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Evaluating newly formulated osteoprotegerin-chitosan gel: An *in vitro* and *in vivo* study

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The binding of the receptor activator of nuclear factor kappa-B ligand (RANKL) to the receptor activator of nuclear factor kappa-B (RANK) on pre-osteoclast is essential for osteoclast maturation and activity. Osteoproteogerin (OPG) is a soluble decoy receptor for RANKL. Its binding to RANK prevents binding of RANKL to RANK and subsequent hinders activation of osteoclast. Various *in vivo* studies and clinical trials have investigated the systemic use of OPG in treatment of bone diseases. Chitosan is a cationic polymer derived from chitin. This material has antimicrobial activity, biodegradability, and muco-adhesive properties, making it an ideal material for biomedical applications. It also promotes cell adhesion, proliferation and differentiation. It is suggested that the local application of new formulated OPG-chitosan preparation may have similar osteogenic potential in the bone defect. The objectives of this study are: (i) to formulate of different forms of OPG-chitosan gels from different molecular weights of water-soluble chitosan (10, 25, 50 kDa), (ii) to evaluate the gels biodegradation, (iii) to determine amount of OPG protein release from gels and (iv) to evaluate the cytotoxicity of gels by Alamar Blue assay and scanning electron microscope. (iv) Efficacy of gel on bone regeneration in rabbit. From our studies we conclude that our gels are (i) non-toxic (ii) biodegradable and (iii) exhibits sustained release property. (iv) OPG-chitosan has a positive effect on bone formation. Therefore, we have proven that OPG-chitosan gel is evidently viable to be used locally for potential bone defect application.

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