



Long-term follow-up of endoscopic totally extraperitoneal direct inguinal hernia repair using the Endoloop technique

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Abstract

Introduction The pre-tied suture Endoloop™ technique for plication of the weakened transversalis fascia is efficient in post-operative seroma prevention, after laparoscopic/endoscopic direct inguinal hernia repair. No studies have evaluated long-term tolerability of this new technique in regards to chronic pain and hernia recurrence.

Methods Prospective longitudinal evaluation study of consecutive patients treated with Endoloop™ for M2 or M3 direct defects, during endoscopic totally extraperitoneal approach. Meshes were secured with fibrin sealant only. All patients had a minimum 2.8 years (median 5.9 years) follow-up. First outcome was chronic groin/testicular pain; secondary outcome parameters included hernia recurrence and Quality of Life (QoL). Patients were assessed by phone interview using the validated Carolinas Comfort Scale (CCS), questioned regarding recurrence and asked to present for clinical review as needed.

Results 112 patients (median age 57 years) with 141 direct hernia defects were included during the study period of 2008–2014. An Endoloop™ was used on 127 occasions—79 M2 and 48 M3 direct hernias. One patient had an early recurrence requiring an open repair and was therefore excluded. Thirty-three of the remaining one hundred and eleven patients (29.7%) were lost to long-term follow-up. According to their CCS range, 70 patients (88.6%) were very satisfied with their results, 8 (10.1%) were satisfied, and only one patient (1.3%) who reported chronic groin pain was unsatisfied. There was no reported long-term hernia recurrence.

Conclusion The PDS Endoloop™ technique for closure of direct inguinal hernia defects is well tolerated with low risk of hernia recurrence, chronic pain, and excellent QoL. This reliability persists to long-term follow-up.

Keywords Direct inguinal hernia · TEP · Endoloop · Outcome

Laparoscopic transabdominal preperitoneal (TAPP) and endoscopic totally extraperitoneal (TEP) inguinal hernia repair are minimally invasive procedures with recognized reduced post-operative pain, faster return to work, and normal physical duties, compared to traditional open surgery [1–4]. Additionally, review of the German Herniated registry found that TEP or TAPP had significant advantages over Lichtenstein repair in regards to overall post-operative complications and complication-related reoperations rates, pain at rest, and on exertion [5]. Furthermore, both techniques allow concurrent bilateral repair through the same

small incisions if necessary, with simultaneous assessment of the femoral canal and obturator foramen, as well as final insertion of a significantly large preperitoneal mesh extending from the midline symphysis pubis to the level of the anterior superior iliac spine (ASIS) laterally, thus offering a generous coverage of the Hesselbach's triangle [6].

With regards to direct inguinal defects, unlike an open repair which typically consists of plicating the posterior wall prior to mesh placement, laparoscopic repair may lead to the creation of a dead space—post reduction of the direct sac—where seroma can accumulate mimicking an early recurrence [7], (or more significantly, mesh migration into this defect, a potential source of pain and failed repair [8]). To counteract those potential problems, use of an Endoloop™ of PDS secured at the base of the inverted attenuated transversalis fascia (TF) is a validated alternative option. This simple technique involves placing a pre-tied loop ligature via the (generally most inferior) 5 mm working port and using

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the other 5 mm port to grasp the attenuated TF, through the loop, with non-traumatic laparoscopic forceps. The TF apex is then grasped, inverted, and flattened by tying the Endoloop™ at its base. Occasionally, a second Endoloop can be fed over the top of the first one (which then serves as a retractor), which can be then tied further down more effectively, flattening and reinforcing the base. This technique has been previously described [9] and is re-illustrated in Fig. 1. Alternatively, the use of traumatic stapling devices to reduce the lax TF and tack it to the symphysis pubis has been also described but carries the disadvantage of creating unnecessary additional pain [7]. To date, no study has objectively assessed the long-term pain issues with either of these techniques or hernia recurrence in this subset of patients.

The aim of this study was to evaluate long-term pain scores and Quality-of-Life (QoL) parameters as well as hernia recurrence, following the Endoloop™ technique during endoscopic TEP repair of direct inguinal hernia.

