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REVIEW

A systematic review of randomised control trials assessing mesh fixation in open inguinal hernia repair

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Abstract
Purpose The technique for fixation of mesh has been attributed to adverse patient and surgical outcomes. Although this has been the subject of vigorous debate in laparoscopic hernia repair, the several methods of fixation in open, anterior inguinal hernia repair have seldom been reviewed. The aim of this systematic review was to determine whether there is any difference in patient-based (recurrence, post-operative pain, SSI, quality of life) or surgical outcomes (operative time, length of operative stay) with different fixation methods in open anterior inguinal hernioplasty.
Methods A literature search was performed in PubMed, EMBASE and the Cochrane Library databases. Randomised clinical trials assessing more than one method of mesh fixation (or fixation versus no fixation) of mesh in adults (>18 years) in open, anterior inguinal hernia repair, with a minimum of 6-month follow-up and including at least one of the primary outcome measures (recurrence, chronic pain, surgical site infection) were included in the review. Secondary outcomes analysed included post-operative pain (within the first week), quality of life, operative time and length of hospital stay.
Results Twelve randomised clinical trials, which included 1,992 primary inguinal hernia repairs, were eligible for inclusion. Four studies compared *n*-butyl-2 cyanoacrylate (NB2C) glues to sutures, two compared self-fixing meshes to sutures, four compared fibrin sealant to sutures, one compared tacks to sutures, and one compared absorbable sutures to non-absorbable sutures. The majority of the trials were rated as low or very low-quality studies. There was no significant difference in recurrence or surgical site infection rates between fixation methods. There was significant heterogeneity in the measurement of chronic pain. Three trials reported significantly lower rates of chronic pain with fibrin sealant or glue fixation compared to sutures. A further three studies reported lower pain rates within the first week with non-suture fixation techniques compared to suture fixation. A significant reduction in operative time, ranging form 6 to 17.9 min with non-suture fixation, was reported in five of the studies. Although infrequently measured, there were no significant differences in length of hospital stay or quality of life between fixation methods.
Conclusions There is insufficient evidence to promote fibrin sealant, self-fixing meshes or NB2C glues ahead of suture fixation. However, these products have been shown to be at least substantially equivalent, and moderate-quality RCTs have suggested that both fibrin sealant and NB2C glues may have a beneficial effect on reducing immediate post-operative pain and chronic pain in at-risk populations, such as younger active patients. It will ultimately be up to surgeons and health-care policy makers to decide whether based on the limited evidence these products represent a worthwhile cost for their patients.

Keywords Surgical fixation devices · Hernia · Mesh

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Introduction

Although the exact figures are unknown, it is estimated that more than 20 million prosthetic meshes are implanted

worldwide each year [1, 2]. Prosthetic meshes used in hernia surgery have undergone constant development since the early twentieth century [3]. The use of mesh has reduced recurrence rates to below 5 % in inguinal hernia repair [4–6] and post-operative morbidity is now often attributed to other outcome measures, especially chronic pain and surgical site infection (SSI). Indeed, it is no longer sufficient to rate success purely in terms of recurrence, but also in terms of wound complications, length of hospital stay, chronic pain and quality of life. Also important, but nevertheless secondary to these patient-based outcome measures are surgical outcome measures, namely handling of materials, ease of implantation, operative time and cost.

Identification of methods to reduce post-operative pain and infection following inguinal hernia repair may significantly affect quality of life. The mesh device itself is only one of several variables influencing the outcome of hernia repairs. The process of securing the mesh in place, 'fixation', has also been implicated in chronic pain and infection [7, 8]. Although this has been the subject of vigorous debate in laparoscopic hernia repair, several methods of fixation in open, anterior inguinal hernia repair also exist. Fixation of synthetic mesh in hernia repair requires a balance between strength of fixation and minimising the risk of trauma to local tissues and inadvertent damage to cutaneous nerves through entrapment. Complications attributed to mesh fixation include mesh migration and recurrence [9–13], meshoma [14], tack hernias [15], chronic pain [16–21] and infection [22, 23]. A number of randomised clinical trials (RCTs) have compared different types of mesh fixation in open inguinal hernia repair. These include comparison of mesh fixation with tacks, staples, self-fixing meshes, fibrin sealants (FSs), glues and sutures. However, a consensus opinion regarding which method is most advantageous has not been reached and currently the method used is often based on individual surgeon's preference. Evidence that a particular fixation method improves patient-based or surgical outcome measures may have a significant impact on clinical practice. The aim of this systematic review is to determine whether there is any difference in patient-based (recurrence, post-operative pain, SSI, quality of life) or surgical outcomes (operative time, length of operative stay) with different fixation methods in open anterior inguinal hernia repair.

