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The Effect of Taper Angle and Spline Geometry on the Initial Stability of Tapered, Splined Modular Titanium Stems

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ABSTRACT

Design parameters affecting initial mechanical stability of tapered, splined modular titanium stems (TSMTSs) are not well understood. Furthermore, there is considerable variability in contemporary designs. We asked if spline geometry and stem taper angle could be optimized in TSMTS to improve mechanical stability to resist axial subsidence and increase torsional stability. Initial stability was quantified with stems of varied taper angle and spline geometry implanted in a foam model replicating 2 cm diaphyseal engagement. Increased taper angle and a broad spline geometry exhibited significantly greater axial stability (+21%–269%) than other design combinations. Neither taper angle nor spline geometry significantly altered initial torsional stability.

There have been significant advances in revision total hip arthroplasty (THA) over the past two decades. In femoral revision surgery, tapered, splined modular titanium stems (TSMTSs) have emerged as a particularly effective option. In short to midterm follow-up, TSMTSs have reported minimum five-year survivorship of 85%–94% [1–5] and have exhibited improved quality of life measures, fewer intraoperative fractures, and better ability to reproduce leg length and offset [5–13].

While these results are encouraging, component subsidence continues to be a cause for early mechanical failure and a cause for re-revision (with increased subsidence associated with severity of bone defect) [5]. Böhm and Bischel [14] reported an average migration of 5.9 mm in 149 TSMTSs at a mean 4.8 year follow-up, with 26 hips exhibiting more than 10 mm of migration. Rodriguez et al. [15] reported a 6.2% rate of subsidence up to 10 mm at 6.2 years follow-up, while Park et al. [5] reported 5% of cases with 10–20 mm of subsidence at 1.6 years. In many of these cases, secondary stability was reported without re-revision, attributed to the tapered design of the stem. Interestingly, the design rationale for the degree of taper angle and spline geometry is not well documented in the literature.

The purpose of this study was to evaluate the effect of two major design elements of a TSMTS (the degree of taper angle and spline geometry design) on the initial mechanical stability of the implant, as measured by implant subsidence and torsional resistance.

Materials and Methods

In order to perform a comparative analysis of axial and torsional stability of revision stem spline designs, custom stem samples were manufactured from wrought titanium (Ti-6Al-4V) per ASTM Standard F1472-08. Experimental groups consisted of two spline configurations (Narrow and Broad) with five taper angle groups per spline configuration (2.5°, 3.0°, 3.5°, 4.0°, 5.0°), for a total of ten distinct sample experimental groups. Three specimens were included in each spline configuration and taper angle combination group. All test specimens consisted of a 102 mm of tapered spline, 18 mm in proximal diameter, with an additional 38 mm smooth cylindrical stub 13 mm in diameter to integrate with the test fixture. Stems included ten longitudinal splines spaced circumferentially at an increment of 36°. The spline geometry in the narrow configuration had a 0.4–0.5 mm wide spline, whereas the broad configuration had a 0.9–1.0 mm wide spline. These spline widths were chosen as they reflected the range of spline widths observed in stems which are currently on the market and available for inspection. Both configurations had a spline height of 1.9 mm (Fig. 1). Solid rigid polyurethane foam blocks (0.64 g/cc, Sawbones, Inc., Vashon, WA) of size 50 mm × 50 mm × 20 mm were used as the test substrate and were reamed utilizing standard manufacturer-supplied reamers,

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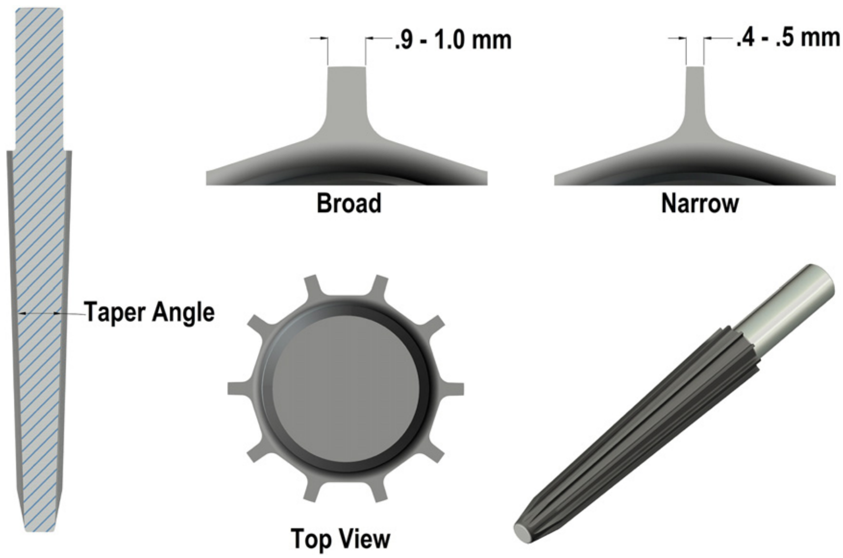

Fig. 1. Mechanical drawings and three dimensional views of broad and narrow spline geometries showing taper angle and spline geometries as variables of interest in this study.

matching stem taper angles, on a digitized mill. Roughing, followed by finishing passes were performed to a diameter at which the center 20 mm of the test specimen was engaged into the foam block.

