

Lymphostasis and Hemostasis in Body-Contouring Surgery Using a Polysaccharide Based Hemostat (4DryField PH)

Mona Rudolph, MD*
Peter M. Vogt, MD†
Klaus Müller, MD*
Tobias R. Mett, MD†

Background: Following liposuction, abdominoplasty is the most frequent body-contouring intervention in the world. The transection of small blood vessels in large areas and subsequent bleeding is a viable risk during this procedure. The resulting microvascular bleedings should be stopped thoroughly to reduce the probability of related complications. In this prospective, monocentric, randomized study, the efficacy of the polysaccharide-based hemostat 4DryField PH (4DF) (PlanTec Medical, Lueneburg, Germany) is examined in classic abdominoplasty and lower body lift after Lockwood.

Methods: For this prospective, monocentric, randomized study, 40 patients underwent surgery for both interventions. Twenty patients received an abdominoplasty, and 20 patients underwent a body lift. In each group, 10 patients have been treated with 4DF, whereas 10 have been served as the untreated control group.

Results: 4DF had neither a beneficial nor a negative effect on necessity of drainages, drainage volume and duration, length of hospital stay or frequency of postoperative seromas, wound healing disturbances, and infections, independent of surgical intervention. Patients in the 4DF group, however, had more individual risk factors, and required extended surgical interventions that might mask primary outcome results.

Conclusions: This is the first prospective, monocentric, randomized study on 4DF in body-contouring surgery. The use of 4DF did not lead to a better postoperative outcome regarding hemostasis and lymphostasis. Potential benefits need further evaluation in high-volume studies. (*Plast Reconstr Surg Glob Open* 2019;7:e2128; doi: 10.1097/GOX.0000000000002128; Published online 25 March 2019.)

INTRODUCTION

The transection of small blood vessels is inevitable in body-countering surgery. Despite proper hemostasis intraoperatively, there is an increased risk for postopera-

tive hematoma and seroma formation by the sheer size of undermined skin. These can lead to tissue repair disruption and infections. Additional risk factors for seroma development are undermining of the dermis, shear forces between underlying tissues and flaps, and dead space formation in general.¹ Next to wound infections and hematomas, seromas are the most common complications after abdominoplasty.² Numerous abdominoplasty studies reported on seroma occurrence with a frequency varying greatly from 2% to 43%,^{3–24} with overall complication rate in abdominoplasty between 20% and 52%.^{17,19–21,23–26} Possible complications caused by seromas include lengthened recovery time, and promotion of scar tissue formation and tissue pressure, or secondary revisions, thereby impairing contour outcome.¹¹

Reducing incidents of postoperative hematoma and/or seroma formation is thus paramount to further increase patient safety and outcomes. Hemostatic products such as 4DryField PH (4DF) represent a potential means toward this end.

From the *Department of Plastic and Aesthetic Surgery, Asklepios Klinik Wandsbek, Hamburg, Germany; and †Department of Plastic, Aesthetic, Hand and Reconstructive Surgery, Burn Center, Hannover Medical School, Hannover, Germany.

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PlantTec Medical GmbH has provided 4DryField PH for 10 patients of the intervention groups and has paid a compensation of 80 Euro to ASKLEPIOS proresearch for each patient. A total of 15 mg of 4DryField PH (PlantTec Medical GmbH, Germany) was used in each patient of the intervention groups.

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The hemostatic effect is based on its water-absorption capability leading to a concentration of coagulation factors and therefore highly accelerated hemostasis.²⁷

Furthermore, recent studies showed that 4DF had a favorable impact on the incidence of seroma, lymphoceles and lymphorrhea.²⁸

In this study, we are evaluating the effect of 4DF on hematoma and seroma formation in abdominoplasty.

METHODS

Study Design and Execution

The study was designed as a prospective, monocentric, randomized study. The study was approved by the Ethics Committee of the General Medical Council Hamburg, no: PV5302. Registration was done in the German Clinical Trials Register Deutsches Register Klinischer Studien (DRKS), no: DRKS00012547, and the International Clinical Trials Registry Platform, no: U1111-1207-2281.