Methods

The PRISMA guidelines for systematic reviews were consulted when designing the review [24]. The research question was to compare and contrast the different methods available for mesh fixation in open, anterior, mesh inguinal hernia repair in adults (>18 years) in terms of the following primary outcomes; recurrence, chronic pain (defined as pain persisting for greater than 3 months post-operatively) and SSI. Secondary outcomes analysed included post-operative pain (within the first month), operative time, length of hospital stay and quality of life. Data were obtained from RCTs meeting the inclusion criteria as outlined below.

Study eligibility criteria

Randomised clinical trials assessing more than one method of mesh fixation (or fixation vs. no fixation) of mesh in adults (>18 years) in open, anterior inguinal hernia repair, with a minimum of 6-month follow-up, and including at least one of the primary outcome measures (recurrence, chronic pain, SSI) was included in the review.

Search strategy and information sources

A literature search was performed in PubMed, EMBASE and the Cochrane Library databases from their inception to August 2012, using the MeSH key words 'surgical fixation devices', 'adhesives', 'self-fixing mesh', self-gripping mesh', self-adhesive mesh' and 'sutures' (using the Boolean operator OR), combined with 'surgical mesh' and 'inguinal hernia' (using the Boolean operator AND) combined with 'laparoscopic surgery' (using the Boolean operator NOT). The following limits were applied: 'RCTs', 'English language or translation', and 'human'. Electronic and bibliographic searches of all retrieved articles were performed to identify further studies of interest.

Study selection, data extraction and risk of bias

Both authors independently identified trials for inclusion and differences were resolved by consensus discussion. In the case of multiple publications of the same study population, only the latest publication was included. Studies that met the inclusion criteria were reviewed in full text, along with those for which it was unclear whether the criteria had been met. Data extraction was performed using a standard pro forma. The following information was obtained: author, publication date, population size, intervention, mesh used, outcomes assessed, length of follow-up, statistical method, quality of evidence and results. The quality of evidence of RCTs was judged according to the Grading of Recommendations Assessment Development and Evaluation Criteria (GRADE), as very low, low, moderate or high [25]. The results were tabulated. Brand names of fixation devices and the mesh used were included where

mentioned. Where patients were lost to follow-up, the remaining numbers have been represented as a numerical fraction. To standardise the visual analogue scale (VAS) scores between studies, a scale of 0–10 was used for the purpose of this review. If the study used a 0–100 VAS, the scores were divided by a factor of 10 to translate to the 0–10 scale.

Statistical analysis

A P value of <0.05 was considered to be statistically significant. Where a P value was not specifically stated but 'no significance' published, this was recorded accordingly. Significant heterogeneity between studies made combined analysis scientifically unsound and therefore no meta-analysis was performed.

Results

The search results yielded 144 publications after duplicates were removed. Once limits were applied, 12 articles were eligible for inclusion (see PRISMA template in Fig. 1). These included 1,992 primary inguinal hernia repairs. The fixation methods assessed in each of the included RCTs are shown in Table 1. Four studies compared *n*-butyl-2 cyanoacrylate (NB2C) glues to sutures, two compared self-fixing meshes to sutures, four compared FS to sutures, one compared tacks to sutures and one compared absorbable sutures to non-absorbable sutures. According to GRADE guidelines, none of the RCTs were rated as high quality, four were of moderate quality, two were of low quality and five of very low quality. The most common reasons for low or very low quality were no formal power calculation, small study numbers, short length of follow-up and poorly matched groups (in terms of age, hernia size and co-morbidity). The characteristics of the included trials are shown in Table 1.

Primary outcome measures

A summary of the pooled results for the primary outcome measures (recurrence, SSI and chronic pain) is shown in Table 2.

Eleven studies assessed recurrence. There was a combined total of 26 (1.3 %) recurrences. Thirteen of the 26 recurrences were recorded in one study utilising NB2C glue, which had a 5-year follow-up [26]. There was no significant difference between fixation methods with respect to recurrence in any of the RCTs.

Only eight studies published infection rates and no distinction between superficial incisional SSI and deep SSI was made in any of the studies. Furthermore, the criteria for diagnosing SSI were infrequently documented. Overall infection rates varied between 0 and 3.5 % and three meshes had to be removed due to infection. There was no significant difference in infection rates between fixation methods in any of the RCTs.

