Choosing the Appropriate Material for Orthopaedic Instrumentation

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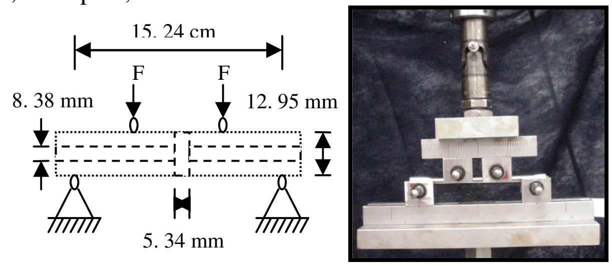
INTRODUCTION: Stainless steels have been used in orthopaedic trauma applications for decades, and their long history of clinical success coupled with their favorable mechanical properties has established them as a viable biomaterial. With the discovery of material-sensitive patients and the growing desire to expand treatment options, however, titanium and titanium alloys have been more recently employed[1]. The overall mechanical properties of each of these biomaterials are well known, but a purview of the literature indicates that comparing their biomechanical fatigue performance may be application dependent and is evaluated at high cycle counts[2,3]. The purpose of this study was to utilize a standardized methodology to compare the mechanical performance of stainless steel and titanium orthopaedic trauma implants in a trauma lifecycle fatigue scenario of no more than one million cycles[4].

METHODS: One hundred twenty three (123) intramedullary nail coupons (Fig 1a) composed of either cannulated ASTM F138 316L stainless steel rod stock (*n*=69) or cannulated Ti-6Al-4V alloy rod stock (*n*=54) were prepared with a 32μin. maximum surface finish. The specimens were tested in the most critical physiological condition by isolating a transverse screw hole and subjecting to four-point bend sinusoidal cyclical fatigue[5] at multiple load levels (Fig 1b) until failure or run-out to one million cycles[4]. Varied load levels were utilized during testing to gain a trend between stress level (range: 480–2200 MPa) versus fatigue survival, with multiple specimens (up to *n*=10 per load level) tested for comparison.

RESULTS: For those specimens without run-out, all failures occurred through the transverse hole. All specimens failed at the highest applied stress, and all specimens achieved run-out at the lowest applied stress. Thus as expected, as nail stress increased, fatigue survival decreased (Fig 2). Additionally, cycle count scatter increased as the stress level decreased, and some of the data points in Figure 2 represent an average of both failed specimens and specimens which ran out. This was especially true for alloyed titanium nails, which exhibited higher cycle count scatter than did stainless steel nails. General trends indicated that at higher stress values, stainless steel specimens survived longer than alloyed titanium specimens. Conversely, at lower stress values alloyed titanium nails survived longer than stainless steel specimens on average. This phenomenon is noticed in Figure 2, since observation shows that the two trendlines intersect between 300,000 and 400,000 fatigue cycles, a time point which through extrapolation could represent 3-5 months of intramedullary nail *in vivo* life[4].



(a) (b)

Figure 1. Schematic (a) and photo (b) of four point bend test set-up.

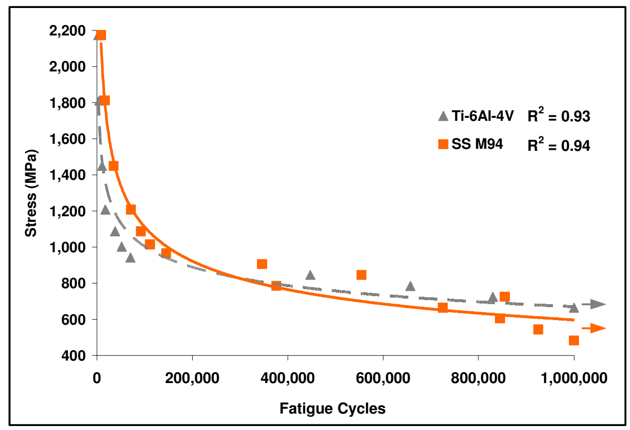


Figure 2. S-N curve generated from survival averages for simulated intramedullary nails tested in air, showing 316L SS (squares, solid line) and Ti-6Al-4V Alloy (triangles, dashed line). Stress levels include a stress concentration factor calculated at the edge of the screw hole.

DISCUSSION: A standardized comparison between two biomaterials under a physiological loading scenario for use in distal screw holes of intramedullary nails is herein presented. This study shows that fatigue survival comparisons among trauma intramedullary nails may not only be design dependent, but is also governed by the relationship between expected *in vivo* lifetime and stress level. The relationship between cycle count and predicted stress level is not universal, however, since the mechanical performance changes based upon the biomaterial chosen, and may do so during the timespan encompassed within the rehabilitative window.

It should be noted that this study cannot be generalized to other situations since the results obtained are for this loading scenario, specimen geometry, and surface finish. A potential limitation is that we used the condition of run-out at one million cycles for test termination, which may not be equivalent to the fatigue endurance limit of the biomaterials used under our loading scenario. However, we chose this parameter constraint due to the relevance to the expected lifespan of fixation devices and believe it to be a reasonable boundary condition based the literature. Stainless steels and titanium are proven biomaterials, and this study indicates that material selection prior to instrumentation should be fully considered.

REFERENCES: [1]Hallab N. JBJS. 2001:83-A;3:428-36. [2]Disegil JA. Injury. 2000:31:S-D2-6. [3]Pohler OEM. Injury. 2000:31:S-D7-13. [4]Antekeier SB. J Ortho Trauma. 2005:19;10:693-7. [5]ASTM F1264-07.