Patients wishing a body-contouring surgery have been recruited from the ambulatory consultation in Asklepios Clinics Wandsbek, Hamburg, Germany. We designed this study as a pilot trial to evaluate the general influence of 4DF on hemostasis and lymphostasis in body-contouring surgery which have not been done to our knowledge.

Group sizes were based on published data by Toman et al.²⁹ who evaluated total drainage volume after abdominoplasty using fibrin glue with 4IU thrombin in comparison to a control group. A power analysis using their means and SDs (glue group: mean = 36ml, SD = 17ml; control group: mean = 79ml, SD = 33ml) with 1 tail, $\alpha = 0.05$, and $\beta = 0.95$ resulted in a necessary group size of 9, which is why 10 patients per group were enlisted.

Criteria of inclusion were written consent by the patient, being 18 years old or older, planning of an abdominoplasty surgery, or lower body lift after Lockwood.

After obtaining written informed consent, patients were randomly assigned to the 4DF or control group. The assignment to one of the groups was done by following a list prepared before. This list includes all planned patients numbered chronologically from 1 to 40 with their number assigned to 1 of the 2 groups at random.

The primary endpoints were blood loss (by blood samples), drainage volume, and duration (optical verification). Secondary endpoint was the incidence of wound healing problems, infections, building of seroma cavities, length of hospital stay, or other complications.

Data have been collected on prepared forms during daily routine, postoperative controls until discharge, and follow-up after 2 weeks at the time of suture removal. Further, 2 different surgical techniques were evaluated: classic abdominoplasty and lower body lift surgery by Lockwood.

Surgical Technique

Incision planning for the classic abdominoplasty included a median vertical line from the sternum to the mons pubis, a circular marking around the umbilicus, a horizontal line on the mons pubis that was prolonged for about 6–7cm in both directions, and then went

transversally to the anterior superior iliac spine considering that the emerging scars can be covered with a slip.

Antibiotic prophylaxis was administered with 2g Cefazolin routinely. The skin was incised using a scalpel and the subsequent cut to the fascia was done with an electric cautery. Minor bleedings were stopped through electrocauterization, and larger vessels were ligated by ligature. Preparation included circumcission of the umbilicus and dissection of the abdominal skin flap along the costal margin and centrally to the sternum. During the preparation, we went down to the fascia but left small amount of fat tissue on it. No progressive tension sutures were made. If present, rectus diastasis was closed with a continuous running 1 Vicryl-suture. Two suction drains were inserted through an additional incision in the pubic area and then secured by a suture. After moving the patient into a flexed of 40° position, the abdominal flap was cut and the marked center line was provisionally fixed with a suture. After verification for symmetry, the skin-fat-flaps were resected on the right and then on the left. The abdominal wall was closed provisionally for determining the new position of the navel. After its fixation, the wounds were closed, cleaned, and a compression bandage was applied. Postoperatively, the patients received Fraxiparine subcutaneously for thrombosis prophylaxis, Metamizole, Oxycodon, and/or Paracetamol for analgesia, and Omeprazole or Pantoprazole for ulcer prevention were administered.

The lower body lift surgeries also included resections on the back. For the additional incision planning, the centerline was marked, followed by the V-shaped incision line on top of the hip bone going laterally to the anterior superior iliac spine while the “V”-tip being positioned centrally. Lines parallel to the centerline were drawn in distances of 5 cm, respectively. The abdominal skin incision was done with a scalpel and the following preparation with a diathermia. Epifascial preparation was started in caudal direction, in the gluteal region above the gluteal muscles slightly caudal to the later resection area. The lateral mobilization caudally across the trochanter was performed bluntly, enabling a good dissection of the fascia adhesences. Preparation was executed in dorsal direction until the spina iliaca anterior superior was reached. Two suction drains were positioned laterally caudal using additional incisions. The detached soft tissues were mobilized across the cranial surgical margin. After the dorsal and subsequently the lateral resection areas had been determined and checked for symmetry, the skin-fat-flaps were resected. Before wound closure, the caudal flaps were fixed in the area of the fascia of Scarpa on strategic points so that the skin margins lay loosely together.

