A Compendium of Scientific Literature

Safety and Efficacy of 4DryField® PH
Supporting Evidence
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Background
Large size peritoneal trauma from extended surgery for high-grade expansive uterus pathology or endometriosis might result in severe diffuse bleeding and peritoneal adhesion formation with objectionable sequelae. This paper introduces 4DryField® PH polysaccharide powder certified for two indications: 1) given as powder 4DryField® PH provides hemostasis; 2) transformed into gel, 4DryField® PH forms an adhesion prevention barrier.

Methods
Twenty-one women with expanded uterus pathology and/or deep infiltrating endometriosis had surgery including repair of intestine lesions (n = 8), ureterolysis/repair of bladder, including retrograde ureteric stents (n = 5). Subjective impression of hemostatic effect, drain loss and infection parameters were recorded. Six women had scheduled second look laparoscopy.

Results
4DryField® PH applied as powder showed an immediate significant hemostatic effect in all instances, especially in profound diffuse bleeding. Mean drain loss was 497 ± 339 mL, moderate considering the extent of disease. Dripped with saline solution, 4Dry Field® PH immediately formed a viscous gel acting as a barrier for adhesion prevention. Second look laparoscopy revealed only one patient with significant adhesions. No adverse events were observed; discharge was at Day 6.2 ± 1.4. In this cohort with extended gynecological laparoscopic surgery 4DryField® PH was very effective for hemostasis. The results of second look laparoscopies showed mainly no or minor adhesions. This can be considered very favorable regarding the extent of disease in these patients.
Conclusion
Considering the twofold effect in hemostasis and adhesion prevention, 4DryField® PH is a very helpful tool especially in extensive and complicated surgeries. Prospective randomized studies are necessary to prove these promising results in a larger cohort.

Summary
- 4DryField® PH was effective in diffuse bleeding control and adhesion prevention
- Adhesion prevention was proven by second-look (Figure 1)
- 4DryField® PH is a helpful tool even in extensive surgeries for deep infiltrating endometriosis affecting multiple organs, myoma resection and hysterectomy

Figure 1: 4DryField® PH powder application for hemostasis followed by transformation into an adhesion prevention gel. Second-look after 8 weeks proves its excellent efficacy.
Purpose
This study evaluates both scopes of 4DryField® PH, certified for adhesion prevention and hemostasis, in patients undergoing surgery for various and severe gynecological disorders.

Methods
is is a two-institutional study. Adhesion prevention efficacy was evaluated using video documentation of first-look laparoscopies (FLL) and second-look laparoscopies (SLL); other patient data were analyzed retrospectively. Twenty patients with various disorders were evaluated, 4 assigned to a uterus pathology, 10 to endometriosis, and 6 to an adhesion disease group. Nine patients received 4DryField® in addition for hemostasis and 11 solely for adhesion prevention. Nineteen patients had SLL after 5 to 12 weeks and one after 13 months.

Results
At FLL with 4DryField®, immediate hemostasis could be achieved in diffuse bleeding. At SLL, effective adhesion prevention was observed in 18 of all 20 women, with only 2 revealing major adhesions. In particular, only 1 of the 6 women with adhesion disease as predominant disorder showed major adhesions at SLL.

Conclusion
Modified polysaccharide 4DryField® is not only effective in diffuse bleeding. In this cohort with extensive surgery for various gynecological pathologies, 4DryField® gel showed effective adhesion prevention as confirmed at SLL. Its use as premixed gel is a convenient variant for treatment of large peritoneal wounds.

Summary
- 4DryField® powder provides hemostasis in diffuse bleedings and 4DryField® gel is highly effective in preventing adhesions after resection of myoma, endometrosis, and endometrium carcinoma and after extensive adhesiolysis, confirmed by second-look.
Background

Uterine perforation is the most common complication of curettage and may result in bleeding. Therefore, urgent control of bleeding from the uterine wall perforation is necessary to avoid an emergency hysterectomy or blood transfusion, to prevent peritoneal adhesion formation, possible chronic pelvic pain, and infertility. In the present case, an active bleeding secondary to a perforation of the uterus during curettage, for diagnosis of endometrial carcinoma, was instantaneously and successfully treated with only the application of a novel modified polysaccharide powder. This is, to the best of our knowledge, the first time that the agent 4DryField® PH has been used for this purpose.

