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ORIGINAL ARTICLE

Learning curve in open inguinal hernia repair: a quality improvement multicentre study about Lichtenstein technique

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Abstract

Purpose Inguinal hernia repair is one of the most performed procedure all over the world with more than 20 million procedures performed each year. Due to the lack of data in literature about the learning curve of the Lichtenstein procedure, we decided to reproduce a research on learning curves with the same methodology proposed in our previous study about laparoscopic hernia repair. The aim of this multicentre study was to analyse how many cases are required to achieve the learning curve for a Lichtenstein procedure.

Methods We performed a retrospective analysis of the first 100 Lichtenstein procedures performed by 4 trainees from three different institutions and compared them with the same number of procedures performed by 3 senior surgeons from the same institutions. The data about the achieving of learning curve were evaluated with CUSUM and KPSS test.

Results No differences about biometrical features were found between the seven groups of patients. CUSUM analysis showed that the trainees achieve the learning curve after 37–42 procedures, reaching an operative time similar to that one of the senior surgeons.

Conclusions In conclusion, we have shown that the number of procedures required to reach the learning curve from the beginning of surgical residency is around 40 hernia repairs. This number, produced in a controlled environment under strict supervision, could be the minimum requirement to start the procedure of accreditation and specialization in hernia surgery and is higher and steeper than previously reported.

Keywords Learning curve · Training · Inguinal hernia repair · Teaching in surgery · Lichtenstein

Introduction

Inguinal hernia repair is one of the most performed procedure all over the world with more than 20 million repairs performed each year. It represents one of the top three most performed procedures [1].

Lichtenstein repair is one of the first procedures that a young trainee learns during his residency program in general surgery, not only for its reproducibility and for the great numbers of procedures that could be done in each department, but also because during inguinal hernia repair the trainee learns several skills which form the basis of subsequent major surgical procedures.

The surgeon's performance can be evaluated by way of established learning curves that can predict the minimum number of procedures required to reach the same intra and post-operative outcomes as an experienced surgeon performing the same technique. This progression can be graphically

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expressed; trainees who are in the initial phase of their curves gradually reach levels of improved individual performance [2].

In our previous paper about the definitions of the characteristics of certified hernia centres in Italy [3], we found only one paper dealing with the learning curve of the Lichtenstein procedure [4], while another one was excluded from our analysis because it was edited in Italian [5]. Even in the European Hernia Society (EHS) guidelines clear indications about the number of minimum procedures to perform before achieving the learning curve were not found [6].

Due to the lack of data concerning the learning curve in the Lichtenstein procedure, we decided to reproduce a research on learning curves with the same methodology proposed in our previous study [7].

The aim of this multicentre study was to analyse how many cases are required to achieve the learning curve for Lichtestein procedure, analysing operative time and outcomes over the course of the residency program in general surgery.

Materials and methods

From January 2014 to December 2017 all Lichtenstein procedures from three different Institutions (*University Hospital of Genoa, Department of Surgical Sciences; "Sapienza" University of Rome, Department of Surgery "P. Valdoni" and "San Camillo" Hospital of Trento, Department of General and Mininvasive Surgery*) were recorded in a prospectively maintained computer database. After internal ethical committee approval all data from each of the participant institution were retrieved.

The results of the first 100 consecutive procedures performed by four different trainees (Trainee A1, Trainee A2, Trainee B, and Trainee C) were compared with three homogeneous groups (for age and BMI) of procedures performed by three senior surgeons from the same institutions of the trainees (Senior A, Senior B, and Senior C). All the senior surgeons have performed over 250 open inguinal hernia repairs at least and have consolidated experience in advanced abdominal wall reconstruction procedures. During all the procedures, the senior surgeon supervised the trainees. All the trainees attended the second year of residency program in general surgery and participated in at least 30 Lichtenstein procedures as first assistant before starting the study. Moreover, they all attended the first- and second level of the ISHAWS (Italian Society of Hernia and Abdominal Wall Surgery) Master Classes, consisting of a 5-day-theoretical and practical course on abdominal wall surgery. Since Italian law forbids the residents from operating without the presence of a specialist in the operating room, during all the subsequent procedures our trainees were supervised by a senior surgeon as the first assistant is allowed to give verbal counselling in case of difficulty, but without the possibility to directly operating (except to prevent serious intraoperative accidents). Primary outcome was considered as the number of procedures needed for the residents to reach a stable operative time (OT) similar to that of senior surgeons, this plateau was considered as the completion of the learning curve. Secondary outcome was frequency of intra and post-operative complications, chronic pain, and numbness 6 months postoperatively, recurrence two years postoperatively compared among trainees and senior surgeons.