In the patients of the 4DF group, before excision of excess skin, 15g of the polysaccharide was applied on the whole dissected wound area. The product comes in a 5g Bellow applicator; therefore, the application could easily be made with just 3 more minutes of operation time. We drizzled 5 drops of saline solution in the areas of the drain holes to avoid drain blocking right away (Fig. 1).

At the time of the study, the market price in Germany was 119 Euro per 5g package. Because 15g was used per

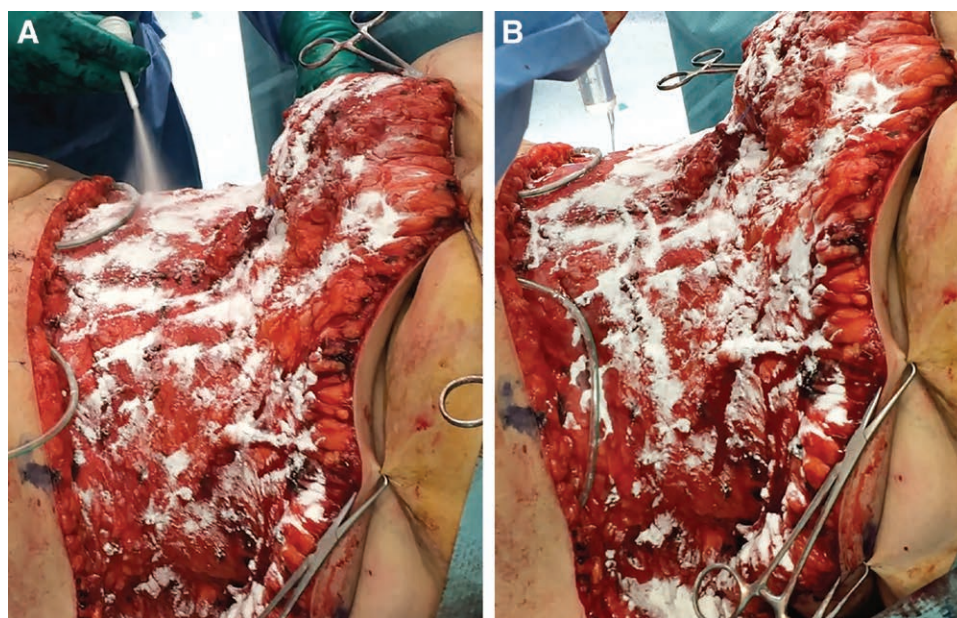


Fig. 1. Representative patient of the 4DF group showing the application of the polysaccharide (A) and subsequent dripping with saline solution in the area of the drainages (B).

patient, the extra cost of 357 Euro applies for each patient, which is not covered by any insurance.

Outcome measures including severity of the surgical intervention, the length of the operation, the median length of tissue resected, and the intraoperative weight loss were assessed. The performance of the hemostat was evaluated based on the volume of blood loss, measured by means of drainage loss volume and quality (bloody and/or serous which was optically verified) and the drain duration, and the necessity of drainages after discharge and the incidences of hematoma-induced complications such as wound healing problems, infections, or seroma cavities. Additionally, the length of the hospital stay was evaluated.

Statistical Analysis

Statistical analyses were performed using Microsoft Excel (Microsoft Corporation, Redmond, Wash.) and GraphPad Prism (GraphPad Software, LLC, Calif.). Normal distribution was assessed using the D'Agostino & Pearson omnibus normality test. If the data were distributed normally, the calculation of *P* values regarding statistical differences between 2 data sets was done using a parametric unpaired 2-sided *t* test, otherwise a nonparametric Mann-Whitney test was employed. Additionally, Mantel-Cox tests

were used as well as 2-sided Fisher exact tests. Calculated *P* values were corrected using the Holm-Sidak method. Corrected *P* values below 0.05 were considered as statistically significant.

RESULTS

Patient Groups

For each technique, abdominoplasty and body lift, 20 patients were included in the study, separated into 2 groups of 10 patients each: 10 treated with 4DF and 10 serving as controls, respectively, adding up to a total of 40 participants in the trial. Statistical analysis as mentioned before has been performed without exclusion of any patient.

