Mechanical Characterization of Pectus Bars for use in Nuss Procedure to Treat Pectus Excavatum: A Comparative Study.

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Disclosures: Eugene Ablordeppey (None), Kyle Ondar (None), Benjamin Hezrony (None), Philip J. Brown PhD (None)

INTRODUCTION: Stainless steel pectus bars are the gold standard material choice for treating pectus excavatum, a condition that causes sunken chest wall deformation[1]. Even though stainless steel is inexpensive and capable of correcting this deformity, 5% of patients develop metal allergies, skin lesions, rashes, and inflammation with symptoms of pain, indicating allergic responses to steel alloying elements[2]. These undesirable side effects have prompted interest in the selection of alternative biomaterials for use in the manufacturing of pectus bar implants. The objective of this study is to test the mechanical viability of titanium as an alternative biomaterial for use in making pectus excavatum implant.

METHODS: A total of 24 specimens were tested under static and fatigue four-point bending conditions. Twelve (12) specimens, consisting of titanium (n = 6) and stainless steel (n = 6) pectus bars, were tested in static four-point bending. Additionally, 12 specimens with titanium (n = 6) and stainless steel (n = 6) pectus bars were tested in fatigue four-point bending. Both bar types were designed with similar cross-sectional bending stiffness. They were tested using a servo-hydraulic landmark MTS testing frame (MTS, Eden Prairie, MN), as indicated in Figure 1(A-B). For the static test, a ramp compression was applied at 0.5 mm/s until 15 mm of mid-span displacement of the bars was detected. For the fatigue test, a sinusoidal amplitude of peak (250N ± 5N) and valley (50 N ± 5 N) was applied to the bars for 1 million cycles at 15 Hz in displacement control. In both tests, force was measured with an inline Interface 5kN load cell, and mid-span displacement was measured via laser caliper at 100Hz. The Mann-Whitney U test (Wilcoxon Rank Sum test) was used to find any statistically significant differences between groups using a *p*-value threshold of $p < 0.05$ for both static and fatigue four-point bending test.

RESULTS SECTION: There were no significant differences in maximum force between stainless steel and titanium bars in a static four-point bending test (p = 0.81), as depicted in Figure 1(C-D). The mean peak force for titanium bars was 938.50 ± 6.72 N and for stainless-steel bars was 937.01 ± 5.29 N, with a relative difference of 0.16 %. Significant differences were observed in plastic deformation, total energy, and stiffness, with titanium bars showing higher values. Titanium had a mean plastic deformation of 4.71 ± 0.05 mm compared to stainless steel's 3.95 ± 0.14 mm (p = 0.0142), a relative difference of 16.14%. The mean total energy was 9.52 ± 0.03 J for titanium and 9.14 ± 0.13 J for stainless steel (p = 0.0051), a relative difference of 3.99%. Titanium's mean stiffness was 85.55 ± 0.38 N/mm, while stainless steel's was 77.47 ± 7.43 N/mm (p = 0.0051), a relative difference of 9.44%. The fatigue test, illustrated in Figure 1(E-H), showed significant differences between titanium and stainless-steel bars in all comparisons of cumulative mean force, center displacement, and stiffness under 50N and 250N loading (p < 0.0001). Relative differences ranged from 1.1% to 9.3%. Neither bar showed damage after enduring 1 million cyclic loads.