Data collected included gender, age, American Society of Anaesthesiologists risk class (ASA), Body Mass Index (BMI), operative time (OT), type of hernia according to EHS classification [8], intra and post-operative complications (bleeding, seroma, wound infection, numbness, chronic pain, recurrence), and hospital stay. Operative time was calculated from the first skin-incision until the last skin-stich was placed. Wound infection was considered as defined by Aufenacker et al. [9].

Chronic pain was defined as pain lasting 3 months or more [10]. Seroma was defined as previously reported [11]. Recurrence was evaluated with clinical examination. Numbness was defined as feeling reduction of tactile sensitivity in the inguinal field, it was evaluated until one month after surgery.

Follow-up was conducted at 7 days, one month, and every year after surgery.

The learning curve was considered complete upon stabilization of the operating time (OT) and frequency of intra and post-operative complications in comparison with the senior surgeon results.

Teaching program and ethical aspects

According to Italian Ministry of Education, University and Research in accordance to the Ministry of Health (art. 38, subparagraph 3, law n. 368/1999) "The residents are allowed to take progressive responsibility of their activity during the residency program, but they cannot act and take autonomous decisions typical of the specialist without supervision". As already mentioned the resident cannot operate alone on the patient, but in each case, when entering a teaching hospital, the patient is informed that she or he could undergo steps or whole procedures performed by supervised residents; in our study all patient signed the informed consent including this possibility.

Every teaching centre follows its own methodology to decide the way residents progress in the program. The first year is dedicated to introduction to basic surgical techniques both for open and laparoscopic approach, subsequently a progression towards major surgery is planned. In particular in their second year along with open anterior hernia repair

the trainees are taught laparoscopic appendectomy and cholecystectomy along with anastomotic techniques. In the third to fourth, advanced open- and laparoscopic procedures are faced (TAPP, colon resection open and laparoscopic, partial gastric resection, incisional hernia repair). The fifth and the sixth year are dedicated to major surgery (hepatobiliary procedures, upper G.I. oncological procedures, etc.). The frequency and type of procedures are related to local expertise and patient recruitment; accordingly, it is quite difficult to establish a predefined sequence of interventions for the surgeon in training and define their effect on the learning curve of hernia repair.

Peri-operative management

Prior to surgery all patients had undergone routine blood test and general physical examination. In accordance with EHS guidelines, antibiotics and thromboembolic prophylaxis were administered only in selected cases [12]. Urinary catheter was not routinely inserted. Postoperative pain was managed with Non Steroideal Anti-inflammatory Drugs (NSAID). Patients were discharged within the next 24 h hours unless complications occurred.

Surgical techniques

As described in our previous papers [13-15], patients were treated either under local anaesthesia in a step-by-step fashion or profound sedation. After oblique inguinotomy and access to inguinal canal, the spermatic cord was isolated. The hernia sac was detached from spermatic cord structures and reduced in the abdomen. In each case, nerves are visualized and preserved if possible. In the case of a nerve resection, the nerve is resected at its muscles' origin. After hernia sac reduction, an 11×6 cm macro-porous mesh was trimmed and its apex sutured to the pubic tubercle using non absorbable suture, as described by Lichtenstein [16]. The same continuous suture was used to join the mesh to the free edge of the inguinal ligament, it was extended up just medial to the anterior superior iliac spine. In male patients, interrupted sutures were used to fix the two cut edges of the mesh together around the spermatic cord. The mesh was anchored to the conjoined tendon by interrupted reabsorbable sutures. The external oblique aponeurosis was closed using absorbable sutures.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics 25. Continuous data were expressed as mean ± standard deviation (SD). An ANOVA univariate test was used to compare continuous variables and a Student Newman–Keuls test for homogeneous sub-group was adopted to evaluate the homogeneity between the trainees group and the respective senior. A Chi-squared test was applied to analyse categorical data. Regarding non-parametric variables (such as length of stay), we used a Mann–Whitney *U* test. Results are presented as 2-tailed values and considered statistically significant if p values < 0.05. A CUSUM test (KnowWare Inc.) was used to determine the learning curve using the senior's mean ± standard deviation of OT as benchmark. Analysis was conducted using the KPSS test (Kwiatkowski–Phillips–Schmidt–Shin test) to verify whether the series was stationary to the trend. If not, the calculation was repeated without inclusion of the first patient and repeated until the variation was no longer statistically significant. From this point the model became stationary or the series developed around a mean with a consistent variance. We compared the results of OT between Groups by dividing them into five subgroups of 20 consecutive procedures each to validate the CUSUM analysis. To compare the incidence of recurrence during the follow-up, Kaplan–Meier curves with log-rank test has been used.

