Use of Resorbable Haemostyptic Traumastem TAF Light in Oncogynecology

Verification of Efficacy, Broadness of Application, Safety and Simplicity of Use

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1. Introduction

Oncology treatment is and will always be a multidisciplinary branch. In this branch the final outcome of treatment is determined by the participation of clinical departments of hospitals and specialized institutes and also as a complement to this we have to include manufacturers of medicaments, curative and therapeutic remedies, devices etc. The continuous priority is the quality of a patient's life. One of the approaches of how to ensure this condition in the setting of highly radical surgical operations is the reduction of peroperational and postoperational blood losses and the reduction, or rather elimination of universally known risks after blood transfers.

2. Traumastem TAF Light

Traumastem TAF Light was available for us for clinical evaluation. It was used in outpatient practise for treatment of the uterine cervix after sample collection for histological examination in routine and radical oncogynecological surgery according to individual diagnoses.

Traumastem® Taf is a sterile resorbable haemostatic reticulum. It is used to stop capillary and venous bleeding. Haemostatic effect is immediate, complete hemostasis is reached several minutes after the application.

It is suitable for general and digestive surgery, plastic surgery, orthopedy, gynecology, urology, dentistry and also in other branches of surgery. It does not start undesirable immune reaction or sensibility after repeated use. It is especially useful for stopping bleeding from resection surfaces of parenchymatic organs. Traumastem TAF Light can be fixed in place with a stitch. It is totally tolerated by the organism and does not disturb the biological healing processes.
Cellulose is a derivative of oxidized cellulose. In principle it is 6-carboxycellulose. The qualities of oxidized cellulose are very important. Most importantly it is manufactured from 100% pure natural cotton. Oxidized cellulose is biodegradable, bioreabsorbable, biocompatible and highly resorbable. It has an antibacterial, haemostathemostatic effect and helps tissue regeneration.

**Composition:** oxidized cellulose 100%

**Size:**
- 1.5 x 5 cm
- 7.5 x 5 cm
- 12.5 x 5 cm
- 35 x 5 cm
- 20 x 10 cm

### 3. Aims of the Study

**Verification of the efficacy, broadness of application, safety and simplicity of use**

The basic requirement for the use of any Haemostatic preparation is it's efficacy. Current surgery uses textile haemostatics, which look like woven knitwear made of oxidized regenerated cellulose. When saturated with blood it changes to brown, nearly to black, gelatinous matter which helps with the formation of blood clots while exerting slight pressure to the bleeding area. A surgeon places a haemostatic in the form of woven knitwear directly to the bleeding area or organ. The bleeding stops in 2 to 8 minutes. Complete absorption of the material occurs in 10–14 days.

The textile form of sterile material allows the perfect adjustment to organs that vary in shape as well as to the various irregular surfaces to which it perfectly adheres.

Traumastem® Taf is hypoallergenic – it does not manifest any sensitising properties or immune system reactions, even after repeated exposure it is well tolerated by the organism and it partakes in faster healing of wounds e.g. scratches, leg ulcers, decubitus etc. It does not irritate the place of application, no granulomas are formed, it has bactericidal and bacteriostatic effects, and no undesirable effects of the preparation are currently known.

### 4. Outpatient Practice

Treatment of the uterine cervix after sample collection for histological examination – during sample collection massive capillary bleeding often occurs, especially with exulcerated carcinoma. A routine procedure means the application of compression tampon packing and in many cases is accompanied by a urinary catheter. With the use of Traumastem® Taf preparation in 14 patients hemostasis occurred in 11.

For one patient the application of compression tampon packing was necessary and 2 patients were hospitalized for unstoppable bleeding and embolisation of iliac vessels was performed on them in combination with the haemostatic application of radium.
Uterine Cervix Carcinoma – before sample collection for histological processing

Uterine Cervix Carcinoma – after sample collection for histological processing
Summary
The application of Traumastem TAF Light was effective in 11 patients, in the rest extended combined Haemostyptic therapy had to be used according to the advance of primary oncological disease.