DISCUSSION: The static and fatigue bending tests revealed that titanium pectus bars have mechanical properties comparable to stainless steel, with relative differences ranging from 0.16% to 16.14%. Although titanium bars are more expensive, their biocompatibility is important for patients with stainless steel allergies. On the other hand, stainless steel is cost-effective and has a well-established track record in medical applications. Under static loading, titanium bars showed higher peak force, greater plastic deformation, and higher bending stiffness than stainless steel bars. These observations are likely due to differences in cross-sectional area, second moment of area, and material properties. In clinical contexts, titanium bars may have better plastic deformation properties and absorb slightly more energy than stainless steel bars. In fatigue testing, titanium bars demonstrated relatively constant stiffness over one million cycles, suggesting better fatigue behavior than stainless steel. The study acknowledges limitations, such as a lack of published titanium vs. stainless steel pectus bar comparisons and a relatively low number of fatigue cycles. For more accurate fatigue results, it's recommended to conduct fatigue tests with a frequency of 0.25-5 Hz and a cycle count of 10^7 or 10^8. Increasing the number of cycles might see an increase in stiffness, reach steady state, and then decline just before fatigue failure. Despite these limitations, this study highlights the need to consider material properties, implant design, and patient-specific factors for clinical outcomes. Titanium offers additional advantages, such as radiolucency, corrosion resistance, and MRI compatibility, making it a compelling choice for treating pectus excavatum[3]. These findings contribute to existing literature and highlight the mechanical effectiveness of titanium bars, coupled with the potential to minimize allergic reactions when used in pectus excavatum treatments.

SIGNIFICANCE/CLINICAL RELEVANCE: This study compares both bar types under clinically relevant conditions and determines that both materials perform equally well mechanically. However, titanium offers several advantages over stainless steel, such as radiolucency for post-operative monitoring, corrosion resistance, MRI compatibility, and a reduced risk of stress-shielding effects on bone, underscoring its potential for treating pectus excavatum in patients with stainless steel allergies.

REFERENCES: [1]Barber et al., (2021), OTA Int.; [2]Nuss et al.(2010), Thoracic surgery clinics; [3]Ebraheim et al.,(1992), Clinical orthopedics and related research.

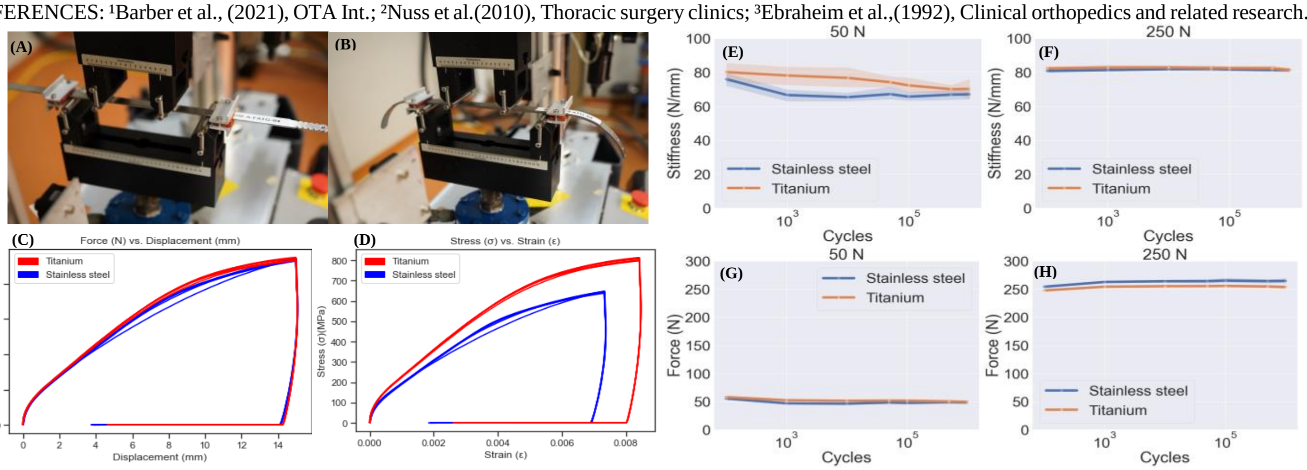

Figure 1: MTS Landmark Servo hydraulic system with four-point grips side view - Stainless steel bar (A) and Titanium bar (B). Compressive force vs. displacement plot(C), Stress-strain plot (D). Mean & standard deviation (±1 SD) of Stiffness vs. cycles log scale (left (E) 50N, right (F) 250N loading condition); Force vs. cycles log scale (left (G) 50N, right (H) 250N loading condition).