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In vivo performance of intraperitoneal onlay mesh after ventral hernia repair

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ABSTRACT

Background: Ventral hernia repair needs to be improved since recurrence, postoperative pain and other complications are still reported in many patients. The behavior of implants *in vivo* is not sufficiently understood to design a surgical mesh mechanically compatible with the human abdominal wall.
Methods: This analysis was based on radiological pictures of patients who underwent laparoscopic ventral hernia repair. The pictures show the trunk of the patient at rest in a standing position and under side bending. The change in the distance between different tacks due to trunk movement was analyzed, which allowed us to determine the *in vivo* elongation of the mesh incorporated into the abdominal wall.
Findings: The relative elongations of the surgical mesh varied from a few percent to greater than 100% in two cases. The median of the median relative elongations obtained for all patients is 9.5%, and the median of the maximum relative elongations for all patients is 32.6%. The maximum elongation occurs between tacks that are next to each other. Trunk movement causes implant deformation, and this study provides quantitative information regarding changes in the distance between fasteners.
Interpretation: The physiological movement of the human abdomen must be regarded as a very important factor in mesh deformation and should be considered in surgical practice to reduce the hernia recurrence rate and postoperative pain.

1. Introduction

Laparoscopic repair has increasingly been used for ventral/incisional hernia repair in recent decades. Compared to open repair, this method has become increasingly popular due to its simplicity, good results and excellent cosmetic effect. Although good results are reported in many case series and randomized trials, recurrence, postoperative pain and other serious complications are still noted (Chelala et al., 2010; Köckerling et al., 2019). Surgical guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias already exist (Bittner et al., 2019), but their authors admit that deeper research on the behavior of meshes in the human body is still needed.

The biocompatibility of implants is often considered mainly in terms of chemical and biological interactions, but the mechanical compatibility of the prostheses working in contact with soft biological tissues, such as the abdominal wall, is also crucial (Mazza and Ehret, 2015). Junge et al. (2001) studied the *ex vivo* elasticity of the human abdominal wall and compared this parameter with the elasticity of select surgical meshes. Similar stiffness investigations were then conducted to compare and evaluate surgical meshes (Eliason et al., 2011; Kirilova et al., 2012; Tomaszewska, 2016). Some papers address identification of the mechanical properties of specific components in the abdominal wall based on *ex vivo* tests, *e.g.*, connective tissues in the abdominal wall (Astruc et al., 2018).

The activities that occur in the abdominal wall-implant system in the long term when various processes of interaction have already taken place, *e.g.*, tissue ingrowth, remain uncertain. Animal models are mainly used to investigate the long-term mechanical behavior of implants, but a lack of standardization complicates comparisons of the outcomes of these studies (Vogels et al., 2017). The mechanical properties of implants with overgrowth tissue were investigated by *ex vivo* tests on samples harvested from animals with implanted meshes (Hernández-Gascón et al., 2012). However, the mechanical behavior observed *ex vivo* may not fully correspond to *in vivo* behavior; therefore, surgical meshes inside living subjects need to be observed. Kahan et al. (2018, 2017) proposed a methodology to measure strains in meshes *in vivo*. They used radio-opaque beads on the implanted mesh and fluoroscopic images to visualize 3D mesh stretch patterns related to

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increased intraabdominal pressure in an animal model and considered open hernia repair. Another concept is the use of implants with embedded iron particles that are visible on magnetic resonance imaging (MRI). Ciritsis et al. (2014) reconstructed the mesh shape and calculated mesh shrinkage using MRI in a phantom study and in patients with repaired inguinal hernias. Köhler et al. (2015) showed mesh demarcations and studied the mesh area in a magnetic-visible intraperitoneal onlay mesh (IPOM) in patients 1 day and 3 months after repair. In an extensive literature review on the mechanical aspects of hernia repair, Deeken and Lake (2017) proposed that a future line of research that should be undertaken is evaluation of mesh-tissue mechanics in living subjects. Other recommended paths concern improved computational modeling.

