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Physical Modification of a Gelatin Sponge Creates a Very Adhesive, Rapidly Absorbable, Blood-Free Hemostat

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Abstract

Background: An effective hemostat not only needs to stop the bleeding whilst it is held in place but importantly, it must stay there securely during the perioperative recovery phases. As patients move during the recovery period, several forces can act on the hemostat leading to its displacement and possible postoperative hemorrhage. Adhesive hemostats have been developed to prevent this, but many contain human blood components or are prohibitively expensive for widespread use.

This study evaluated a physical surface modification of a plain gelatin sponge with no additives (chemical/biologic), designed to securely adhere to bleeding tissue and create a long-lasting hemostatic matrix (TenaTac[®], Selentus Science, UK).

Methods: Adhesion and hemostasis were tested in a standard leporine hepatic bleeding model against the adhesive hemostats, TachoSil[®] and Hemopatch[®]. Absorption was tested in a porcine hepatic implantation model against plain gelatin sponge.

Results: TenaTac was very well tolerated in the porcine model and was completely reabsorbed by day 14. TenaTac demonstrated a 69% improvement in adhesion over TachoSil (p<0.001). Hemostasis was also significantly better than TachoSil at the 6- & 9-min endpoints (p=0.016 & p=0.002). With systemic heparinization (300 u/kg) TenaTac's adhesion score was 42.5% higher than non-heparinized TachoSil (p=0.003). After delivery through a laparoscopic cannula, the hemostasis and adhesive capabilities were not different from Hemopatch (p>0.05 for all).

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Copyright © 2023 Hayes PD. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. **Conclusion:** Physical surface modification of a gelatin sponge has resulted in a rapidly absorbable hemostat that demonstrates superior adhesion and hemostasis to other advanced hemostats.

Introduction

Failure to properly control bleeding during surgery can enhance the risk of complications and increase morbidity and mortality [1]. Topical hemostatic agents fulfil a crucial role in the cessation of less severe bleeds, thus improving clinical outcomes [2], reducing operating times [3] and usage of blood products in transfusions which carry safety concerns [4] and are a heavy economic burden [2]. Excessive bleeding increases the risk of morbidity and mortality [5,6] and multiple blood transfusions are associated with decreased long-term survival after cancer resection [7,8].

In most types of surgery, it is preferable that the hemostatic pad or sponge remains in situ after hemostasis is achieved. Within this context it is essential for the hemostat to actively adhere to relevant tissues as to prevent post-operative bleeding, which can at times require further surgery and transfusions. Active adhesion to the bleeding site prevents dislodgement & reduces the risk of post-operative bleeding [9,10] and complications [10].

Despite there being a plethora of hemostatic agents commercially available, none are ideal in this context; agents either have issues regarding storage, efficacy, cost or safety as some use bloodderived ingredients [11,12]. For instance, one of the current market leaders Tachosil[®] (Corza Medical, USA) is costly and contains two blood products: Thrombin and fibrinogen that form an adhesive fibrin layer.

Implanted hemostats can act as foreign bodies. The impact of the foreign body is greater in

those hemostats with longer absorption times. Products made from oxidized cellulose (e.g., Veriset^{**}, Surgicel^{*}) have been reported to cause a range of tissue responses from localized allergic reactions, to seromas, to foreign body reactions requiring surgical removal [13]. Although generally absorbed in 4 to 8 weeks, one study reported that the site of oxidized cellulose implantation had only lost 20% of its volume post-implantation when examined at week 30 [14]. There are many case reports documenting the investigation of masses investigated and found to be due to previous oxidized cellulose use [15].

Gelatin sponges are cheap to manufacture, contain no bloodderived ingredients, can be safely reabsorbed by the body and are effective hemostats. However, unlike TachoSil or other active patches, plain gelatin sponges do not strongly adhere to wounds and thus are not ideal for this secure post-operative hemostasis. We report on a gelatin sponge with precise surface modifications (TenaTac^{*}) developed by Selentus Science Ltd. These modifications transform the flat, uniform wound contact surface of the sponge into a series of columns or "fingers" (Figure 1), enhancing its adhesiveness without adding any materials. Over 1,000 columns are created on the wound contact surface of an 80 mm × 50 mm sponge each measuring 3 mm to 4 mm deep with a cross sectional area of 2.3 mm². This increases the sponge's surface area by over ten-fold and this in combination with increased interdigitation with the wound surface, dramatically increases adhesion.