Patients' Demographics

All results regarding patients demographics are summarized in Table 1.

In the abdominoplasty group, the mean age of patients was 39.9 years for the control and 45.2 years for the 4DF patients; in the lower body lift group, it was 39.8 and 43.1 years, respectively. The mean body mass index (BMI) for the abdominoplasty patients was 28.4 kg/m² for the control and 30.4 kg/m² for the 4DF patients and 26.4 and 28.0 kg/m²,

Table 1. Patients' Demographics Regarding Age, Body Mass Index, and Smoking Habit

Group	Age (yr)			BMI (Preoperative) (kg/m ²)			Smoker	
	AM	SD	<i>P</i>	AM	SD	<i>P</i>	Total	<i>P</i>
Abdominoplasty								
Control	39.9	9.8	0.538	28.4	2.2	0.538	4	0.656
4DF	45.2	9.1		30.4	5.6		6	
Lower body lift								
Control	39.8	7.5	0.617	26.4	3.2	0.617	2	0.999
4DF	43.1	8.4		28.0	3.1		2	

AM, arithmetic mean. SD, standard deviation

Table 2. Operative Data Regarding Duration of Surgery, Median Resectate Length, and Intraoperative Weight Loss

	Duration of Surgery (min)			Resectate Length (cm)			Intraoperative Weight Loss (g)		
	AM	SD	<i>P</i>	AM	SD	<i>P</i>	AM	SD	<i>P</i>
Abdominoplasty									
Control	84.7	33.0	0.290	40.0	10.8	0.490	2,342	1,090	0.341
4DF	110.8	33.4		43.5	11.4		3,247	1,784	
Lower body lift									
Control	174.5	30.3	0.121	43.0	9.5	0.774	4,058	2,292	0.434
4DF	205.2	28.6		44.2	8.7		5,199	1,866	

AM, arithmetic mean.

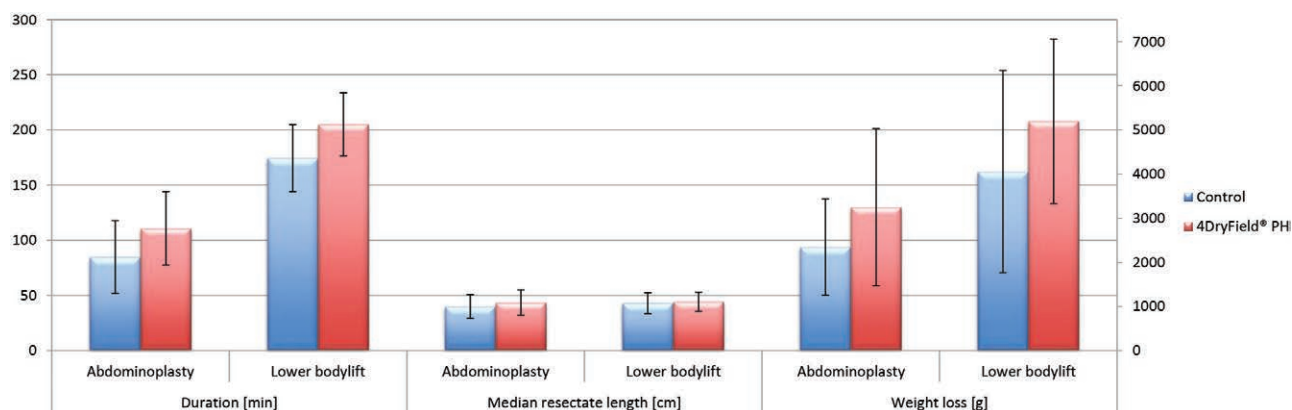


Fig. 2. Operative data regarding duration of surgery, median resectate length, and intraoperative weight loss. Duration and median resectate length refer to the first y axis, intraoperative weight loss to the second.

respectively, for the lower body lift patients. The percentage of abdominoplasty patients smoking was 40% in the control and 60% in the 4DF group, whereas in the lower body lift group, 20% of the patients smoked in both groups. Although multiple individual risk factors including higher age, BMI, and nicotine abuse were elevated in the 4DF group, none of the differences were statistically significant.

