

A new crosslinked hyaluroan gel is able to prevent intrauterine adhesion following hysteroscopic adhesiolysis: A randomized, multi-center, controlled study ¹

Background: Intra-uterine (IUA) is one of the common disorders in gynecology. Patients with IUA may have pelvic pain, menstrual abnormalities, and infertility. Hysteroscopic adhesiolysis is usually performed to remove the scar tissue, restore uterine cavity, and ideally the functional of endometrium. However, reformation of adhesion was reported to be as high as 60% in patients with severe adhesions². Therefore, methods preventing re-adhesion need to be implemented to ensure a successful hysteroscopic adhesiolysis.

Objectives: To evaluate the effectiveness and safety of a new crosslinked hyaluronan gel (MateRegen[®] Gel) in preventing reformation of IUA after adhesiolysis.

Study Design: Randomized Clinical Trial. Patients with moderate to severe IUA according AFS scoring system³ were enrolled. After hysteroscopic adhesiolysis, patients in the treatment group (N=60) received MateRegen[®] Gel together with Foley balloon catheter; whereas patients in the control group (N=60) received only Foley balloon catheter. Second look hysteroscopy was performed at 3 months after surgery and adhesion was scored. The primary endpoint was the percentile of patients in each group without adhesion (Non-IUA rate) at 3-month hysteroscopic examination. The secondary endpoint was AFS score.

Results:

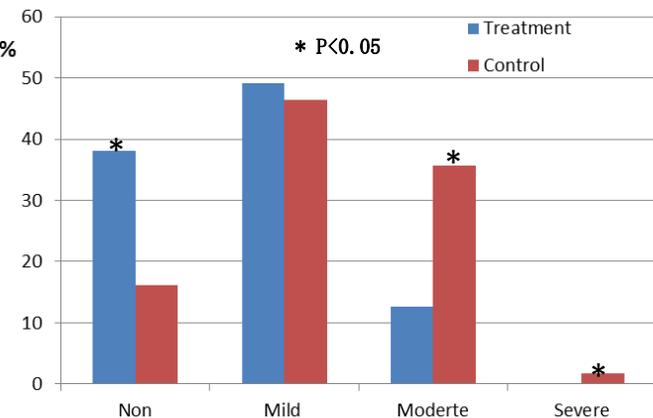


Fig. 1. Application of MateRegen[®] Gel significantly reduced IUA reformation and the severity of IUA.

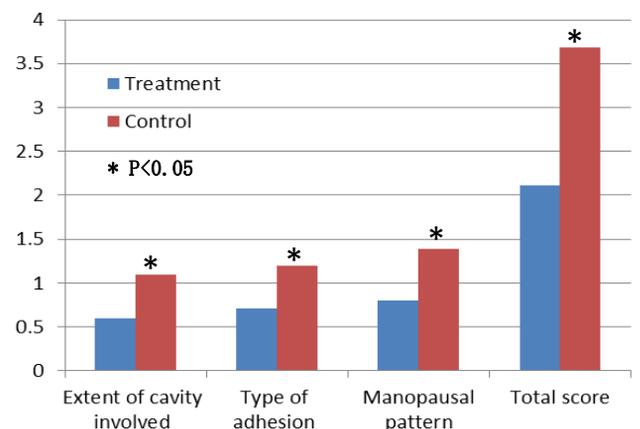


Fig. 2. The ASF total score and score of individual category were all reduced by MateRegen[®] Gel.

1. Xiao SS et al. Manuscript submitted for publication.
2. Pabuccu R, et al. Fertil Steril 1997;68:1141-3
3. The American Fertility Society Scoring system. Fertil Steril 1988;49:944-55 (table below)

Extent of cavity involved	<1/3 (1)	1/3-2/3 (2)	>2/3 (3)
Type of adhesions	Filmy (1)	Filmy and dense (2)	Dense (3)
Menopausal pattern	Normal (0)	Hypomenorrhea (2)	Amenorrhea (4)

Stage I (Mild): 1-4; Stage II (Moderate): 5-8; Stage III (Severe): 9-12

Hyaluronic acid used for preventing post-surgery adhesions

Hyaluronic acid (HA) based materials have been widely used for prevention of post-surgery adhesions in gynecology, ENT, hand surgery, and general surgery. HA is the natural molecule in the body extracellular matrix and therefore HA-based material has excellent biocompatibility. It was also reported that HA molecules could modulate inflammatory processes and regulate secretion of cytokines by macrophages.

However, natural HA material degrades quickly in the body (24-48 hours) and does not have proper viscosity to stay in the implanted site for long enough. Therefore, HA has been modified by crosslinking methods to increase the viscosity and to decrease the degradation profile in order to cover the traumatized tissue surfaces during the critical repair processes. Crosslinked HA has been reported to effectively prevent post-surgery adhesion in abdominopelvic cavity, intrauterine cavity and sinus cavity.

MateRegen® Gel

MateRegen® Gel (BioRegen Biomedical Co. Ltd.) is developed using a proprietary thiolated chemistry to crosslink the non-animal sourced HA molecules. The modification/crosslinking is well controlled so that the crosslinked HA gel has adequate degradation profile and viscosity to match the critical period of tissue repair processes and is able to prevent adhesion.



How is supplied

MateRegen® Gel is prefilled in a glass syringe containing 5cc gel. Package of 1 syringe (5cc gel) or 2 syringes (10cc gel) are available. Individually packaged 5 cm long moldable cannula is also provided to assist delivery of the gel.



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