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The occurrence of squeaking under wear testing standards for ceramic on ceramic total hip replacements

Oscar O'Dwyer Lancaster-Jones [a,*], Rebecca Reddiough [b]

[a] DePuy International Ltd, Leeds, West Yorkshire, UK
[b] Cardiff University, UK

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ABSTRACT

Ceramic on ceramic total hip replacement clinical reports may on occasion note a noise or squeaking. There is much debate on whether this is an actual concern, but some medical centres want to avoid any possible negative impact on the patients' wellbeing due to the noise generated.

The aim of this study was to determine what sound frequencies can be picked up from hip testing standards for ceramic on ceramic under different lubrication conditions. The ISO-14242-1 (35° cup angle) and ISO-14242-4 (55° cup angle with a 4 mm translational mismatch) standards were used for testing with dry, water and serum lubrication conditions up to 10000 cycles.

No sound was detected for water and serum conditions under standard walking (ISO-14242-1) testing. An audible noise with a frequency range of 0.4–0.8 kHz was picked up within 600 cycles under water and edge loading (ISO-14242-4) conditions. All dry testing produced a high pitch squeak when the frequency was higher than 2 kHz. One sample under dry edge loading conditions had an audible noise of 0.8 kHz, considered not as squeaking, as it was not high pitch. Dry testing for both, standard walking (ISO-14242-1) and edge loading (ISO-14242-4) conditions, which resulted in a high pitch noise, had a frequency range of 2–8 kHz and 5–9 kHz respectively. One sample tested with edge loading and serum produced a faint squeak noise after 6000 cycles with a frequency of 7 kHz.

Edge loading due to ISO-14242-4 conditions had an increased torque which may be playing a role in increased friction leading to noise. Edge loading conditions were more prone to the generation of audible noise and squeaking whilst under lubricated conditions.

1. Introduction

The current generation of ceramic on ceramic (CoC) hip joint replacements have addressed minimising the wear from the joint articulation (Stewart et al., 2003, Al-Hajjar et al., 2013) and increasing the fracture resistance (Kurtz et al., 2014). Clinical studies support the success of CoC with long term performance (Blumenfeld et al., 2022) and lower fracture rates (Massin et al., 2014). One area of debate is the ad-hoc reporting of squeaking or noise, leading in some cases to revision. There is no clinical literature on hip replacements with design features claiming to help reduce the incidence of squeaking for CoC.

Clinical reports of squeaking vary, with the highest occurrence reported at approx. 20% of cases (Keurentjes et al., 2008; Mai et al., 2010; Ki et al., 2011; McDonnell et al., 2013, Owen et al., 2014a). However, most of the reviews in the literature indicate low occurrences of less than 10% (Chevillotte et al., 2012; Owen et al., 2014b; Wu et al., 2016). The revision rate due to squeaking is 0.3% (Owen et al., 2014b), and generally, the revision of fractured ceramics with squeaking is also low (Toni et al., 2006; Dacheux et al., 2013; Abdel et al., 2014; Baruffaldi et al., 2019). There are however, cases of fractured ceramics with an audible noise that result in a higher revision rate (Traina et al., 2012). Some medical centres are moving away from CoC due to concerns over the possible negative impact of squeaking on the patient's wellbeing (Barrow et al., 2019).

Squeaking in CoC has been categorised as multifactorial as it may be related to impingement (Parvizi et al., 2011), stripe wear (Taylor et al., 2007) or edge loading (O'Dwyer Lancaster-Jones et al., 2017). In vitro testing for squeaking has yielded some results, but nothing conclusive that can be translated to directly impact or reduce the noise or squeak clinically. Mainly the testing for squeaking has been carried out without

* Corresponding author.
E-mail address: oodwyer@its.jnj.com (O. O'Dwyer Lancaster-Jones).

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lubrication (Chevillotte et al., 2010; Currier et al., 2010; Bishop et al., 2013; Fan et al., 2013).

The aim of this study was to determine the effect of dry and wet conditions on the occurrence of noise in ceramic on ceramic using current standards (ISO 14242–1, ISO 14242–4) for hip wear testing.