Case presentation

A 71-year-old German woman with serometra and endometrial hyperplasia suffered a perforation of the anterior wall of the uterus during the hysteroscopic resection of submucosal polyps and a fractional curettage. Subsequently, an immediate laparoscopy showed an active bleeding from the wound, which was promptly stopped with the application of the hemostatic powder, 4DryField® PH. As gel the product prevents adhesions. There were no postoperative complications. Nine weeks later, a laparoscopic hysterectomy with bilateral salpingoophorectomy for endometrial carcinoma (histology: stage IA, pT1a, cN0, L0 V0 M0/G2) was performed. The former injured area looked slightly prominent, was completely healed, and showed a shiny serosa. All her pelvic organs were free of adhesions, and there was one 0.5-mm calcified granuloma in the Douglas pouch.

Conclusions

The efficient hemostasis combined with the adhesion prevention effect of 4DryField®, allowed a fast control of the uterine wall bleeding, saved operation time, avoided the risks of other procedures for bleeding control and contributed to the normal healing of the uterine wall without any adhesion formation.

Summary

- Efficient hemostasis, adhesion prevention and good healing with 4DryField®
- Reduced operation time and risk via fast bleeding control
Introduction

Seroma formation is one of the most prevalent complications after liposuction, abdominoplasty, mastectomy or hernia repair. They can disappear without treatment, but also may persist and require complex therapy. This report describes how 4DryField® PH polysaccharide powder successfully was applied for chronic seroma therapy.

Presentation of the case

An 80 year old male patient presented with a persistent seroma (1000 cm³ volume) resulting from liposuction about 15 years ago. In a first approach he was treated using en bloc excision without opening the capsule. Three month later the patient presented with a recurrent seroma of the same size. This time 1100 cm³ bloody discolored fluid was aspirated. The skin was lifted using a redon tubing drawn through the whole length of the wound cavity. This allowed even distribution of 4DryField® PH powder (10 g) within the former seroma cavity. Computed Tomography (CT) imaging after 4.5 month and sonographic examination after an additional year confirmed treatment success.

Discussion

Besides conventional methods for hemo-/lymphostasis several adjunct measures like fibrin sealants, medication with corticoids and diurectics have been proposed for seroma prevention/therapy, unfortunately, with conflicting evidence. In an experimental study seroma prevention with a polysaccharide was demonstrated; however, clinical proof is missing. This case provides first clinical evidence that 4DryField® PH polysaccharide powder evenly distributed in the former seroma cavity can prevent its recurrence.

Summary

- 4DryField® PH powder treatment is a promising new approach for prevention and treatment of seroma.
Background

Adhesions occur after up to 97% of abdominal interventions causing chronic pain, infertility and intestinal obstruction. Various concepts to prevent adhesions have been presented, but mostly either have low efficacy or are not applicable in resective intestinal surgery or incomplete hemostasis. In this retrospective one-center clinical trial, the course of patients with extensive abdominal adhesiolysis and application of a recent starch-based formulation, 4DryField® PH (4DF), is analyzed.

Case Report

Five female patients (age 65–83 years) underwent extensive open adhesiolysis with application of 4DF gel for adhesion prevention, premixed extra-corporally with saline or Ringer’s solution (60–70 mL per 5 g 4DF) for homogeneous gel distribution on intestinal loops and in the peritoneal cavity. In addition, dry 4DF powder was dispersed on the greater omentum and subsequently transformed into a gel by dripping with saline or Ringer’s solution directly before abdominal closure. Patients were followed up for more than two years, except for one patient who died after nine months due to metastases. One patient with complex situation due to Gore-Tex mesh in the lower abdomen showed no adhesions at scheduled second look operation, but after six months had relaparotomy for adhesiolysis. All other patients have remained free of adhesions or adhesion-related symptoms during follow up.

