Surgical Endoscopy (2023) 37:1781–1788
https://doi.org/10.1007/s00464-022-09699-5

ORIGINAL ARTICLE

Is mesh fixation necessary in laparoendoscopic techniques for M3 inguinal defects? An experimental study

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Received: 15 June 2022 / Accepted: 29 September 2022 / Published online: 13 October 2022

Abstract

Background Although international guidelines recommend not fixing the mesh in almost all cases of laparoendoscopic repairs, in case of large direct hernias (M3) mesh fixation is recommended to reduce recurrence risk. Despite lack of high-quality evidence, the recommendation was upgraded to strong by expert panel. The authors conducted a research experiment to verify the hypothesis that it is possible to preserve the mesh in the operating field in large direct hernias (M3) without the need to use fixing materials.

Method The authors conducted an experiment with scientists from Universities of Technology in a model that reflects the conditions in the groin area. By simulating conditions of the highest possible intra-abdominal pressure, they examined the mesh behavior within the groin and its ability to dislocate under the forces generated by this pressure. The experiment involved six spatial implants and one flat macroporous mesh.

Results Heavyweight spatial meshes and lightweight spatial-individualized meshes showed no tendency to dislocate or move directly to the orifice, which was considered a rapid hernia recurrence. Lightweight meshes, both spatial and flat, underwent significant migration and shifting toward the hernial orifices.

Conclusion Based on the results, we believe that mesh fixation is not the only alternative to preventing recurrence in complex defects. Similar effects can be achieved using a larger, more rigid, and anatomically fitted implant. The type of implant (rather than its fixation) seems to be a key factor from the point of view of mechanics and biophysics. Clinical trials confirming the results in vivo will allow to supplement or amend the guidelines for the treatment of large inguinal hernias.

Keyword Mesh · TAPP · TEP · Direct hernia · Hernioplasty · Hernia

More than 20 million patients undergo inguinal hernia repair annually. Symptomatic groin hernias require treatment, and surgery is the only effective option [1]. Currently, hernia societies are working to unify and update the recommendations to standardize the treatment process, reduce the risk of complications, and optimize outcomes. There are numerous hernia repair methods, but the Lichtenstein repair and laparoendoscopic repair are the best researched and most commonly used. The latter has been proven as beneficial in terms of faster recovery and a reduced risk of chronic pain; economic profits are also relevant. Introducing minimally invasive methods to the treatment of inguinal hernias in the early 90s has led to a steady increase in the number of operations performed with this technique [2]. According to existing literature, the recurrence of laparoendoscopic surgeries is similar to that of Lichtenstein procedures and therefore assessing its effect on perioperative pain has become a core issue [3].

International guidelines for the treatment of groin hernia were published in 2018 by the HerniaSurge Group—a group of experts associating doctors from around the world. This 165-page document addresses the most critical

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issues and attempts to answer the most pressing questions about groin hernia surgery [4]. The conclusions recommend laparoendoscopic methods as the first-line treatment of primary groin hernias, subject to the availability of appropriate resources and the experience of the surgical team [4].

Two techniques—TAPP (transabdominal preperitoneal approach) and TEP (totally extraperitoneal approach) seem to be in the lead among laparoendoscopic methods, but there are no conclusive studies that would recognize the superiority of one over the other [2, 4]. The frequency of their use is largely related to the training and education system of surgeons in a given country.

