Time Depended Strain Response of Biomedical Alloys used in Spinal Surgery

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Statement of Purpose: In a clinical application, failure of spinal instrumentation is of significant concern after surgical treatment for scoliosis. While not extensively addressed in the literature, there is reported evidence of the loss of rod curvature[1] presenting a disturbing situation that may result in the pullout of pedicle screws. Failure of various spinal instrumentation is well described[2-6] however many possible explanations are offered, including, but not limited to; 1) fatigue; 2) overloading (under-sizing of instrumentation or patient movement beyond the limitations of the instrumentation); 3) wear; 4) corrosion; and 5) improper surgical technique. In the first case the anelastic properties of the titanium must be considered as it is established that structurally loaded titanium, implant or otherwise, in environments other than air can have significant leaching as well as movement of the alloying elements or the adsorption of oxygen and hydrogen from the surroundings promoting unanticipated anelastic responses.[6-12]. However, before the specific mechanics can be described, the time resolution of rod springback must be refined in order to develop a clear understanding of any short term responses where self deforming rods impose forces on pedicle screws. The work presented addresses such a requirement. In so doing specific material mechanisms can be elucidated and data used to develop a methodology enabling surgeons to reduce these effects.

Methods: Spine rods of Commercially Pure (CP) Ti, two types of Ti-6Al-4V, a beta-phase titanium alloy TNTZ Ti, and CoCrMoC (all Provided by Dr. Evalina Burger) were contoured using a 3-point bender an angle of approximately 25° as shown if Figure 1.

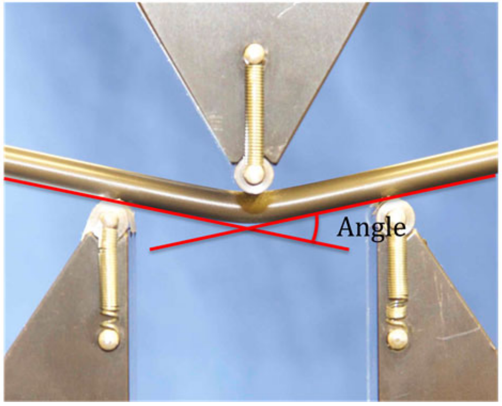

Figure 1: Example of sample in 3-point bender and how each angle was measured

Following contouring, the rods were aged in an incubator in either air (97% humidity, 37±2°C) or in a simulated body fluid (SBF) (Dulbecco's modified eagles medium supplemented with 10% (v/v) heat inactivated fetal calf serum). The sample size (N) for each material/ageing condition is listed in Table 1.

At nine time points, the bend angles were measured (as shown in Figure 1). The time points measured were: as received, in bender, immediately post contour (elastic springback), 24-hours, 48-hours, 72-hours, 144-hours, 192-hours, 288-hours. Comparison between rod materials and environment was measured by ANOVA with Tukey's HSD post-hoc testing, with an α level=0.05, to determine if the observed changes are significant.

Table 1: Sample size of each material for each ageing environment

Material	SBF	Air
CoCrMoC	12	12
CP Ti	12	12
Ti-6Al-4V (L)	12	12
Ti-6Al-4V	9	6
TNTZ	9	6

Results: Figure 2 shows that CP Ti exhibited a significant negative change in angle in the first 48 hours, e.g. bends closed. This then significantly reversed, e.g. bends opened, in the following 96-120 hours. The final 96 hours there as little to no change in the bends. The other alloys tested follow a similar trend, albeit not as significant, with the opening of the bends occurring at an earlier time point, before 48 hours.

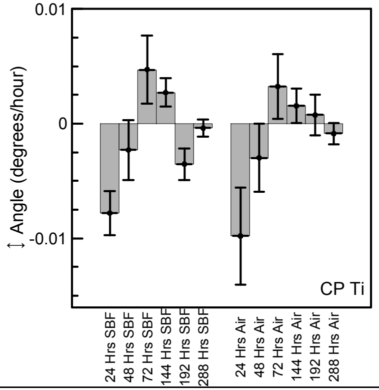

Figure 2: Angle change (degrees/hour) for CP Ti aging in SBF or Air for 288 hours

Conclusions: The initial angle change and especially the reversal in this change suggests several underlying and potentially competing mechanism(s), as stated previously, at play. This supports previous work showing changes in spine rod curvature post implantation and warrants further investigation in order to develop new surgical methodologies for better patient outcome as well as new material design. This work was accomplished under NIH Grant 1R15AR060011-01

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