Summary

Considering extent and complexity of adhesions, treatment with 4DF gel for adhesion prevention after open adhesiolysis appears promising. Prospective randomized trials should further elaborate on this clinical concept. The agent can generally be applied in acute and chronic intestinal obstruction, healing of anastomoses does not seem to be impaired.
Purpose
To investigate impact of polysaccharide hemostat 4DryField PH (4DF) applied on lymph node dissection area after radical retropubic prostatectomy (RRP) on lymphorrhea and lymphocele (LC) formation.

Methods
104 consecutive patients underwent RRP, 51 without 4DF treatment (CT-group) and 53 with 4DF treatment (4DF-group). Groups were comparable (age, risk profile, and lymph node numbers). Postoperative drain loss (PDL) and development of early and late LC were analyzed (mean follow-up at 7 months: 100%).

Results
PDL was 452.5 ± 634.2 mL without and 308.5 ± 214 mL with 4DF treatment. PDL > 1000 mL only occurred in CT-group (5/51). Overall, 45 LC (26 in CT- versus 19 in the 4DF-group) were diagnosed. At day 8, LC were equally distributed between groups. Incidence of late LC, however, was twice in controls (16/51) versus 4DF-patients (8/53). Symptomatic LC (4 in untreated patients, 2 in 4DF-patients) were treated with percutaneous drainage (duration: 45 days in untreated patients versus 12 days in 4DF-patients).

Conclusion
Application of 4DF on lymph node dissection areas lessened total drain loss and significantly lowered high volume drain loss. Furthermore, 4DF reduced frequency of late lymphoceles and lymphoceles requiring treatment by half, as well as duration of percutaneous drainage by more than two-thirds.

Summary of 4DryField® effects
- Less total drain loss and especially high volume drain loss
- Incidence of late and treatment requiring lymphoceles was reduced by half
- Treatment time was reduced by two-thirds
First experience with the haemostat 4DryField at the burn centre in Aachen

Background
In burn medicine surgical bleedings are a severe clinical complication because of the large wound areas. Polysaccharide based haemostats allow for new ways of treatment. They absorb wound secretion and thereby promote formation of a fibrin-based surface covering network of blood clots ultimately leads to wound closure. 4DryField® PH is a new solely plant-based product, which is CE certified in Germany for treatment of bleeding surgical wounds. According to the manufacturer the product is not pyrogenic or allergenic, it has good flow properties and is easy to apply during surgery. In this study we focused on the question whether 4DryField® can reduce or prevent complications such as drop of haemoglobin levels or circulatory instability and the resulting consequences in burn patients.

Methods
Since May 2013 8 patients (n=8) were treated with the haemostat 4DryField® at the burn centre of the university clinic RWTH Aachen and retrospectively analysed. The application was primarily performed at tangential and epifascial necrotomy wounds and sites of split skin removal. A preliminary analysis comparing 4DryField® treated patients to a control group (patients treated without 4DryField®) was performed. The evaluated parameters were haemoglobin levels, possible haemorrhage, erythrocyte consumption and hospitalisation.

Results
Based on our results of this clinical study we would like to present different modes of application and our experience with 4DryField® in burn surgery. For a more precise statement more patients and a comparison with other haemostats are necessary and planned.

Summary
- 4DryField is a useful tool in the field of burn surgery
Purpose
To evaluate in vitro cytotoxicity/biocompatibility as well as in vivo tolerability of the novel polysaccharide 4DryField® PH, certified for haemostasis and adhesion prevention.

Methods
*In vitro* cytotoxicity/viability testing according to ISO EN 10,993 using murine and human tumour cell lines incubated with 4DryField® PH (PlantTec Medical GmbH). Using a rat model the impact of 4DryField® PH on animals viability and in vivo effects were macro- and micropathologically assessed.

Results
*In vitro* testing revealed no cytotoxic effect of 4DryField® PH nor enhancement of viability to tumour cell lines. In vivo viability of rats was unimpaired by 4DryField® PH. Bodyweight loss in animals with abdominal injury plus treatment with 4DryField® PH was in the range of controls and less than in injured rats without treatment. At day 7 after surgery no formation of adhesions, neither macroscopic nor histological remnants nor signs of foreign body reaction were present in animals without injury. In animals with peritoneal injury and 4DryField® PH application, histopathological observation revealed minor residuals of polysaccharide in the depth of wound cavity embedded in a thickened subperitoneal layer; however, with a suggested intact neoperitoneum. The presence of mononuclear cells surrounding polysaccharide particles in varying states of degradation was observed as well.