Materials and methods

This is a prospective longitudinal evaluation study population comprising all consecutive patients, 18 years of age or older, referred to a single surgeon for endoscopic TEP direct inguinal hernia repairs from June 2008 to March 2014. All operations were standardized and the specific technique has been previously described [10].

At the time of surgery, every identified moderate (M2) or large (M3) size direct inguinal defects as defined according to the European Hernia Society (EHS) [11] were systematically closed utilizing the Endoloop™ technique. (Fig. 1).

The lax TF was inverted and plicated with a pre-tied loop of 2/0 Polydioxanone (PDS) (Endoloop® Ligature, Ethicon Endo-Surgery, Cincinnati, OH) [9].

Between 2008 and 2009, an unmodified (no slit) Bard 3D® polypropylene mesh was used and subsequently replaced by a softer, hydrophilic, and more compliant pre-shaped polyester mesh (Parietex™ Anatomical Mesh 15 × 10 cm, TECT 1510ADP2, Covidien, Mansfield, MA), designed to ‘wrap’ around the cord structures without any additional modifications. This conforms to the International Endohernia Society Guidelines that recommend (Grade B) not to cut a slit in the mesh [12]. All meshes were solely secured using fibrin sealant (Tisseel, Baxter, Deerfield, IL).

Pain and QoL were prospectively assessed by phone interview using the Carolina Comfort Scale (CCS) score, a validated hernia pain scoring system summarized in Table 1 [13]. Patients were also questioned regarding groin swelling or for any concern suggesting hernia recurrence. They were requested to present for outpatient clinical review if needed.

The primary outcome was chronic groin/testicular pain; secondary outcome parameters included hernia recurrence, urinary symptoms, and QoL. All data were prospectively recorded including co-existing indirect/femoral/obturator hernias and the type of mesh. The study was conducted over

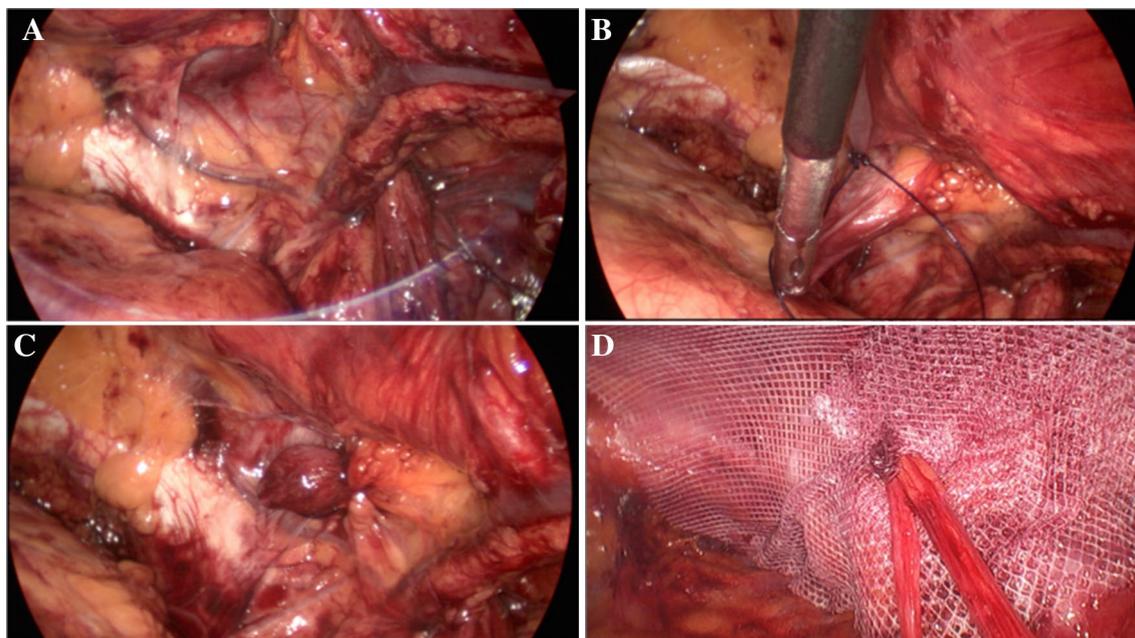


Fig. 1 Endoscopic TEP right-sided direct hernia repair with PDS Endoloop™ **A** weakened transversalis fascia (TF), **B** TF inversion with placement of a pre-tied Endoloop™ PDS at its base, **C** plicated