Surgery Data

Mean operation duration was on average 98 minutes for the abdominoplasty and 190 minutes for the lower body lift surgeries, whereas the mean intraoperative weight loss was 2,795g during abdominoplasty surgeries and 4,659g during lower body lift (the median lengths of tissue resected were almost identical). Both differences were statistically significant with corrected *P* values of 0.0003 and 0.0058, respectively, indicating that lower body lift surgery is a much more severe intervention and the 2 types of tissue resection are hardly comparable.

In the abdominoplasty group, the mean duration of the operation was 84.7 minutes for the control and 110.8 minutes for the 4DF patients, and the mean median length of the resected flaps was 40.0cm for the control and 43.5 cm for the 4DF patient. The tissue mass resected was 2,342g and 3,247g, respectively. In the lower body lift group, duration of the operation was 174.5 minutes for the control and 205.2 minutes for the 4DF patients. The mean median length of tissue resected was 43.0 cm for the control and 44.2 cm for the 4DF patients. The tissue mass resected was 4,058g and 5,199g, respectively. Although not statistically significantly different, the 4DF patients

had longer operation time and more tissue resected intraoperatively in both the abdominoplasty and lower body lift groups. This indicates that the extent and severity of the surgical interventions were equally distributed among the control and 4DF patients. The surgery data are summarized in Table 2 and Figure 2. The hemostatic efficacy of 4DF was not quantified, but based on optical assessment, it stopped the existing bleeding immediately.

Postoperative Outcomes

The data of the postoperative outcomes are summarized in Tables 3 and 4 and Figure 3.

In the abdominoplasty group, no statistical significant differences were found between the control and 4DF patients. The mean duration of the hospital stay was 6.8 days for the control and 6.9 days for the 4DF patients. The mean duration of drainage was 13.1 days for the control and 11.6 days for the 4DF patients. The mean total drain volume was 1,551 ml for the control and 1,879ml for the 4DF patients. Blood collection in the drainage container was 20.7% for the control and 24.5% for the 4DF patients, whereas these frequencies were 14.8% and 18.0%, respectively, for serous collections. Three of the control and 4 of the 4DF patients were discharged with a suction drain. In the control group, 1 patient had a seroma, 1 had an infection, and 1 had a wound healing disturbance; of the 4DF patients, 2 had a seroma, 1 had an infection, and none has a wound healing problem.

In the lower body lift surgery group, the differences regarding the frequency of bloody and serous drainages were found to be statistically significant, all others were not.

Table 3. Postoperative Outcomes Regarding Duration of Hospital Stay, Duration of the Drainage, Total Volume of All Drainages Per Patient, and Total Amount and Percentage of Bloody or Serous Drainages Per Patient

	Hospital Stay (d)			Drainage Duration (d)			Drainage Volume (ml)			Bloody Drainages			Serous Drainages		
	AM	SD	P	AM	SD	P	AM	SD	P	Total	%	P	Total	%	P
Abdominoplasty															
Control	6.8	3.8		13.1	9.4		1,551	1,438		35	20.7		25	14.8	
4DF	6.9	1.9	1	11.6	10.3	0.628	1,878	1,955	0.999	38	24.5	0.988	28	18.1	0.988
Lower body lift															
Control	5.8	1.8		8.1	8.3		1,072	874		24	13.6		12	6.8	
4DF	6.2	2.0	0.988	7.5	3.1	0.997	1,214	689	0.994	65	39.6	0.001*	55	33.5	0.001*

AM, arithmetic mean.
*Statistically significant difference.