Computational models can be used to effectively examine mechanical compatibility between a surgical mesh and the abdominal wall. Numerical models allow us to test many variants and optimize the selected parameters for hernia repair, *e.g.*, the properties of the implant. Moreover, models can help us to understand the mechanical behavior of the system. Some models with realistic human geometry were developed to simulate the behavior of the abdominal wall with a surgical mesh shortly after laparoscopic repair (Todros et al., 2018) and to optimize the properties of the surgical mesh (He et al., 2020). To establish clinically important recommendations based on the results of computer simulations, the credibility of a numerical model must first be assessed (Anderson et al., 2007; Viceconti et al., 2005). One of the important steps in assessing the predictive capability of a model is validation, which is usually performed by comparison with experimental observations. The authors of the aforementioned studies compared models of healthy (He et al., 2020; Todros et al., 2018) and herniated (Todros et al., 2018) abdominal walls with data reported in the literature. However, He et al. (2020) reported that validation of the model of a repaired abdominal wall with an implant is currently missing due to a lack of sufficient data. Simón-Allué et al. (2018) proposed a combined numerical *in vivo* and *ex vivo* study, but the study concerned open repair in rabbits. Podwojewski et al. (2014) investigated *ex vivo* strains in the human abdominal wall subjected to pressure loading in the following states: healthy (intact) and incised and repaired with an intraperitoneal implant. In this study, strains on the internal and external surfaces of the abdominal wall were also compared. Displacements and strains on the external surface of the abdominal wall are relatively easy to measure, for example, using optical methods (Breier et al., 2017; Simón-Allué et al., 2015) or laser scanners (Todros et al., 2019). However, in the case of laparoscopic repair using the IPOM technique, the implant is attached to the internal side. Therefore, accurate information about strains in the internal abdominal wall surface may be more important.

High intraabdominal pressure is believed to be responsible for hernia recurrence (Cobb et al., 2005), and this type of loading is mainly considered in biomechanical studies on ventral hernia issues. An experimental study on the pressure applied in physical models to assess the capacity of mesh fixation to porcine tissue was reported by Tomaszewska et al. (2013). An *in vitro* surrogate abdominal model has been described by Lyons et al. (2015). The authors used the model to study mesh overlap requirements for abdominal wall hernia repair. A similar model has been described by Kallinowski et al. (2019), where the necessary fixation strength is discussed for various hernia sizes. The aforementioned numerical models were also subjected to intraabdominal pressure. In addition to the passive behavior of the abdominal wall, muscle contraction may be included in numerical models of the abdominal wall (Todros et al., 2020). Although not supported by the literature, in many cases of recurrence, patients report repair failure to be related to either some kind of extensive work or extreme forced movement. This type of loading acting on a surgical mesh during human daily activity has not yet been widely studied in the literature. In our previous study (Szymczak et al., 2012), the strains in the external abdominal wall caused by normal activities such as side bending were investigated, and then Lubowiecka (2015) conducted a mechanical analysis of the forces in the joints of the surgical mesh when implanted in different zones of the human abdomen. Next, a procedure for optimization of the implant choice and orientation for different hernia locations within the abdominal wall was proposed based on a numerical model including displacement of tacks (joints of the implant and the abdominal wall) caused by torso movement (Lubowiecka et al., 2016). In that study, the significance of proper orientation of orthotropic implants within the anisotropic abdominal wall was shown. The optimization objective function was to minimize the maximum forces in the tacks joining the surgical mesh to the human tissue because insufficient fixation is the most common reason for hernia recurrence (see, *e.g.*, Hollinsky et al., 2010). The number of tacks and transabdominal sutures used should ensure a secure connection between the mesh and the front abdominal wall; however, the use of a large number of tacks increases the risk of pain at the application site. The load bearing capacities of the different fasteners were investigated by Tomaszewska et al. (2013). The optimization was also extended to a two-criteria procedure (Szymczak et al., 2017) including minimization of the maximum forces and a criterion for implant deflection to prevent excessive mesh bulging. In this case, intraabdominal pressure was also considered. For the purposes of simulations and optimization, the strains measured on the external surface of the abdominal wall were downscaled to obtain the values of the strains on the internal layer of the abdominal wall (see Podwojewski et al., 2014). The limitation of both studies (Lubowiecka et al., 2016; Szymczak et al., 2017) was the unknown displacements of the tacks *in vivo* in humans.

