Gynecol Surg (2013) 10:247–252
DOI 10.1007/s10397-013-0805-5

ORIGINAL ARTICLE

LiquiBand® Surgical S topical adhesive versus sutures for the closure of laparoscopic wounds. A randomized controlled trial

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Received: 13 April 2013 / Accepted: 24 June 2013 / Published online: 10 July 2013

Abstract Cyanoacrylate adhesives offer the surgeon and patient an alternative to subcuticular suturing. LiquiBand® Surgical S (LBSS) is a new formulation with a blend of monomeric *n*-butyl and 2-octyl cyanoacrylates. In this study, the effectiveness, safety, and clinical utility of LBSS was compared to Vicryl™ sutures for the closure of laparoscopic incisions. This was a prospective randomized study of LBSS skin adhesive versus Vicryl™ sutures for the topical closure of laparoscopic surgical incisions. Subjects were asked to return at 2 weeks postsurgery to report complications and adverse events. Wounds were evaluated for apposition and cosmesis using a modified Hollander Wound Evaluation Scale (HWES). The Shapiro–Wilk test of normality was done. Independent-samples *T* test, Mann Whitney *U* test, and chi-square test were used to compare variables between the two wound closure methods. A total of 114 subjects participated in this trial completing all aspects of the study. Fifty-five subjects received sutures for topical wound closure, with 59 subjects receiving LBSS. Surgeons were found to be satisfied with 100 % of all applications using the LBSS device. One hundred percent of wounds closed with sutures and 98.9 % wounds closed with LBSS achieving an optimal HWES of 0. There was no statistical difference in cosmesis or complications for either method. Closure with LBSS was significantly faster by a mean of 2 min. LiquiBand® Surgical S is as good as sutures for the closure of laparoscopic wounds in terms of cosmesis and complications with the added benefit of being significantly faster.

Keywords LiquiBand® Surgical S · Vicryl · Randomized trial · Laparoscopy

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Background

Throughout history, various exotic materials have been used to close surgical wounds. Leather has been used as far back as 1100 BC [1]. Woven horse hair, cotton, and linen are examples of natural fibers used in sutures; in fact, silk is still used today. With the evolution of advancing technology, arrays of synthetic polymeric threads have replaced natural fibers for the majority of purposes with Vicryl™ (Ethicon, Kirkton, Scotland) absorbable sutures becoming one of the most popular. Cyanoacrylate adhesives offer the surgeon and patient an alternative to suturing wounds. They offer a fast and less traumatic closure for appropriately selected wounds and typically do not require the use of local anesthesia [2]. These adhesives are commonly used for the closure of topical skin incisions and trauma-induced lacerations in areas of low skin tension [3]. Numerous potential advantages have been reported for both surgeons, healthcare system providers, and patients compared to conventional surgical wound closure techniques, including faster closure time, good cosmesis, non-invasive, less tissue trauma, no requirement for secondary dressing, ease of bathing, and no requirement for suture or staple removal [4]. Additionally, they spontaneously slough off in a short time period of time (5–10 days), thereby not requiring clinician removal [5]. These unique benefits have resulted in a significant increase in both the use and acceptance of the product within the medical community.

LiquiBand® Surgical S (Advanced Medical Solutions, Plymouth, UK) is a new formulation with a blend of monomeric *n*-butyl and 2-octyl cyanoacrylates. The blend combines the fast setting wound closure properties of the butyl-cyanoacrylates with the more flexible liquid wound dressing capabilities of the slower setting octyl-cyanoacrylates. It is indicated for the closure of clean and easily approximated incisions or trauma-induced lacerations, used in conjunction with but not in place of deep dermal stitches. The applicator features a narrow cannula and flow control tip for precise

wound closure that can be removed to reveal an integrated foam pad for applying a broad occlusive wound dressing (Fig. 1). It has sufficient volume of octyl-blend monomer to close and protect wounds up to 8–10 cm in length.

