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Screw Insertion Damage Effects on Nitinol Corrosion Resistance in Spinal Fixation Plates

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Introduction

Nitinol is commonly used as a retention clip to prevent backout of fixation screws in spinal anterior cervical plates (ACP). During implantation, however, there is metallic contact between the screw and retention clip. The effects of this surface damage on corrosion resistance of the Nitinol clip have not been thoroughly investigated and may be dependent on the level of screw-clip interference in the construct design. Therefore, the goal of this study is to characterize the effects on the Nitinol corrosion resistance using varying levels of screw-clip interference in a modified ACP assembly.

Experimental Methods and Results

Generic Nitinol retention clips were manufactured with two different surface finishes - dark oxide (DO) and chemically etched (CE) with interference levels of 0.9 mm, 0.5 mm, 0.1 mm, and -0.2 mm, from high to no interference, respectively. An assembly procedure was developed to simulate the clip damage upon Ti-6Al-4V screw insertion through a Ti-6Al-4V cervical plate with a clinically relevant torque of 7 N-m applied. A 15 PCF Sawbones block was used to simulate vertebral bone during screw insertion. Potentiodynamic polarization testing was conducted per ASTM F2129-19a with a sample size of N=6 per finish and group (N=48 total). The results for the DO and CE clips indicated a significant decrease in breakdown potential between the highest and no interference levels through a two-tailed t-test ($p<0.05$) as shown in Fig. 1 (DO: $E_{b,0.9}$=211 mV vs. SCE vs. $E_{b,-0.2}$=282 mV vs. SCE) (CE: $E_{b,0.9}$=505 mV vs. SCE; $E_{b,-0.2}$=710 mV vs. SCE).

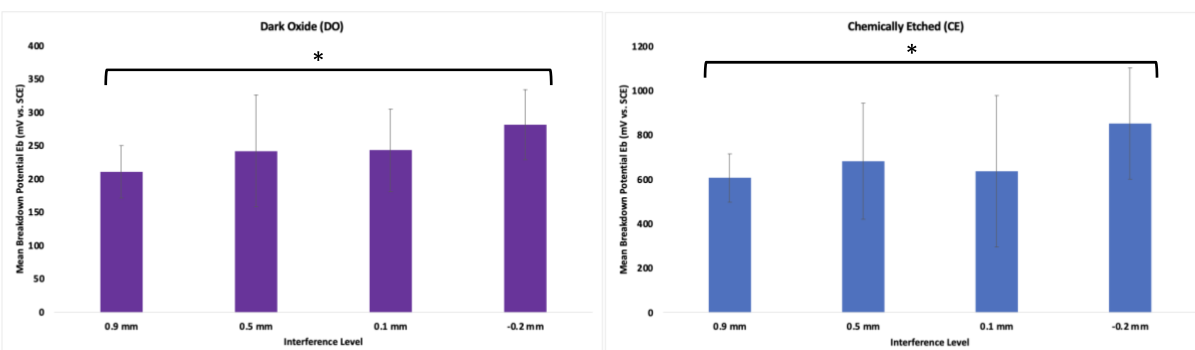

Figure 1: ASTM F2129 breakdown potentials for the DO (left) and CE (right) clips.
Error bars indicate ± one standard deviation. Asterisk indicates significance between interference level.

Figure 2 shows scanning electron microscopy (SEM) images of the native surface and after simulated use. The imaging aligned with the F2129 data suggesting that the highest interference had more damage and negatively influenced corrosion behavior for both DO and CE surface finishes.