Summary
- 4DryField® PH is not cytotoxic
- 4DryField® PH does not enhance viability of tumour cells
- High dose of 4DryField® PH of up to 1.09g/kg bodyweight is well tolerated
- Weight loss in animals with peritoneal injury is reduced with 4DryField® PH
- The biocompatibility of 4DryField® PH is excellent
Background
Adhesions due to pelvic/abdominal surgery are a common serious pathology possibly entailing severe complications. This study investigates the adhesion prevention capability of the novel starch-based agent 4DryField® PH, which together with saline solution forms a barrier gel. Herein, an optimized adhesion model (OPAM) inducing severe adhesions/agglutinations with high reproducibility was used.

Methods
In 19 Lewis rats, a 1 × 2 cm abdominal wall defect was created, the peritoneum of the neighbouring cecum was abraded, and both injured areas were approximated by suture. Rats were randomized to control (n = 10) or 4DryField® PH treatment (n = 9) groups. Another 8 rats had sham surgery for safety assessment of 4DryField® PH. At day 7, the quantity and quality of adhesions were assessed macro-/microscopically and evaluated statistically.

Results
4DryField® PH treatment significantly reduced the incidence and severity of adhesions as verified by significantly improved adhesion scorings (0.4 vs. 4.5; 1.1 vs. 9). Histology revealed reconstitution of the cecum and abdominal wall including regeneration of the visceral/parietal peritoneum. In sham-operated rats, 4DryField® PH did not induce adhesion formation.

Summary
- 4DryField® PH gel was highly effective in preventing adhesions
- Injured cecum and abdominal wall regenerated well in the presence of 4DryField® PH (histological examination)
- Considering the severity of OPAM trauma, the potential of 4DryField® PH to prevent adhesions can be rated excellent
In vivo studies

<table>
<thead>
<tr>
<th>Title</th>
<th>Evaluation of the Effectiveness of Peritoneal Adhesion Prevention Devices in a Rat Model</th>
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<tr>
<td>Author</td>
<td>Daniel Poehnert, Leonie Grethe, Lavinia Maegel, Danny Jonigk, Torsten Lippmann, Alexander Kaltenborn, Harald Schrem, Juergen Klempnauer, Markus Winny</td>
</tr>
<tr>
<td>Source</td>
<td>International Journal of Medical Sciences 2016, 13(7), 524-532.</td>
</tr>
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**Background**
Abdominal operations are followed by adhesions, a prevalent cause of abdominal pain, and the most frequent cause for bowel obstruction and secondary female infertility. This rat study addresses adhesion prevention capability of Adept®, Interceed®, Seprafilm®, and a novel device, 4DryField® PH.

**Methods**
Sixty-eight male Lewis rats had cecal abrasion and creation of an equally sized abdominal wall defect, and were grouped randomly: A control group without treatment (n=10); two groups treated with 4DryField® PH using premixed gel (n=15) or in-situ gel technique (n=16); one group each was treated with Seprafilm® (n=8), Interceed® (n=9), or Adept® (n=10). Sacrifice was on day 7 to evaluate incidence, quality, and quantity of adhesions, as expressed via adhesion reduction rate (AR). Histologic specimens were evaluated. Statistical analyses used ANOVA and unpaired t-tests.

**Results**
4DryField® PH significantly reduced incidence and severity of adhesions both as premixed gel (AR: 85.2%) and as in-situ made gel (AR: 100%), a comparison between these two application techniques showed no differences in efficacy. Seprafilm® did not reduce incidence but severity of adhesions significantly (AR: 53.5%). With Interceed® (AR: 3.7%) and Adept® (AR: 16.1%) no significant adhesion-reduction was achieved. Except for inflammatory response with Interceed®, histopathology showed good tissue compatibility of all other devices.