All 12 studies measured chronic pain rates. Most of the RCTs defined chronic pain as pain persisting beyond 3 months; however, there was significant heterogeneity in the post-operative time at which pain was measured and for one study this was not even recorded [27]. Five studies measured the incidence at 3 months [26, 28–31], whilst three studies assessed the incidence only at 6 months [32, 33], a further three studies assessed the rates only at 1 year [34–36], and one study utilised a composite end point of pain, numbness and groin discomfort and at 1 year and at 6 months (if 1-year data were not available) [37]. The most common method for assessing pain was a VAS, and this was used by nine of the RCTs. Two studies did not state how pain was assessed [26, 27, 36] and one study utilised a predesigned questionnaire, asking if the patient experienced any groin pain [36]. Furthermore, there were variations in determining the significance of the findings. Most of the included RCTs classified chronic pain as any groin pain at 3 months post-operatively; however, three studies deemed pain significant only if the VAS score was ≥ 2 [35], ≥ 3 [37] and ≥ 4 accordingly [30]. Overall chronic pain rates ranged from 0 to 36.3 %. Although meta-analysis of the 12 RCTs was not performed, combined chronic pain rates after mesh fixation with sutures was 14.7 %, with NB2C glue 7.6 %, with FS 3.7 % and with self-fixing meshes 18.2 %. However, nine studies reported no significant difference between fixation methods.

Three RCTs identified a significant reduction in chronic pain with NB2C glue [30] or FS [32, 37] compared to sutures. The first, a moderate-quality RCT comparing Tisseel®/Tissucol® with 2/0 Prolene® sutures in 316 randomised patients identified a significant reduction in chronic pain rates (defined as VAS >3) at 6 months with FS compared to sutures (8.1 vs. 14.8 %, $P = 0.035$) [37]. This was supported by a very low-quality RCT of 148 patients randomised to either Quixil® FS fixation of lightweight mesh or Vicryl® suture fixation of a heavyweight mesh. Chronic pain (determined by mean VAS scores) was lower in the FS/lightweight mesh group at the 6-month follow-up (0 vs. 7.8 %, $P < 0.001$) [32]. However, in this underpowered study, it is unclear whether the result is related to the beneficial effect of lightweight mesh or FS, or is due to a type 1 error. A further low-quality RCT comparing NB2C glue to 2/0 Prolene® suture fixation in 110 patients reported lower chronic pain rates (defined as VAS ≥ 4) at 3 months follow-up in the NB2C group (0 vs. 10.9 %, $P = 0.027$) [30].

