings, the influence of different ball *radii* on the λ-values was assessed.

Respective results are shown in Fig. 5 exemplarily for a CoCrMo-on-CoCrMo pairing. As expected from equation (1), a reduction of the ball *radius* resulted in a reduced λ-value and *vice versa*. Notably, the effect of different bearing materials on the λ-value seemed to be much more pronounced than the influence of the ball *radius*.

3.2. *In vitro* wear situation

The calculated λ-values for the motion profile of the *in vitro* wear testing set-up are shown in Fig. 6 (1Hz) and Fig. 7 (2Hz). Again the same four bearing material pairings were considered and the ball *radius* was set to 16.5mm.

The ranking order remained the same as in the *in vivo* case with largest λ-values for Ceramic-on-Ceramic and smallest λ-values for UHMWPE-on-CoCrMo. However, in the case of 1Hz test frequency the λ-values for the Ceramic-on-Ceramic bearing lay between 0.65 and 1.43 indicating a mixed lubrication regime through a considerable part of the wear cycle. At 2Hz test frequency the λ-values were between 1.04 and 2.23 for the same material pairing and between 0.61 and 1.30 for CoCrMo-on-CoCrMo thus indicating mainly mixed lubrication. For UHMWPE-on-CoCrMo and PEEK-on-PEEK bearings the model predicted boundary lubrication for both test frequencies as λ-values were well below unity in both cases (see Table 5 for details).

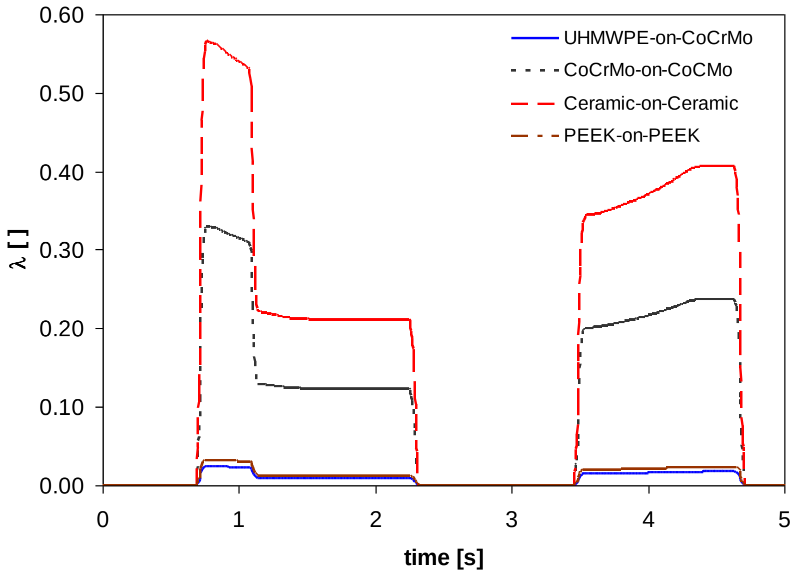

***Figure 4:** λ-values as calculated with the Hamrock-Dawson equation for picking up an object and considering the load and motion cycle as shown in Fig. 2, comparison of different bearing material combinations for an articulation radius of 16.5mm.*