Results

Database from the three different institutions were reviewed from January 2014 to December 2017. Data from 700 patients were reviewed. There were no differences between the biometric features of patients as reported in Table 1. Intra and post-operative outcomes were reported in Table 2. Analysing the operative time for homogeneous sub-group with Student Newman–Keuls test we did not find any statistical differences between the seniors and the trainee from the same institution (Table 3).

The CUSUM evaluations (Fig. 1a–d) estimated that the trainees reached an OT comparable to that of the senior operator after 37–42 procedures. Moreover, by dividing patients into five subgroups of 20 patients for each trainee, we could see how the operative time became similar to that of the senior surgeon after the second sub-group, thereby confirming the results of the CUSUM test (Fig. 2a–d).

Complication rates were similar between the groups as reported in Table 2. The most frequent complication (Table 2) was numbness with a total of 33 cases, all of them solved during the first postoperative month with a watchful waiting approach. Haematoma was reported in 25 cases; in six cases (1 Senior A; 1 Senior C; 1 Trainee A2; 2 Trainee B; 1 Trainee C) drainage of the hematoma was necessary. All reported seroma was solved with medical therapy within one month. Chronic pain was referred by five patients: in two cases (1 Senior A; 1 Trainee C) mesh removal and triple neurectomy were performed to achieve symptoms resolution. The other three cases were solved after drug therapy.

Table 1 Biometric features

	Senior A	Senior B	Senior C	Trainee A1	Trainee A2	Trainee B	Trainee C	*p*
Sex (M/F)	89/11	83/17	88/12	87/13	85/15	85/15	86/14	0.912
Age mean ± SD years	54.14 ± 17.51	57 ± 13.15	57.14 ± 9.82	54.32 ± 17.54	54.3 ± 17.55	54.67 ± 17.8	57.12 ± 13.24	0.497
BMI mean ± SD kg/m^2	24.78 ± 2.5	25.52 ± 3.35	25.42 ± 4.2	25.85 ± 2	24.95 ± 2.4	25.24 ± 3.38	24.91 ± 4.2	0.231
ASA								
I	24	26	28	30	35	30	28	
II	51	52	48	52	49	53	52	
III	25	22	24	18	16	17	20	
Inguinal hernia classification according to EHS								
PL1M0F0	12	16	11	18	16	22	15	
PL1M1F0	16	13	17	6	9	8	14	
PL1M2F0	9	18	10	15	17	10	12	
PL1M3F0	9	9	6	11	7	10	6	
PL2M0F0	15	11	10	12	14	16	13	
PL2M1F0	16	14	14	11	17	15	21	
PL2M2F0	9	7	11	12	10	7	6	
PL2M3F0	1	0	2	1	0	1	0	
PL3M0F0	5	4	9	7	6	5	8	
PL3M1F0	7	8	7	6	4	5	4	
PL3M2F0	1	0	3	1	0	1	1	
PL3M3F0	0	0	0	0	0	0	0	

BMI Body Mass Index, *ASA* American Society of Anesthesiologists, *EHS* European Hernia Society

Table 2 Intra and post-operative outcomes

	Senior A	Senior B	Senior C	Trainee A1	Trainee A2	Trainee B	Trainee C	*p*
Operative time (mean ± SD) min	46.18 ± 8.51	39.95 ± 8.9	49.89 ± 9.36	46.45 ± 7.03	44.65 ± 10.53	41.78 ± 7.2	48.30 ± 7.89	< 0.05
Intra-operative complications	0	0	0	0	0	0	0	1
All postoperative Complications	38			57				0.545
Seroma								
Seniors vs trainees	7			16				0.22
Numbness								
Seniors vs trainees	15			18				0.75
Chronic pain								
Seniors vs trainees	4			1				0.092
Hematoma								
Seniors vs trainees	8			17				0.26
Recurrence %								
Seniors vs trainees	4			5				0.92

Using the KPSS test we found that the operative time of Trainee A1 was stationary to his trend after 30 procedures, as well as 14 procedures for Trainee A2, 13 procedures for Trainee B, and 35 procedures for trainee C.