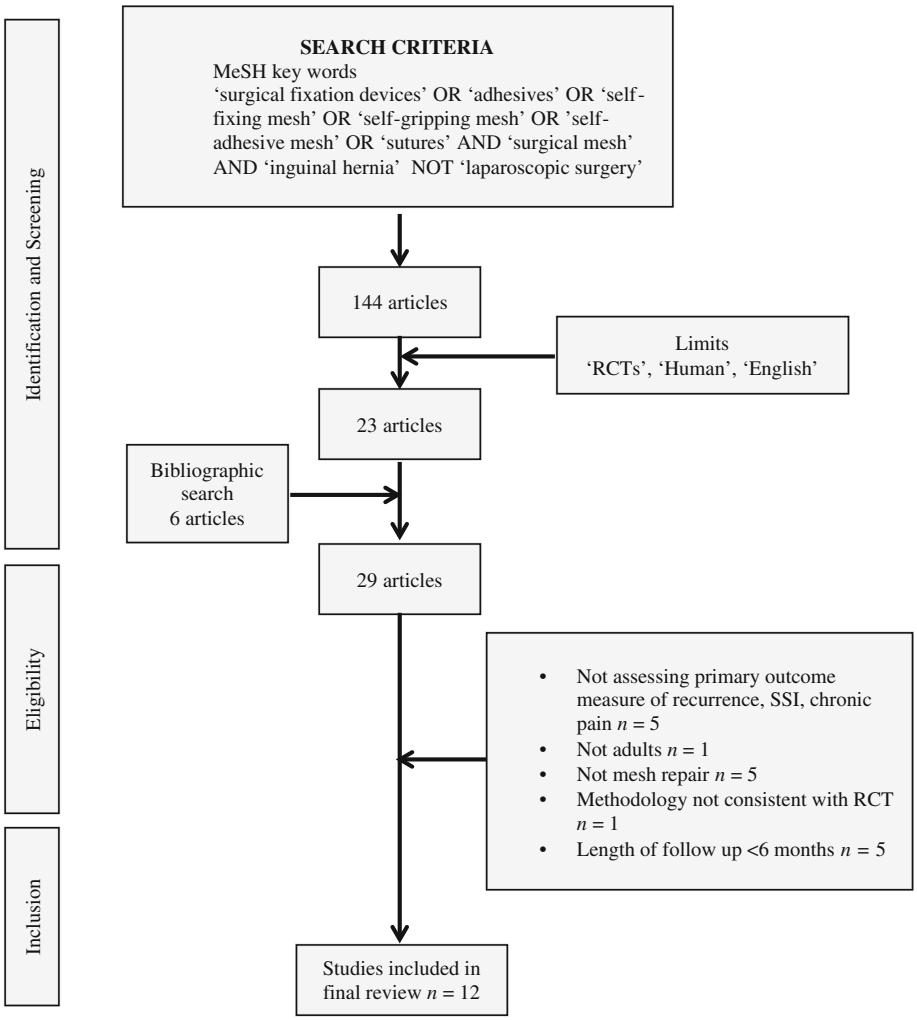

Fig. 1 PRISMA flow diagram for the systematic review

Secondary outcome measures

Six of the included RCTs specifically assessed pain within the first week post-operatively. Two studies reported significantly lower mean VAS scores at one or more assessment times within week 1, with FS [32], NB2C glue [29] or self-fixing mesh [33] compared to suture fixation (see Table 3). Conversely, two RCTs reported no significant difference in mean VAS scores between fixation methods [31, 37]. A significant reduction in post-operative pain was observed within the first 24 h with non-suture compared to suture fixation in three RCTs. The mean difference in VAS scores was 0.80 ($P < 0.001$) with FS [32], 1.44 ($P = 0.031$) with self-fixing mesh [33] and 0.90 ($P = 0.003$) with NB2C glue [29]. However, all of these RCTs were rated to be of very low quality based on small study numbers or confounding variables. Furthermore, only one of these studies (assessing FS compared to suture fixation) showed a maintained difference in pain rates at 1-week post-operatively [32].

Ten RCTs compared mean operative time between fixation methods (see Table 4). Five of these reported significantly shorter operative time with non-suture fixation techniques. Two of these studies compared self-fixing meshes with suture fixation and reported a reduced mean operative time of 9 min ($P = 0.01$)[34] and 12.2 min ($P = 0.008$)[33], respectively. Similarly, a reduced mean operative time of 6 min was reported in two studies comparing NB2C glue with suture fixation [26, 30] and of 17.9 min ($P < 0.001$) in one study comparing FS with suture fixation [32].

Four studies reported mean length of hospital stay and in these studies no significant difference was reported between fixation methods (see Table 4) [26, 29, 30, 37].

Only the Campanelli study assessed quality of life. This was assessed using Short Form 12 version 2 (SF12v2) and no significant difference between FS and suture fixation was observed at the 1-year follow-up. However, in the same study, more patients answered positively when asked if they would have the procedure again in the FS group (98.7 vs. 92.2 %, $P = 0.004$) [37].

Table 1 Characteristics of included RCTs

First author	Year	*n* total	Mesh used[a]	Fixation methods assessed	*n* in each group	Mean length of follow-up (months)	Quality (GRADE)
Campanelli [27]	2012	316	PP	FS (Tisseel®/Tissucol®)	158	12	Moderate
				Sutures (2/0 Prolene®)	158		
Pierides [28]	2012	394	ProGrip®	Self-fixing	198	12	Moderate
			Parietene Light®	Sutures (2/0 Prolene®)	196		
Kim-Fuchs [26]	2012	264	Vypro II®	NB2C Glue (Histoacryl®)	131	60	Moderate
				Sutures (2/0 PDS®)	133		
Shen [29]	2012	110	ProLite Ultra®	NB2C Glue (Compont®)	55	13	Low
				Sutures (2/0 Prolene®)	55		
Lionetti [30]	2011	148	UltraPro®	FS (Quixil®)	72	6	Very low
			Prolene®	Sutures (Vicryl®)	76		
Paajanen [31]	2011	302	Optilene®	NB2C Glue (Glubran®)	151	12	Moderate
				Sutures (3/0 Dexon®)	151		
Wong [32]	2011	56	PHS or Kugel Patch	FS (Tisseel®/Tissucol®)	30	6	Very low
				Sutures (Vicryl®)	26		
Kapischke [33]	2010	50	ProGrip®	Self-fixing	24	6	Very low
			Optilene®	Sutures (2/0 Surgipro®)	26		
Hidalgo [34]	2005	110	PP	FS (Tissucol®)	55	12	Very low
				Sutures (2/0 Prolene®)	55		
Nowobiliski [35]	2004	46	PP	NB2C Glue (Indermil®)	22	6	Very low
				Sutures (3/0 Dexon®)	24		
Douglas [36]	2002	34	PP	Spiral tacks (StatTack®)	17	6	Very low
				Sutures (2/0 Prolene®)	17		
Paajanen [37]	2002	162	PP	Absorbable sutures (2/0 Dexon®)	81	13	Moderate
				Non-absorbable sutures (2/0 Prolene®)	81		

