A Simplified Method for In Vitro Patella Durability Evaluation

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INTRODUCTION: Potential patellar complications following total knee arthroplasty may include patellar maltracking, anterior knee pain, implant loosening, and fracture/wear of the patellar implant[1]. Patellar component design and surgical implantation technique affect the contact forces experienced by the patellar component, which can lead to premature failure due to excessive loading[2]. Patella durability mechanical testing follows ISO 14243-5 and uses a modified knee wear simulator to articulate the patella against a femoral component, with damage modes (e.g., delamination, cracking) qualitatively assessed[3]. Although the ISO 14243-5 standard can induce relevant patellar failure modes, the specified test method is aggressive and difficult to implement correctly. This study aimed to assess the effectiveness of a simplified ISO 14243-5 patella durability method in reproducing relevant failure modes for testing and ranking patellar designs.

METHODS: As noted in the introduction of ISO 14243-5, the standard is complex to implement, perhaps the most complex in its particular field[3]. For the test apparatus, a modified knee simulator is required to flex the femoral component relative to the patella while allowing patellofemoral translation and axial rotation under a varying compressive load[3]. The patellar component must be free to track within the femoral component trochlear groove while a patellofemoral mediolateral (ML) force mechanism maintains a ML to compressive force ratio of 10±1%[3]. The test method requires implant size specific calculations to determine the appropriate waveforms for both walking (low flexion) and squat (high flexion) activities, as well as a reproducible means for component alignment/positioning within the simulator[3]. The samples are submerged in a bovine calf serum solution at 37°C for the test duration[3].

The complexity of the ISO 14243-5 method has been reduced for the current study, as shown in Figure 1. The primary change involved the use of an unrolled femoral component, where the curved articular surfaces of the femoral condyles were unrolled from a standard J-curve shape into a linear form. Thus, variation of the patellofemoral angle was achieved via femoral component translation instead of femoral component rotation. This change enabled the test to be run on a load frame with biaxial actuators instead of a custom knee wear simulator. As a result of the unrolling process, the patellar translation was fixed at 0mm throughout the test, eliminating the need for an additional degree of control. The ML to compressive force ratio of 10±1% was achieved using an inclined bearing. The loading waveforms were restricted to the deep squat activity of ISO 14243-5, as this applies the highest axial force and previous testing showed damage primarily occurred during this activity (Figure 3). The fluid test medium was altered to a room temperature deionized water drip.

In this study, four 26mm all-poly UHMWPE patellas were evaluated against a 17-4PH stainless steel unrolled femoral component modeled after a size 1 PS femoral component. The compressive waveform and ML shear force ratio were applied per the ISO 14243-5 standard, with a peak compressive force of 2610N and a constant ML shear force ratio of 10%[3]. Due to the unrolling process, the patellofemoral angle from the ISO 14243-5 standard was converted to a patellofemoral translation, resulting in a linear translation of approximately 20.65mm throughout the gait cycle. Three of the patellas were run following the simplified ISO 14243-5 loading strategy for 50k cycles, while the fourth patella was run to 50k cycles with a modified compressive force that was 125% of the ISO 14243-5 specified compressive force. Images and 3D scans of the patellar samples were taken after testing to evaluate damage.

RESULTS SECTION: All 26mm patellas exhibited plastic deformation, breakup of the articulating surface, and delamination. Damage was isolated to the medial and lateral sides of the patella, where contact with the femoral component was made; damage was more severe on the lateral side.

DISCUSSION: Comparison with previous ISO 14243-5 durability tests using the same patellar components and model femoral component (Figure 3) revealed consistent damage patterns and locations. A key difference is that the ISO 14243-5 method was more severe than the current method, as failure (defined as femoral contact with the PMMA sublayer) for the ISO 14243-5 method occurred between 5,000 and 25,000 cycles whereas all samples completed 50,000 cycles in the current study. Increasing the applied force to 125% of the ISO 14243-5 force led to increased damage that was severe enough to create contact between the femoral component fixture and the PMMA sublayer. The simplified method developed in this study successfully replicated the damage patterns and failure modes of the full ISO 14243-5 standard, validating its use for testing and ranking patellar designs.

SIGNIFICANCE/CLINICAL RELEVANCE: In vivo patellar forces can induce patellar component damage that leads to patellofemoral complications such as knee pain, UHMWPE damage/wear, and loosening. The current study provides a simplified in vitro testing method alternative to the complex ISO 14243-5 method for evaluating the effects of patellar design and material on patellar durability.

REFERENCES: [1] Putman et al. Orthop Traumatol Surg Res, 105 (2019) S43-S51. [2] Yu et al. Arthroplasty, 5:44 (2023).
[3] ISO 14243-5:2019(E).

IMAGES AND TABLES:

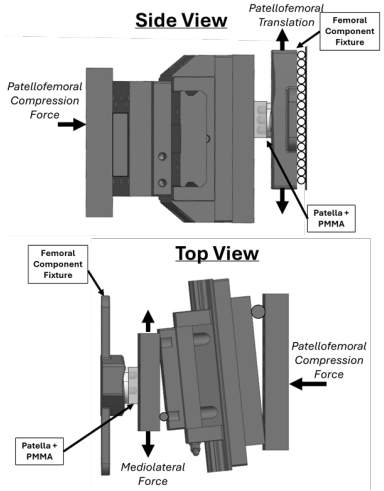

Figure 1. Simplified loading schematic.

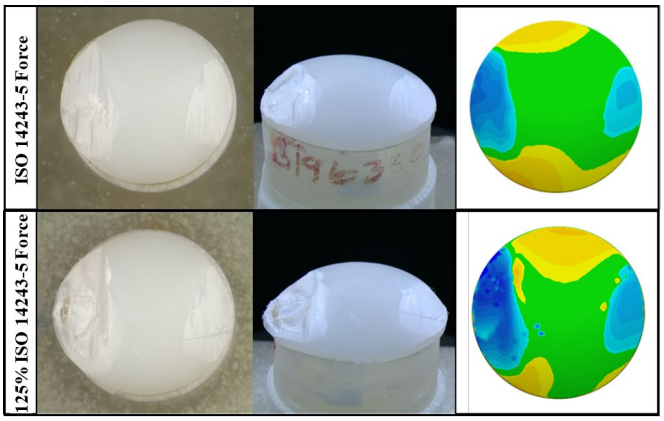

Figure 2. Simplified loading results for the 26mm patella. Data shows representative results for ISO 14243-5 specified force and 125% of ISO 14243-5 specified force.

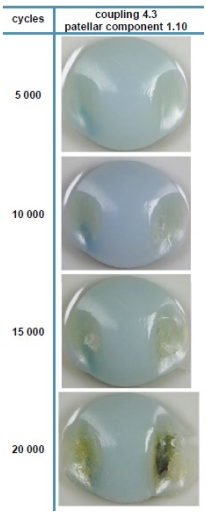

Figure 3. Representative results for the 26mm patella run per ISO 14243-5.