Axial and torsional mechanical testing was conducted utilizing a biaxial electrodynamic load frame (ElectroPuls E10,000 A/T, Instron, Norwood, MA). Proximally, specimens were gripped in the upper pneumatic grip of the load frame. Distally, reamed foam specimens were placed within a hollow support chamber enabling stem insertion and rotation, while allowing for free x-y translation and constraining foam rotation. Axial tests were performed by inserting the test specimen at a displacement controlled rate of 1 mm/s until a maximum specimen displacement of 15 mm was reached. Maximum compressive load was calculated from the axial output of the load frame. Axial resistance was calculated utilizing a data analysis package (LoggerPro 3.8.5, Vernier Software & Technology, Beaverton, OR) as the slope of the linear region of the displacement–force curve in each trial. Specimens were cleaned and inspected for damage after each trial, with tests repeated five times per specimen in a new foam block for each trial.

Following axial testing, torsional resistance was quantified for each spline configuration and taper angle using the same experimental fixturing. Preliminary testing of axial insertion forces incrementally from 0 to 1000 N revealed an axial force of 400 N as the minimum threshold for spline penetration into the surface of the reamed foam. For this reason, a constant compressive axial preload of 400 N was applied to the stem specimen during all torsional tests as means to simulate slight cortical bone engagement at the onset of torque application. Each stem specimen was rotated within the foam block at a rate of 0.5° per second until a peak rotation of 10° was reached. As with axial testing, repeated measures were conducted for a total of five trials per specimen. Torque, rotation, and axial load data were collected from the load frame controller. Peak torque at 1° of stem rotation was quantified. Peak torsional resistance was measured as the linear slope of the rotation–torque curve within the first 0.2° of stem rotation within the foam block.

The mean diameter of the 3.5° taper at the most proximal point of implantation in our foam model is 15.5 mm. By calculating the length of the arc created at the perimeter during component rotation around the central axis, it was determined that a 1° rotation of the test specimen equates to a 140 μm relative micromotion between the spline and the foam model. Because micromotion at the stem-bone interface greater than 150 μm at any aspect in the component may inhibit bone ongrowth and proper biological fixation [16], evaluating the rotational stability at this small rotational increment was deemed helpful in order to identify any subtle differences in stability between designs at the level of micromotion critical to bone ongrowth.

In summary, we evaluated two metrics of both axial and rotational stability as derived from load frame displacement, load and torque transducers. Higher observed values in maximum axial load, the load required to generate 15 mm of subsidence, along with the axial resistance, the load required per 1 mm of subsidence, serve to indicate a more axially stable construct. Likewise, higher observed values in peak torque, the torque required to induce 1 degree of stem rotation, and axial resistance, the torque required per degree of rotation at the first 0.2° of rotation, serve to indicate increased rotational stability in the stem design.

Statistical analysis was performed utilizing repeated-measures multivariate linear regression techniques. For both axial and rotational tests the spline geometry, taper angle, and the interaction between each were analyzed for covariance. Least square means were derived for each test response for comparison between combinations of spline geometry and taper angle. A *P*-value of less than 0.05 was considered statistically significant. Our study was adequately powered (with power = 0.80, two-sided alpha = 0.05, and beta [probability of type II error] = 0.20) to detect differences between designs in means of 600 N maximum axial load and 100 N/mm of axial resistance in axial tests, as well as differences of means of 0.2 Nm of peak torque and 0.8 Nm/deg of axial resistance.

Results

The broad spline design produced significantly higher maximum compressive loads than the narrow spline design taper angles of 3.5°, 4°, and 5°, representing an increase in axial stability over narrow splines of 33%, 42%, and 32% respectively ($P < 0.0001$) (Fig. 2A). Within both the broad and narrow spline configuration, the smallest maximum compressive load was observed within stems with taper angles of 2.5° and 3°. Overall, stem specimens with broad spline configurations and a 5° taper angle exhibited 21%–137% greater axial stability than the other spline combinations ($P < 0.0001$). There was found to be an overall greater than additive effect when considering the interaction between design and taper angle ($P < 0.0001$). Simply put, a greater difference in maximum axial stability between broad and narrow design was observed at higher taper angles. As a second measure of axial stability, axial resistance closely corresponded with maximum compressive load data (Fig. 2B). In this measure of axial stability the broad splines