Tisseel® Tissucol® (Baster Healthcare, Deerfield, IL, USA), Prolene® (Ethicon®, Johnson and Johnson, Somerville, NJ, USA), ProGrip® (Covidien, Dublin, Ireland), Parietene Light® (Covidien, Dublin, Ireland), Vypro® II (Ethicon®, Johnson and Johnson, Somerville, NJ, USA), Histoacryl® (Braun Medical, Sempach, Switzerland), PDS® (Ethicon®, Johnson and Johnson, Somerville, NJ, USA), ProLite Ultra® (Atrium Medical Co., Hudson, NH, USA), Compont® (Compont Medical Devices, Beijing, China), Optilene® (B. Braun, Melsungen, Germany), Glubran® (GEM, Viareggio, Italy), Dexon® US Surgical, Norwalk, Connecticut, USA), Vicryl® (Ethicon®, Johnson and Johnson, Somerville, NJ, USA), PHS + Prolene Hernia System (Ethicon®, Johnson and Johnson, Somerville, NJ, USA), Kugel Patch (Davol, Inc., Cranston, RI, USA), Indermil® (Loctite, Dublin, Ireland), StatTack® (unknown), Surgipro® (Covidien, Dublin, Ireland), Quixil® (Ethicon®, Johnson and Johnson, Somerville, NJ, USA), UltraPro® (Ethicon®, Johnson and Johnson, Somerville, NJ, USA)

[a] Mesh make if stated otherwise polymer, *FS* fibrin sealant, *PP* Polypropylene, *NB2C* *n*-butyl-2 cyanoacrylate

Discussion

We identified 12 RCTs that compared fixation methods in open, anterior inguinal hernia repair. According to GRADE guidelines, the overall quality of RCTs was low. Significant heterogeneity existed in the definition and measurement of end points. Nevertheless, the current review shows that based on current evidence, there are no significant differences in recurrence or SSI rates between fixation methods. Three trials reported significantly lower rates of chronic pain with FS or glue fixation compared to sutures [30, 32, 37]. A further four studies reported lower pain rates within the first week with non-suture fixation techniques compared to suture fixation [29, 32, 33, 37]. A significant reduction in operative time, ranging form 6 min to 17.9 min with non-suture fixation, was reported in five of the studies [26, 30, 32–34]. Although infrequently measured, there were no significant differences in length of hospital stay or quality of life between fixation methods.

We have included studies that compare NB2C glues, FSs, tacks, self-fixing meshes and sutures. NB2C glues are synthetic cyanoacrylate-based compounds similar to 'Superglue', which work by contact-induced exothermic hydroxylation of the monomer to form a stable polymer. Originally used for traumatic wound closure during the Vietnam War, Farouk et al. [38] first described the use of glue for mesh fixation in hernia surgery in 1996. Despite promising results, the study received criticism related to the local production of heat when using the glue and possible nerve and tissue damage as a result. In contrast, FSs

Table 2 Primary outcome measures (recurrence, SSI and chronic pain)

First Author	Fixation method	*n* in each group	Primary outcomes (*n* (%) and significance)		
			Recurrence	SSI	Chronic pain
Campanelli [27]	FS (Tisseel®/Tissucol®)	158	1 (0.006)	No sig	**13 (8.1)**
	Sutures (2/0 Prolene®)	158	2 (0.013)		**24 (14.8)**
			No sig		$P = \mathbf{0.035}^{*,¥}$
Pierides [28]	Self-fixing	198	0 (0.0)	1 (0.5)	65/179 (36.3)
	Sutures (2/0 Prolene®)	196	1 (0.006)	3 (1.5)	61/179 (34.1)
			$P = 1.000^{f}$	No sig	$P = 0.658^{\dagger}$
Kim-Fuchs [26]	NB2C Glue (Histoacryl®)	131	8/70 (11.2)	No sig	13 (10.1)
	Sutures (2/0 PDS®)	133	5/85 (5.8)		21 (16.0)
			$P = 0.379^{f}$		$P = 0.597^{f}$
Shen [29]	NB2C Glue (Compont®)	55	0 (0.0)	–	**0 (0.0)**
	Sutures (2/0 Prolene®)	55	0 (0.0)		**6 (10.9)**
			No sig^{f}		$P = \mathbf{0.027}^{*,f}$
Lionetti [30]	FS (Quixil®)	72	1 (1.4)	–	**0 (0.0)**
	Sutures (Vicryl®)	76	1 (1.4)		**6 (7.8)**
			No sig		$P < \mathbf{0.001}^{*,\dagger}$
Paajanen [31]	NB2C Glue (Glubran®)	151	2/144(1.4)	5/142 (3.5)	29/144 (20.1 %)
	Sutures (3/0 Dexon®)	151	2/142(1.4)	2/144 (1.4)	22/142 (15.5 %)
			$P = 1.0^{f}$	$P = 0.448^{f}$	$P = 0.318^{f}$
Wong [32]	FS (Tisseel®/Tissucol®)	30	0 (0.0)	1 (3.3)	2 (6.7)
	Sutures (Vicryl®)	26	1 (3.8)	0 (0.0)	2 (7.7)
			$P = 0.464^{f}$	$P = 1.000^{f}$	$P = 1.000^{f}$
Kapischke [33]	Self-fixing	24	–	1 (4.2)	0 (0.0)
	Sutures (2/0 Surgipro®)	26		0 (0.0)	3/25 (12.0)
				No sig	$P = 0.07^{f}$
Hidalgo [34]	FS (Tissucol®)	55	0 (0.0)	–	0 (0.0)
	Sutures (2/0 Prolene®)	55	0 (0.0)		0 (0.0)
			No sig		No sig
Nowobiliski [35]	NB2C Glue (Indermil®)	22	0 (0.0)	–	0 (0.0)
	Sutures (3/0 Dexon®)	24	0 (0.0)		0 (0.0)
			No sig		No sig
Douglas [36]	Spiral Tacks (StatTack®)	17	0 (0.0)	0 (0.0)	0 (0.0)
	Sutures (2/0 Prolene®)	17	0 (0.0)	0 (0.0)	0 (0.0)
			No sig	No sig	No sig
Paajanen [37]	Absorbable sutures (2/0 Dexon®)	81	1 (1.23)	1 (1.23)	21(26.0)
	Non-absorbable sutures (2/0 Prolene®)	81	1 (1.23) No sig^{f}	0 (0.0) No sig^{f}	19 (24.0) No sig^{f}