Methods

Tolerance and absorption in a porcine model

To assess the absorption and tolerance of TenaTac and a control gelatin sponge (CuraSpon') following surgical implantation, a Large White hybrid porcine model was used. TenaTac and CuraSpon are made from identical gelatin sponges, with the only difference being the physical modification of the sponge surface in the case of TenaTac. The liver was selected as the implantation site as it is easily accessible and observable. Nine animals were observed. The procedures and all subsequent evaluations of efficacy in the porcine model were undertaken by the independent veterinary surgical team at Covance Laboratories (Huntingdon, UK) under home office license in accordance with the applicable sections of the United Kingdom Animals (Scientific Procedures) 1986, Amendment 2012.

Surgical procedure in the porcine model

Following general anesthesia, a laparotomy was performed, and the liver exposed. Two types of defect (wound) were made on separate liver lobes: (i) eight oblique incision wounds, 1 cm depth by 3 cm long were made on the largest lobe and four gelatin sponges and four TenaTac sponges were inserted, all 1 cm \times 3 cm in size. Each pig was therefore treated with both types of sponges to reduce the effect of any inter-animal variations. The incision sites were sutured closed with interrupted 4-0 prolene to ensure that all sponges were retained *in situ*. A marker stitch was placed at a 12 o'clock position for each excision site to enable later identification. (ii) Six-eight 1 cm diameter \times 0.2 cm depth biopsy punch (excision wounds) were made on the second lobe and only TenaTac (2.5 cm \times 3 cm) was applied flat onto the wound to assess medium term adhesion.

Tolerance and absorption assessment

The pigs were recovered and observed over 4, 14 or 42 days. On days 4, 14 and 42, three porcine livers were recovered then evaluated at each time point.

Macroscopic Pathology & Histology

General examination, with specific examination of the liver. Each wound site was examined, and an assessment made of any swelling, and degradation/ absorption of the test or control item. Each wound site was excised and processed into tissue blocks and then 4-to-5-micron sections were stained with hematoxylin and eosin. The microscopic examination included grading of wound healing and degradation/absorption of test or control items was undertaken by the independent pathologist at Covance.

Hemostasis and wound tissue adhesion in a rabbit model

To investigate hemostatic efficacy and adhesion of different sponges including TenaTac, an anaesthetized New Zealand White rabbit liver biopsy injury model was used. Previous trials showed this model to be challenging for commercially available products yet within the range of bleeding normally treated with topical hemostats and thus appropriate for testing hemostat application. These studies were undertaken by the independent veterinary surgical team at the Griffin Institute (Northwick Park Hospital, London, UK) who are experienced in testing several different hemostats in this model. The study was performed under Home Office Project License 80/2639.

Surgical procedure

Following general anesthesia, laparotomy and exposure of the liver, depending on the liver size and thickness, up to 7 biopsy punch wounds (10 mm diameter \times 2 mm deep) were made sequentially on each of the three liver lobes. Each rabbit was tested with a variety of products, and no rabbit was ever tested with just a single device. This was done to reduce the effect of any inter-animal variation.

Hemostatic efficacy assessment

Conventional hemostatic methods were not applied prior to application of test article. The strength of each bleeding site was assessed by weighing a small swab that was applied to the wound for 15 sec and allowed to soak up any blood released. Products to be evaluated (plain gelatin sponge, CuraSpon, n=10, TachoSil n=27 and TenaTac n=35) were placed on the excision wounds and compressed gently for 3 min using a gauze swab moistened with normal saline. Gauze was then removed, and bleeding assessed by the independent Griffin veterinary staff. Hemostasis was assessed at three time points: upon removal of swab (3 min), 6- and 9-min post-injury. If the site was still bleeding when assessed, compression was re-applied but if hemostasis was obtained, then no further compression was applied. The data were normalized against the strength of the pre-application bleeding. In addition to assessing hemostatic success (complete cessation of bleeding), the degree of bleeding was scored on a scale of 0 to 5, where 0 is no bleeding and 5 is severe. In the event a particular hemostat failed to control bleeding, a second sponge was applied then the compression and observation process was repeated.

To stress-test the performance of TenaTac, it was used in a highly heparinized model (iv 300 u unfractionated heparin/Kg, n=21) and the outcomes compared against the data for TachoSil in a non-heparinized model. For this test, an ACT wasn't measured.

