Acetabular liner pop-out: How component design and bench testing can help reduce liner dissociation in Total Hip Arthroplasty (THA)

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INTRODUCTION: THA implants available in the United States vary in acetabular component design, which can be associated with different clinical outcomes. Post-operative liner pop-out can occur and lead to revision surgery. The majority of THA devices contain an acetabular polyethylene liner and are brought to US market through the premarket notification (510(k)) pathway. Submitters of these 510(k)s need to provide adequate performance data to confirm their new THA device is substantially equivalent to a legally marketed predicate device. However, companies often have challenges obtaining components of 510(k) cleared predicate devices for side-by-side bench testing. This study aims to summarize disassembly performance data obtained from bench testing of THA acetabular polyethylene liner and metal shell components with different locking mechanism designs. The results from this study will help provide a range of acceptable performance data for predicate comparison in support of 510(k) clearance so that patients can obtain earlier access to safe and effective THA devices.

METHODS:

We collected device information including design features, dimensions, and materials. We also collected mechanical testing data (*ASTM F1820-13 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices*) about the disassembly performance of THA acetabular polyethylene liner from metal shell devices cleared for marketing in the U.S. between 2010 and 2022. The data were de-identified and analyzed in aggregate to determine ranges of design characteristics and disassembly performance. The data included devices with different pre-testing assembly methods (e.g., 2kN axial assembly, drop-weight assembly, surgical technique assembly) and different locking mechanisms (e.g., snap-fit, anti-rotation tabs (ART), taper, ring-lock, or a combination of these). Test results were aggregated and the 10th, 25th, 50th, 75th and 95th percentiles were calculated for the performance testing results for each test type. Analysis was not conducted on the offset pull-out test data group due to small sample size.

RESULTS: We identified ranges of critical THA liner and shell design characteristics (e.g., liner inner and outer diameter, liner offset types, shell outer diameter, number of screw holes in shell). We also identified the ranges of disassembly force (F) and torque (Nm) observed in the data, reported from the 10th to 95th percentiles (Table 1). The push-out performance percentiles (10th to 95th) ranged from 393N to 2866N, and designs that included a snap-fit locking mechanism required a higher disassembly force. The lever-out performance percentiles ranged from 273N to 1167N, and designs with a taper only locking mechanism required a higher disassembly force (potentially due to small sample size and array of variables in the test set-up). The offset pull-out performance percentiles ranged from 260N to 810N. The torque-out performance percentiles ranged from 8.6Nm to 83Nm, and designs that included an ART locking mechanism required a higher disassembly torque.

DISCUSSION AND CONCLUSION: The analysis demonstrates that disassembly performance of acetabular liner and shell devices can vary significantly due to differences in locking mechanism designs. The data indicates that most modern THA acetabular liner and shell devices have a snap-fit and ART locking mechanism combination, which leads to superior attachment strength and reduced likelihood of disassembly during clinical use. Acetabular disassembly strength data from our study can inform standardized performance testing and development of future THA implant systems.

		Count	Percentile					Coefficient of Variation (median [IQR])
			10th	25th	50th	75th	95th	
Push-Out	Force (N)	45	392.6	628	1041	1275	2866	0.068 [0.033, 0.112]
Lever-Out	Force (N)	25	273	506	645	784	1167	0.084 [0.000, 0.098]
Offset Pull-Out	Force (N)	12	260	336	482	538	810	0.116 [0.067, 0.152]
Torque-Out	Torque (N-m)	38	8.6	19.4	34.3	44.1	82.9	0.053 [0.032, 0.099]

Table 1: ASTM F1820 Mechanical Testing Results.