TF, **D** Parietex™ anatomical mesh covering the entire Hesselbach's triangle and fixed with fibrin glue

Table 1 Carolinas Comfort Scale questionnaire (max: 115points)

Number	Question	Scores
1	When laying down, do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
2	While bending over, do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A
3	While Sitting up, do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
4	While performing activities of daily living (getting out of bed, bathing, getting dressed), do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
5	When coughing or deep breathing, do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
6	When walking or standing, do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
7	When walking up or down stairs, do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
8	When exercising (other than work related), do you have	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A

79 Patients were asked to answer each question scoring 0 for no sensation of mesh, no pain, or no movement limitations and up to 5 for the worst symptoms

N/A not applicable

a seven-year period with intent to contact patients after a minimum of two-and-a-half-years follow-up to maximize the long-term durability of the data. Prior to statistical analysis, all data were collected and categorized in a database. The data were further analyzed using statistical tests for univariate categorical data (student's *t* test) to assess for a trend where appropriate.

Results

112 patients were prospectively recorded during the study period of 2008–2014. There were 109 males and 3 females, with a median age of 57 years. 141 direct inguinal hernias were repaired endoscopically (TEP) and an Endoloop™

was used on 127 occasions (79 M2 and 48 M3 direct defects). The remaining 14 M1 direct hernias were considered too small to require plication of the TF and hence no Endoloop™ was used. No patients had isolated M1 direct hernia defects and hence all CCS scores collected pertain to M2 and M3 direct repairs. 83 were combined with an indirect defect (58.9%) as summarized in Table 2. Only 4 patients (3.6%) initially developed a small non-symptomatic post-operative groin seroma, which all spontaneously and rapidly subsided. One patient had an early recurrence requiring an open repair and thus was excluded from the long-term results analysis.

Seventy-nine patients (70.5%) were successfully contacted at a minimum of 2.8 years (median 5.9 years) post surgery, while 33 of them (29.5%) were lost to long-term

Table 2 Study population characteristics

	Overall patient number (n = 112)	Long-term follow-up (n = 79; 70.5%)	No long-term follow-up (n = 33; 29.5%)
Male (n)	109 (97%)	77	32
Female (n)	3 (3%)	2	1
Mean age (years) (SD)	56.6 (± 13.1)	54.5 (± 12.4)	61.8 (± 13.2)
Male	56.3 (± 12.9)	54.2 (± 12.4)	61.2 (± 12.9)
Female	70 (± 15.7)	64.5 (± 17.7)	81 (NA)
Median age (years)	57.5	56	61
Male	57	56	60.5
Female	77	64.5	81
Follow-up (years)			
Mean	–	5.6	–
Median	–	5.9	–
Range	–	2.8–7.8	–
Direct hernias			
(M1) ^a	14 ^a	9 ^a	
M2	79	50 ^b	
M3	48	40 ^b	
Recurrent	18	9	
Bilateral	56	35	
Mixed (D+I)	83	62	
Mesh type			
ADP2 Parietex®	107	71	
3D Bard®	34	28	

D direct, *I* indirect

^aM1 direct hernias excluded from study—not treated with Endoloop

^bTotal of 11 (M2 or M3) bilateral direct hernias treated in 79 long-term follow-up patients

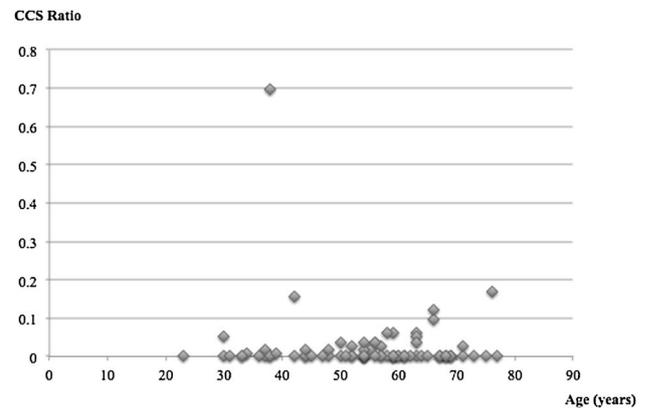
Table 3 Long-term follow-up results by Carolinas Comfort Scale symptom severity groupings