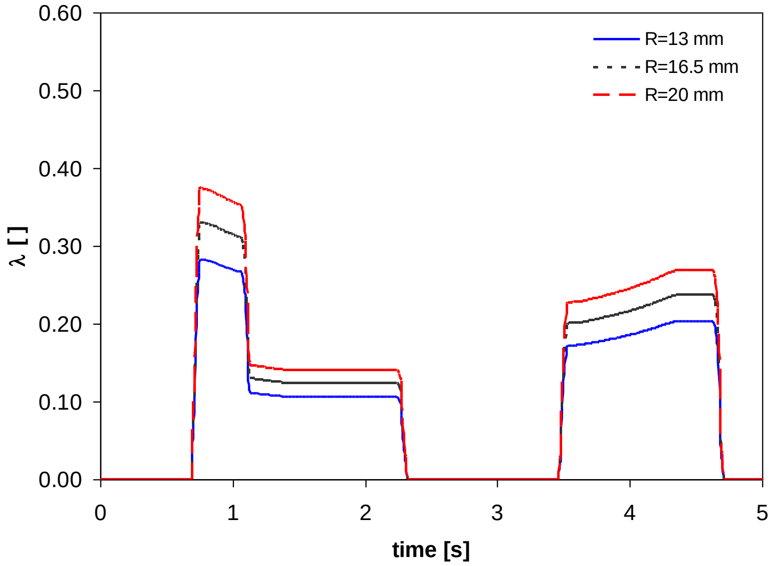

***Figure 5:** λ-values for picking up an object and considering the load and motion cycle as shown in Fig. 2, influence of articulation radii, CoCrMo-on-CoCrMo.*

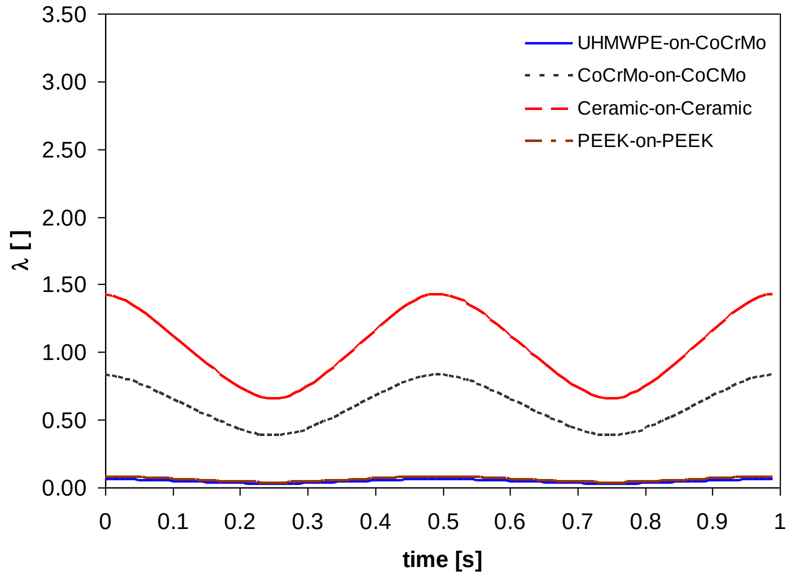

Figure 6: λ-values for in vitro testing following ISO 18192 Standard, lumbar test protocol, comparison of different bearing material combination for an articulation radius of 16.5mm, 1Hz test frequency.

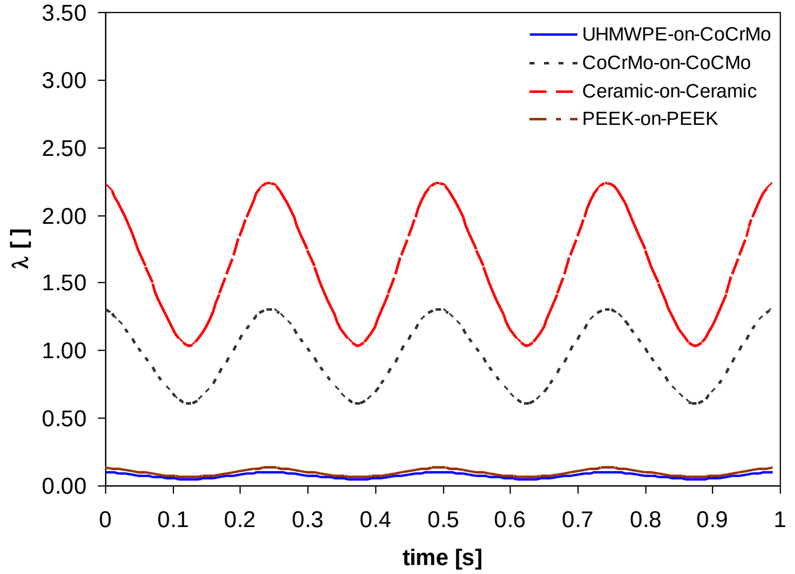

Figure 7: λ-values for in vitro testing following ISO 18192 Standard, lumbar test protocol, comparison of different bearing material combinations for an articulation radius of 16.5mm, 2Hz test frequency.