In this study, the effectiveness, safety, and clinical utility of LiquiBand® Surgical S (LBSS), formerly marketed as LiquiBand® Laparoscopic, was compared to sutures (Vicryl™) for the closure of laparoscopic incisions. The two devices were evaluated for time to complete wound closure, user and patient satisfaction with closure, cosmesis, and complication rates following the use of either device.

Methods

This was a prospective randomized study of LBSS skin adhesive versus suture for the topical closure of laparoscopic surgical incisions. Female patients 18 years and older, scheduled for laparoscopic surgery, and willing to return for a 2-week follow-up visit were invited to participate in this trial. Exclusion criteria included known sensitivity to cyanoacrylates, wounds under high tension, pregnancy or breastfeeding, or the presence of a disease or condition that interferes with wound healing such as diabetes mellitus. The protocol and informed consent received regional ethics committee approval and study subjects provided full consent prior to participating in any study-related procedures.

Subjects were randomly assigned to receive either LBSS or sutures for topical wound closure of laparoscopic incisions. A random number generator determined the assignment to either LBSS or sutures at time of surgery. The sutures used were 3-0 Vicryl™ and a subcuticular method of dermal closure was used. Due to the inherent differences between the two closure methods, it was not possible for the surgeon, study subjects, or evaluator to be masked from the knowledge of the randomized treatment assignments.

Fig. 1 The LiquiBand® Surgical S device

All enrolled study subjects, regardless of randomized device assignment, received the same preoperative cleansing routine as per hospital standard operating procedures. It involved a chlorhexidine alcohol mix. Additionally, hemostasis was achieved prior to any wound closure and study surgeons were instructed to use each study device according to their respective instructions for use.

Closure technique

LBBS was applied to a clean, dry wound with careful use of tissue forceps to obtain skin edge approximation and tissue aversion. We avoided having instruments or gloved fingers coming into contact with freshly applied adhesive as they can become stuck to the skin. Once the edges of the incision were adherent and opposed, the fine tip of LBSS device was removed and an oval dressing of the glue spread over the wound. This adheres to the glue in the wound edge and spreads the tension forces over a greater area as well as providing a waterproof dressing.

In the group that had sutures used, the following technique was used: The needle was inserted deep to the subcutaneous layer of the skin and pierced the subcutaneous fascia just underneath the skin. Once removed from one side of the wound, it was then inserted subcutaneously on the opposite skin surface and removed deep to the subcutaneous plane. The suture was tied using a surgical knot that was buried deep to the subcutaneous layer.

The surgeons taking part in the study were all senior gynecologists of consultant or subconsultant level with greater than 10 years experience in gynecological surgery. Along with subject demographics including subject age and body mass index (BMI), the length (in millimeter) of each incision requiring closure, and whether the incision required deep tissue suture was captured at wound closure.

The primary outcome measure of the study was to show a reduction in the time taken to close laparoscopic port site skin wounds with LBBS when compared with wounds closed with were 3-0 Vicryl™ using a subcuticular method.

Secondary outcome measures were as follows: Surgeons were asked to document whether they were satisfied or dissatisfied with the wound closure device and whether they found the device easy to use. Subjects were asked to return at 2 weeks postsurgery at which time any applicable wound complications (erythema, edema, pain, inflammation, discharge, odor, and dehiscence) were recorded along with any reported adverse events. Wounds were evaluated for apposition (<50, 50–99, and 100 %), and also for cosmesis using a modified Hollander Wound Evaluation Scale (HWES) [6]. The HWES was modified to a five-point scale with one point

assigned to any of the following observed wound appearances; step off borders, contour irregularities, margin separation, edge inversion, and excessive distortion. A HWES of 0 indicated an optimal wound appearance, with each point between 0 and 5 indicating a less adequate appearance of the wound. The same evaluator also rated wound appearance as either acceptable or unacceptable. Study subjects were asked to rate their satisfaction with their wound appearance as either satisfied or dissatisfied.

Sample size and power calculation

The sample size was calculated to detect a 50 % reduction in wound closure time from 240 s with sutures to 120 s, with a standard deviation of 120 s, with tissue adhesive at a two-tailed significance level of 0.05 with a power of 95 %. Allowing for a dropout rate of 30 %, 163 wounds were needed in each of the two treatment arms.