KM curves for recurrence are reported Fig. 3. The log-rank test did not show any statistically significative difference among the groups in terms of recurrence, during the median follow-up of 44 ± 12 months ($p = 0.827$).

Discussion

In the present paper, we have shown that the learning curve for a supervised resident to reach a stable operative time, similar to that one of the senior, for Lichtenstein hernia repair is estimated at 37–42 procedures.

Table 3 Distribution of operative time among the subgroups

Group	No. of pts	Mean operative time	Mean operative time	Mean operative time
Seinor A	100	46,1800		
Trainee A1	100	44,6520		
Trainee A2	100	46,4515		
Senior B	100		39,9500	
Trainee B	100		41,7800	
Senior C	100			49,8900
Trainee C	100			48,3064
p		0.299	0.132	0.192

It is interesting how the learning curve of open inguinal hernia is poorly investigated in current literature. Conversely, even if more recently introduced, TAPP and TEP are techniques that could be considered "fully dissected" in each step of the procedure as outlined in guidelines, too. The possible reason behind this aspect is probably related to the fear of serious complications or the perceived major technical complexity of the endoscopy in comparison to open surgery, this lack of knowledge could be considered as a sort of superficial evaluation of a well-established technique ubiquitarily performed.

Our paper, the second to deal with this topic, shows how the number of repetitions to master the open repair, even if less, it is not so different from laparoscopy and steeper than commonly thought [5]. Clearly minimally invasive hernia repair is an advanced surgical technique approached when the surgeon has already gained anatomical and technical skills in other procedures, both open and laparoscopic. Open hernia repair, on the other side, represents the first step of surgical teaching when learning dissection and hand movements are still in developmental phase, with a number of sequential steps and anatomical concepts which can be difficult to understand and confusing for the young resident. Accordingly, most part of the learning curve is represented by the true comprehension and acquisition of the correct sequence of movements.

Nevertheless, the determination of the real learning curve for open hernia repair becomes of paramount importance in light of the idea of surgical proficiency and the evidence that