To summarize the current state of research on hernia repair, little is known about the deformation of the internal layer of the living human abdominal wall or about the mechanical behavior of implanted intraperitoneal onlay meshes *in vivo* in humans from a long-term perspective. Therefore, the present paper seeks to address these knowledge gaps. The aim of this article is to study *in vivo* displacements of tacks joining a surgical mesh to the internal layer of the abdominal wall caused by side bending of the human torso. Data collected *in vivo* from patients previously treated for incisional hernia using intraabdominal mesh in a laparoscopic procedure are presented to show how the deformation of the front abdominal wall can cause mesh deformation.

2. Methods

X-ray images of ten patients, including six men and four women with average BMI of 34.2 and average age of 57, were used for the present analysis. The patients were admitted to the hospital with abdominal pain. The X-ray images were taken for diagnostic purposes within standard screening to identify signs of ileus. Pain was found to be correlated with ileus caused by adhesions (5 cases), acute appendicitis (2 cases), acute cholecystitis (1 case) and an unknown source in one case (which resolved after conservative treatment). All of these patients had previously undergone laparoscopic ventral hernia repair with the use of intraabdominal implants (PROCEED® Surgical Mesh, Ethicon, Somerville, NJ, USA). The implant was composed of nonabsorbable polypropylene mesh and an absorbable cellulose layer and fixed with nonabsorbable staples (ProTack™ Fixation Device, Covidien, Medtronic, Minneapolis, USA). The mesh in each patient was aligned according to the manufacturer's recommendation, with the blue stripes in the craniocaudal direction. The time from mesh implantation to examination varied over 12 months (average, 5.7 months). In this period, the tissue is already ingrown into the mesh, and the absorbable components of the mesh have been absorbed. Images taken in the upright standing (reference) position and of the patients' maximum side bend position were analyzed. A sample image is shown in Fig. 1.

Engineering software based on *computer-aided design* (CAD) for work on vector graphics was applied to precisely position the joints fixing the implant. The positions of all the tacks in the patient reference and side bend positions were collected. The coordinates were then imported to custom code prepared in the MATLAB® environment. Although

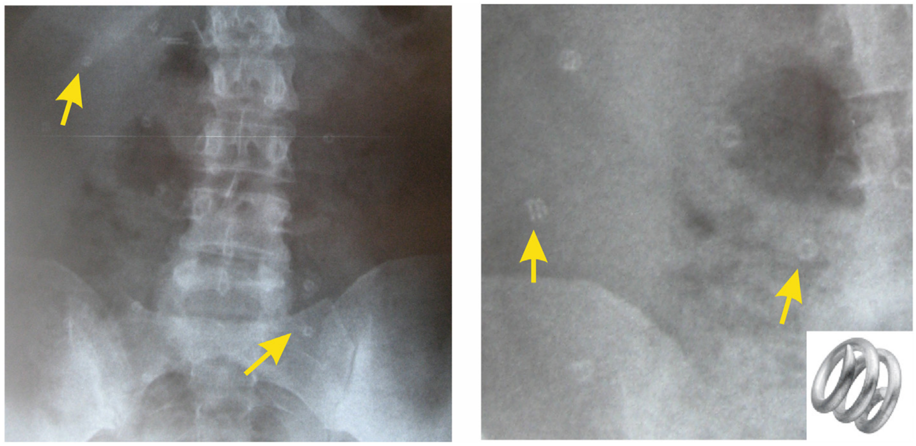


Fig. 1. An X-ray image of one patient and a magnified image showing visible tacks.

previously cited articles refer mostly to strains, in this research, we investigate elongation of the sections defined by every pair of joints specified in every studied case. Such choice is due to the long distance between fasteners, which does not allow us to use the strain measure of deformation of the implant.

The relative elongation measure described by Eq. (1) is applied

$$\delta l = \frac{l - l_0}{l_0} \tag{1}$$

where

l is distance between every two joints of the selected pair after deformation of the abdominal wall (after body movement), and l_0 is the distance between every two joints of the selected pair before deformation of the abdominal wall (reference position, before any movement). Additionally, the relative area change is calculated by$\delta A = (A - A_0)/A_0$, where A is the area of a polygon with vertices at all the visible tacks in the deformed state, and $A_0$is the area in the reference state. It should be emphasized that relation (1) is valid for the arbitrary initial distance between fasteners and may be a good approximation of the axial strain if the length l_0 is small in comparison with the implant dimensions. This is not the case in our study, but still relative elongation provides interesting information, which can be in the future used to estimate tension in the implant and forces in the implant-fascia connections.