Bold values indicate significant result

P value stated if mentioned in original publication

– Indicates not recorded

* Indicates statistically significant result

¥ Mixed linear regression, ^{f}x squared or Fisher's exact, † ANOVA

are biological glues whose mechanism of action is based on reproducing the final steps in the coagulation cascade. This involves the simultaneous application of two components: concentrated human fibrinogen and lyophilised factor XIII that is reconstituted with aprotinin (antifibrinolytic agent) and thrombin reconstituted with calcium chloride or distilled water [39]. In 1997, Chevrel et al. [40] first documented the use of human FS for mesh fixation in incisional hernia repair. More recently, Morales-Conde et al. [41] performed a systematic review of 38 publications assessing the use of FS in hernia repair. The authors concluded that FS was an efficacious alternative for mesh

Table 3 Post-operative pain within the first week

First author	Fixation method	*n* in each group	Post-operative pain within first week (mean VAS score 0–10 mm scale)	
			Day 1	Day 7
Campanelli [37]	FS (Tisseel®/ Tissucol®)	158	–	2.34
	Sutures (2/0 Prolene®)	158		2.47
				No sig
Lionetti [32]	FS (Quixil®)	72	**3.20**	**2.00**
	Sutures (Vicryl®)	76	**4.00**	**4.00**
			$P < \mathbf{0.001}^{*,\dagger}$	$P < \mathbf{0.001}^{*,\dagger}$
Paajanen [31]	NB2C Glue (Glubran®)	151	5.00	3.00
	Sutures (3/0 Dexon®)	151	5.00	3.00
			$P = 0.242^{\ddagger}$	$P = 0.742^{\ddagger}$
Wong [31]	FS (Tisseel®/ Tissucol®)	30		
	Sutures (Vicryl®)	26	No sig	No sig
Kapischke [33]	Self-fixing	24	**1.79**	–
	Sutures (2/0 Surgipro®)	26	**3.23**	
			$P = \mathbf{0.031}^{*,f}$	
Nowobiliski [29]	NB2C Glue (Indermil®)	22	**2.34**	5.00
	Sutures (3/0 Dexon®)	24	**3.24**	4.10
			$P = \mathbf{0.003}^{*,\ddagger}$	$P = 0.69^{\ddagger}$

Bold values indicate significant result

P value stated if mentioned in the original publication

– Indicates not recorded

* Indicates statistically significant result

† ANOVA, ‡ Mann–Whitney U, f Fisher's exact

fixation compared to mechanical fixation devices. The use of FS has also been advocated by Fortelny et al. [42] in a systematic review published in 2012, which included 36 studies assessing Tisseel/Tissucol in a total of 5,993 patients undergoing various abdominal wall hernia repairs (both open and laparoscopic). Tisseel compared favourably with traditional methods of mesh fixation, being associated with shorter operative times and hospital stays and a lower incidence of chronic pain. Similarly, after laparoscopic/endoscopic inguinal hernia repair, FS was associated with less use of post-operative analgesics and less acute and chronic post-operative pain than tissue-penetrating mesh fixation methods. The use of surgical tacks has been widely adopted in laparoscopic abdominal wall hernia repair (inguinal and incisional). Tacks are usually spiral in design and can be made of non-absorbable titanium or absorbable material (such as polyester, e.g. AbsorbaTack™ Covidien™). They can be used in both open and laparoscopic surgery, but have a distinct advantage in laparoscopic surgery where suturing is often technically challenging and time consuming. Self-fixing meshes utilise absorbable polylactic acid hooks on one side of the mesh. These act like 'Velcro' holding the mesh in place.

