Total hip wear simulation with dynamic separation per ISO 14242-4 on an orbital hip simulator

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INTRODUCTION: A dynamic separation wear model for total hip arthroplasty (THA) devices was historically developed to simulate adverse wear conditions for hard-on-hard (HoH) bearings observed in vivo [1]. This test method has also been applied to hard-on-polyethylene (HoP) bearings [2]. A recently published revision to ISO 21535 requires testing of all bearings with steep cup inclination per ISO 14242-4 as well as with dynamic separation per ISO 14242-4 for HoH bearings. Many of the studies leveraging this test method have, however, been conducted on a single simulator type (per ISO 14242-1). The purpose of this study was to apply this test method to an orbital hip simulator, per ISO 14242-3, and assess the impact on common THA bearing materials.

METHODS: A 32 mm fixed bearing THA (Trident X3, LFIT CoCr, Stryker, Mahwah, NJ) was evaluated under edge-loading (n=2) and edge-loading with dynamic separation (n=2) conditions per ISO 14242-4. An orbital hip joint simulator (MTS, Eden Prairie, MN), per ISO 14242-3, was used for testing with cups positioned superior at an inclination of 55°. In order to conduct testing with dynamic separation, the manufacturer supplied self-aligning bearing was replaced with independent linear bearings to allow for individual medial-lateral and anterior-posterior translations (Figure 1). This allowed for a 100 N/mm spring to be positioned to obtain the required 4 mm medial-lateral offset. Testing was conducted for 3.0 million cycles (mc) and volumetric wear rates were measured for each condition. Dynamic separation was recorded using an LVDT. Following this test, a single 32 mm ceramic-on-ceramic bearing THA (V40 Alumina Head, Trident Alumina Liner, Stryker, Mahwah, NJ) was evaluated for 0.5 mc to assess the ability of this test method to generate stripe wear in a HoH system.

RESULTS SECTION: The wear rate of the 32 mm fixed HoP bearing was approximately 8.30 ± 0.92 mm^3/mc and 3.36 ± 0.20 mm^3/mc with and without dynamic separation respectively (Figure 2). The pilot test on the ceramic-on-ceramic bearing showed stripe wear (Figure 3). A representative medial-lateral displacement curve recorded during a dynamic cycle is shown in Figure 4, suggesting approximately 3.0 mm of dynamic separation. The LVDT output during the stance phase, however, showed approximately 1.2 mm offset from the head center .

DISCUSSION: The study demonstrates the capability of running dynamic separation testing per ISO 14242-4 on an orbital hip simulator. The pilot study showed an approximate 2.5-fold elevation in UHMWPE wear rate, consistent with evaluations performed on an anatomic hip simulator per ISO 14242-1 [2]. In addition, the pilot study on a HoH ceramic bearing couple showed stripe wear consistent with that reported previously [1]. The medial-lateral displacement recorded during the stance phase, however, did not show a return to the zero head center position as the ISO 14242-4 suggests. This is likely due to the position of the LVDT relative to the head center in conjunction with the overall stiffness of the assembly. Ideally, the spring and displacement transducer should be placed as close to the articulation as possible to minimize effects of compliance in the test set-up. Alternatively, a correlation between the LVDT readings and the true head-center travel may need to be established.

SIGNIFICANCE/CLINICAL RELEVANCE: Dynamic separation during gait, sometimes known as “pistoning”, is a known in-vivo phenomenon that results in edge loading. This study demonstrates the ability for an orbital hip simulator (per ISO 14242-3) to simulate this condition.

REFERENCES

[1]Stewart,T.,J.Mater.Sci.Mater.Med, 12:1053-1056,2001. [2]Ali,M.,Biotribology,33-34,2023,100238.

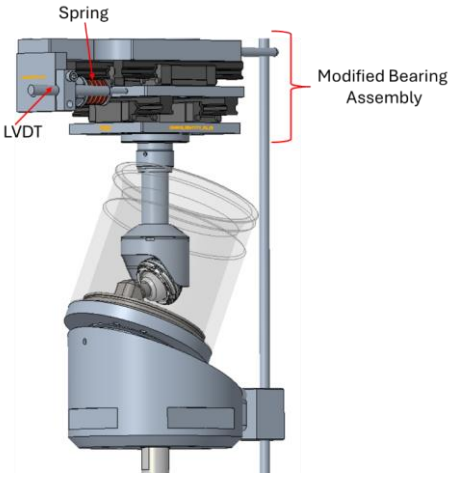

Figure 1: Fixturing for ISO 14242-4 testing with dynamic separation on an orbital simulator

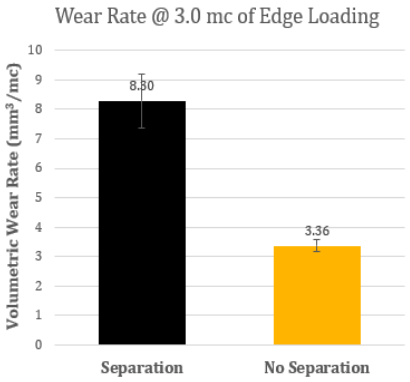

Figure 2: Wear after 3.0 mc of edge loading with and without dynamic separation

Figure 3: Stripe wear was produced on a pilot ceramic-on-ceramic bearing

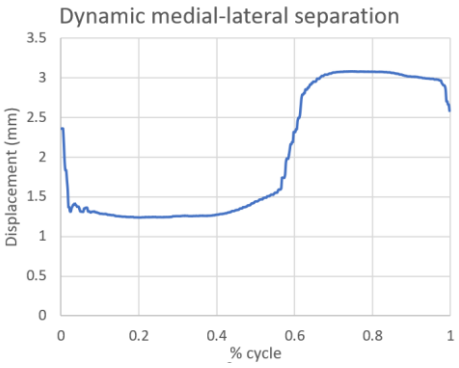

Figure 4: LVDT output for medial-lateral displacement during dynamic separation cycle