Notably, the analysis is based on two-dimensional images, which may cause inaccuracy in elongation calculations. For instance, in reality, some of the tacks may not be placed on the assumed plane parallel to the image plane. Nevertheless, a simplified assumption is made that the surgical mesh incorporated with the abdominal wall is planar and that the tacks do not displace out of this plane during the considered side bending movement.

3. Results

Analysis of the images shows that all the implanted meshes had been placed to cover midline defects (according to European Hernia Society classification types M2, M3 and M4 (Muysoms et al., 2009). None of the meshes had been placed in the subxyphoidal or suprapubic region. The locations of the tacks in the reference and deformed positions of the patient torso are presented in Fig. 2. The deformation of the mesh is visible by comparison of the locations of tacks in these two states. Three example cases are selected to show different situations. The sections with maximum δl are marked by thick lines. The maximum δl of the mesh occurs in different areas of the abdominal wall in different patients, as underlined in Fig. 2a and Fig. 2b. In the presented example, the maximum δl occurs in the lower part of the tack crown (yellow line in Fig. 2) in patients 2 and 7, while in patient 9, the maximum δl occurs in the upper part. The most extreme δl value observed in the study is marked in Fig. 2c. Tacks locations in two states for all patients are shown in Fig. 3.

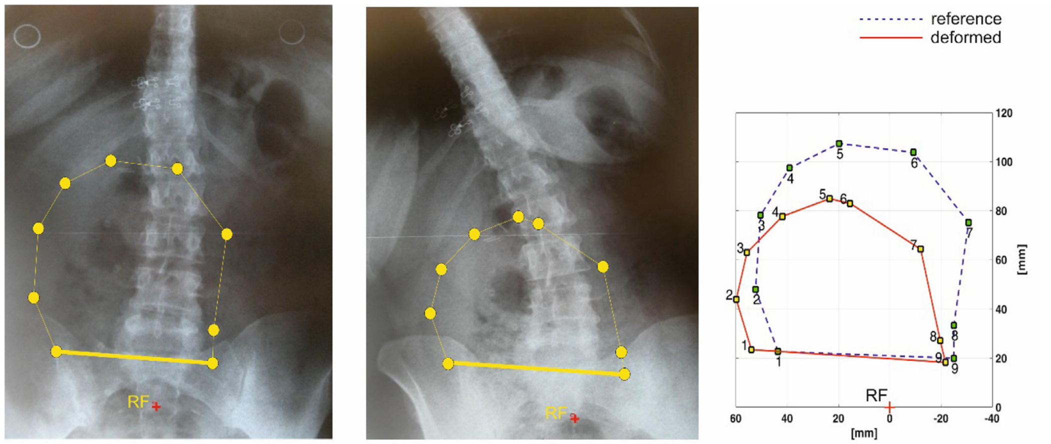
The obtained δl in the mesh are presented in histograms for each patient in Fig. 4. In a further statistical analysis, only positive values of elongations are considered because they refer to mesh stretching, which is a potential cause of fixation damage. Mesh stretching may lead to failure of the implant-abdominal wall connection, especially at the first stage of hernia repair, when tissue has not yet been incorporated into the abdominal wall. Negative values correspond to mesh shortening, which does not induce force on the fasteners. The statistics of the results are shown in Table 1 and in the boxplot (Fig. 5). The histograms (with a 0.1 bin width) show that the range of δl up to 0.1 is the most frequent range for more than half of the patients. The range of the most frequent results for patient 6 is the highest (0.2–0.3) among the patients. Nevertheless, δl values higher than 0.3 occur in the analyses of 6 of 10 patients. For two patients (7 and 8), the maximum δl exceeds 1 (even 2 in one observation, which indicates 200% elongation). The median of the maximum δl among the observed patients is 0.326, and the median δl = 0.095. The maximum δl appears between tacks positioned next to each other in most cases. The median δl between tacks that are next to each other (δl in the pentagonal circuit) is 0.125, and the median δl between other nonneighboring tacks is 0.069.