The common denominator of both surgical techniques is that the implant (mesh) must be placed in the preperitoneal space to repair the posterior wall of the inguinal canal. Here, the preperitoneal space is a potential space (not present physiologically), which requires prior dissection during the procedure. Both TAPP and TEP currently exclude the routine recommendation to fix the implant to the surrounding tissue to prevent subsequent migration. It is believed that an adequately prepared preperitoneal space (pocket) and intra-abdominal pressure in the peritoneal cavity are sufficient to prevent implant migration. The exception to this rule, included in the recommendations of the HerniaSurge Group, are M3 hernias (large medial) in line with the EHS (European Hernia Society) classification. The purpose of this procedure is to reduce recurrence, which is alarmingly high for this defect. Mayer et al. observed that the size of the hernial orifices in the analyses of German Hernia Register (Herniamed) had a major impact on the recurrence rate and a detailed analysis of the variables showed that the potential solution seems to be mesh fixation and proper overlap (mesh size), as the number of recurrences was significantly reduced by implant fixation in large direct and complex hernias [5]. Retrospective analysis was performed on 11,228 male patients [5]. However, various authors pointed that lack of fixation is the main reason of recurrence, and authors know from previously published own studies that other factors play important role in holding the implant in proper position [6–8]. In our opinion, that is why the pure fixation thesis should be readdressed in future studies and why it became the aim of the presented study. Mesh dislocation, directly responsible for recurrence in large defects, was also demonstrated in experimental studies [9–12]. This is due to forces generated as a result of sudden increases in intra-abdominal pressure. Resting intra-abdominal pressure is approx. 1–10 mmHg; coughing, vomiting, or bouncing may cause a sudden rise up to 270 mmHg [9, 12, 13]. Given the above facts and data from hernia registers, the international guidelines strongly recommend mesh fixation with large direct hernias repairs [4]. Recommendation was upgraded to strong by expert panel.

This recommendation poses another issue for herniologists—how to perform mesh fixation? The literature has repeatedly raised the question of an increased risk of exacerbation of perioperative pain symptoms and an increased frequency of chronic groin pain in patients undergoing mesh fixation with staplers and tackers [4, 14–18]. Based on the above, the recommendations indicate atraumatic fixation methods (fibrin and cyanoacrylate adhesives) to reduce the risk. This recommendation was described as weak [4].

In 2020, Usmani et al. presented the so-called "TAPP plus" technique, which is presumed to prevent complications in large direct hernias (M3) in a different manner [11]. The key element in TAPP plus preceding mesh implantation is closure of the hernial orifice and cavity of the hernial sac with suture of the transverse fascia. This creates additional support for the implant and, in addition to reducing the risk of recurrence, helps to reduce the incidence of postoperative seroma [11].

Mesh fixation in complex groin defects area aims at maintaining mechanical stability. Fixation with sutures, tackers, or staples carries the risk of inflicting damage to branches of the inguinal nerves, whose course is characterized by a high anatomical variability. This was proven in post-mortem studies [19, 20]. The above has led to a poor recommendation for the use of atraumatic fixation (fibrin glue, cyanoacrylate glue) as a factor preventing recurrence while reducing the risk of damage to surrounding tissues [4]. Cost-effectiveness and shorter application times also work in favor of adhesives over traumatic fixation [21].

Research hypothesis

Due to the ongoing discussion regarding the need to perform mesh fixation in inguinal hernia surgery, the authors conducted a research experiment to verify the hypothesis that it is possible to preserve the mesh in the operating field in large direct hernias (M3) without the need to use fixing materials.

Our hypothesis is that fixation is redundant based on the existing research and recommendations [4, 5]. We observed that most of the conclusions from the world literature are based on publications where lightweight, flat, and macroporous meshes were used. The implants were often cut and adjusted to the individualized shape of the groin in an attempt to obtain the appropriate margin and compliance with its anatomy.

We believe that laparoendoscopic procedures require an individualized approach. When seen from the "inside" in minimally invasive procedures, the groin and myopectineal orifice are significantly different than during open procedures [22]. This applies to both the anatomy and the shape, as well as the forces acting in this area. In early 2000s, three-dimensional mesh was introduced, and its shape was

adapted to a certain averaged model of the groin [23]. In principle, three-dimensional mesh was to facilitate implantation, provide an appropriate margin around the defect, and thus eliminate the need for mesh fixation. However, there is no publication that would compare the recurrence rate in large direct hernias depending on the type of implant used.

In our opinion, alongside the mesh margin, appropriate mesh shape and stiffness are crucial in preventing migration which leads to recurrence in large direct hernias. On the basis of these assumptions, we conducted an experiment with scientists from the Gdańsk and Kraków Universities of Technology to confirm or refute the above hypothesis. We created a model that reflects the conditions in the groin area. Next, by simulating the highest possible intra-abdominal pressure, we examined the mesh behavior within the groin and its ability to dislocate under the generated forces. The experiment involved six spatial implants available on the market and one classic mesh (flat, lightweight, macroporous).