5. Surgery – most frequent modalities of use
Surgical treatment of tumours and pre-tumour states of uterine cervix carcinoma with application of preparation Traumastem TAF Light
According to disease spread and with respect to the preservation of fertility in earlier stages of the disease we distinguish surgical operations as either conservative or radical.

Conservative: fertility preserving operations
a) conization of the uterine cervix
b) trachelectomia with uterine cervix plastic and simultaneous laparoscopical pelvic lymfadenectomy of navigated nodes

Radical operations
Extrafascial hysterectomy (with the preservation or removal of the adnexa) is sufficient operation for stadium Ia1.

With stadium Ia2 we extend the operation with pelvic and paraaortal lymfadenectomy

Conservative: fertility preserving operations
Conization presents the simplest treatment for precancerous stages and early stages of cancerous diseases of the cervix uteri. Technical implementation consists of cutting the relevant cone into healthy tissue with subsequent hemostasis.
State After Uterine Cervix Conization

Application of Traumastem TAF Light
Summary
The application of Traumastem TAF Light was effective in 7 patients after conization of uterine cervix was performed, one patient has been hospitalised on the 3rd day after release for isolated vascular bleeding.

Radical Hysterectomy with Pelvic Lymfadenectomy
Operation Preparation

Application of Traumastem TAF Light

Summary
The application of Traumastem TAF Light was effective in 12 patients, in 2 patients it was necessary to perform compression tampon packing and to make specific sutures of a small venous connection.
Vaginal cancer belongs among rare gynecologic malignant neoplasma - 1 patient in group

Carcinoma of the Vagina – preoperational finding

Carcinoma of the Vagina – operation procedure
Carcinoma of the Vagina – operation preparation

Application of Traumastem TAF Light

Summary
In quoted localisation we have not encountered any complications
Uterine Cancer – 20 patients

Operation Preparation

Pelvix Lymfadenectomy
Application of Traumastem TAF Light

Summary
Uterine cancer represents the widest surgical spectrum in oncogynecology. In our group we have encountered neither peroperational nor postoperational complications.

Ovarian Cancer - 8 patients

Operation Preparation
Tumor Bed

Application of Traumastem TAF Light in Tumour Bed

Summary
The application of Traumastem TAF Light in a tumour bed is an ideal procedure after the extirpation of a tumour firmly adhering to pelvic walls. Due to the fast adherence and hemostasis, Traumastem TAF Light is becoming a preferred therapeutic option in wounds bleeding superficially.
Other Surgeries

Benign tumors

Summary
Six patients were operated on for benign gynecological tumours with the use of Traumastem, Traumastem TAF Light was usually applied in the tumour bed or to the vaginal stump. No complications were noted.
6. Results

<table>
<thead>
<tr>
<th>Operation type</th>
<th>Number of Operations</th>
<th>Complications</th>
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</thead>
<tbody>
<tr>
<td>Cervical Biopsy</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Conization</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Radical Hysterectomy</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Vaginal Cancer</td>
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<tr>
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<tr>
<td>Ovarian Cancer</td>
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<tr>
<td>Nononcological Operations</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

Recorded complications don’t have a causal connection with the application of the preparation Traumastem TAF Light, but are normally recorded surgical complications.

7. Conclusion

The presented study has confirmed the efficacy, broad application, safety and simplicity of use of the preparation Traumastem TAF Light in oncogynecological outpatient practise and surgical practice.

By proper and specific application we have proven an immediate haemostatic effect, perfect absorption without any undesirable allergic reaction and the broad application in the whole range of oncogynecology.

8. Recommendation

Traumastem TAF Light is a completely safe haemostatic for widest usage in oncogynecology and due to it’s fundamental qualities – biodegradability, bioresorbability, biocompatibility, an antibacterial effect and a haemostatic effect it presents one of the approaches to decrease the bleeding risk and therefore it also opens the possibility of the application of blood derivates.