The results of the present study suggest that FS, NB2C glues, self-fixing meshes and tacks produce comparably low recurrence rates to traditional suture fixation. These findings are supported by biomechanical models and animal studies which have shown comparable strength of fixation with FS [43–47], NB2C glues [48, 49] and self-fixing meshes [50] compared to sutures. Interestingly, half of all the pooled recurrences in the present review came from a single study [26]. Whilst this study had the longest follow-up of patients (mean of 60 months), the reported recurrence rates (mean of 8.5 %) were above the accepted rates from the wider literature, of <5 %[4–6]. These long-term results suggest that there may be increased recurrence rates with NB2C glues and other studies raise similar concerns for absorbable sutures [35, 36], but not for absorbable sutures that retain long-term strength [35, 36].

The role of suture material as a nidus for bacterial contamination and infection has been the subject of speculation for more than 30 years in surgery [23, 51–54]; however, there is a paucity of published data specific to mesh herniaoplasty. In support of the theory that bacteria adhere to suture material, an animal model assessing bacterial adherence to the mesh after hernia repair in contaminated fields reported lower bacterial adherence rates with glue fixation compared to suture fixation ($P < 0.001$)[55]. However, the present review identified no significant difference in SSI rates between suture and non-suture fixation methods. In inguinal hernia repair, the risk of superficial incisional SSI is between 0 and 14.4 % [56–60] and 0.3 and 6 % for deep incisional SSI [61–63]. Consequently to detect a difference between fixation methods, very large study numbers are required and it is unlikely that any of the included trials were powered appropriately to detect this.

The International Association for the Study of Pain defines chronic pain as 'that which persists beyond the normal time frame for healing, usually taken to be 3 months' [64]. The method of mesh fixation may influence chronic pain by the fixation device trapping cutaneous nerves, placing the muscle under tension or due to a periosteal reaction if a mechanical fixation device is placed over a bony prominence. Three RCTs identified a significant reduction in chronic pain with NB2C glue [30] or FS [32, 37] compared to sutures. The remaining nine studies reported no difference in chronic pain rates between fixation devices; however, a number of these studies did not

Table 4 Secondary outcome measures (operative time, length of stay, QOL)

First author	Fixation method	*n* in each group	Secondary outcomes		
			Mean operative time (mins)	Mean length of stay (h)	QOL (SF12 v2)
Campanelli [27]	FS (Tisseel®/Tissucol®)	158	39.8	No sig	8.5
	Sutures (2/0 Prolene®)	158	41.5		7.7
			No sig		No sig
Pierides [28]	Self-fixing	198	**36.0**	–	–
	Sutures (2/0 Prolene®)	196	**45.0**		
			$P < \mathbf{0.010}^{*,\ddagger}$		
Kim-Fuchs [26]	NB2C Glue (Histoacryl®)	131	**73**	80.4	–
	Sutures (2/0 PDS®)	133	**79**	81.4	
			$P = \mathbf{0.010}^{*,\S}$	$P = 0.816^{\S}$	
Shen [29]	NB2C Glue (Compont®)	55	**39.0**	48.0	–
	Sutures (2/0 Prolene®)	55	**43.0**	48.0	
			$P = \mathbf{0.001}^{*,\S}$	$P = 0.668^{\S}$	
Lionetti [30]	FS (Quixil®)	72	**44.4**	**–**	**–**
	Sutures (Vicryl®)	76	**62.3**		
			$P < \mathbf{0.001}^{*,\S}$		
Paajanen [31]	NB2C Glue (Glubran®)	151	34.0	–	–
	Sutures (3/0 Dexon®)	151	36.0		
			$P = 0.113^{\ddagger}$		
Kapischke [33]	Self-fixing	24	**51.0**	–	–
	Sutures (2/0 Surgipro®)	26	**63.2**		
			$P = \mathbf{0.008}^{*,w}$		
Nowobiliski [35]	NB2C Glue (Indermil®)	22	40.2	30.0	–
	Sutures (3/0 Dexon®)	24	42.1	42.0	
			$P = 0.510^{\S}$	–	
Douglas [36]	Spiral tacks (StatTack®)	17	86.0	–	–
	Sutures (2/0 Prolene®)	17	105.5		
			No sig		
Paajanen [37]	Absorbable sutures (2/0 Dexon®)	81	36.0	–	–
	Non-absorbable sutures (2/0 Prolene®)	81	38.0		
			No sig		