Ratio (CCS/total score)	N (%)
Very satisfied (≤ 0.05)	70 (88.6)
Satisfied (> 0.05 to ≤ 0.3)	8 (10.1)
Neutral (> 0.3 to ≤ 0.6)	0 (0)
Unsatisfied (> 0.6)	1 (0.13)

CCS calculated as 'x' value divided by maximum result of 115 (or 100 if unable to exercise)

follow-up. Of those remaining 79 patients, only one experienced persistent testicular/groin pain at 8 years post surgery (1.3%) and declined further review for assessment and investigation. According to their CCS range, the vast majority of patients (70, 88.6%) were very satisfied with their long-term results, eight of them (10.1%) were satisfied, and only one (1.3%) was unsatisfied (See Table 3). A graphic representation of those results is also illustrated in Fig. 2.

Of further significant importance is that 68 patients reported a perfect score of 0 out of a maximum of 115

**Fig. 2** Graphic representation of the 79 long-term follow-up patients according to their respective age and CCS ratio

points, as per the CCS score. Due to the quality of those results, we were unable to identify any clinical variable such as mesh choice (Bard 3D® vs. Parietex™ Anatomical) or hernia type (medial vs. combined medial/lateral defects) likely to influence outcome. Finally,

with long-term follow-up there were no reported hernia recurrences.

Discussion

As inguinal hernia repair continues to be the most commonly performed Western surgical abdominal operation, debate continues regarding the best technique option to ensure both long-term effective repair and tolerability to the patients. The EHS guidelines suggest laparoscopic TAPP or endoscopic TEP repair be the standard treatment in adult patients with both bilateral and recurrent inguinal hernias [4, 14]. Other randomized evidence also recommends their use as preferable choices for primary unilateral inguinal hernia repairs, over open herniorrhaphy [15]. We do agree with this statement, as long as the procedure is completed in the hands of adequately trained surgeons in both techniques.

Chronic groin pain after laparoscopy is considerably lower than with traditional open Lichtenstein repair (6% vs. 18%) [16], with the other advantages of the ability to diagnose and repair any associated occult, obturator, or femoral hernias, to offer faster return to normal physical activity and potential improved cosmetic appearances. As a consequence, many surgeons now favor TEP or TAPP techniques as their preferred method for the surgical treatment of most inguinal hernias [15, 17, 18]. The focus of recent research has been on mesh selection, looking at the best material usage (hydrophilic polyester mesh vs. polypropylene), mesh design (macro- vs. micro-porous, or mono- vs. multi-filament), and method of fixation (mechanical vs. glue vs. no fixation) [19] in order to reduce even further the risk of developing chronic groin pain that can have detrimental effect on the QoL.

The Carolinas Comfort Scale (CCS) specifically designed for hernia repairs measures post-operative satisfaction levels and QoL, based on severity of post-operative pain, mesh sensation, and movement limitations in eight different categories [13]. In our study, at a median follow-up of 5.9 years, only one patient (1.3%) complained of significant dissatisfaction with his repair (Table 3). He had already complained of some testicular/groin discomfort at week 2 of follow-up but failed to attend any subsequent post surgical consultation. He refused our requests to review him clinically, making it difficult for us to objectively assess the cause of his dissatisfaction. However, he did deny any subsequent surgery or signs of likely recurrence. This extremely low long-term incidence of chronic groin pain corroborates our earlier findings [8, 20]. To our knowledge, these outstanding results can only be explained by the combination of mesh selection with fibrin glue fixation.

Our preference for the pre-shaped polyester mesh (Parietex™ Anatomical) is mainly driven by three advantages: due to its softness, the prosthesis can be effortlessly introduced

through a working port and positioned without difficulty, as it is hydrophilic the mesh has a natural tendency to spontaneously stick to the abdominal wall making it easier to fix and finally, it does not have a propensity to shrink as the prosthesis will induce a well-balanced inflammatory response, thus creating a harmonious integration within surrounding tissues. This is nicely demonstrated in Fig. 3.

