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Effect of Passivation Treatments on Nickel Release from Nitinol

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While the good performance of NiTi implants has been reported, the high nickel content of the alloy and its possible influence on biocompatibility continues to be an issue of concern. This concern is further complicated by the conflicting literature results on NiTi corrosion resistance. However, a careful review of these references reveal that NiTi material processing history and surface conditions are generally not well documented. Recently, several studies have shown the favorable effect of passivation treatments in improving the active corrosion resistance of this material.[1,2] Still, there is limited information on the effect of these treatments in minimizing passive Ni release. Therefore, the purpose of this study was to quantify Ni release from NiTi after passivation treatment and compare it to the Ni release from common biomaterials.

Material & Methods

NiTi (55 wt% Ni), MP35N cobalt-based material (35 wt% Ni) and 316L stainless steel (11 wt% Ni) discs underwent various passivation treatments based on ASTM F86 recommendations (refer to Table 1).

Table 1. Surface treatments

Material	Surface treatments	
NiTi	MP NiTi	Mechanically polished
	EP NiTi	Electropolished
MP35N	MP MP35N	Mechanically polished
	PA MP35N	Acid passivated
316L SS	MP 316L	Mechanically polished
	EP 316L	Electropolished

All samples were sterilized under UV light. The samples were placed in tissue culture plates and the plates were filled with 4 mL of Hank's physiological solution using aseptic procedure. The samples were then placed in a water-jacketed incubator with humidity, temperature and multiplex gas control. The tests were conducted under a mixed-gas environment (20.9% O_2, 5.0% CO_2, and air) at 37° C. The samples were removed 1 h, 6 h, 12 h, 24 h, 48 h, 72 h, 96 h, 120 h, 7 d after placing in the incubator. Three samples of each group were removed per time period. The media was extracted, made up to 4 ml to normalize concentration effects resulting from evaporation, and analyzed using AAS to determine the ionic content of Ni.

Results & Discussion

The Ni release measured over a 24h period is reported in Figure 1. Ni release for all samples decreased as a function of time. MP NiTi initially released the highest amount of Ni (159±40 ppb) but after 24h all samples converged to undetectable Ni release except MP MP35N who released 4±2 ppb (0.1 ppb detection limit).

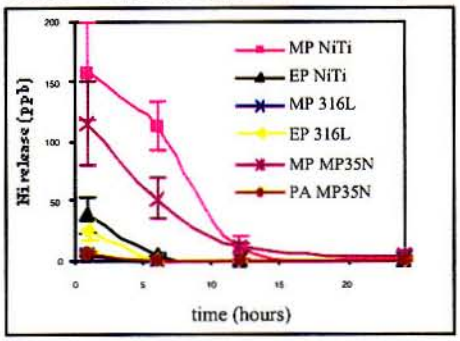

Figure 1. Ni release for different sample groups

Initially, EP NiTi and PA MP35N specimen released significantly less Ni than the mechanically polished groups. Ni release from 316L samples was low for the mechanically polished sample group and did not improve with the passivation treatment. These results confirm the importance of adequately passivating the surface of NiTi to minimize Ni release (after 1h Ni release was 37±15 ppb for EP NiTi compared to 159±40 ppb for MP NiTi) during implantation. Nevertheless, several studies have reported that a threshold value of 30 ppm is needed to trigger a cytotoxic response during *in vitro* experiments.[3,4] Our results on NiTi, MP35N and 316L show that this Ni release threshold is far from being reached, even without passivation, after 7 days of immersion in Hank's physiological solution.

Surface analyses are being performed to determine the effect of the passivation treatments on surface chemical composition and how they relate to Ni ion release.

References

[1]C. Trepanier et al, *JBMR*, 1998, 43, 433.
[2]B. Thierry et al, *JBMR*, (submitted).
[3]W. Jia et al, *JBMR*, 1999, 48, 488.
[4]R. Messer, L. Lucas, *Dent Mater*, 1999, 15, 1.