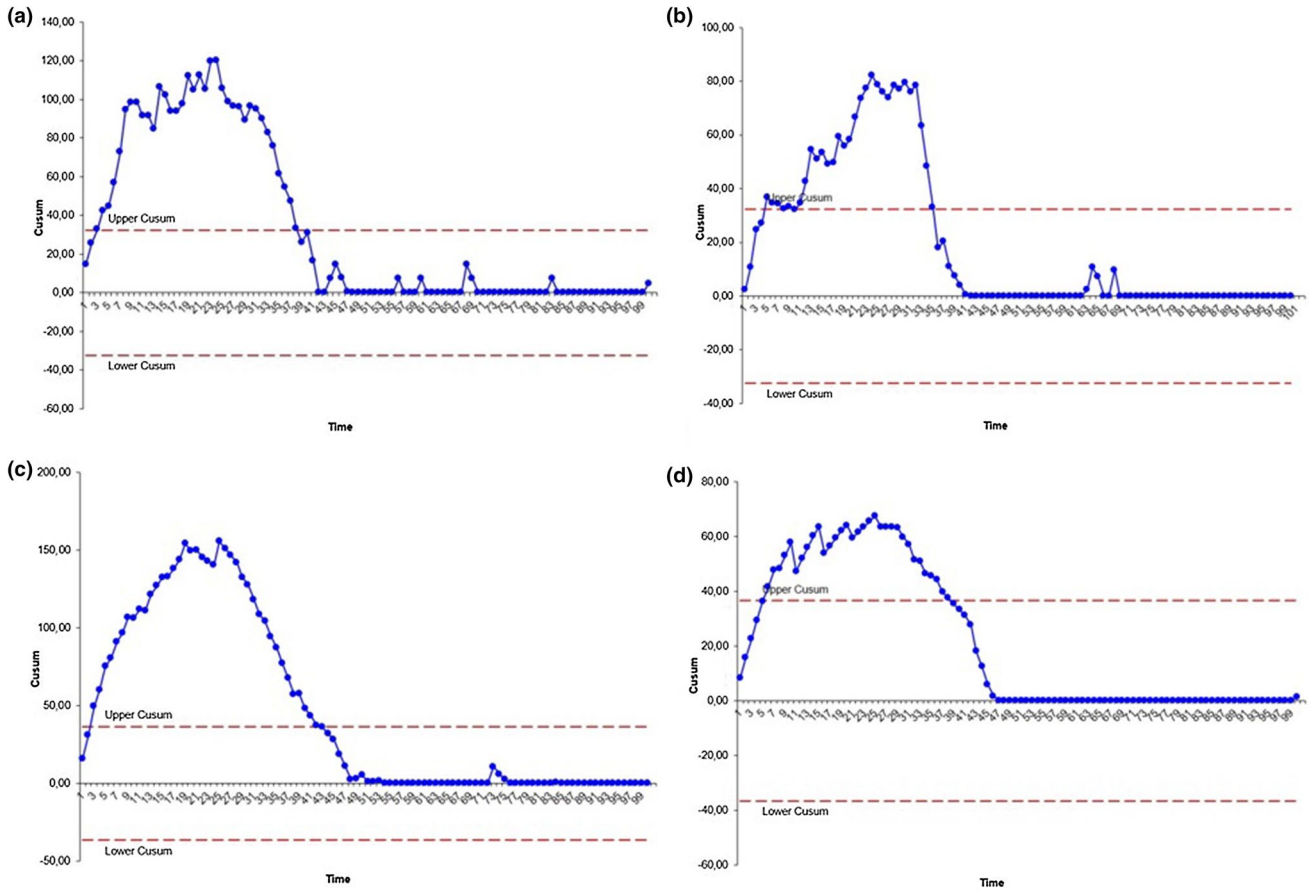

Fig. 1 **a** CUSUM graph for trainee A1; **b** CUSUM graph for trainee A2; **c** CUSUM graph for trainee B; **d** CUSUM graph for trainee C