Table 4. Postoperative Outcomes Regarding the Total Number of the 10 Patients Per Subgroup Who Were Discharged with a Revised Drainage or Had One of the Specified Complications

	Revisions		Seromas		Infections		Wound Healing Disturbances	
	Total	P	Total	P	Total	P	Total	P
Abdominoplasty								
Control	3		1		1		1	
4DF	4	1	2	1	1	1	0	
Lower body lift								
Control	2		2	1	0		1	1
4DF	3	1	1		0	1	0	

The mean duration of the hospital stay was 5.8 days for the control and 6.2 days for the 4DF patients, and the mean duration of drainage was 8.1 and 7.5 days, respectively. The total drainage volume was 1,072 ml for the control and 1,214 ml for the 4DF patients, whereas the percentages of bloody drainages were 13.6% and 39.6% and the ones for serous drainages were 6.8% and 33.5%, respectively. Two of the control and 3 of the 4DF patients were discharged with a suction drainage. In the control group, 2 patients had a seroma and 1 had a wound healing disturbance, whereas in the 4DF group, only 1 patient had a seroma and none had a wound healing disturbance. None of the body lift patients had an infection.

In the abdominoplasty patients, most of the values of the smokers are higher than in the nonsmokers (total drainage volume, proportions of bloody and serous drainages, drainage duration, proportion of patients with suction drainages, and seromas), lower are only rates of wound healing disorders and the hospital stay.

In Lockwood patients, it is more balanced, smokers have higher overall drainage volume, more bloody drains, and longer drainage durations; nonsmokers have more serous drainage, serous and wound healing disorders, and prolonged hospital stay.

None of the differences are statistically significant as it is shown in Table 5.

DISCUSSION

The application of a hemostat reducing the formation of seroma development in the typical locations after body-contouring surgery might be an optional approach. Accordingly, in the present study, we have studied the effect of the hemostat 4DF, a substance that can be applied even to large resection areas. The product is a white powder consisting of sterile, hydrophilic microparticles, which are made from highly purified, modified potato starch. The hemostat carries the advantage of being free of human and animal com-

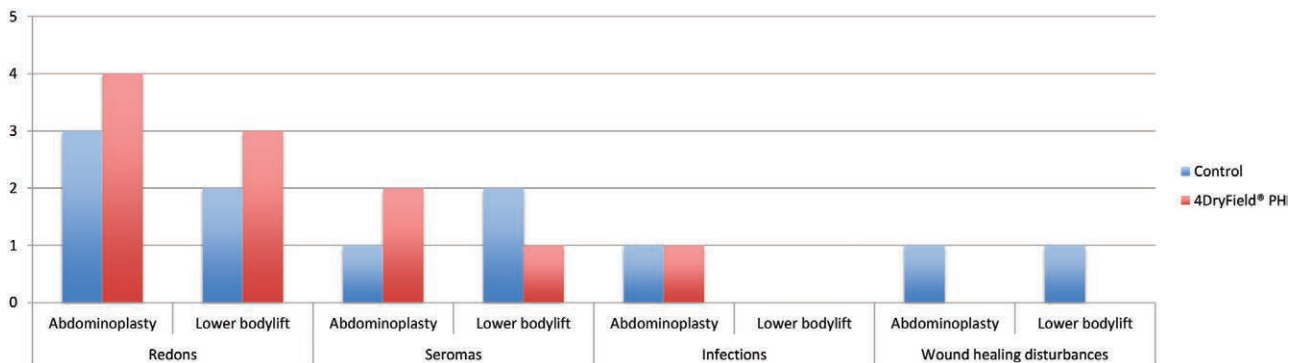


Fig. 3. Postoperative outcomes regarding the total number of the 10 patients per subgroup, who were discharged with a suction drainage or had one of the specified complications.

Table 5. Outcome Parameter Regarding History of Smoking

	Volume (ml)	Drainage Duration (d)	Bloody	Serous	Drainage until (d)	Hospital Stay	Left with Drain	Seroma	Wound Healing Disturbance	Infection
Abdominoplasty patients										
Smokers										
Average	1,780.4	—	—	—	13.4	6.4	—	—	—	—
Total	—	160	39	28	—	—	5	2	0	1
%	—	—	24.375	17.5	—	—	—	—	—	—
Nonsmokers										
Average	1,649.6	—	—	—	11.3	7.3	—	—	—	—
Total	—	164	34	25	—	—	2	1	1	1
%	—	—	20.7	15.2	—	—	—	—	—	—
<i>P</i>	0.4813	—	0.5063	0.8804	0.633	0.4195	0.3498	>0.9999	>0.9999	—
Lockwood patients										
Smokers										
Average	1,629.75	—	—	—	12.5	5	—	—	—	—
Total	—	84	25	16	—	—	2	0	0	0
%	—	—	29.8	19.0	—	—	—	—	—	—
Nonsmokers										
Average	904.5	—	—	—	6.6	6.1	—	—	—	—
Total	—	220	64	51	—	—	3	2	1	0
%	—	—	29.1	23.2	—	—	—	—	—	—
<i>P</i>	0.5052	—	>0.9999	0.5363	0.1708	0.2906	0.5327	>0.9999	>0.9999	—