Bold values indicate significant result

P value stated if mentioned in original publication

– Indicates not recorded

* Indicates statistically significant result

‡ Mann–Whitney *U*, § Student's *t* test, w Wilcoxon rank-sum test

perform routine follow-up at the 3-month stage and may consequently have underestimated the number of patients with chronic pain. Furthermore, there were variations in determining the significance of the pain. Most of the included RCTs classified chronic pain as any groin pain at 3 months post-operatively; however three studies deemed pain significant only if the VAS score was ≥2 [35], ≥3 [37] and ≥4 accordingly [30]. Further confounding the issue, one of the studies reporting a difference in pain rates utilised a lightweight mesh with FS fixation compared to a heavyweight mesh with suture fixation. The reduction in pain rates with FS may have been due to the lightweight mesh rather than the FS. Indeed, in other studies lower rates of chronic pain with the use of a lightweight mesh compared to standard heavyweight or multifilament mesh have been attributed to a reduced inflammatory response, less scar tissue and less restriction of abdominal wall movement [65]. Nevertheless, the highest-quality RCT included in this review reported a 45 % reduction in the prevalence of moderate to severe chronic pain with the use

of FS compared to suture fixation [37]. Supporting this finding, the number of patients requiring analgesia was lower in the FS group. Interestingly subgroup analysis comparing chronic pain in the active versus the retired population found that the beneficial effect of FS was only significant in active patients (55 % reduction in active patients vs. 30 % reduction in retired patients). Whilst subgroup analysis must always be interpreted with caution, this result suggests that FS my be more suited to younger, active patients, who in previous studies were repeatedly shown to be more at risk of developing chronic pain [6, 66, 67].

The two RCTs, comparing self-fixing mesh and suture fixation reported no significant difference in chronic pain rates. In contrast, other trials which did not meet the inclusion criteria of this review (based on length of follow-up) have reported chronic pain rates in favour of self-fixing mesh [68]. A reduction in VAS score compared to pre-operative baseline pain of −24.3 % was reported in the ProGrip™ self-fixing mesh group ($n = 149$) versus −7.7 % in the group randomised to suture repair ($n = 153$), $P = 0.01$[68]. However, these interim results were published prior to trial completion and before the appropriate number of patients had been recruited to ensure that the study was appropriately powered and should therefore be interpreted with caution.

Six RCTs included in the review assessed acute pain, within the first week of operation. Three of these studies showed a significantly lower mean pain score with non-suture fixation techniques within the first post-operative day. The clinical significance of this difference is unclear and was not reflected in a shorter hospital stay, which although infrequently assessed was not significantly different between the groups.

The measurement of the impact of acute and chronic pain on quality of life is complex, but appears to pivot on the ability to return to work, resume normal daily activities and to an extent the improvement from baseline pain. Indeed, one might question whether mild pain or occasional discomfort is really disturbing in all patients. It is likely that this will depend on factors such as the significance of pre-operative pain, patient activity and occupation. Quality of life assessments rather than VAS scores may better answer these questions. Disappointingly, only one RCT measured quality of life. Interestingly, despite showing a significant reduction in pain with FS compared to sutures, the result was not mirrored by improved quality of life scores [37].

Half of the studies in which operative time was measured reported a significantly shorter operative time with non-suture fixation techniques. This ranged from 6 to 17.9 min. Whilst the time savings were statistically significant, the clinical significance was less clear. For a time saving to be clinically beneficial, it must allow for an increase in theatre capacity. Even in a high-throughput hernia centre, it is questionable whether a 6-min time saving would provide for this. In contrast, a time saving of 17.9 min may have a significant clinical effect on theatre capacity.

The majority of studies included in this review share significant limitations: namely, no formal power calculation, small study numbers, short length of follow-up and in some instances poorly matched groups (e.g. mean patient age, size of hernia, co-morbidity). Consequently, the majority of studies were rated as being of low or very low quality when the GRADE recommendations were applied. However, these problems are common with RCTs in hernia surgery. RCTs usually only provide mean rates to be compared, limited by the heterogeneity of patients, hernias and surgeons. Furthermore, one might wonder whether clinical trials are appropriate for assessing fixation devices. Most fixation-related complications are relatively uncommon, reflect a lifelong risk and can occur many years after mesh implantation. The median interval between operation and complication is 17 months for chronic pain [69] and 2 years for infection [70]. Consequently, the long delay between operation and recognition of the complication would restrict the usefulness of RCT methodology. The requirement of a long-term follow-up coupled with large study numbers and high study costs would be reflected in the reduced speed of development and the final cost of the commercial product. It may be that long-term registries provide a better basis to compare fixation methods. Nevertheless, the results of this review suggest that non-suture fixation techniques do not increase the short-term risks of infection, recurrence or chronic pain. There is currently insufficient evidence to promote FS, self-fixing meshes or NB2C glues ahead of suture repair. However, a moderate-quality RCT has suggested that FS may have a beneficial effect in chronic pain in at-risk populations, such as younger and active patients [37]. The cost benefit of any intervention is an important consideration and unfortunately none of the trials has included this. Invariably FS, self-fixing meshes and NB2C glues will cost more than sutures. It will ultimately be up to surgeons and health-care policy makers to decide whether, based on the limited evidence, these products represent a worthwhile cost for their patients. Future studies must ensure that they are appropriately powered, the groups are well matched, end points are clearly defined and that long-term follow-up (a minimum of 1 year) is achieved to make a significant further contribution to the literature.

Conflict of interest DLS and SW declare no conflict of interest.

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