Additionally, Langenbach et al. found polyester meshes produce less foreign body reactions and hence less early seroma and post-operative pain compared to polypropylene in the setting of TAPP repair [21]. However, there is some conflicting evidence available, with Cu et al. finding comparable complication rates between the two meshes in the TEP repair setting [22].

Owing to the potential risk of vascular and nerve injuries, development of chronic pubalgia [23, 24] and the suggestion that fibrin sealant possess similar tensile strength to staples [25], it has been our practice for over 10 years to only use fibrin sealant for mesh fixation irrespective of the defect size [18]. In comparison and in the absence of fixation, the risk of mesh dislocation or folding may lead to increased recurrence rate and chronic pain [26]. Furthermore, as it is non-traumatic our technique has the considerable advantage of

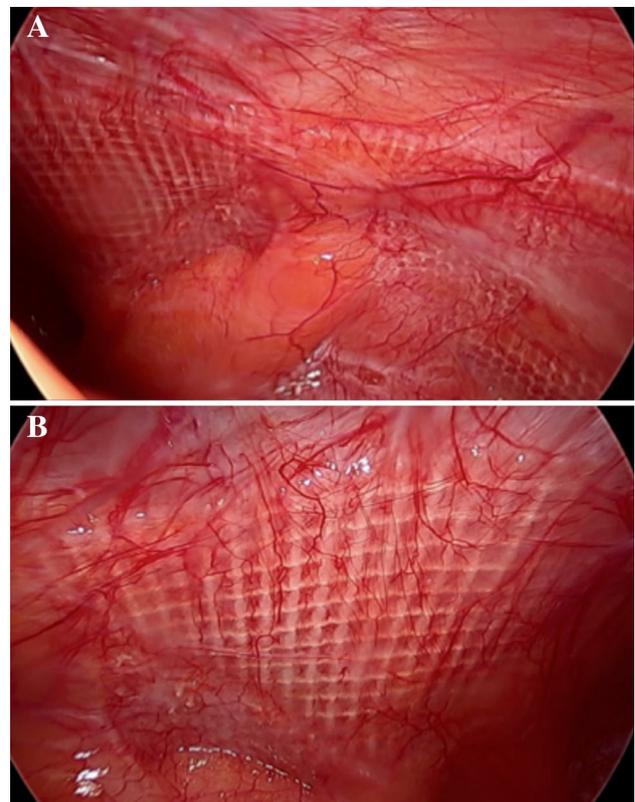


Fig. 3 Laparoscopic view of previous TEP fibrin glue repair of inguinal hernia **A** right-side extraperitoneal Parietex™ mesh, **B** left-side extraperitoneal (Parietex™ mesh), showing two laparoscopic views of previous TEP fibrin glue mesh repair of inguinal hernias

allowing safe fibrin glue application on the inferior aspect of the mesh, at the level of the triangles of doom and pain, which undoubtedly reduces the risk of hernia recurrence [27]. Fibrin glue fixation has also been recommended in the 2015 Guidelines of the International Endohernia Society (Level 1B) [12] and in the 2018 HerniaSurge Group guidelines—where atraumatic mesh fixation techniques are favored to reduce early post-operative pain in TEP repairs [4]. Although these latest guidelines state that only larger (M3) direct defects require mesh fixation, it is our practice to routinely fix meshes regardless of size with fibrin glue. Their statements are based on meta-analyses comparing recurrence and post-operative pain between non-fixation and fixation; however, we noted the RCTs used contained only limited information regarding the proportion of larger M3 defects versus smaller hernias and hence only a statement (with ‘moderate confidence’) is made (as opposed to an all inclusive recommendation) in regards to this point [4]. Furthermore, a significant proportion of our patients had combined (medial and lateral) hernias (83/74%) where there is an increased risk of recurrence with non-fixation [28]. It is therefore our standard practice to use fibrin glue fix meshes in all TEP inguinal hernia repairs.