Materials and methods

The three-dimensional model of the groin (Fig. 1) was made on the basis of averaged analyses of CT images from 40 patients and post-mortem impressions made from sculptural clay and digitized with a structured white light scanner (after smoothing the surface of the model scan in the Catia V5 CAD system). The model maps the surface of the groin; it includes a direct hernial orifice (lying medially from the epigastric vessels) with a transverse dimension of 4 cm. Also, a collar was created to fix the groin model in the measuring device. The model was made by FFF (Fused Filament Fabrication) 3D printing technology from polylactide (PLA). It omits the groin flexibility for purpose. The structure of the groin (myopectineal orifice) differs from the layered structure of the anterior abdominal wall, where the elasticity of in vitro models is usually 25–30% [6]. This is associated with structure of the groin limited by the bone elements, but also its physiology. Upon increased intra-abdominal pressure (coughing, vomiting, jumping), the groin muscles tense reflexively. This is influenced by the shutter and sphincter mechanism of the groin, which creates a hard, inelastic structure from the myopectineal orifice. Taking into account the minimum tensile susceptibility of such a structure, the elasticity was assumed at 0.

The resulting model was placed in the measuring device (Fig. 2), previously used in papers [24, 25]; in it, the main element is a chamber in the shape of a flat cylinder, closed tightly at the top with an opening in the lower base, which was used to embed the groin model. The model was covered with a layer of medical vaseline in order to reproduce the in vivo conditions as closely as possible. Medical vaseline allows to obtain a coefficient of friction between the model and the mesh close to its value in natural conditions. The use of the aforementioned substance was previously validated in studies based on a similar experimental model to the one used in this study [6, 26, 27].

Next, the mesh was placed in the model and arranged to mimic a surgical setting. A thin foil was placed on the mesh and wrinkled so as not to obstruct its free movement. The foil corresponded to the parietal peritoneum covering the implant from the force side. In this way, we obtained a tight "intra-abdominal" space, which simulated the pressure acting on the mesh in the human groin by introducing compressed air into the chamber. Under pressure, the mesh was pushed against the groin model and its behavior was observed.