Adhesion assessment in the rabbit model

The independent veterinary surgeon undertaking the procedure tested adhesion by lifting the corner of each test article and scoring the adhesion on a scale of 0 to 3. No apparent adhesion was scored as 0, mild resistance to removal scored 1, difficult to remove scored 2 and where the sponge lifted the liver or had to be ripped off, a score of 3 was given.

Effect of sponge pre-compression

To use TenaTac for hemostasis during laparoscopic surgery, it may be necessary to compress the sponge to allow it to be rolled-up and then passed through a laparoscopic cannula. To test whether this impaired TenaTac's hemostatic and adhesion qualities, $4 \text{ cm} \times 5 \text{ cm}$ pieces of TenaTac were compressed using a standard rolling cylinder (n=7) until they could be passed through a 10 mm laparoscopic cannula. Following this, they were applied to the rabbit liver bleeding models described above and compared to uncompressed TenaTac (n=7) and the adhesive patch Hemopatch (Baxter, USA) (n=7), which can also be rolled up and passed through a cannula.

Data analysis

Continuous data are reported as means and standard deviations. The bleeding data were normalized against the weight of blood collected on the swab applied to the bleeding site for 15 sec before the application of the hemostat. The data were not normally distributed and so analyzed with the Mann-Whitney U-test in GraphPad Prism 9.5.0.730. Categorical data were analyzed using Fisher's exact test. A p-value <0.05 was taken as significant. Variability of sample results were tested with F-Test Two-Sample for Variances in Excel.

Results

Tolerability and absorption of TenaTac in the porcine model

TenaTac and CuraSpon were well tolerated when applied to bleeding liver wounds in the porcine model and assessed up to 42 days post-surgery. Clinical signs, bodyweight and food consumption were normal and there was an absence of pathological changes other than those expected following surgical procedures and the reparative process following trauma to the liver when assessed by the pathologist. Macroscopic examination by the pathologist indicated that no increase in sponge expansion was observed for TenaTac compared to CuraSpon.

In a test of adhesion strength, 95% (19/20) of the TenaTac sponges that were applied to the surgical excision biopsy sites were still present attached to the liver surface after 4 days of recovery and normal movement by the pigs. As seen with the TenaTac implanted into the liver (see below), all the TenaTac had been reabsorbed by day 14.

In the incision sites, both products were macroscopically visible at 4 days but there was a highly significant fall in the numbers present at day 14, with no visible TenaTac remaining (p<0.001). TenaTac



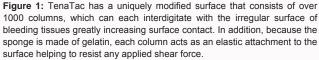


Table	1:	Histopathological	observations	of	sponge	degradation	and	wound
healing	g at	4-, 14- & 42-days	post-surgery in	n th	e porcine	e model.		

		4 days	14 days	42 days
Sponge present*	TenaTac (n=12)	11/12	0/12	0/12
	Curaspon (n=12)	11/12	0/12	0/12
Blood clot in wound**	TenaTac (n=12)	0.67	n/a	n/a
	Curaspon (n=12)	0.67	n/a	n/a
Sponge degradation**	TenaTac (n=12)	3.17	n/a	n/a
	Curaspon (n=12)	2.17	n/a	n/a
Inflammatory cells **	TenaTac (n=12)	0.67	n/a	n/a
	Curaspon (n=12)	1	n/a	n/a
Fibrosis at incision site**	TenaTac (n=12)	0.67	0.67	0
	Curaspon (n=12)	0.83	0.83	0

^{* =} incidence of macroscopically visible sponge

** = grading minimal (0) to severe (4)

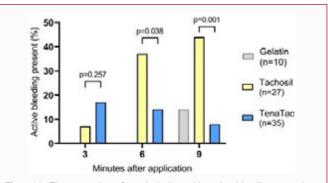
was more rapidly absorbed, scoring 3.17/4 (79.3%) on the sponge degradation score, compared with 2.17/4 (54.3%) for the plain sponge (p=0.11) at day 4. Inflammation and inflammatory cell infiltrate were also reported at 4 days for both sponges, representing a normal wound healing process. Fibrosis around and within the incision site was minimal at day 4, with a return to normal liver structure 42 days post-surgery (Table 1). Normal reparative tissue was observed in the microscopic histological analysis at all wound sites on days 14 and 42.