2. Method

Three CoC Biolox Delta bearings (DePuy Synthes, The Orthopaedic Company of JnJ) were used in total. These were mounted on fixtures using a potted titanium shell (PINNACLE, DePuy Synthes, The Orthopaedic Company of JnJ) for the acetabular liner and a stainless steel tapered spigot for the femoral head.

All samples were tested under an edge loading test with a 4 mm translational mismatch (ISO 14242–4:2018) first and followed by standard walking cycle (ISO 14242–1:2014), as in Table 1. Each sample was tested sequentially under three different lubricating conditions, these were dry, deionized water and 25% serum with a concentration of 17 g/l with added Sodium Azide and EDTA. Each sample was alternated to start with a different lubricating condition as per Table 1.

All samples were first tested under an edge loading test with a high inclination angle (55°) from the horizontal plane and then the cup fixture was tilted to a low inclination angle as per the ISO 14242–1:2014. The equipment used was a EM1 ProSim Hip Simulator where all the rotation are about the femoral component and the load is applied through the cup as per the ISO-14242–1:2014 standard and the loading measured with a six-axis loadcell. A 4 mm translational displacement was applied to the cup holder as per the ISO 14242–4:2018 and measured with an linear variable displacement transformer (LVDT). Tests had a 50 cycle loading ramp-up.

Each test ran up to when an audible noise was detected or up to a maximum of 10000 cycles. When noise was detected a Zoom H4n recorder with a RODE NTG-2 microphone was used to record the sound at a sampling rate of 44.1 kHz. The audio signals were analysed with MATLAB (MathWorks, USA) through an fast fourier transform (FFT) function. Audio files were re-played, compared to FFTs graphs and cross-referenced to the spectrogram graphs to identify the frequency of distinctive sounds.

3. Results

After running the CoC samples through the standard walking cycle (ISO 14242–1:2014) and edge loading test with a 4 mm translational mismatch (ISO 14242–4:2018), the frequencies and torques were evaluated for the different lubricating conditions. Some tests were stopped prior to completing the 10000 cycles, as an audible sound was heard (see Table 2).

Under a standard walking cycle with serum conditions, no noise was detected for all 3 samples. This condition was used as a baseline for background noise comparison of the frequencies when the equipment was running. The background noise had the following frequencies; a range from 0.0 to 0.6 kHz, 8 kHz and 16 kHz. For the purpose of comparison, these have been set to 0 kHz in Fig. 1. With water lubricating conditions, no audible noise was detected either. When tested dry, samples didn't have a distinct frequency. All samples produced a high pitch sound with frequencies in the 2–8 kHz range as shown in Fig. 1.

Under an edge loading test with a 4 mm translational mismatch with serum conditions, only one sample produced a faint audible noise after 6000 cycles with a frequency of 7 kHz, with no further noise up to 10000 cycles, while the other two samples had no audible noise detected up to 10000 cycles. With water lubricating conditions, all samples produced an audible noise, these frequencies were in the 0.4–0.8 kHz range (Fig. 1). When tested dry, high pitch sound was detected on samples with a frequency range of 5–9 kHz, and also an audible noise with a frequency of 0.8 kHz.

A sample characterisation of the frequency for all testing conditions can be seen in Fig. 2.

The torque output varied depending on the type of standard. Under a standard walking cycle with lubricated conditions (i.e. water and serum), low torques with a max of 5 Nm were measured. The effect of the 4 mm translation mismatch was detected on the Abduction/Adduction (AA) torque compared to the standard walking cycle for lubricated conditions, with water having approximately 45 Nm and serum approximately 30 Nm (Fig. 3).

Under unlubricated conditions (i.e. dry) large torques ranging from 20 to 45 Nm were measured for both the standard walking cycle and the edge loading under a 4 mm translational mismatch on the AA and Flexion/Extension (FE) rotational axis (Fig. 3).

Table 1
Sequence of testing conditions.

Sample #	Condition (ISO 14242–4)			Condition (ISO 14242–1)		
Sequence	1	2	3	4	5	6
#1	Dry	Water	Serum	Dry	Water	Serum
#2	Water	Serum	Dry	Water	Serum	Dry
#3	Serum	Dry	Water	Serum	Dry	Water

Table 2
Occurrence of noise from testing ceramic on ceramic for dry, water and serum lubrication conditions and following the ISO 14242–1 and ISO 14242-4 methodology.