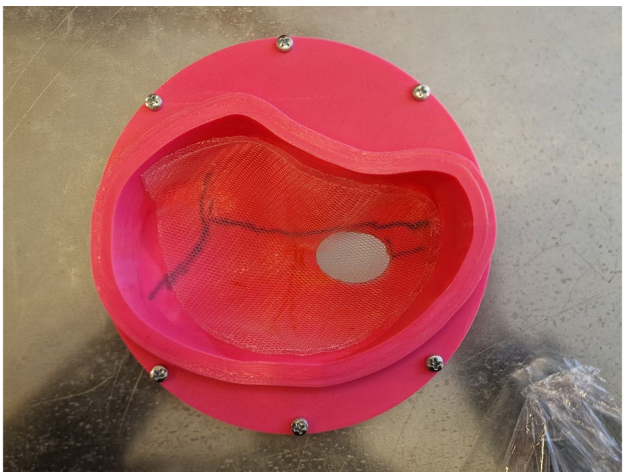

Fig. 1 Three-dimensional groin model with mesh

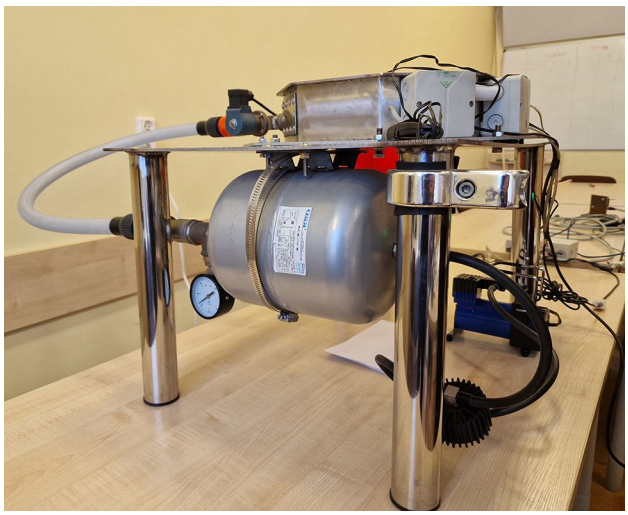

Fig. 2 Measuring device—chamber

The research involved the use of six spatial implants available on the market and one classic flat mesh (Table 1). 3dMax™ Mesh, 3dMax™ Light Mesh (BD™, New Jersey, USA), Merigrow 3d™ Mesh, Filaprop 3d™ Mesh (Meril™, Gujarat, India), and Dextile™ Anatomical Mesh (Medronic™, Dublin, Ireland) implants are three-dimensional meshes with a structure that is assumed to correspond to the shape of the groin. Optilene™ Mesh LP (B. Braun™, Melsungen, Germany) is a flat, macroporous 20 × 20 cm mesh cut to the shape of the groin. The Optomesh™ 3d ILAM (Tricomed™ S.A., Łódź, Poland) implant was ultimately made for the groin model used in the experiment. The shape and size were matched directly to the previously printed groin model used in the study. At the time of research, Meril™ spatial implants (Merigrow 3d™ Mesh and Filaprop 3d™ Mesh) were not validated for use outside India.

Each implant was placed sequentially in the groin model, taking care of the appropriate margin and spatial arrangement in accordance with the guidelines from the studies of the HerniaSurge Group (Fig. 3) [4]. The generated pressure of 34–36 kPa (approx. 270 mmHg) in the chamber corresponded to the highest possible pressure in the abdominal cavity. The pressure was registered during the experiment. Because the meshes were not fixed in the groin model, the possibility that they would remain in a given position was ensured by the friction force between the mesh and the model, created as a result of pressing the mesh against the walls of the model under pressure, and by mesh stiffness which ensured that its shape would be maintained under load. The behavior of each implant under load was documented electronically in the form of video and photos. In order to objectify the results, each test was repeated three times and the results were recorded. Mesh dislocation was considered as an implant displacement that prevented the provision of an appropriate margin around the defect or mesh deformation causing migration directly to the hernial orifices.

Ethical approval and written consent was deemed unnecessary. All protocols were maintained according to law regulations in Poland.

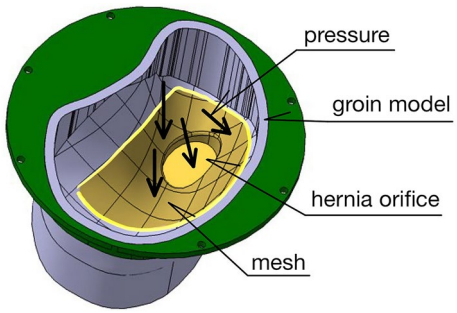

Fig. 3 Schematics of experimental model

Results

The results of the experiment carried out on the designed model are presented in Table 2 and confirm the research hypothesis. The mesh stiffness and shape play a major role in maintaining the implant in the correct position and preventing migration as a result of a sudden rise in intra-abdominal pressure. Heavyweight meshes (HWM) did not deform or migrate, and the changes in position were minimal. Dextile™ Anatomical Mesh, 3dMax™ Mesh, and Filaprop 3d™ Mesh showed no tendency to dislocate or move directly to the orifice, which was considered a factor for rapid hernia recurrence. The greater amount of material (polypropylene) used in the mesh structure resulted in a greater stiffness and thus a lesser susceptibility to deformation due to a sudden increase in intra-abdominal pressure to the maximum values. This was already visible when the mesh was placed in the model.