Statistical methods

Data was analyzed in SPSS. The Shapiro–Wilk test of normality was done for the continuous variables including age, BMI, length of incision, number of incisions, and closure time in seconds.

Independent samples *T* test was used to compare normally distributed data and Mann–Whitney *U* test used to compare non-normally distributed data. A chi-square test was used to compare the nominal data including the difference between the dressings used, the wound infection rate, the complication rate, and satisfaction rate. A *p* value of 0.05 was used as the critical level for determining statistical significance.

Findings

A total of 152 subjects were enrolled in this study between 14 August 2009 and 2 April 2012 with 126 subjects completing all study-related procedures by 17 April 2012. Twenty-six subjects did not complete the study and were terminated due to voluntary withdrawal, not meeting inclusion/exclusion criteria, or being lost to follow-up. Twelve subjects were omitted from data analysis due to missing or incomplete data points, resulting in a total of 114 subjects used in the data analysis. Of the 114 subjects assessed, 55 subjects received sutures for topical wound closure, with 59 subjects receiving LBSS (Table 1). The subjects were well matched for both age and BMI with no significant differences between the two groups (Table 1). Pre-existing medical conditions for study subjects (14.7 % of subjects assigned with sutures and 6.8 % for LBSS) included eczema, psoriasis, active infection, and previous surgical site infection. Subjects from either treatment group had a median of three incisions closed with a total number of 167 incisions closed by sutures and 178 by LBSS. There was no significant difference in wound length between each group ($p=0.775$). The time taken to close wounds using LBSS was found to be significantly faster ($p<0.001$) than by sutures (Fig. 2). The median closure time for LBSS (approximately 78 s) was around two and a half times faster than closure by suture (approximately 210 s), with a difference between the medians of approximately 2 min 20 s. Following surgery, dressings (Opsite®, Smith and Nephew Inc.) were applied to the majority of wounds closed with sutures (92.2 %), while most wounds closed by LBSS (94.9 %) required no dressings after application.

Surgeons were found to be satisfied with 100 % of all applications using the LBSS device and also found the device easy to use for all wound closures. Surgeons were also found to be satisfied with 100 % of the wounds closed with subcuticular stitching.

At the 2-week visit, wounds were assessed by an evaluator for apposition and cosmesis (Table 2). Most wounds achieved apposition of >50 % with 18.6 % wounds closed by sutures and 18.5 % wounds closed by LBSS resulting in 100 % apposition which was not statistically significant ($p=0.906$). Only one wound closed by LBSS resulted in apposition of <50 %. High levels of cosmesis were also reported for all wounds regardless of closure device with no statistical significance between them ($p=0.17$). One hundred percent of wounds closed with sutures and 98.9 % wounds closed with LBSS achieved an optimal HWES of 0. Further inspection of wound sites closed with LBSS found that the adhesive had sloughed off either partially or completely from most sites (94 %), with 6 % of sites still retaining an intact adhesive layer. The adhesive typically remained intact for 5–7 days. All wounds were evaluated as acceptable by the evaluator at the 2-week visit with 100 % of subjects of both treatment groups satisfied by the appearance of their wounds.

Adverse events expected in this trial were complications typically experienced from wound closure following surgery and restricted to the site of treatment. Complications were assessed at the 2-week visit and included assessments at the wound site for erythema, edema, inflammation, odor, pain, and dehiscence (Table 3). There was no significant difference in complication rates ($p=0.956$). Of the 178 wounds closed with LBSS, a total of 39 wounds (21.9 %) reported complications and of the 167 wounds closed with sutures; the incidence of complications was 38 (22.8 %). Erythema was the most reported complication with 29 cases reported for each wound closure method (approximately 75 % of the reported complications for both treatment groups). The next most common complication was pain or tenderness at the wound site with six cases reported for both LBSS and sutures. Other complications reported were one case of edema from sutures, one case of