Test	ISO 14242-1			ISO 14242-4		
Lubricating condition	Dry	Water	Serum	Dry	Water	Serum
Sound detected at/within	200 cycles	N/a	N/a	100 cycles	600 cycles	6000[a] cycles

[a] Only characteristic of one sample.

4. Discussion

In this study, two hip wear testing standards were investigated with different lubricating conditions on CoC to determine if an audible noise was present and to characterise the sound emitted by measuring the frequency. When tested with water and under edge loading (4 mm translational mismatch, ISO 14242–4), an audible noise was detected with a frequency of 0.6 (±0.2 CI) kHz. The standard walking cycle (ISO 14242–1) test with water and serum conditions did not produce an audible noise. When applying edge loading conditions and using serum as a lubricant, a low occurrence of a detectable but faint squeak of 7 kHz was found. For dry conditions, both testing standards produced either a high pitch squeak sound with frequencies in the range of 2–9 kHz or an audible noise at 0.8 kHz.

Previous studies have evaluated simple reciprocating dry conditions which have led to a noise due to the increased friction in CoC (Brockett et al., 2011; Hothan et al., 2011; Bishop et al., 2013). The dry conditions tested in this study indicated high friction, detected by the torques measured (approx. 30 Nm). The friction factor at a high torque of 30 Nm for our dry conditions would equate to 0.7. Normally CoC with serum conditions operate with a friction factor of approximately 0.04 under concentric friction testing conditions (Brockett et al., 2007). Lower torques were measured in our study under the standard walking cycle with water and serum (approx. 5 Nm) conditions, and this would equate to a lower friction. Our testing indicates the low torque conditions did not result in a detectable audible noise.

Interestingly, there was a torque difference of 15 Nm between the water and serum conditions under edge loading, where the water conditions measured a higher torque of approx. 45 Nm. A decrease in protein concentration has previously demonstrated to decrease the friction and when operating only with water conditions it further reduced the friction factor to 0.02 (Brockett et al., 2007). However, under edge

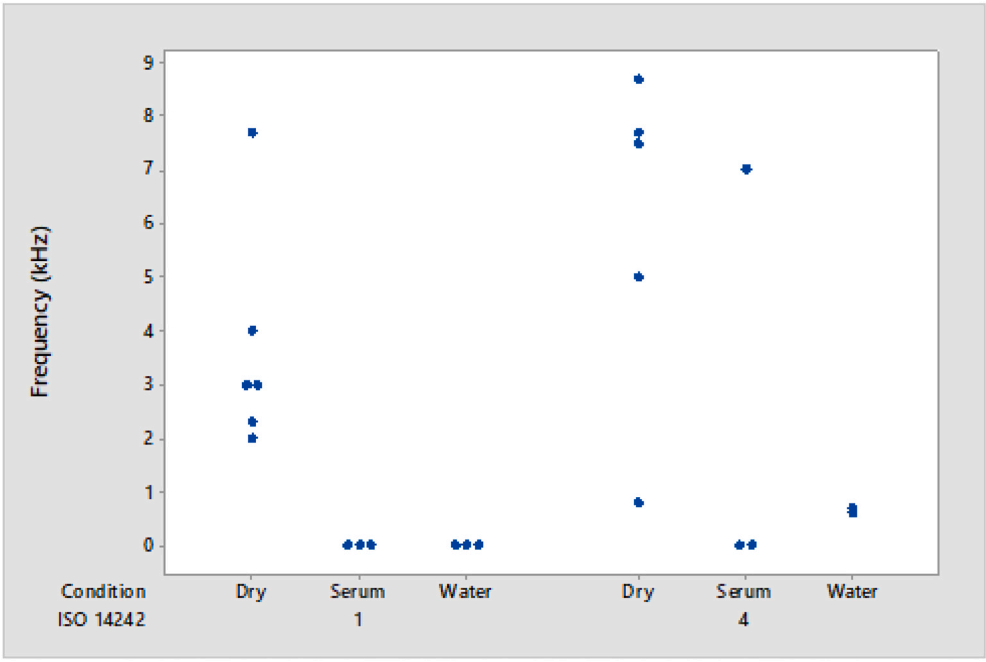

Fig. 1. Frequencies from testing ceramic on ceramic for dry, serum and water lubrication conditions and following the ISO 14242–1 (left) and ISO 14242–4 (right) methodology.

loading conditions, our testing with water in this instance has increased the friction relative to when testing with serum. To note there are differences in the contact geometries between bearing only and rim loading that can cause a different result. When considering non-bearing contact testing such edge loading, the difference in friction may be due to proteins which have impacted the contact conditions in ceramics and increased friction in water compared to serum compositions (Ma and Rainforth, 2012; Li et al., 2022). This increase in friction may be a factor resulting in an audible noise when testing CoC bearings.