In both cases, three-dimensional lightweight implants, i.e., 3dMax™ Light Mesh and Merigrow 3d™ Mesh, significantly migrated and shifted toward the hernial orifices (Fig. 4), which was defined as an early recurrence. This was also true for the classic flat, macroporous implant Optilene™ Mesh LP. The implant was cut to 12 × 17 cm to ensure an appropriate margin and to optimize the shape adjustment to the groin model. In all three attempts, the mesh protruded significantly through the hernial orifices

Table 1 Characteristics of the test implants; n/a (not available)—manufacturer did not provide data

	3dMax™ Light Mesh	3dMax™ Mesh	Dextile™ Anatomical Mesh	Filaprop 3d™ Mesh Soft	Merigrow 3d™ Mesh	Optomesh™ 3d ILAM	Optilene™ Mesh LP
Manufacturer	BD™, New Jersey, USA	BD™, New Jersey, USA	Medronic™, Dublin, Ireland	Meril™, Gujarat, India	Meril™, Gujarat, India	Tricomed S.A., Łódź, Poland	B. Braun™, Melsungen, Germany
Thickness (mm)	n/a	n/a	n/a	0.34	0.48	0.75	0.39
Pore size (mm)	2.4 × 0.7	0.9 × 0.7	1.1 × 1.6	0.8 × 1.0	1 × 1.2	n/a	1
Weight (g/m^2)	< 50 (light)	80–85 (heavy)	90 (heavy)	45 (light)	100 (heavy)	45 (light)	36
Size (cm)	12.2 × 17	12.4 × 17.2	16 × 12	12.8 × 17.2	12 × 17	12 × 17	12 × 17

Table 2 Results of the experiment

Attempt No.	3dMax™ Light Mesh	3dMax™ Mesh	Dextile™ Anatomical Mesh	Filaprop 3d™ Mesh Soft	Merigrow 3d™ Mesh	Optomesh™ 3d ILAM	Optilene™ Mesh LP
1	−(36 kPa)	+(36 kPa)	+(34 kPa)	−(36 kPa)	+(35 kPa)	+(36 kPa)	−(36 kPa)
2	−(34 kPa)	+(36 kPa)	+(34 kPa)	−(35 kPa)	+(35 kPa)	+(36 kPa)	−(36 kPa)
3	−(35 kPa)	+(36 kPa)	+(36 kPa)	−(31 kPa)	+(35 kPa)	+(34 kPa)	−(36 kPa)

+positive stress test (the mesh did not dislocate) −negative stress test (the mesh did dislocate). In the brackets is the pressure generated in the chamber during the attempt

Fig. 4 Mesh shifting toward the hernial orifices which was considered recurrence

and changed its original position. The behavior of the individualized Optomesh™ 3d ILAM implant was different; despite its structure (categorized as LWM—Lightweight Mesh due a grammage of approx. 45 gsm), the stress tests were passed positively, with no implant migration or dislocation in any trial.

Discussion

The main influence on the implant position is exerted by the forces generated by intra-abdominal pressure, whose role shifts depending on the surgery performed. The implant placed from the back of the groin (in TAPP or TEP) is held in position by intra-abdominal pressure, which acts somewhat mechanical stabilizer of the mesh. In Lichtenstein method, the slightest increase in the same pressure generates forces that try to tear out the attached implant.

The results confirm the hypothesis that mechanical stability is possible without the need to fix the mesh or to first close the hernial orifices first in large direct hernias. This is guaranteed by an implant with an appropriate structure (stiffness, size, and/or spatial shape). The clear superiority of one of the above factors over the others remains unresolved. It seems that the mesh stiffness and weight are key in ensuring that the position is maintained—all spatial implants from the HWM category have passed the stress tests. However, the spatial shape seems to be of no less importance. The lightweight, flexible Optomesh™ 3d ILAM spatial mesh maintained its original position in the designed model. The key here may be the appropriate shaping and arrangement of the individualized mesh, which guarantees a greater (maximum) number of contact points between the tissue and the implant. This generates a friction force that compensates for the forces which displace the implant toward the hernia opening, resulting from a sudden rise in intra-abdominal pressure even with low implant stiffness.