**Summary**
- 4DryField® PH showed excellent biocompatibility and significant adhesion prevention capabilities applied as pre-mixed gel as well as in-situ mixed gel
- 4DryField® PH achieved the highest adhesion prevention effectiveness compared to Seprafilm®, Interceed® and Adept®
- Interceed® showed an inflammatory tissue response
Introduction

Intraperitoneal onlay meshes (IPOM) can be associated with intestine-to-mesh adhesion formation, implementing risks like pain, enterocutaneous fistula, infection, and female infertility. This study investigates, whether a treatment of impaired intestinum with the anti-adhesive and hemostyptic agent 4DryField® PH prevents adhesion formation.

Material and methods

In 20 male LEWIS rats uncoated polypropylene meshes were sewn to the inner abdominal wall and the cecum of the respective animal was de-peritonealized by peritoneal abrasion by a gauze swap, and meso-sutures ensured a constant contact of injured areas. Rats were treated with 4DryField® PH gel either premixed or applied as a powder with in-situ transformation (100 mg powder plus 0.4 ml 0.9% saline solution). One week postoperatively, the extent of intestine-to-mesh adhesions and the quality of mesh ingrowth were evaluated macroscopically by two independent investigators using two scoring systems. Furthermore, specimens were analysed microscopically. All data were compared with control animals without 4DryField® PH treatment and analysed statistically using student's t-test.

Results

Treatment of de-peritonealised cecum with 4DryField® PH significantly reduced intestine-to-mesh adhesions in both treatment groups as compared to controls without 4DryField® PH treatment (68% reduction with premixed gel, P<0.0001; 80% reduction with in-situ gel, P<0.0001). There was no impact on the quality of mesh ingrowth, confirmed histologically by a single-layer mesothelial coverage.
In vivo studies

Summary

- These experiments mimic clinical IPOM implantation scenarios with adjacent bowel depleted from peritoneum.
- 4DryField® PH gel treatment resulted in intestinal mesothelial surface recovering without development of bowel-to-mesh adhesions.
- Concurrently, integration of mesh into the abdominal wall is undisturbed by 4DryField® PH treatment.
Introduction

Adhesions to intraperitoneally implanted meshes (IPOM) are a common problem following hernia surgery and may cause severe complications. Recently, we showed that missing peritoneal coverage of the intestine is a decisive factor for adhesion formation and 4DryField® PH (4DF) gel significantly prevents intestine-to-mesh adhesions even with use of uncoated Ultrapro® polypropylene mesh (UPM). The present study investigates adhesion prevention capability of coated Parietex® mesh (PTM) and Proceed® mesh (PCM) in comparison to 4DF treated UPM.

Material and methods

20 rats were randomized into two groups. A 1.5 x 2 cm patch of PTM or PCM was attached to the abdominal wall and the cecum was depleted from peritoneum by abrasion. After seven days incidence of intestine-to-mesh adhesions was evaluated using Lauder and Hoffmann adhesion scores. Histological specimens were evaluated; statistics were performed using student’s t-test. The data were compared with recently published data of 4DF treated uncoated UPM.

Results

Use of PTM or PCM did not significantly diminish development of intestine-to-mesh adhesions (adhesion reduction rate PTM: 29%, p = 0.069 and PCM: 25%, p = 0.078). Histological results confirmed macroscopic finding of agglutination of intestine and abdominal wall with the mesh in between. Compared to these data, the use of UPM combined with 4DF gel reveals significantly better adhesion prevention capability (p < 0.0001) as shown in earlier studies. However, in clinical situation interindividual differences in adhesion induction mechanisms cannot be excluded by this experimental approach as healing responses towards the different materials might vary.
Summary

- This study shows that in case of impaired intestinal peritoneum coated PTM and PCM do not provide significant adhesion prevention.
- In contrast, use of UPM combined with 4DF gel achieved a significant reduction of adhesions.
- Hence, in case of injury of the visceral peritoneum, application of a polysaccharide barrier device such as 4DF gel might be considered more effective in reducing intestine-to-mesh adhesions than coated mesh devices.
**Title**
**Effects of a New Microporous Polysaccharide Powder on Viscoelastic Characteristics of Clot Formation**

**Author**
Alexander A. Hanke, Felix Flöricke, Lion Sieg, Kai Johanning, Niels Rahe-Meyer

**Source**
ANESTHESIOLOGY 2011 – American Society of Anesthesiologists Annual Meeting, Chicago

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**Background**
Microvascular bleeding is a dreaded complication in major surgery and its treatment is matter of discussion in literature. A novel approach is the use of hemostatic polysaccharide microbeads which are directly applied onto bleeding lacerations to establish hemostasis by building a tight viscous mesh of gel and blood components.