All conditions under edge loading with a 4 mm translational mismatch resulted in the formation of a stripe wear on the head. The increase in surface roughness of the stripe wear on the head could be a contributing factor in the increase in friction and the noise generated. Chevillotte et al. (2010) tested CoC samples with stripe wear damage in serum lubricating conditions which did not result in audible noise. However, in our study, the edge loading conditions increase the contact stress (Liu et al., 2015) relative to standard walking conditions where the articulation only occurs within the bearing surface.

The squeaking phenomenon has been previously evaluated by assessing the friction of CoC. Some of the bearing factors evaluated include the clearances (Hothan et al., 2011), lubrication (Brockett et al., 2013), and contact region (Sariali et al., 2010; Bishop et al., 2013). These studies have informed us that squeaking occurs when the friction factor is > 0.2. However, squeaking has only been reproduced consistently in dry conditions (Affatato et al., 2009; Chevillotte et al., 2010; Hothan et al., 2011; Bishop et al., 2013; Fan et al., 2013). The current testing methodologies leading to squeaking need further development as dry testing conditions aren't ideal to determine factors of the ceramic bearing design that can help reduce the occurrence of squeaking since squeaking would occur for every condition when tested dry.

Squeaking clinically has been reported with frequencies generally averaged to 2 kHz (Piriou et al., 2016; Baruffaldi et al., 2019). Our study generated high pitch noises, which we define as squeaking, mostly under dry conditions with frequencies higher than 1 kHz (i.e. 2-9 kHz). Other in vitro studies reproducing squeaking tend to vary between 2 and 4 kHz (Piriou et al., 2016). There is a small tendency that in vitro testing has reproduced frequencies with a range of 1–3 kHz higher than those reported clinically (Piriou et al., 2016). However, we detected an audible noise (with lower frequency than 1 kHz) under lubricated conditions with water and edge loading which has not been reported in the literature previously. Water may not be clinically a relevant condition, but it is interesting that such a condition can arise and generate the lower frequency (0.6 kHz) audible noise.

This study used a very small sample size, but it was intended as an exploratory baseline study. Our small sample size limitation and short test duration may not capture an adequate sampling frequency of edge loading with serum or water conditions. Another limitation from our small sample is that the stripe wear which resulted from the edge loading conditions may have influenced the results of dry testing conditions under the standard walking, however dry testing leading to squeaking has been previously confirmed in the literature.

Squeaking is multifactorial and current studies struggle to identify a single primary cause. Some cases can be linked between the range of motion, elevated metal shell rims, acetabular positioning, short neck length and impingement leading to higher occurrences of squeaking (Ecker et al., 2008; Keurentjes et al., 2008; Parvizi et al., 2011; Sarrazin et al., 2022).

The previous in vitro studies have demonstrated how deprived lubrication conditions lead to squeaking. Our study is the first to demonstrate that audible noise can also occur in lubricated conditions due to edge loading. Adding further parameters and developing methods may help to identify further reasons for squeaking in vivo and could help to create a strategy to reduce its occurrence. Our baseline study is only a small step forward in reducing the multifactorial complexity of squeaking as current literature suggests that a simple solution is unlikely to be available within the CoC configuration. We think that a way forward to reproduce squeaking in a simulator under lubricated conditions is to disrupt the local fluid film with high loading conditions for a prolonged amount time.