No significant differences of drainage volume, seroma formation, or wound healing disturbances could be seen in both abdominoplasties and body lifts.

ponents²⁷ and, therefore, not bearing the danger of possible pyrogenicity or allergenicity. The product mostly consists of hygroscopic polysaccharide particles, and the hemostatic effect is based on its water-absorption capability leading to a concentration of coagulation factors and therefore highly accelerated hemostasis.²⁷ A clot formed under the influence of 4DF is a mixture of blood cells, quickly degradable polysaccharides, and more poorly degradable protein components from blood which is why a 4DF thrombus can be degraded much faster than a native one. Besides its function as a hemostat, 4DF can also be turned into a gel through the addition of saline solution and then functions as an adhesion prevention barrier.^{30–36} Ex vivo studies have shown the ability to form blood clots with the same physical qualities as regular clots even under 50% hemodilution while clot firmness maintained its original optimum.^{37–39}

Its efficacy as a hemostat was shown in different studies, where it was utilized for different gynecologic surgeries,^{33,34,40} burn surgery,⁴¹ and prostatectomies.^{42,43} In the latter case, 4DF also had a favorable impact on the incidence of seroma and lymphoceles, lymphorrhea development, and was shown to reduce the length of hospital stay. In addition to that the successful treatment of a chronic seroma was reported in a recent publication.²⁸

Based on the published results, it can be expected that 4DF has a blood-saving effect and leads to reduced blood and drainage losses and a shortened treatment. Additionally, it might be possible to reduce postoperative complications like seroma, infections, and wound healing disturbances, which is why we decided to use it for body lift and abdominoplasty surgery.

As it was already shown that cauterization or local hemostats like fibrin glue are ineffective in reducing seroma incidence,⁴⁴ these measures were not regarded in the present study.

The results of patients treated with the hemostat 4DF and control patients are almost similar. A reduction of se-

roma formation by 4DF was described by Kuthe,²⁸ who reported on a persistent seroma of 1,000 cm³ volume, resulting from a liposuction 15 years before, which had been unsuccessfully revised twice during the postoperative course. After recurrence following en bloc excision, the seroma cavity was aspirated and subsequently treated with 4DF powder leading to successful healing.²⁸ However, the seroma incidence was very low in the present study, so that larger patient populations would be required to detect any influence. Nevertheless, it is still apparent that 4DF did not promote seroma formation like other hemostats did. Azoury et al.,⁴⁴ for example, examined the effect of the fibrin sealant TISSEEL (Baxter International, Inc., Deerfield, IL, USA) on seroma formation following abdominal wall hernia repair. They found increased incidences of seromas in the treated group (11%) when compared with an untreated control (4%).⁴⁴

Compared with the control groups, patients treated with 4DF had a slightly longer time of hospitalization (abdominoplasty group: +1.5%, lower body lift group: +6.9%) and total drain volume was higher (abdominoplasty group: +21.1%, lower body lift group: +13.2%), whereas their drainage duration was shorter (abdominoplasty group: -11.5%, lower body lift group: -7.4%), but these differences were not significant. The higher total drainage volume in the 4DF group was unexpected because it differed from former results. 4DF application in lymph node dissection after radical retropubic prostatectomy led to a 33% reduction of postoperative drain loss volume, and a reduction of drainage duration by nearly 75%. It was assumed that reduced drain loss volumes were also a result of improved coagulation of lymph fluid because lymphatic fluid contains coagulation factors similar to blood plasma.⁴² However, the slightly higher drain loss of the present study might be explained by the more severe and extensive surgical interventions in the 4DF group (indicated by longer operations and higher intraoperative weight losses) when compared with the control patients. Higher