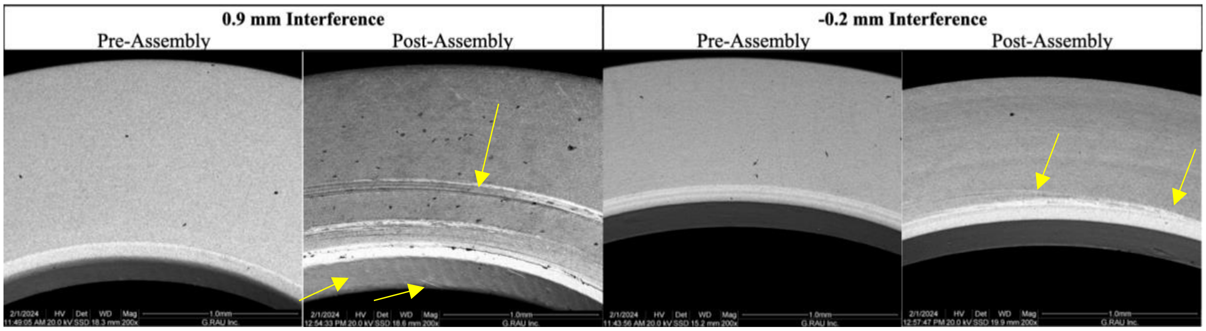

Figure 2: SEM of the Dark Oxide Nitinol clips before and after ACP assembly (arrows indicate surface damage)

Due to the significant decrease in E_b values for the 0.9 mm and -0.2 mm interference levels, electrochemical impedance spectroscopy (EIS) was used to characterize the oxide resistance for the DO and CE clips (N=3 native surface and N=3 after simulated use) [1]. The data was fit to a Randle's cell model with a constant phase element. The chi-square values of the Randle's equivalent circuit fit were less than 0.024 for all tested specimens indicating good fit. Figure 3 reveals that the EIS measured oxide resistance (R_{ox}) was not significantly different between clips with and without simulated use for both the highest and no interference groups as well as CE and DO surface finishes ($p>0.21$).

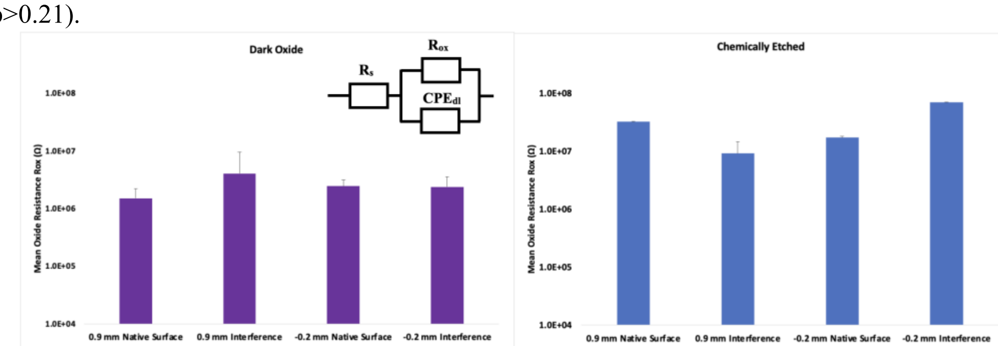

Figure 3: Oxide resistance (R_{ox}) for the 0.9 mm and -0.2 mm interferences of the native surface and after simulation. Error bars indicate ± one standard deviation.

Conclusion

The Nitinol clips manufactured with the highest interference fit for both DO and CE surface finishes exhibited significantly lower breakdown potentials after simulated use. In fact, the data indicate the corrosion resistance of CE clips decreased from optimal to marginal resistance after ACP assembly based on previous literature [2]. Microscopic inspection supports the hypothesis that damage introduced through simulated use can have an adverse effect on corrosion resistance. However, this impact is dependent on the interference fit as the more moderate interferences possessed lower corrosion resistances but were not significantly different. Preliminary EIS data showed that ACP assembly did not lead to a decrease in oxide resistance for either DO or CE groups; however, further testing in a larger sample size is needed. Overall, these data highlight the consequences of metal-metal contact during orthopedic device assembly on corrosion resistance of Nitinol components. Future work will continue ASTM F2129 and EIS evaluations using MP clips subjected to simulated use in the ACP assembly.

References

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