Purpose of our study was to determine effects of such a novel polysaccharide (4DryField® (4DF), PlantTec Medical, Bad Bevensen, Germany) on viscoelastic coagulation parameters as assessed by rotation thrombelastometry.

**Methods**
Following IRB approval and informed consent blood samples were taken from 10 healthy volunteers. To assess effects of 4DF rotation thrombelastometry after extrinsic activation (EXTEM) was performed with addition of either 5 mg, 10 mg or 20 mg 4DF to the test (sample volume 300 μl). Recorded parameters were coagulation time (CT) and maximum clot firmness (MCF). Baseline was EXTEM without test substance. For evaluation of effects under dilution all test were also performed with 50 % diluted samples (Haes 6 %). Analysis of variance with Bonferroni post hoc testing was performed. A p-value below 0.05 was considered to be significant.
Results
After adding 20 mg (normal dose) 4DF rotation thrombelastometry was not able to assess clot formation resulting into irregular curves indicating highly increased coagulation time and increased clot firmness.

Results with underdose 4DF (5 mg, 10 mg) indicate that 4DF significantly reduces CT (p=0.011) and increases MCF (p<0.001) in native blood as it does in 50% diluted blood (CT: p=0.002; MCF: p<0.0001). In native blood coagulation parameters were improved to the upper level of normal range. In 50 % Haes diluted blood EXTEM values were improved from severely reduced to normal range (Figure 1).

Summary
- Application of 4DryField® PH significantly increases speed of coagulation and clot firmness - even under conditions of dilutional coagulopathy
- With normal dose 4DryField® PH the firmness of clot in 50 % Haes diluted blood is comparable to that of a native coagulum
- 4DryField® PH might be capable to seal microvascular bleeding

Figure 1: Clotting time (CT) and maximal clot firmness (MCF) with and without 4DryField® (4DF) in native and 50% Haes diluted blood.
Introduction
Trauma is still a major reason for global morbidity and mortality. Massive bleeding is the major cause for trauma related deaths. One part of bleeding control is the use of topical haemostatic agents in combination with other surgical measures. A novel approach is the use of polysaccharide microbeads which are directly applied onto bleeding areas to initiate hemostasis by building a tight viscous mesh of gel and blood components. Purpose of our study was to determine effects of such a novel polysaccharide (4DryField (4DF)) on viscoelastic coagulation parameters as assessed by rotational thromboelastometry.

Materials and Methods
Following IRB approval and informed consent blood samples were taken from 10 healthy volunteers. To assess effects of 4DF, rotational thromboelastometry after extrinsically activation was performed either native or with addition of 5 mg, 10 mg or 20 mg 4DF to the test sample volume of 300μl. Recorded parameters were speed of coagulation and clot firmness. Furthermore, to simulate treatment under conditions of dilutional coagulopathy all tests also were performed after 50% HAES dilution.

Results
Application of 4DF significantly increases coagulation speed and clot firmness in both, native blood and in diluted blood. In native blood, coagulation parameters were improved to the upper level of normal range. In 50% HAES diluted blood, coagulation was significantly improved from severely reduced to slightly below normal range.

Conclusion
Application of 4DF improves coagulation even in 50% HAES diluted blood and thus, 4DF might be capable to seal bleeding areas. Further clinical trials are necessary to prove in vivo efficacy.
4DryField® PH is the **first and only** product CE certified for hemostasis and adhesion prevention

**Proven safety**
- Purely plant-based → No risk of disease transmission
- Excellent tolerability¹
  - Not cytotoxic
  - Up to 1 g/kg body weight is well tolerated
  - Does not enhance viability of tumor cells
  - Promotes recovery
- Free of pyrogens²
- Resorption within 7 days¹
- No duty of documentation as per transfusion law

**Proven efficacy**
- Immediate hemostasis³⁴⁸
- Highly effective adhesion prevention⁵¹¹
- 5 g 4DryField® are enough for at least 100 cm²