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## Stability of ranibizumab and aflibercept for sustained release and their delivery from thiolated chitosan-based hydrogels

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**Statement of the problem:** The Anti-Vascular Endothelial Growth Factor (VEGF) agents such as ranibizumab (Lucentis®) and aflibercept (EyLea®) are currently used as monthly or bimonthly intravitreal injections to treat potentially blinding retinal diseases such as wet Age-Related Macular Degeneration (AMD) or Diabetic Macular Edema (DME). Because of the complications associated with repeated intra-vitreous injections, there is considerable interest in developing a sustained delivery system. The purpose of this study was to examine the stability of both therapeutic proteins under physiological conditions as well as when incorporated into drug delivery systems (DDS). Furthermore, these two therapeutic proteins were entrapped into thiolated chitosan-based hydrogels and their release was modulated by different degree of crosslinking. A detailed study of characterization of released protein was performed.

**Results:** Using several complementary and stability-indicating analytical methods, we have demonstrated that both ranibizumab and aflibercept were stable in an extended range of different pH conditions as well as when incubated at 37°C for up to 30 days. In addition, we investigated the stability of both proteins after a rapid screening method that simulates the first homogenizing step during the protein microencapsulation process. Finally, optimal controlled release of active released proteins from thiolated chitosan-based hydrogels was characterized.

**Conclusion & Significance:** The stability of ranibizumab and aflibercept may be considered optimal for long-term sustained release, maintaining their capacity to bind VEGF. Controlled bioactive release for one month was achieved for both proteins *in vitro* using thiolated chitosan hydrogels. These ones may be advantageous ocular carriers for improving wet AMD and DME.

### Biography

Miguel Moreno has a passionate interest in Drug Delivery and Innovation Management. He really looks forward to transferring his research to commercially feasible technology. He is a committed Biomedical Research Scientist with over 15 years of experience in Biophysics (protein-protein and protein-liposome interactions), Biochemistry, Polymer Chemistry, Drug Delivery Systems, Sustained Release, and Biomedical Applications. He has developed a polymer-based platform for carrying peptides, bringing out a targeted pro-cytotoxic drug delivery system based on wasp venom for cancer therapy, which has been awarded. At present, he is involved in a large "Ocular Diseases" project, from NTU-Northwestern Institute for Nanomedicine (NNIN), for developing new carriers to deliver anti-inflammatory drugs and anti-VEGF proteins for the treatment of wet age-related macular degeneration (AMD) and diabetic macular edema (DME). He has expertise in designing, optimizing and evaluating entrapment of therapeutic proteins, peptides and small molecules into a wide variety of nano- and microcarriers and hydrogels.

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