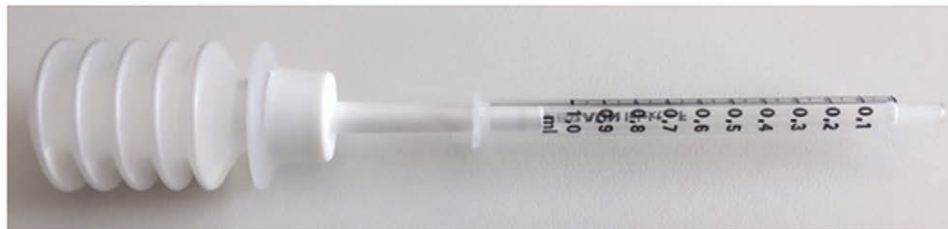


Fig. 4. Applicator of 4DF with a 1-ml syringe (B. Braun Melsungen GmbH, Melsungen, Germany) put on top to create a second turbulence chamber for achieving a finer and more even distribution of the powder.

amounts of bloody and serous drainages in 4DF patients were found in the lower body lift, but not in the abdominoplasty group. There is no known mechanism that would explain why applying a hemostat like 4DF could lead to more serous or bloody drainage, neither has an effect like this been reported in the literature. The additional fact that the effect completely vanished in the abdominoplasty group leads to the assumption that this result is distorted due to the low number of participants and would not reappear in a larger study with higher patient numbers. We felt encouraged to proceed this preliminary work with the selected volume by reviewing other studies from Schettino et al.⁴⁵ and Walgenbach et al.,⁴⁶ both with 20 patients per arm and Pilone et al.⁴⁷ comparing 15 versus 20 patients. Now that we are aware of the small differences between the single groups of our study, a power analysis can be performed to offer the needed number of patients to treat to draw significant conclusions.

Known risk factors regarding these kinds of surgeries include age, BMI, and nicotine abuse.^{48–51}

In the abdominoplasty group, the 4DF patients had a higher age (+13.3%), a higher BMI (+7.0%), longer operations (+30.8%), bigger skin flaps resections or panniculectomies (+8.8%), higher intraoperative weight losses (+38.7%), and a higher rate of smokers (+50%). Although none of these factors were significantly different on their own when compared with the control patients, the fact that all these risk factors were elevated in this group might have influenced the outcome to the disadvantage of this group. Precise data regarding a possible additional risk elevation through the combined rise of multiple risk factors do not exist. Similarly, these values were also almost all elevated regarding the 4DF patients of the lower body lift group (age: +8.3%, BMI: +6.1%, operation time: +17.6%, resectate length: +2.8%, intraoperative weight loss: +28.1%). In addition, 4DF patients had clearly longer operations and higher intraoperative weight losses in both the abdominoplasty and lower body lift groups, indicating more extensive and severe surgical interventions. Higher patient numbers would have been desirable and might have evened out these factors. Furthermore, a finer and more even distribution of the polysaccharide powder might have had a positive effect on the outcome. This could be achieved by putting a 1-ml syringe on top of the 4DF applicator to create a second turbulence chamber (Fig. 4).

The good tolerability of 4DF reported in previous studies^{33,34,42,52} was confirmed in our study.

CONCLUSIONS

4DF had neither a beneficial nor a significant negative effect on primary outcome parameters drainage volume and duration, length of hospital stay, or complications in abdominoplasty surgery. However, multiple individual risk factors, and extent and severity of the surgical intervention, were elevated in the 4DF patients compared with the control patients, so that possible favorable effects of 4DF in abdominoplasty surgery might be overlapped by these risk factors.

Nevertheless, based on optical assessment the good hemostatic efficacy of 4DF could be seen by stopping existing bleedings immediately.

Further studies with larger patient cohorts are though warranted.

Tobias R. Mett, MD

Department of Plastic, Aesthetic, Hand
and Reconstructive Surgery
Burn Center
Hannover Medical School
Carl-Neuberg-Str.1
30625 Hannover, Germany
E-mail: tobias.mett@gmail.com

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