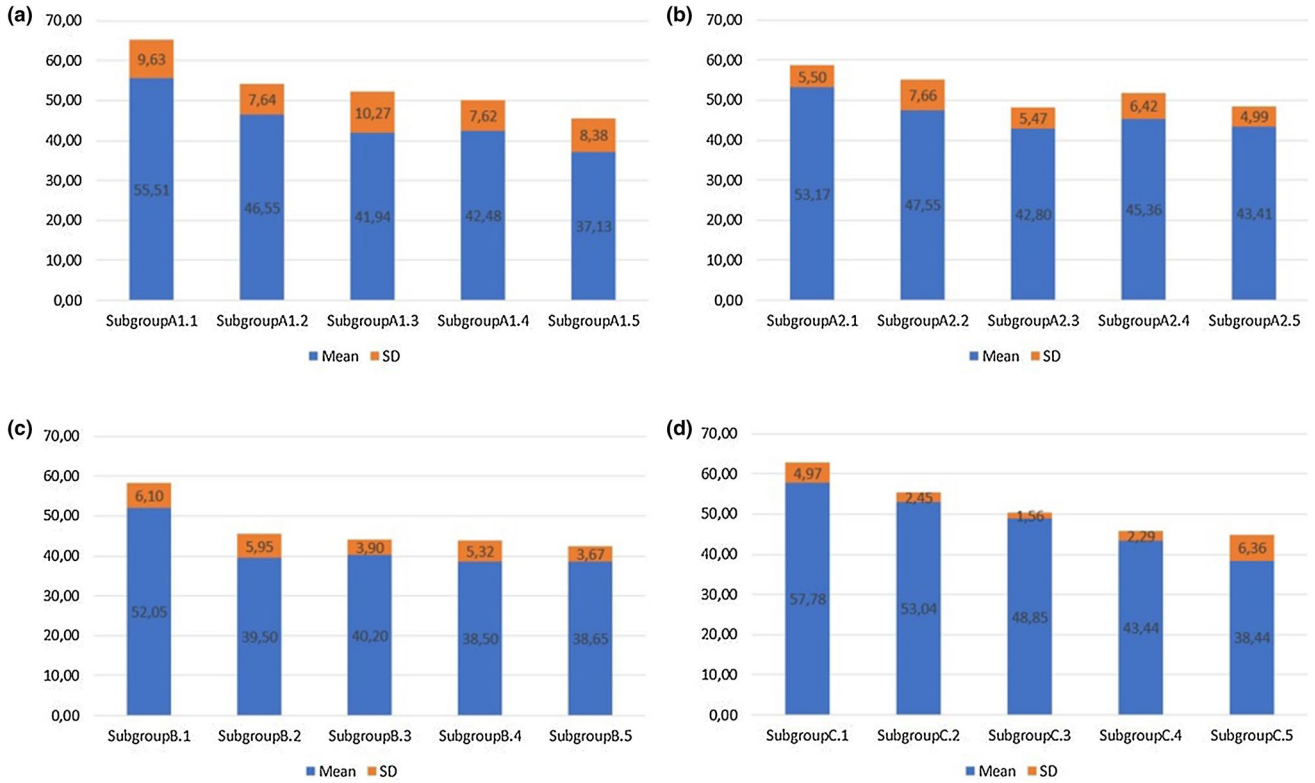

Fig. 2 **a** Mean time distribution in the five sub-group of 20 patients for trainee A1; **b** Mean time distribution in the five sub-group of 20 patients for trainee A2; **c** Mean time distribution in the five sub-group of 20 patients for trainee B; **d** Mean time distribution in the five sub-group of 20 patients for trainee C

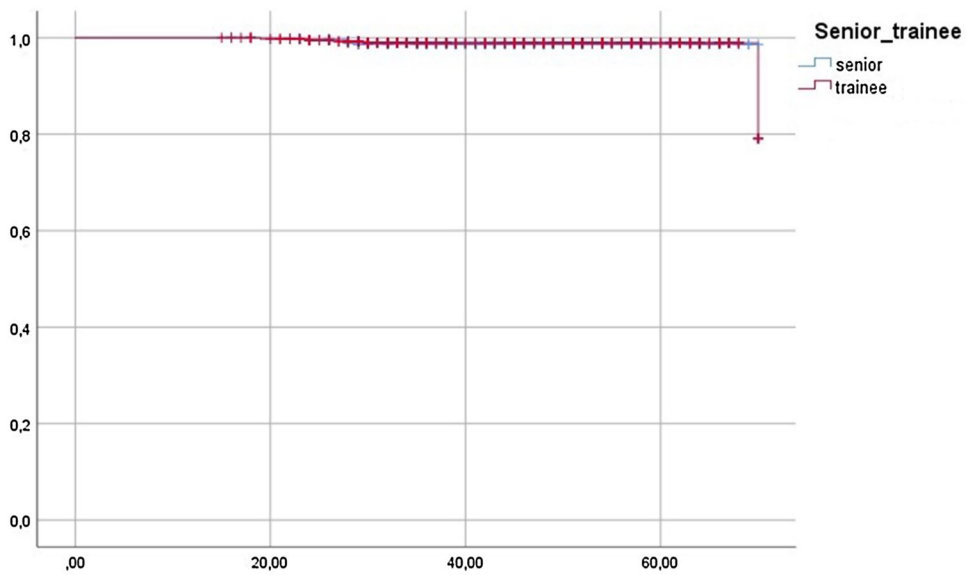

Fig. 3 Kaplan–Meier curves for recurrence

learning curve and volumes strictly affect results as outlined for recurrence [17] and chronic pain occurrence [18].

As previously mentioned, this topic has been poorly considered in current literature and our results are partially conflicting with those reported. After a previous revision performed for a systematic review on surgical accreditation and for the present paper, we were able to identify only two studies dealing with this topic and reporting discordant values of 5 [5] and 64 [4] procedures, respectively, to reach competency in open inguinal hernia repair. The study

from Tocchi et al. claimed that residents, after performing at least 5 procedures as first operator, are comparable to proficient surgeons in terms of operative time and perioperative morbidity. No definitive statement on recurrence can be drawn because of the very poor follow-up rate (34% at 24 months to 28.5% at 60 months, respectively). The study, even if very detailed, has several biases that make it too optimistic and probably misleading in its results. The approach adopted in the paper from Brown et al. is more interesting. The evaluation of proficiency was made with a procedure-based assessment, with resident being judged according to a 4-level-scale and correlated to caseload when the highest level was reached. The threshold they identified is more similar to ours. The judgement on proficiency, even if made by three experienced consultants, is only part of the global skill assessment and is influenced by several subjective factors. Nevertheless, the hypothetical caseload to reach proficiency is consistent with the stabilization of the operative time observed in our series. The values reported in their study are probably higher because comprehensive of the level of proficiency required to deal with all the aspects of the procedure, in particular complications.