Table 1 Demographics and Wound incision characteristics

	Sutures	LBSS	*p* value
Number of subjects	55	59	N/A
Mean age of subjects (SD)	45.4 (10.1)	41.7 (11)	0.06
Median BMI of subjects (SD)	25	24	0.52
Medical history			N/A
Total pre-existing, *n* (% subjects), by type	8 (14.7)	4 (6.8)	
Eczema	3 (5.5)	2 (3.4)	
Psoriasis	2 (3.7)	0	
Active infection	1 (1.8)	0	
Previous SSI	2 (3.7)	2 (3.4)	
Total number of incisions	167	178	N/A
Median length of incisions (SD)	5	5	0.78
Median no. incisions per subject (min/max)	3	3	0.85
Dressing used post closure, *n* (% of wounds)			Yates chi-square
None	13 (7.8)	169 (94.9)	$p<0.0001$
Opsite®	154 (92.2)	9 (5.1)	
Status of tissue adhesive, *n* (% wounds)	N/A		N/A
Intact		10 (6)	
Completely sloughed off		63 (38.2)	
Partially sloughed off		92 (55.8)	
Median closure time per subject, in seconds (SD)	210	78	$p<0.0001$

inflammation from LBSS, two cases of drainage/discharge from sutures, one from LBSS, and one case each of odor and dehiscence for LBSS. All complications reported were minor in nature and resolved without further treatment. No serious adverse incidents were reported throughout the duration of the study. Not all fields for the status of the tissue adhesive were at 2 weeks were completed. Thirteen wound evaluations were incomplete. The percentage calculated was based on the 165 completed not the 178 total wounds. The trial ended once the number of patients required was reached.

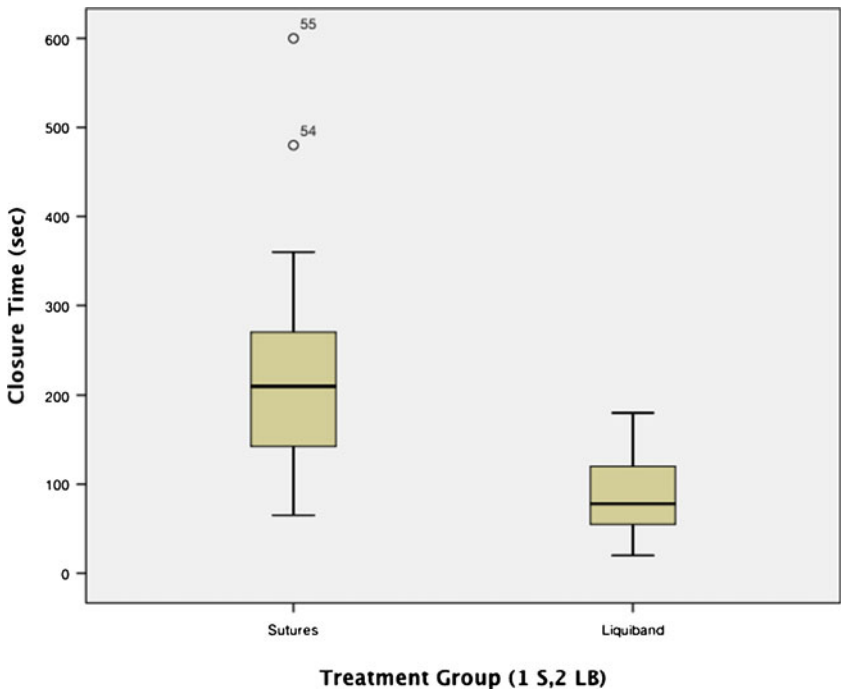

Fig. 2 Comparison of closure times between the 2 groups

Table 2 Two-week follow-up visit

		Sutures	LBSS	*p* Value
Assessed by evaluator	Apposition	*N* (%)	*N* (%)	Yates chi-square
	100 %	31 (18.6)	33 (18.5)	$p=0.906$
	50–99 %	136 (81.4)	144 (80.9)	
	<50 %	0 (0)	1 (0.6)	
	MHWES (% score=0)	100	98.9	0.17
	Overall appearance (% acceptable)	100	100	N/A
	Patient satisfaction with wound appearance (%)	98.9	100	N/A

