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ABSTRACT

A total of thirty New Zealand white male rabbits were injected intradermally using multiple dorsal sites with collagen fleece (Novacol) or fibrous form (Avitene), either plain or in an emulsion with Freunds adjuvant. Identical booster injections of the same dose as the initial challenge were given 22 days later. All animals were bled at 28 days after the booster injections. Using the sensitive ELISA method, it is concluded that collagen fleece did not induce antibody formation.

INTRODUCTION

The antigenicity of implantable biomedical products based on collagen protein has been rightfully a continuing concern of involved researchers as well as regulating agencies. The voluminous literature on collagen antigenicity could be summarized as follows: the pure collagen molecule is a rather weak antigen, approximately 50 times weaker than globular proteins, such as serum bovine albumin. Further reduction of the antigenicity can be achieved by cleaving the nonhelical peptides at N- and C-terminals of a collagen polypeptide chain or by introducing artificially new intra or intermolecular cross-links in the collagen triple-helical molecules. Three antigenic determinants have been identified in collagen:

1) The major antigenicity is in the telopeptides region. As indicated, telopeptides can be cleaved by pepsin digestion as in the case with collagen-Zyderm, manufactured by Collagen Corporation (CA).
2) The other antigenic determinant resides in a cyanogen bromide cleaved peptide 5.
3) The third determinant is associated with the helicity-crystallinity of collagen[1-8].

Collagen-based products used for topical hemostasis consist mostly of noncross-linked