Flat, lightweight, macroporous implants, which are successfully used in the Lichtenstein method, seem unsuitable in laparoendoscopic surgeries. A flat implant placed within the previously created space in minimally invasive techniques does not provide sufficient adherence to the surface to counteract the sudden rise in intra-abdominal pressure. The three-dimensional groin model reveals a number of physiological curves that are emphasized within the most important structures: the pubic symphysis, the pubic bone, and the iliac vessels. A flat implant placed in this space "protrudes" in many areas and loses contact points, which are responsible for creating the appropriate friction. The use of an appropriate margin above the defect border (the implant was cut to 17 × 12 cm) proves insufficient.

The behavior of 3dMax™ Light Mesh and Merigrow 3d™ Mesh implants was similar. Despite the manufacturers' assurances about the spatial adjustment to the averaged shape of the groin, the presented assumptions involve many imperfections. The implants have stiffer edges (peripheral ring in the 3dMax™ Light Mesh or thicker stitching on the edges in the Merigrow 3d™ Mesh) and therefore they are easily applicable during surgery. Unfortunately, it seems that somehow the same rigid rings prevent precise adherence to the key points, necessary to generate the appropriate frictional forces. While this means little in small inguinal hernias, it is a key factor in large direct hernias (M3).

The spatial structure of Filaprop 3d™ Mesh, Dextile™ Anatomical Mesh, and 3dMax™ Mesh implants is

comparable to 3dMax™ Light Mesh and Merigrow 3d™ Mesh, although Dextile Anatomical Mesh provides a better fit to the groin shape within the iliac vessels in the designed groin model. Additional attributes in the form of increased implant weight and stiffness ensure effective mechanical stability in the groin.

Retrospective analysis conducted by Meyer et al. on the basis of data from the Herniamed database proved that mesh fixation in large hernias has a beneficial effect on the reduction of recurrence [5]. The above conclusions had a direct impact on the recommendations from the HerniaSurge guidelines of 2018 [4]. Large direct and complex groin hernias represent a risk factor for hernia recurrence; however, both the above paper together with publications contain no comparisons on how the type of implant affects recurrence. We strongly believe that the type of implant is the key factor in this case.

Mayer et al. mentioned that a large group of surgeons more likely to choose a larger, self- fixating or stiffer mesh in large direct hernias; in view of our results, this seems justified [5]. It seems that the surgeons acted reflexively, somehow intuitively predicting the behavior of the implant in large hernial orifices and a possible rise in intra-abdominal pressure. However, the register shows that the vast majority are flat implants, and mesh fixation with proper overlap seems the only alternative to prevent recurrence in this case. Multivariable analysis of the whole group in terms of potential influence factors (age, ASA, BMI, risk factors, defect size, mesh fixation, localization of defect, mesh size) did not identify any factor that impacted recurrence on 1-year follow-up. Only for medial and combined defect localization versus lateral localization was a highly significant effect identified ($p < 0.001$). For TAPP repair of an inguinal hernia, mesh fixation is not necessary in a significant number of patients. Patients with a medial and combined hernia are at higher risk of recurrence. With mesh fixation and larger mesh size, it was possible to significantly reduce the recurrence rate for larger medial hernias in this series ($p = 0.046$) [5].

Mesh fixation involves a number of potential complications. Apart from the obvious ones, such increased costs, and extended procedure time, the literature mentions implant migration with formation of meshoma [28], adhesions, chronic postoperative pain [17, 18], and infection [4, 29]. Each mesh fixation carries the risk of damage to the surrounding tissues, as well as accidental damage to the nerves. Therefore, a search for solutions that would inspire abandoning unnecessary risk and generating additional costs seems justified, and this assumption formed the basis of our research.

Appropriate implant selection depending on the type of defect is part of the currently preferred approach of personalized medicine in the treatment of hernias. It also supports the concept of implant individualization used in specific cases. In 2020, Chrzan et al. examined computed tomography analyses of the groin and found that classic flat meshes are sufficient in merely 1/3 of the population. Due to significant anatomical variability, spatial meshes should be used in the remaining population [30]. However, the above statement was for open hernia repair.

Heavy and lightweight implants in terms of large and complex groin hernias are not much commented in literature. Most of the papers concern abdominal hernias which are not the essence of this manuscript. Although, it seems that trend of favoring heavier meshes in laparoendoscopic repairs is starting to appear. Some papers revealed the superiority of heavier meshes over lightweight meshes in terms of large and complex groin hernias, especially when no fixation method is applied [31–33].