Although relatively high elongations are observed, the area of the polygon with vertices at all the tacks decreased during movement in half of the cases (see Table 1).

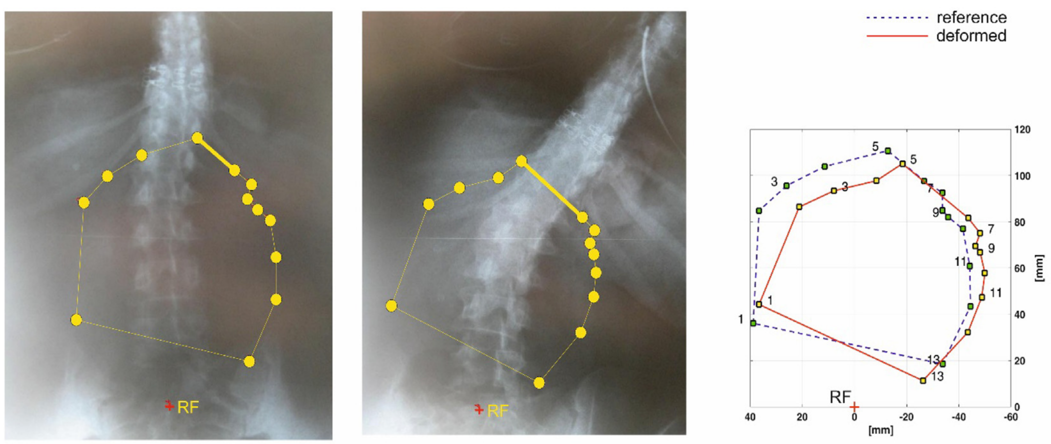
4. Discussion

Visualization of tacks on X-ray images provided us the opportunity to observe tack displacements *in vivo* and therefore determine the relative elongation of meshes incorporated with the human abdominal wall.

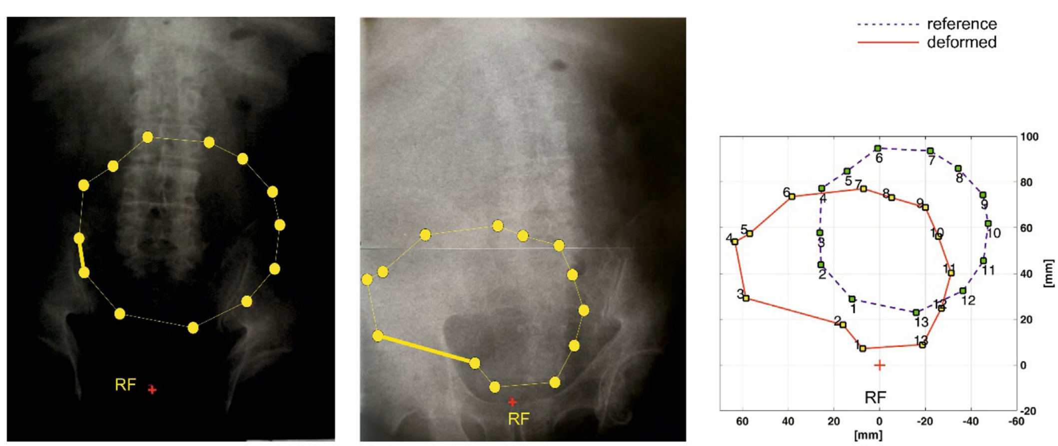
Relatively high elongation was observed, although in a previous analysis, the PROCEED® implant was found to be one of the stiffer meshes compared to others (Szymczak and Śmietański, 2012). Following our computational study, this feature leads to high forces in joints with abdominal tissue (Szymczak et al., 2017). Moreover, the PROCEED® implant was oriented with its stiffest axis, which is along the blue stripes, in the craniocaudal direction. Mechanical studies have shown that the alignment of the stiffer axis in the transverse direction in most hernia locations should improve the mechanical compatibility of the implant with the abdominal wall (Lubowiecka et al., 2016). This mesh shows a limit strain of 10% in the direction of the blue strips and 50% in the perpendicular direction (Szymczak and Śmietański, 2012), which is lower than the extreme elongation observed in the current study. However, these limits are derived from uniaxial tensile tests of



a) Patient 2



b) Patient 9



c) Patient 7

Fig. 2. The locations of joints in reference and deformed torso positions; the thick line represents the site of maximum elongation; RF - reference point; (a) patient 2, (b) patient 9, and (c) patient 7.

