

These results demonstrate very clearly that using this severe animal model for surgical adhesions, there is no observed benefit to the use of the aqueous polymer solutions of this invention if used according to conventional or prior art methods. Using the method of this invention, however, the polymer solutions effect a dramatic reduction in adhesions as shown in Examples 2 and 3.

EXAMPLE 5

This example illustrates the surprisingly beneficial qualities of the hydrophilic polymer solutions of this invention when used by the method of this invention (i.e., coating of tissues prior to surgical manipulation) even when this is followed by the use of conventional surgical irrigating solutions such as physiological or normal saline or Ringer's lactate and without further use of the polymer solutions prior to closure.

As in Example 1, each rat underwent laparotomy through a midline incision after being anesthetized (I.M. injection of Ketamine, 100 mg/kg, and xylazine, 11 mg/kg), prepped and draped in a sterile fashion. The cecum was located, exposed and irrigated with the test solution. The distal portion of this organ then was abraded, in a standard consistent manner using solution-soaked gauze sponges. Intraabdominal irrigation with the test solution (ca. 6 ml per animal) was done before incision of peritoneum, prior to contact, exposure and manipulation of internal organs. Ringer's lactate solution (6 ml per animal) was applied before closure of the abdominal wall, performed as in other examples in two layers, with 3-0 Vicryl sutures. Two weeks later the animals were subjected to reoperations in which the peritoneal cavity was examined for the presence of adhesions which were graded according to the 0-4 scale.

The following results show very surprising effectiveness of the high molecular weight polymer solutions of this invention in inhibiting post-operative adhesions when applied to tissues prior to the surgical procedure and surgical manipulation of tissue even when a conventional surgical irrigating solution is used before closure:

Test Solution	# of Test Animals	% Significant Adhesions (scored 2 or greater)
Ringer's lactate (control)	15	73%
1.5% CMC	9	11%
0.6% HA	10	10%

EXAMPLE 6

This example illustrates the effectiveness of the aqueous polymer solutions and method of this invention in reducing pericardial adhesions in open heart and thoracic surgery using 1.0% CMC in a pericardial dog adhesion model. The following surgical procedure was followed:

Ten mongrel dogs weighing 15-20 kgs were divided into two groups of 5 each. One group was treated with a 1.0 wt. % aqueous solution of CMC (Hercules 7H3SF, mol. wt. ca. 800,000) and the other was treated with Ringer's lactate (RL) solution to serve as a control group.

Dogs were anesthetized initially with Biotol (0.04 mg.kg, I.V.). General anesthesia was maintained with

2% Enthrane and controlled ventilation following tracheal intubation. Each dog underwent a left thoracotomy through an incision at the fifth intercostal space, followed by ipsilateral pericardiectomy. Upon exposure of epicardium and prior to manipulation of internal organs, the pericardial sac was thoroughly irrigated with 20 ml of the test solution. The epicardium and the inner surface of the pericardium on the left side were abraded with 20 strokes of a gauze sponge wet with test solution to induce a hemorrhagic lesion. The pericardial sac was irrigated three times, each time with 20 ml of solution (60 ml total): immediately following pericardiectomy, 15 minutes follow-pericardiectomy, and prior to pericardial closure. After the epicardium and inner surface of the pericardium had been exposed for 30 minutes, to simulate intraoperative dessication, the pericardium was closed loosely with 2-0 silk sutures. Thoracotomy closure was performed in the usual fashion including aspiration of air and fluid from the left chest. Intercostal nerve blocks were induced with 1% Xylocaine and 1/100,000 epinephrine. All dogs received normal diets post-operatively.

Six weeks later the animals were subjected to reoperation. Bilateral thoracotomies, under general anesthesia, with subsequent pericardiectomy were performed and the pericardial cavity was examined. Two independent observers unaware of the study solutions used in each animal evaluated the extent and severity of pericardial adhesions on the 0-4 grading scale. All animals were sacrificed and biopsies of abraded and unabraded epicardium along with those of the pericardium underwent histological evaluation.

The CMC treated group showed a marked reduction in pericardial adhesions as compared with the RL control group; 20% adhesions scored 2 or greater for the CMC group compared with 100% scored 2 or greater for the RL group. Histological sections of epicardium and pericardium which were evaluated for thickness, inflammation, fibrosis and neovascularity revealed no statistical differences in any parameter comparing the CMC solution with the RL control solution. These results confirm the effectiveness and safety of using the polymeric materials and method of this invention for prevention of pericardial adhesions.

The hydrophilic, polymer material may be dissolved in any suitable aqueous solution conventionally employed in surgery, e.g., Ringer's lactate, normal saline, or any other isoosmolar physiological medium.

We claim:

1. A method of preventing post-operative surgical adhesions of tissue in surgery comprising providing said tissue surfaces involved in said surgery with a wet coating of a physiologically acceptable aqueous solution of a hydrophilic, polymeric material prior to manipulation of said tissue during said surgery, wherein:

A) said polymeric material is a water-soluble, biocompatible, pharmaceutically acceptable polyelectrolyte polysaccharide, excluding hyaluronic acid having a molecular weight above about 1,500,000; a salt or complex of said polysaccharide or mixtures thereof; and

B) said polysaccharide has a molecular weight of about 500,000 or above, and the concentration in said aqueous solution of said polysaccharide is in the range of from about 0.01% to about 15%, by weight; said molecular weight and concentration