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BONE RESPONSE TO 316L-SS AND ZINALCO IMPLANTS

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When a metallic alloy is in contact with physiological fluids it corrodes releasing small metal particles and ions that accommodate in the surrounding tissues or are, even, incorporated to blood. The released metal ions may follow the same metabolic routes as the essential to life ions. They can, then, participate in unsuitable oxidation reactions and/or interfere in ion exchange processes (1). Some metallic ions play an important role in bone regeneration as the enzyme associated to osseous growth require these ions. Indeed, the differentiation and the proliferation of the bone cells require enzymes whose activity depends on metals like Cu and Zn (2).

The most often used metallic implants are titanium, titanium alloys and special stainless steel. Nevertheless, new materials are continuously tested to improve the performance of prostheses. In this context zinalco is a promising material, with mechanical properties adequate to substitute bone, its composition is 80% Zn, 18% Al and 2% Cu (3)
In previous works, we have shown through SMART test in wing cells of the fruit fly *Drosophila melanogaster* that zinalco was not genotoxic (4).

The effect of Zinalco on the mitotic index was carried out to detect cell damage in cultured human lymphocytes; there were no differences between control and samples exposed to 5, 50 or 200 μg of zinalco/ml (5-7). The Zinalco was not cytotoxic with lymphocytes.

Zinalco alloy shaped as small plaques was implanted subcutaneous or intramuscularly in rats, no evidence of Zn, Al, or Cu presence in blood was observed up to 8 months. There were neither toxicity nor rejection. Furthermore, the implanted rats turned out to be healthier than the control rats, rats implanted with 316L-SS steel (8-10).

When four dogs were implanted with cylinders made of zinalco and 316L-SS at proximal distal thirds of right femur, adjacent bone formation to the implants occurred. No severe periosteal irregular reactions nor osseous reabsorption or rejection were observed. The concentration of Zn, Al or Cu in the blood of implanted dogs did not change (11).

When 15 dogs were implanted with zinalco and 316L-SS nails, no rejections neither infections and no symptoms of disease were observed in the implanted dogs. Furthermore, the healing of the wound was normal in time for all animals. However, only dogs implanted with steel could support on their right back leg.

The comparative study of 316L-SS and zinalco implanted bones after one month has shown that there is zinc released in the implant surrounded tissue, by the corroded zinalco alloy. After six months the ratio mineral to organic tissue turns out to be the same for both implants although the bone growth in zinalco implanted animals has been disordered and the dog cannot use his leg. Zinalco then not only releases a high amount of zinc, which, can be toxic but it releases it as ions

and small particles. The mechanism of growth of the corresponding bone is altered. Most interesting is the organism response, which, manages to resorb this organic tissue and reaches after six months the normal proportion of mineral to organic tissue. However it is not able to correct the shape of the growth.
The organic-mineral ratio is not helpful, since in spite of being the same one for both implants, the dogs with zinalco implant do not have a functional bone structure.
It does not show, indeed, if the amount of Zn released by zinalco is toxic. The mechanisms of bone growth are altered by the presence of zinalco, this does not happen with steel.

Small particles and ions of the metals present in the alloy are free to react with bone tissue. It has been often reported that zinc which, is the main component of the alloy, may, if in small amounts promote bone formation but, in high concentration it causes cytotoxicity (12). Zinc inhibits osteoclastic bone resorption *in vitro*. Then, it has to be emphasized as far as zinc is bond to the metal alloy it is "safe", but when ions and small metal particles are incorporated to the tissue, bone responds with a great deformation. Hence the adverse effect of zinalco is due to the coordination or charge of metal ions. Zinc effect could explain in this way the irregular growth of bone.

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