5. Conclusion

Dry conditions under the current hip testing standards resulted in a range of frequencies between 1 and 9 kHz. High pitch noises were only identified with frequencies between 2 and 9 kHz. The occurrence of noise was hardly detectable (one out of three) under edge loading testing

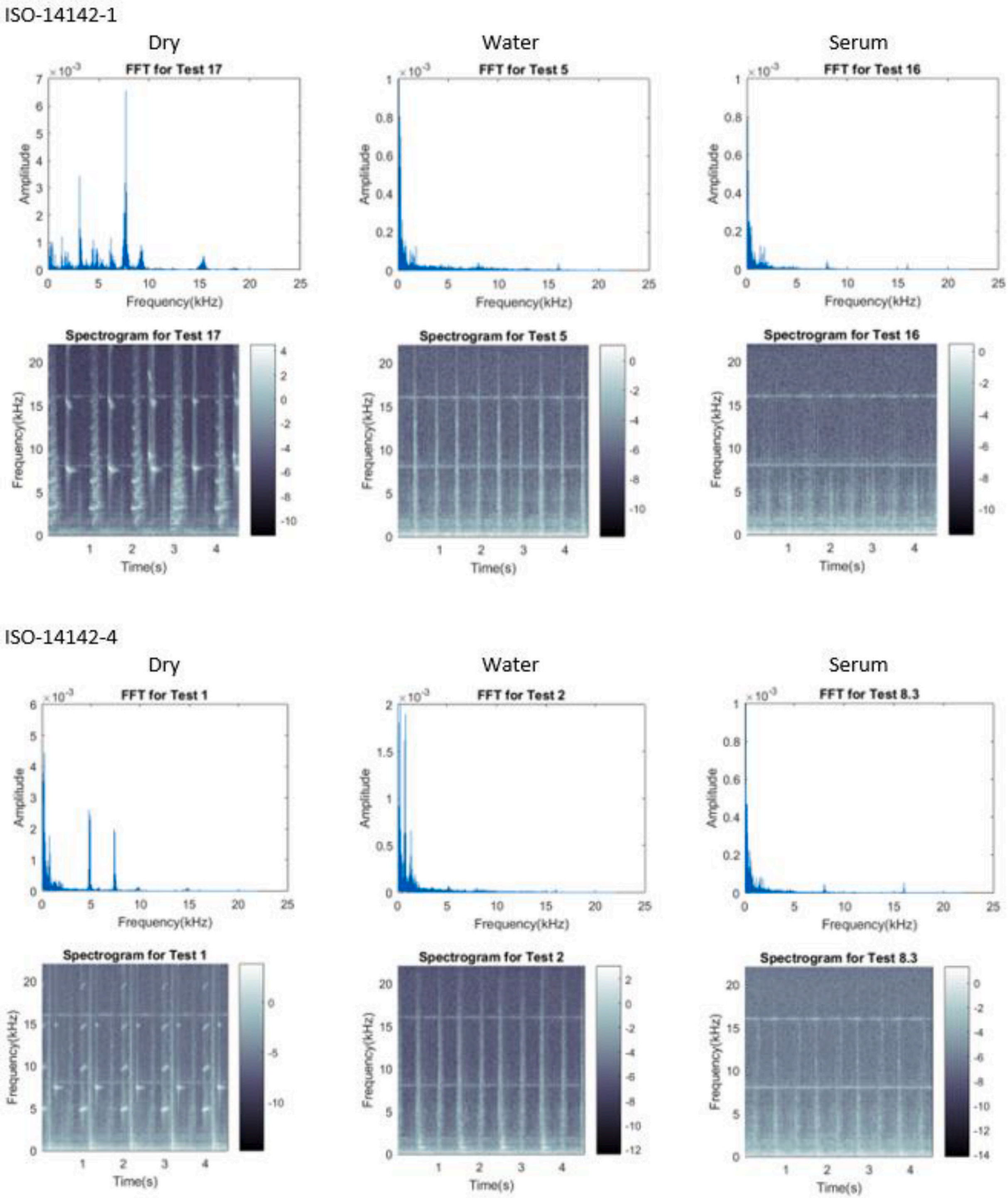

Fig. 2. FFT and spectrogram example for testing ceramic on ceramic for dry, water and serum lubrication conditions and following the ISO 14242–1 (top) and ISO 14242–4 (bottom) methodology.

conditions with serum for short test duration of fewer than 10000 cycles. However, lubrication conditions with water under increased torque due to edge loading produced an audible noise with a frequency of 0.6 kHz. This study has given us a direction on conditions that disrupt the lubrication to consistently reproduce audible noise under lubricated conditions.