Recent study by Novik et al. compared mesh types and fixation types or lack thereof by analyzing the data from Swedish Hernia Registry. The conclusions are consistent with the results of our experiment—the lack of fixation in rigid, large meshes does not increase recurrence rates in terms of large and complex groin hernias [34].

The mesh shape, appropriate margin, and rigidity seem to be key for the mechanical stability of large inguinal hernias (M3). This was confirmed in an experiment based on the proposed model. In our opinion, this gives a serious incentive to continue and confirm these conclusions in a clinical setting. Our study was performed in vitro, in a model designed to possibly closely reflect the conditions in the body. The fact is, however, that the experimental model can simulate in vivo conditions merely to some extent. This is an undeniable disadvantage of our study. Creating a polyamide model of the groin is associated with the assumption of a rigid groin, which could impact false-negative results. Therefore, unequivocal conclusions that three-dimensional lightweight implants fail to fulfill their role in large direct hernias (3dMax™ Light Mesh and Merigrow 3d™ Mesh) are not fully justified. Furthermore, it is clearly difficult to determine how the friction generated in the tested model corresponds to that in physiological conditions, although we estimate that the use of a stiff, smooth groin model makes it lower compared to natural conditions. As a result, the conditions presented above are more stringent than in vivo ones.

The use of only XL implants (large, at least 12×16 cm) resulted from the team's previous studies on the behavior of the implant in the surgical field and was intended to maintain an appropriate margin in terms of large and complex hernias that are the target of this experiment. This is essential for maintaining mechanical stability and counteracting the migration of the mesh into the hernial orifices [5–8, 24, 25].

In 2017 Kallinowski et al. introduced GRIP concept to help reducing the recurrence rate in large and complicated ventral hernia (those with high mesh-defect area

ratio—MDAR). The main assumption of GRIP is that reconstructions of incisional hernias can be improved on a biomechanical basis. GRIP is basically a parameter used to check if hernia repair achieved durability and a tool to assess the mechanical stability of mesh reconstruction. GRIP depends strictly on tissue, mesh (size and rigidity), and fixation properties. Although the concept is directly related to ventral hernias, we are certain that it can be transferred to inguinal hernias, as we believe it was proven in the study [35–37].

It is worth mentioning that the above conclusions do not disqualify "TAPP plus" as an effective solution and that it is also used in clinical practice by the authors. The main purpose of its application, however, is to close the dead space and thus reduce the risk of seroma.

Conclusion

As the first in the world, we investigated the behavior of a groin implant under maximum intra-abdominal pressure increase in our model in the presence of large direct hernia (M3) orifices. Based on the results, we believe that mesh fixation is not the only alternative to preventing recurrence in complex defects subject to laparoendoscopic surgery. Similar effects can be achieved using a larger, more rigid, and anatomically fitted implant. The type of implant (rather than its fixation) seems to be key from the point of view of mechanics and biophysics. In view of the above-mentioned results, the next step should be reverification of large databases (Herniamed, EuraHS, etc.), determination of the correlation between recurrence and implant type for large and complex groin hernias, and conducting studies (RCTs, cohort studies) to confirm the aforementioned results and complement or amend the guidelines for large and complex groin hernias.

Acknowledgements This work was partially supported by the National Science Center (Poland) [Grant No. UMO-2017/27/B/ST8/02518].

Declarations

Disclosures Mateusz Zamkowski, Agnieszka Tomaszewska, Izabela Lubowiecka, Krzysztof Karbowski, and Maciej Śmietański have no conflicts of interest or financial ties to disclose.

Ethical approval This research study was conducted retrospectively from data obtained for clinical purposes. Ethical approval was deemed unnecessary by Ethics Committee by District Medical Chamber in Gdansk. All methods were performed with the relevant guidelines and regulations. No experimental protocol was included. All protocols were maintained according to law regulations in Poland.

Informed consent Informed written consent was obtained from all subjects included in the study.

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