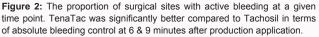
Evaluation of hemostasis in the rabbit model

TenaTac was compared against a widely used adhesive sponge, TachoSil (Corza Medical, MA, USA) and plain gelatin sponge in terms of hemostatic efficacy. The ability of these different sponges to promote hemostasis was assessed by measuring percentage of wounds actively bleeding at three time points (Figure 2) and assessing the Bleeding Severity score (Figure 3).

To stress-test the performance of TenaTac, it was used in a highly heparinized bleeding model (300 u/kg) and the outcomes compared against the data for TachoSil in a non-heparinized model.

Despite the high level of anticoagulation by the end of the study period, there was a significant improvement in hemostasis for the heparinized TenaTac group (bleeding score 0.24) over the non-heparinized TachoSil group in bleeding severity (score 0.50) (p=0.034). In the initial stages of the test, TachoSil controlled the bleeding more effectively but by 6 min there was no difference between the groups before TenaTac became superior (Table 2).





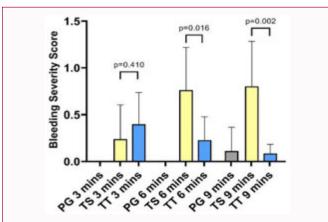
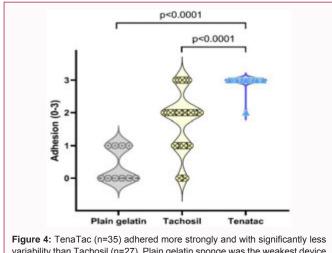


Figure 3: The bleeding severity score was significantly lower with TenaTac at 6 & 9 minutes. There were no differences between TenaTac and plain gelatin sponges.



variability than Tachosil (n=27). Plain gelatin sponge was the weakest device in terms of adherence (n=10).

Evaluation of adhesion in the rabbit model

TenaTac's ability to adhere to wounds was compared to TachoSil and plain gelatin sponge in the rabbit bleeding model. TenaTac gave the maximum level of adhesion in 94.3% (33/35) of cases whilst TachoSil only provided maximum adhesion 22.2% (6/27) of the time (p<0.0001). None of the plain gelatin sponges achieved maximum adhesion (p<0.0001 *vs.* TenaTac and TachoSil). Importantly, failure of adhesion (scores of 0 or 1) occurred in 37.1% (10/27) of TachoSil cases and in none of the TenaTac cases (p=0.0002). None of the plain gelatin sponges scored more than 1 in terms of adhesion. Overall, the level of adhesion provided by TenaTac was significantly greater than TachoSil (p<0.0001), increasing the adhesion by 69% (2.94/3 *vs.* 1.94/3 respectively) (Figure 4). In addition, TenaTac was much more reliable in its level of adhesion, with the variability of TachoSil adhesion being significantly greater (TenaTac mean 2.94, variance 0.055, df 34; TachoSil mean 1.74, variance 0.834, df 26; F=15.03; P<0.0001).

The ability of TenaTac to adhere to bleeding surfaces was not reduced by the presence of anticoagulation. In the highly heparinized model, there was a 15.6% reduction between the adhesion of TenaTac in the presence (2.5/3) or absence (2.94/3) of 300 u/kg of heparin. However, when compared to non-heparinized TachoSil (1.94/3), the heparinized TenaTac group 2.5/3) adhered 42.5% more strongly (p=0.003).

Effect of compression on TenaTac performance

After compression, TenaTac was reduced in height from 10 mm to 2 mm in thickness. Despite the reduction in height, its properties were not significantly altered from uncompressed TenaTac or Hemopatch. There were no differences in the proportions of wounds achieving hemostasis at any time point (p>0.05). Similarly, the bleeding severity (at 9 minutes: Uncompressed TenaTac 0.0, compressed TenaTac 0.43 and Hemopatch 0.29) and adhesion scores (uncompressed TenaTac 0.27, compressed TenaTac 2.86 and Hemopatch 2.57) were not statistically different between the three test products (p>0.05) (Table 3).

Discussion

The laser guided surface modification of a gelatin sponge has created a novel and effective hemostat, TenaTac, that is surprisingly adhesive given its relatively simple structure. Changing the surface from a uniform single plane to a complex and irregular one significantly increased its adhesive properties. This is proposed to occur through 3 mechanisms. Firstly, the single plane is converted into over 1,000 individual columns, and this leads to a 10-fold increase in the surface area, creating much larger surface tension. Secondly, nearly all tissue surfaces are irregular and rough rather than

Table 2: Evaluation of bleeding severity and adhesion in a highly heparinized bleeding model (300 u/kg of unfractionated heparin).