Table 5: Summary of λ-values and lubrication regimes for an articulating *radius* of 16.5mm and different material combinations of the bearing

Material pairing:	***In vivo***		***In vitro***	
	λ-value range	**lubrication regime**	**λ-value range**	**lubrication regime**
UHMWPE-on-CoCrMo	0.21-0.56	boundary lubrication	1.41-2.23	mixed lubrication
CoCrMo-on-CoCrMo	0.12-0.32	boundary lubrication	0.61-1.30	boundary/mixed lubrication
Ceramic-on-Ceramic[1]	0.01-0.03	boundary lubrication	0.06-0.13	boundary lubrication
PEEK-on-PEEK	0.01-0.02	boundary lubrication	0.05-0.10	boundary lubrication

[1] Biolox Delta®, Ceramtec, Germany

IV. DISCUSSION

In this paper the likely lubrication regimes for lumbar TDRs for a representative *in vivo* situation as well as for an *in vitro* wear testing situation have been investigated. While for total hip replacement a standard gait cycle has been defined, no such standard load and motion cycle was readily available for lumbar TDRs. Therefore, a representative load and motion cycle has been defined based on existing literature on kinematics and loads for the lumbar spine. For the subsequent analysis the Hamrock-Dawson equation has been considered and four different bearing material combinations as well as three different articulating *radii* have been assessed.

For the *in vivo* situation bending forward (= flexion movement) was chosen as a representative model case for the following reasons: Bending forward involves a comparably high load as well as a significant ROM of the lumbar spine and represents a maneuver with significant angular velocity. In addition this maneuver is a standard situation for spinal motion for which sufficient information is available from literature.

The calculated angular velocities for this model case were a factor of 6 to 7 lower than the expected angular velocities during the gait cycle of the hip (refer *e.g.* to [28] & [29]). Consequently, in the case of lumbar TDR the resulting minimum lubrication thickness h_{min} and the corresponding λ-values are comparatively small, indicating a boundary lubrication regime for all assessed bearing material combinations. This result signifies that *in vivo* any lubrication regime other than boundary lubrication is very unlikely for lumbar TDR. This finding is irrespective of articulating *radii* (investigated range between13 and 20mm) or bearing material combinations and contrasts with the situation for total hip replacement where in specific cases mixed lubrication or fluid film lubrication are assumed [29].

In contrast to the *in vivo* case the assessment for the *in vitro* situation leads to a different result. For all material combinations and at a test frequency of 1Hz the λ-values are by a factor of 2.5 larger than for the corresponding *in vivo* assessment. In all cases boundary lubrication is predicted by the model except for a ceramic-on-ceramic bearing for which - at least in part - mixed lubrication is predicted. If the testing frequency is doubled, a mixed lubrication is predicted in the case of a ceramic-on-ceramic bearing and a combination of boundary and mixed lubrication is found for a CoCrMo-on-CoCrMo bearing.

V. CONCLUSION

By applying the Hamrock-Dawson elasto-hydrodynamic lubrication theory to a lumbar TDR set-up and by considering a load and motion profile which is representative for an *in vivo* situation it was shown in this study that the formation of a lubrication film was very unlikely. On the contrary, the lubrication was shown to be mainly governed by boundary lubrication for which the articulating surfaces are assumed to be in close contact.

As the lubrication regime may dramatically influence the wear behavior of an artificial joint and as the *in vitro* wear is intended to mimic the *in vivo* wear situation, the lubrication regimes for both the *in vivo* and the *in vivo* situations were compared. The observed differences between the two in terms of λ-values and lubrication regimes must be carefully considered when choosing the parameters for wear testing of lumbar TDR.

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