All the residents, in our study, were trained in units directed by active members of EHS and Italian Society of Hernia and Abdominal Wall Surgeons (ISHAWS) with high specialization and interest in hernia surgery. Moreover, they all attended the ISHAWS School and the master class of first and second level which is made of 5-day-course with lecture and live surgery held in Rome followed by a three-days hands-on course in one of the certified hernia centres across Italy. This environment, the higher specialization and knowledge of materials and technique could have in some way influenced the earlier achievement of good surgical performances. Nevertheless, our residents were not submitted to a formal simulation-based training program and its possible effect on learning remains unexplored. Currently, several models for training in minimally invasive techniques are available in literature and very few have been developed and validated for open approach [19, 20]. These later are the most difficult to use in practice for the well-known low similarity to real human tissue out of cadaveric preparation. So far, very few results have been published consistently [21, 22] but they still address and try to overcome one of the greatest challenge in open hernia surgery: understanding the 3D spatial relations of the complex anatomy of the groin which is maybe the first limit to a quicker learning curve.

The residency program in Italy has a well defined structure: the resident is trained for 5/6 years and during surgical procedures is always supervised by a senior surgeon. According to current normative and insurance agreements, for residents it is forbidden to perform unsupervised procedures on patients. Accordingly, on one hand we didn't explore the influence of a well-trained tutor assistant and his/her possible interference during the procedure by artificially speeding up the operative time, helping in decision making or preventing technical errors, as well as its effect on recurrence rate; similarly, it is unknown, in our study, the postoperative outcome when the senior resident is helped by a younger one which could be a further factor to influence the reaching of a stable plateau. As a matter of fact the adverse event rate and recurrence in our series is clearly within the limits highlighted in current literature [3], confirming the importance of supervision as a guarantee of safety for the patient and limiting the detrimental higher hernia recurrence observed when the resident is not helped by a consultant [17].

Differences in operative time were observed among centres even if operative times were consistent among consultants and trainees. This could be explained by little local differences in some technical aspects or habits.

Quality of surgery, sub-specialization and surgical accreditation has become an important topic in current literature [3, 23, 24]. When dealing with groin hernia surgery a clear recommendation on completion of the learning curve is frequently issued, accompanied by the concept of additional experience needed to master complicated scenarios, but numbers are seldom defined, and a clear quantification of these variable has not been done. So, our results represent a possible starting point for the certification process for a single surgeon.

A common limitation of the study is represented by the non-randomized nature of the study, in which a possible selection of highly motivated residents could have occurred, thus introducing a positive bias when reaching the plateau.

We do not have data concerning procedures performed in the same period by our residents out of hernia repair, thus we ignore the cumulative effect on learning offered by the performance of different and maybe more complex type of procedures.

Another limitation is represented by the selected type of hernia performed: clearly the repair of a primitive unilateral groin hernia is less challenging than mastering the procedure in any possible clinical scenario (emergency, incarceration, scrotal hernia, and recurrent hernia). Published literature is completely lacking on the experience required. Accordingly, the proficiency shown in our study represents the achievement of a conditional ability to technically repeat the correct gesture of the procedure and cannot be generalized to every type of open hernia repair.

In conclusion, in the present study we have shown that the number of procedures required to reach the learning curve from the beginning of surgical residency is 37–42 hernia repairs. This number, produced in a controlled environment under strict supervision, could be the minimum requirement to start the procedure of accreditation and specialization in

hernia surgery and is higher and steeper than previously reported.

Compliance with ethical standards

Conflict of interest All the authors declare that they have no conflict of interest.

Ethical approval All procedures performed were in accordance with the ethical standards of the institute and regional research committee and with the 1694 Helsinki declaration and its later amendments or comparable ethical standards. Moreover, ethical approval was sought but not deemed necessary by the hospital research committee, due to retrospective nature of the paper.

Human and animal rights There are no human and animal rights issue to declare.

Informed consent Due to the retrospective nature of the study a formal consent is not required.

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