Discussion

The use of cyanoacrylates for tissue adhesion was first described in 1959. Although it was very effective, the degradation products had significant tissue toxicity [7]. Through time, newer products have emerged without tissue toxicity including LiquiBand® Surgical S. It contains a 90 % *n*-butyl and 10 % 2-octylcyanoacrylate blend. The *n*-butyl cyanoacrylate dries faster but potentially a more brittle glue, while the 2-octyl cyanoacrylate is more flexible but takes longer to dry. Various studies have demonstrated the effectiveness of 2-octyl cyanoacrylate [8–12] and *n*-butyl cyanoacrylate [13] to subcuticular stitching for the closure of laparoscopic wounds. This study is the first reported using a combination of both monomers in the literature.

There was no significant difference in cosmesis or complication rates in the use of LBSS as compared to subcuticular stitches for the closure of laparoscopic wounds. This makes it a realistic and useful alternative to sutures. Surgeons were very happy with the application particularly with the very quick drying time and excellent wound apposition.

The high surgical satisfaction is likely due to the fact that this form of closure is very easy to use. The placement of the tissue adhesive is a simple procedure, less technically demanding than placement of subcutaneous sutures. The learning curve is extremely rapid and is described to require the use of a glue with at least three incisions [11]. This could easily be achieved in one or two cases. One key note to all users is that the surgeon must avoid placing adhesive directly in the wound, in the deeper layers, as it will create a barrier, affect tissue healing, and will extrude through the wound [10].

Patient satisfaction was very high which is in part aided by the ease of bathing immediately after surgery, with no need to replace the dressings, and lack of requirement for suture or staple removal [4]. The lack of requirement for secondary dressing was apparent in this study and consistent with other cyanoacrylate studies in the literature [4].

The material costs of LBBS are higher than those for sutures and dressings. The NHS cost of LiquiBand® Surgical S is £13.45 per device as compared to the cost of a single 3-0 vicryl of £2.11 together with and Opsite dressings cost of £0.28 each per wound. In addition, patients are often given extra dressings to take home to replace after bathing.

However, when the total closure costs of material expenses and operating room time are considered, LBBS closure is more economical than suture closure. This study demonstrated that the time taken to close wounds using LBSS was consistently faster than using sutures with an average saving of 2 min per patient. Routine use extrapolated to 105 cases a week would potentially free up 210 min a week equating to freeing up a half day operating list per week. In addition, it has been estimated that theater time costs approximately US$30 per minute in the US and £20 per minute in the UK [14]. This can provide a substantial cost reduction based on the time saved [11].

Table 3 Complications at 2-week follow-up visit

		Device		p-value
		Sutures	LBSS	
Incidence, *N* (% of complications per device)	Total no. complications (% of total incisions)	38 (22.8)	39 (21.9)	Yates chi-square $p=0.956$
	Erythema	29 (76.3)	29 (74.3)	
	Edema	1 (2.6)	0	
	Pain or tenderness	6 (15.8)	6 (15.4)	
	Inflammation	0	1 (2.6)	
	Discharge/drainage	2 (5.3)	1 (2.6)	
	Odor	0	1 (2.6)	

Additional cost saving can be taken into account when comparing LBBS to non-absorbable sutures. With LBBS, there is no need for appointments to be made to remove any suture material [15], although this is not a factor with dissolvable subcuticular sutures.

Other potential benefits include a reduction in the risk of allergic reactions associated with sutures [16] and the fact no needles are required essentially eliminates the risk of needle stick injury for wound closure [16, 17].

LiquiBand® Surgical S is as good as sutures for the closure of laparoscopic wounds in terms of cosmesis and complications with the added benefit of being significantly faster to apply and provides an immediate impermeable dressing.

Conflict of interest Funding of the study was provided by Advanced Medical Solutions (Plymouth) Ltd. Western Wood Way, Langage Science Park, Plympton, Plymouth, Devon PL7 5BG, England. Advanced Medical Solutions (Plymouth) Ltd funded the presentation of the paper at a national conference. The authors report no other conflicts of interest.

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