Vantris®, a biocompatible, synthetic, non-biodegradable, easy-to-inject bulking substance. Evaluation of local tissular reaction, localized migration and long-distance migration

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Resumen

Biodegradable injectable bulking agents of animal origin present a fast rate of bio-reabsorption and may cause an allergic reaction. Biodegradable elements of synthetic origin have a high rate of reabsorption after a year. Nonbiodegradable agents of synthetic origin lead to the formation of a fibrotic capsule, giving stability and long-term permanence. VANTRIS® is categorized into this last group; it belongs to the family of Acrylics, particles of polyacrylate polyalcohol copolymer immersed in a glycerol and physiological solution carrier. Molecular mass is very high. When injected in soft tissues, this material causes a bulkiness that remains stable through time. The carrier is a 40% glycerol solution with a pH of 6. Once injected, the carrier is eliminated by the reticular system through the kidneys, without metabolizing. Particles of this polyacrylate polyalcohol with glycerol are highly deformable by compression, and may be injected using a 23-gauge needle. The average of particles size is 320 mm. Once implanted, particles are covered by a fibrotic capsule of up to 70 microns. Particles of this new material are anionic with high superficial electronegativity, thus promoting a low cellular interaction and low fibrotic growth. The new polyacrylate polyalcohol copolymer with glycerol was tested for biocompatibility according to ISO 10993-1:2003 in vitro, showing that they are not mutagenic for the Salmonella T strains analyzed. The extract turned out to be non-cytotoxic for cell lines in culture and non-genotoxic for mice. In in vivo studies, acrylate did not cause sensitization in mice. The macroscopic reaction of tissue irritation was not significant in subcutaneous implants and in urethras of rabbits. Seven female dogs were injected transurethrally with VANTRIS® to evaluate short and long-term migration (13 weeks and 12 months respectively). No particles or signs of inflammation or necrosis are observed in any of the organs examined 13 weeks and 12 months after implantation. To conclude, this new material meets the conditions of ideal tissue bulking material.

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