	Ble	Bleeding severity 0 to 5 (SD)		
	3 mins	6 mins	9 mins	Score 0 to 3
TenaTac (no heparin) (n=35)	0.30 (0.98)	0.24 (0.73)	0.06 (0.28)	2.94 (0.24)
Heparin (300 u/kg) + TenaTac (n=21)	0.86 (1.55)	0.43 (1.05)	0.24 (0.68)	2.48 (0.50)
Tachosil (no heparin) (n=27)	0.17 (0.92)	0.54 (1.15)	0.50 (1.22)	1.74 (0.90)
Tachosil v heparin grp (p=)	0.015	0.227	0.034	0.003

Table 3: Mean (SD) bleeding severity and adhesion scores compared between standard TenaTac, compressed TenaTac and Hemopatch. There were no statistical differences between the products at any time point, nor in terms adhesion (p>0.05 for all tests).

	Bleeding severity score 0 to 5 (SD)			Adhesion
	3 mins	6 mins	9 mins	Score 0 to 3
Uncompressed TenaTac (n=7)	0 (0)	0 (0)	0 (0)	2.57 (0.5)
Compressed TenaTac (n=7)	0 (0)	0.57 (1.4)	0.43 (0.7)	2.86 (0.3)
Hemopatch (n=7)	0 (0)	0.43 (0.5)	0.29 (0.5)	2.57 (0.7)



Figure 5: A still image of TenaTac adhered to the surface of a bleeding liver. The elastic columns can clearly be seen as the surgeon attempts to pull the TenaTac away from the liver surface.

smooth and the independent columns can interdigitate with peaks and troughs much more effectively than a smooth regular surface. Thirdly, since the product is made of gelatin, as it becomes warm and moist, each of the columns becomes much more elastic than a uniform plane can thus aiding its ability to resist shear forces which can cause perioperative dislodgment and postoperative hemorrhage (Figure 5 and Video 1).

The magnitude of the impact of the surface modification can be observed in the adhesion tests that were conducted during the evaluation of TenaTac. Although simple gelatin sponge can be an effective hemostat, it is very weakly adherent and is easily dislodged with minimal shear force. TenaTac is significantly more adherent than plain gelatin sponge, scoring 2.94/3 vs. 0.4/3 (635% increase over the plain patch). In order to place TenaTac's adherence in context, it was evaluated in a rabbit bleeding model against the leading adherent hemostatic patch, TachoSil. Overall, TenaTac exhibited a significantly improved adhesion over TachoSil but perhaps even more importantly it provided a much more consistent user experience. This is important since although postoperative hemorrhage is an infrequent event, its consequences can be devastating. During the bleeding liver evaluations, Tachosil's adherence was rated by the independent surgeons as "0" or "1" in 10/27 (37%) of cases, compared with no scores at all in this range for TenaTac. TachoSil was statistically more variable in its adherence than TenaTac (p<0.0001). This benefit in adherence persisted even when TenaTac was used in a strong anticoagulation model, and its performance compared against TachoSil in a non-anticoagulation setting.

Effective adherence is of limited value if the device being evaluated has limited ability to generate a stable blood clot to stop the bleeding. During the course of the hemostasis tests, TenaTac generally became more effective over the 3-to-9-min period, whereas TachoSil's performance worsened (Figures 2, 3). In order to understand this dynamic, it is important to look at the structure of the products. TenaTac is a porous 3D structure that absorbs blood and stimulates blood clotting in its matrix, whilst adhering strongly to the bleeding tissue. TachoSil has an active surface coated with human blood proteins, fibrinogen and thrombin. Once the surface is wet, the thrombin cleaves the fibrinogen and stimulates the clotting cascade. Whilst in theory, this provides a strong clotting stimulus, it really exists only in a single plane and what was observed in these studies was that un-clotted blood pooled beneath the film of clot on the active TachoSil surface, until the pressure of the active bleeding led to the seal at the edge of the TachoSil giving way and then the active bleeding was observed. So, in this setting, whilst TachoSil appeared to do well at the first time point, bleeding was actually still ongoing under the patch but not observed until it leaked out of the side. Koea et al reported that care needed to be used with Fibrin Patch (FP) application "... if the FP does not conform to the tissue. This is a particular risk in the liver if the FP is incorrectly applied to focal parenchymal defects so that they are bridged rather than covered. This can result in ongoing bleeding in the defect and eventual lifting of the FP" [12]. With TenaTac, no pooling of blood occurs as the sponge soaks the blood up, leading to a larger more stable clot.

