Fixation of Interceed does not improve its efficacy against adhesion formation in rats

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Summary: A randomized controlled trial was performed in 30 Sprague-Dawley white rats to compare the efficacy of the synthetic adhesion-barrier Interceed (Johnson & Johnson Medical Inc.) when fixed in place using 6/0 vicryl sutures or lying freely on damaged tissues. The rats were randomly assigned to 3 groups; control, Interceed (fixed) and Interceed (free). Adhesion formation was measured 2 weeks later, using a scoring system related to extent and density.

There was no significant difference whether the adhesion-barrier was fixed in place with sutures or not, so that the fixation of Interceed to cover traumatized tissues does not appear to promite the fixation of the promite that the promit

vide any benefits against adhesion formation in rats.

Key words: Pelvic adhesions; Interceed; Adhesion barrier.

INTRODUCTION

Adhesion formation is a recognized complication of pelvic surgery which can alter anatomical relationships of tissues, cause tubal blockage and thus be a factor in subsequent infertility. Surgery specifically designed for enhancing fertility must therefore utilize any means possible to prevent adhesion formation.

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Apart from the application of microsurgical techniques, continuous irrigation of tissues and other mechanisms, adhesion barriers such as Interceed (Johnson & Johnson Medical Inc., New Jersey, USA) and Gore-Tex (W. L. Gore & Associated Inc., Arizona, USA) have been developed and are currently in use (Interceed-TC7 Adhesion Barrier Study Group, 1989 (3); Boyers et al., 1988 (2).

Interceed is an oxidized regenerated cellulose patch which is absorbable over a period of a few days. However, recent studies have questioned the value of Interceed in adhesion prevention. Pagidas and Tulandi, 1992 (⁴), using a rat model, suggested that Ringer's lactate instillation was the most effective in decreasing adhesion formation when compared with Interceed and Gore-Tex. Best *et al.*, 1992 (¹) performed their studies in rabbits and they concluded that Interceed

was an ineffective adhesioprophylactic agent.

The Authors have used Interceed but have been concerned that the material showed an ability to be easily shifted from its intended placement site over the damaged tissues. This view is alluded to by Montgomery-Rice *et al.*, 1993 (5), who suggest that repositioning a patient to a level attitude from a Trendelenburg position can introduce irrigating fluid collected in the abdomen into a previously dry field, thus displacing the Interceed.

The aim of this study was to compare the efficacy of Interceed against adhesion formation depending upon whether the material was held in place or not.

MATERIALS AND METHODS

Thirty female Sprague-Dawley white rats of reproductive age and birth weight 200-300 g were obtained from the School of Veterinary Medicine and all procedures were performed at The Experimental Surgery facility there. The rats were randomly assigned to three groups as follows:

Group I: Control;

Group II: Interceed/free placement;

Group III: Interceed/fixed placement with 6/0 vicryl.

Antibiotic prophylaxis (ampicillin 0.1 mg subcutaneously) was given to all subjects pre-operatively.

After induction of general anaesthesia using intraperitoneal injection of ketamine hydrochloride, laparotomy was performed via a midline incision and a standardized denuding lesions was performed over 1 cm of the right uterine horn using electrocautery. A corresponding 1 cm patch of tissue was denuded from the right pelvic side-wall according to the method previously described by Montgomery-Rice *et al.*, 1993 (5) as these lesions are known to produce a high adhesion formation rate. The lesions were approximated by a single suture of 3/0 vicryl (*) placed 0.5 cm inferior to the denuded tissue and, when applicable, a patch of Interceed was placed over each raw surface. For

fixation, 6/0 vicryl was used to tack each corner of the Interceed.

Routine abdominal closure was performed in layers using 3/0 vicryl. After two weeks, the rats were killed using thiopentone overdosage and the extent of adhesions were scored by the original surgeons who did not know the identity of the rats.

Scoring was carried out using the system of Steinleitner *et al.*, 1988 (6) modified as follows:

Grade 0 - no adhesions;

Grade 1 - filmy intrahorn or intralesional adhesions;

Grade 2 - thick, vascular intrahorn or intralesional adhesions;

Grade 3 - filmy adhesions connecting the uterine horn to the bowel or to the anterior abdominal wall;

Grade 4 - thick, vascular adhesions connecting the uterine horn to the bowel or to the anterior abdominal wall.

Statistical evaluation was performed using the Kruskal-Wallis one-way analysis of variance.

RESULTS

Table 1 shows the ranked scores obtained for each rat in the three groups. Statistical analysis showed no difference among the three groups (p > 0.05) so that fixation of Interceed did not appear to decrease the development of pelvic

Table 1. — Adhesion scores (ranked) in each group.

Subject Number	Group I (Control)	Group II (Interceed- free)	Group III (Interceed- fixed)
1	0	0	0
2	1	0	1
3	1	0	1
4	2	0	1
5	2	2	2
6	3	3	4
7	4	3	4
8	4	3	4
9	4	4	4
10	4	4	4
Total (SEM)	25 (0.48)	19 (0.54)	25 (0.52)

p < 0.05 (Kruskal-Wallis).

^(*) Ethicon Ltd., Edinburgh, U.K.

adhesion. When Interceed was freely placed however, there were more instances of zero or filmy quality adhesions.

DISCUSSION

The high scores in the control group serve to underscore the reliability of this model as an adhesion provoker (5). Similar high scores were obtained when Interceed was fixed in place to cover and separate the traumatized tissues. This finding therefore does not support the hypothesis that shifting of the material from its intended placement site may be a factor in allowing adhesion formation to take place.

It is intriguing that such marked intergroup variation occurred when Interceed was placed freely onto traumatized sites and that in the maority of cases (7/10) there were either no adhesions or only filmy quality bands. Since filmy adhesions can be easily freed by minimally invasive laparoscopy with excellent results it appears from our findings therefore that Interceed has been of some value.

It is possible that the vicryl material used to tack the Interceed may have itself worked as a foreign-body which encouraged dense adhesion formation similar to that seen in the control animals.

In conclusion, this study does not support the concept of fixation of Interceed to cover traumatized tissues.

REFERENCES

- 1) Best C., Rittenhouse D., Vasquez C., Norng T., Subias E. and Sueldo C.: "Evaluation of Interceed (TC7) for reduction of post operative adhesions in rabbits". Fertility and Sterility, 1992, 58, 817-820.
- 2) Boyers S., Diamond M. and De Cherney A.: "Rduction of postoperative pelvic adhesions in the rabbit with Gore-Tex surgical membrane". Fertility and Sterility, 1988, 49, 1066-1070.
- 3) Interceed (TC7) Adhesion Barrier Study Group: "Prevention of post surgical adhesions by Interceed, an absorbable adhesion barrier: a prospective randomized multicenter clinical study". Fertility and Sterility, 1989, 51, 933-938.
- Pagidas K. and Tulandi T.: "Effects of Ringer's lactate, Interceed (TC7) and Gore-Tex surgical membrane on postsurgical adhesion formation". Fertility and Sterility, 1992, 57, 199-201.
- 5) Montgomery Rice V., Aida S., Moghissi K. and Leach R.: "A comparative evaluation of Poloxamer 407 and oxidized regenerated cellulose (Interceed TC7) to reduce post operative adhesion formation in the rat uterine horn model". Fertility and Sterility, 1993, 59, 901-906.
- 6) Steinleitner A., Lambert H., Montoro L., Kelly E., Swanson J. and Sueldo C.: "The use of calcium channel blockage for the prevention of postoperative adhesion formation". Fertility and Sterility, 1988, 50, 818-821.

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