INTRODUCTION

Modular stems are becoming a popular choice for THA. Their popularity can be attributed to their adaptable nature, which provides the surgeon with choice of diameter, stem length, fixation type and proximal stem size and orientation [1]. This intraoperative flexibility presents the patient with a better fit stem. For new implant development it is important to verify the design against predicate devices and standardized testing. However, modularity has introduced new failure modes, such as fracture of the neck or stem taper, that are not necessarily captured using current test methods. The current standardized test [2] applies to both modular and non-modular designs and recommends embedding the stems in potting media up to the resection level; this potting method shields the taper junction of the modular stem and may mask clinically relevant failure modes in the taper region (Figure 1). Therefore, the purpose of this study was to develop a more severe fatigue performance test to evaluate the neck and taper region of modular stem/neck constructs using a modified ISO neck test model.

MATERIALS AND METHODS

Test Samples

Two sizes of a cementless primary modular stem (Rejuvenate Modular, Stryker Orthopaedics, Mahwah, NJ) were tested in order to evaluate the strength of both the neck and stem’s taper region. The size 9 stem represents the worst-case size from a neck-strength standpoint, while size 7 is worst-case from a stem taper-region standpoint due to the thinnest wall thickness. The size 9 stem was paired with 42 mm of total neck length (defined as neck length + head offset), while the size 7 stem was paired with 38 mm of total neck length – these were the maximum allowable neck lengths for the respective stem sizes at the time. 16° is the largest neck version offered in this system, and results in the greatest bending moments in the taper region. Eight production equivalent samples of each construct were evaluated.

Neck Fatigue Strength: Rejuvenate Modular Stem Size 9; 42mm, 16° Retroverted Neck; Ø28 mm, -4 mm offset femoral head.

Stem Taper Region Fatigue Strength: Rejuvenate Modular Stem Size 7; 42mm, 16° Retroverted Neck; Ø28 mm, -4 mm offset femoral head.

Sample Preparation

Each stem was potted in a stainless steel cylindrical holder with a 10° valgus, 9° flexion orientation as recommended by the ISO standard. Devcon-Plastic Steel (ITW Devcon, MA) was used as an embedding medium and encapsulated the stem up to 1 mm below the most inferior aspect of the internal taper cavity (Figure 1). The medium was allowed to fully cure before testing. After curing, the neck was assembled onto the potted stem with 16° of retroversion to maximize the stresses within the construct. The femoral head was then secured to the neck using a head impactor.

Sample Testing

A vice was used to secure the potted sample to a single axis Instron 456 testing system (Instron, MA). A bath was used to provide a consistent level of phosphate buffered saline above the neck-body junction of the sample. Loading was maintained through the center of the head of the sample. A maximum load of 5334 N (1200 lbf) was applied to the size 9 samples as recommended by ASTM F 2068-03 [3]. A maximum load of 4626 N (1040 lbf) was applied to the size 7 samples – this load level is the demonstrated fatigue strength of an equivalently sized predicate stem tested in a similar manner, also as recommended per ASTM F 2068-03. A loading rate of 15Hz was applied with a maximum cycle count set as 10x10⁶ cycles. Testing was carried out until the maximum cycle count was reached or failure occurred, which was defined as the inability of the construct to sustain load. Following testing, the head and neck were disassembled and the taper surfaces were inspected using SEM analysis.

RESULTS

All size 9 samples withstood 5336 N for 10x10⁶ cycles without failure. Likewise, all size 7 samples withstood 4626 N for 10x10⁶ cycles without failure. SEM inspection of both stem sizes revealed no cracks and minimal amounts of material transfer between the stems and necks.

DISCUSSION

Currently, standardized testing procedures recommend embedding stems to a level corresponding to the resection plane of the implant [2]. While this potting level may be clinically relevant immediately following implantation, proximal bone loss is a well-documented phenomenon that may leave portions of the proximal stem, including the taper region, unsupported [4]. Potting modular stems in a manner consistent with the current ISO standard extends the potting media into the taper region, shields the taper junction from clinically relevant stresses, and may mask areas of peak stress and thereby fail to evaluate clinically relevant failure modes. Other static load-to-failure tests of the modular neck region have been described, yet such tests do not accurately represent the loading cycle seen by the modular junction in a clinical setting. We therefore developed a more severe fatigue performance test that results in a fully unsupported taper region and challenges the taper junction in a clinically relevant manner.

Verification testing confirms that, when tested using the modified ISO method described above, worst case Rejuvenate Modular stems demonstrate minimum fatigue strengths that meet the recommended performance criteria outlined in F 2068-03.

The efficacy of this modified testing procedure to test the neck and taper regions of modular stems supports its use as a standardized test for current and future modular stem systems.

REFERENCES