As increasing numbers of patients are taking anticoagulant medications, it was important that TenaTac was evaluated under these conditions too. A level of 300 u/kg of unfractionated heparin was chosen to represent a highly anticoagulated patient, as this dose would typically be used to place patients on cardiac bypass [16]. To minimize the number of animal tests performed, this was only undertaken for a group using TenaTac and then compared against a non-heparinized TenaTac and TachoSil groups. At the early 3-min time point, the scores favored TachoSil, by 6 min they were even and by 9 min, the heparinized TenaTac outperformed the nonheparinized TachoSil by 52%. The ability of the TenaTac to achieve significantly better levels of hemostasis here is due to the ability of the sponge to absorb the blood and form a large stable clot, rather than a thin film. It is noteworthy that TenaTac outperformed TachoSil here despite the presence of thrombin and fibrinogen on the TachoSil surface.

Laparoscopic surgery is being performed increasingly over conventional open surgery and it was therefore important that TenaTac was evaluated in this setting. On removing TenaTac from its packaging, it is fairly stiff and approximately 10 mm thick, but it undergoes a marked transformation after modest compression, becoming very flexible. This ability allows the 4 cm \times 5 cm TenaTac sponge to be compressed using manual compression and then rolled up and passed through the laparoscopic cannula. It isn't practical to try and undertake true laparoscopic surgery on the rabbit bleeding model and as such after passage through the cannula, the hemostatic products were applied directly to the liver surface. The adhesion scores were not significantly different between the 3 products tested, with compressed TenaTac scoring 95.3% of maximum possible adhesion, with uncompressed TenaTac and Hemopatch both scoring 85.7%. At the same time point, compressed TenaTac scored 8.6% of the maximal Bleeding Severity Score, with uncompressed TenaTac at 0% and Hemopatch at 5.8%. In summary, all three hemostats performed well in the laparoscopic test, with no indication that compression of the TenaTac affected its hemostatic or adhesion performance.

Effective hemostats also need to be safe, and this was evaluated through the porcine liver implant model. TenaTac is based on a gelatin sponge, which have been used as implantable hemostats for over 75 years and have an excellent safety track record, with very few hemostats, if any, having a longer period of evaluation [17]. During the manufacture of TenaTac, no chemicals or biological agents are added to the gelatin sponge, the structure of the surface is simply altered with a laser-guided cutting process.

A number of hemostats are made from compounds that degrade slowly in the human body and can give rise to a number of complications by acting as a foreign body [14,15]. This study determined that the change in surface structure didn't affect the degradation rate of the material, and if anything, there were suggestions that it was absorbed more quickly than plain gelatin sponge. The microscopic analysis of the implant sites found that TenaTac was present at 4 days, long enough for a stable clot to have formed and tissue healing to have begun but that by 14 days the TenaTac had been completely reabsorbed. This rapid degradation makes foreign body formation very unlikely and further adds to the safety profile of the product.

The data provided in this manuscript form part of a long chain of product development. The initial testing was undertaken in an *ex vivo* setting where different device prototypes and iterations were assessed over a prolonged period of time. The data presented here were collected once the team were fairly certain about the potential for the device to work and the positive results generated have been able to support the award of a CE-mark. The next steps of collecting first-in-man data have now begun and will be reported in the near future.

As surgeons' results are increasingly scrutinized, many are choosing to use advanced hemostats with the security of postoperative adherence and the potential for reducing post-surgical bleeding and its serious complications. The data from the studies performed indicate that TenaTac can achieve hemostatic performance and levels of adherence that at least match the advanced hemostats, and in a number of cases outperform them.

Conclusion

Gelatin sponges have an excellent safety record but fail to adhere to the bleeding tissue. A unique surface modification has produced TenaTac which adheres strongly and demonstrates hemostatic performance at least as good as other advanced hemostats but without the addition of blood derived proteins. The relatively rapid product absorption may also be of clinical benefit.

Video Link

Video 1: A video of TenaTac adhesion testing against an advanced hemostat can be seen here:

Link 1: https://youtu.be/mpymvGLqL1g

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