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Title: SOFT TISSUE REACTION AND HEALING CHARACTERISTICS ASSOCIATED WITH URYX, A NEW BULKING AGENT PROPOSED FOR THE LOWER URINARY TRACT ETC.

Aims of Study:

Many new, biological and synthetic, materials are currently being evaluated for potential use as lower urinary tract bulking agents. Uryx (Genyx Medical, Aliso Viejo, CA) has previously been used for neurovascular, embolization indications with an acceptable efficacy and tolerability profile. The current study evaluated the safety and local implantation site response of Uryx within the lower urinary tract.

Methods:

Test or saline control material was injected into the urethral submucosa of 36 Sinclair swine. 3 Uryx and 1 control animal were sacrificed at 2 days, 1 week and 1, 3, 6, 9, 12, 18 and 24 months post implantation. Gross and histologic evaluation was performed to assess the implant site reaction.

Results:

Test animals demonstrated congestion, mild peri-implant fibrosis and macrophagic foreign body response at the implant site. A few animals demonstrated localized mucosal ulceration. These effects were most evident prior to 3 months and moderated after 6 months. At 9, 12, 18 and 24 months a stable fibrous capsule surrounded the implant material with sequestration of the implanted material within the implant site. Distant migration of Uryx was not observed. Control animals demonstrated mild to moderate congestion with areas of focal acute and chronic inflammation at the earlier sacrifice periods.

Conclusions:

Submucosal implantation of Uryx, in the urethra resulted in a well-encapsulated implant with minimal foreign body response at the implant tissue interface. It appears to remain stable in the anatomy without exaggerated inflammatory response or evidence of distant migration.

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