CRediT authorship contribution statement

Oscar O'Dwyer Lancaster-Jones: Writing – review & editing, Writing – original draft, Supervision, Methodology, Formal analysis. **Rebecca Reddiough:** Investigation, Formal analysis, Data curation.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Oscar O'Dwyer Lancaster-Jones is a paid employee from DePuy Synthes JnJ.

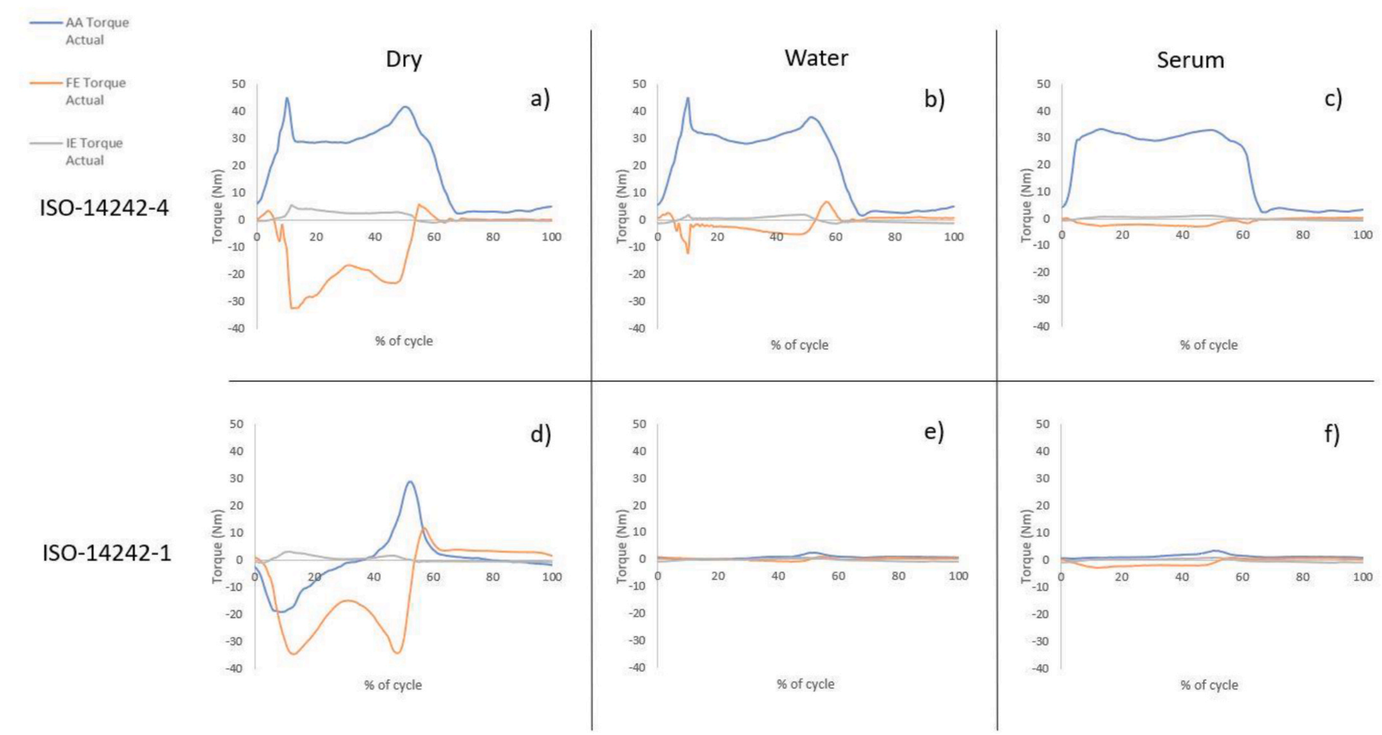

Fig. 3. Torque (AA – Abduction/Adduction, FE – Flexion/Extension, IE – Internal/External) measurements for edge loading (ISO 14242–4) for a) Dry b) Water and c) Serum, and standard walking (ISO 14242–1) for d) Dry e) Water and f) Serum ceramic on ceramic testing.

Data availability

Data will be made available on request.

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