The incidence of seroma formation in TEP repair has been found to be 0.5–12.2% [9]. Seroma formation may be influenced by factors such as medial versus lateral or combined hernias, old age, larger defects, inguinoscrotal sac extension, and presence of a residual indirect sac [29]. Interestingly, Köckerling et al. also mentioned a relationship between the use of glue fixation (vs tacks or no fixation) and an increased incidence of seroma. This assertion must be taken with great caution as the “non-fixation” group had significantly less percentage of type III defect size (13.57%) as compared to tacks (26.95%) or glue (19.41%) fixation, and we know that the risk of developing post-operative seroma will be proportionally higher with a larger (type III) defect. Secondly, in their “tacks” group they reported a 2.08% incidence of seroma formation versus 3.92% with glue. The reason for such discrepancy is mainly due to the fact that most surgeons tacking their meshes will also use tackers to reduce and fix the lax TF to Cooper’s ligament, thus significantly reducing the incidence of seroma formation [9]. In comparison, fibrin glue alone for mesh fixation will not prevent seroma formation in the presence of a large groin defect. Therefore, in order to minimize the risk of post-operative seroma formation, following TEP/TAPP repair of large direct inguinal hernia that can be a potential source of stress and pain for the patient, we described several years ago the valuable and easily reproducible Endoloop™ technique [9]. Our data have now confirmed that even after long-term follow-up, this pre-tied suture loop does not generate any additional symptoms for the patient and thus validates its unrestricted usage for M2 or M3 direct defects. This technique has been adopted by the International Endohernia Society updated

guidelines as a valid alternative to the fixation of the extended transversalis fascia to Cooper’s ligament, in dealing with large direct defects [4, 12].

The only one patient excluded from long-term analysis deserves further explanation. This 79-year-old male suffered from chronic AF for which he was on Warfarin. He underwent TEP bilateral inguinal hernia repair for combined left L1, M2 and right L1, M3 defects found during surgery. On the second post-operative day, he recommenced his treatment of Warfarin that was complicated by the formation of a large right-sided groin haematoma, causing the Endoloop to snap with formation of an early recurrence as the mesh suddenly migrated through the attenuated TF. This required subsequent open repair two months later. His case illustrates the potential risk of anticoagulation in the perioperative period and could possibly represent a relative contraindication to TEP or TAPP repair, although not supported by others [27]. Notably, none of the 79 patients successfully contacted during our study reported any inguinal hernia recurrence. This pleasing result must be offset by the fact that a significant number of patients (33 in total, 29.7%) were uncontactable. This does lend to the possibility of bias, with > 20% loss to follow-up posing a possible threat to validity [30]. The local patient demographics presenting for hernia repair included those from non-English speaking communities and lower socioeconomic status, which may have also contributed to this observed difficulty in follow-up [31]. Furthermore, the nature of a long-term follow-up study whereby patients are more likely to have moved or changed their contact is also a significant contributing limiting factor. Having said that, one advantage of phone survey is that it minimizes the inconvenience to the patients to attend physical follow-up, which they may be more likely to avoid in the absence of any significant problems such as pain or impaired QoL. This technique has been investigated previously and found to be a feasible and effective tool as a safe substitute for routine post-operative clinic visits in ambulatory surgical patients [32, 33]. It has been further specifically investigated in laparoscopic inguinal hernia repair patients using a validated PINQ-PHONE telephone questionnaire to detect both asymptomatic and symptomatic recurrences remotely—finding concordance with physical examination when the same patients were seen in clinic (sensitivity 1.00, specificity 0.86) [34]. This provides objective evidence that phone follow-up for investigation of both chronic pain and recurrence in laparoscopic inguinal hernia repair is an appropriate methodology.

Conclusion

Our data strongly support the use of Endoloop™ PDS technique during TEP repair of direct moderate (M2) or large (M3) inguinal hernia defects, as it is safe and reliable with

excellent long-term outcome in terms of QoL, risk of developing chronic groin/testicular pain, and with minimal incidence of recurrence when combined with mesh glue fixation.

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Compliance with ethical standards

Disclosures Emma Clout, Mirun Thayaparan, Cameron Douglas, and Christophe Berney have declared no conflict of interest or financial ties to disclose.

Informed consent Informed consent was obtained from all individual participants included in the study.

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