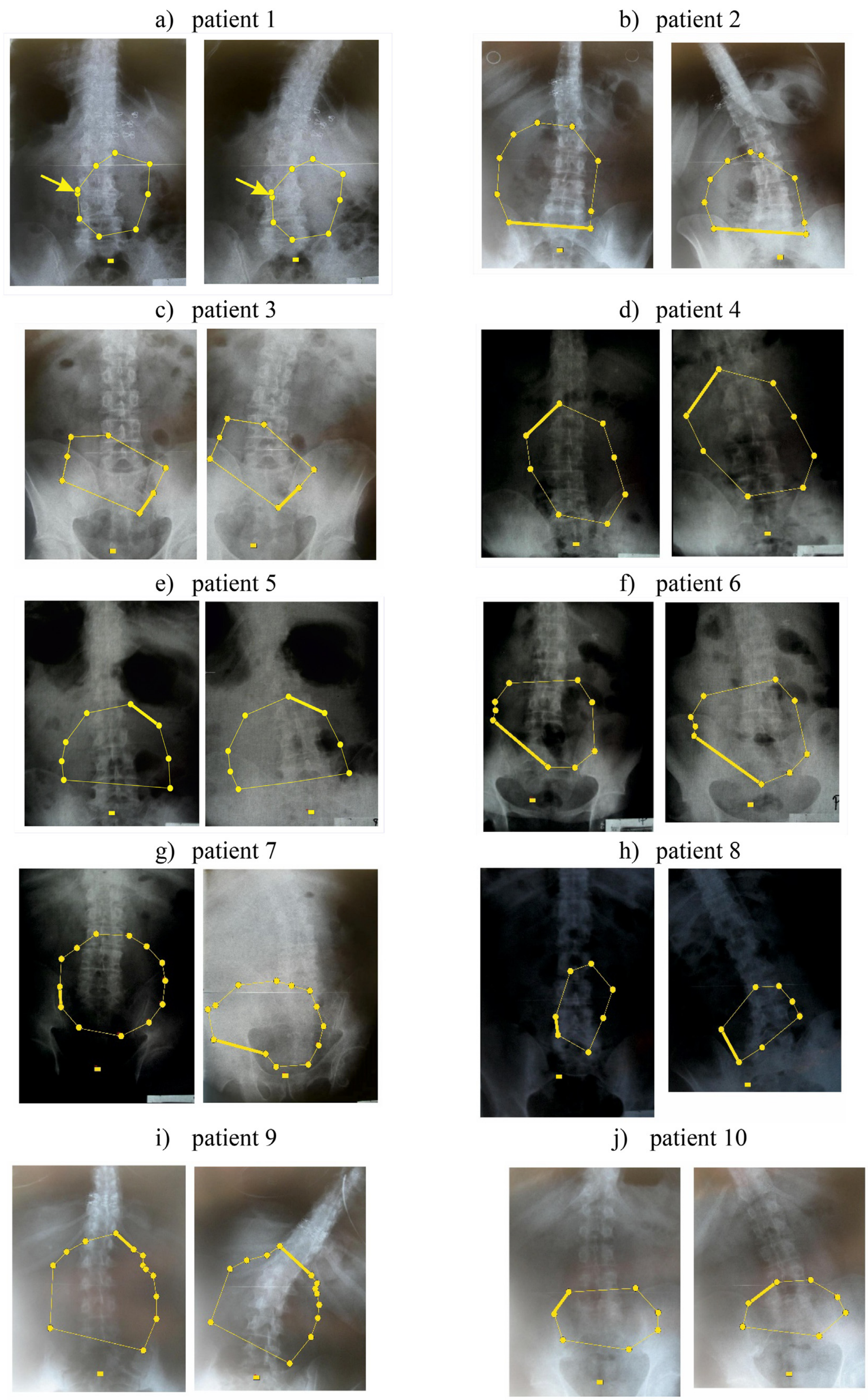


Fig. 3. The locations of joints in reference and deformed torso positions; thick line represents the site of maximum elongation (in a) additional arrow is used); rectangle - reference point.

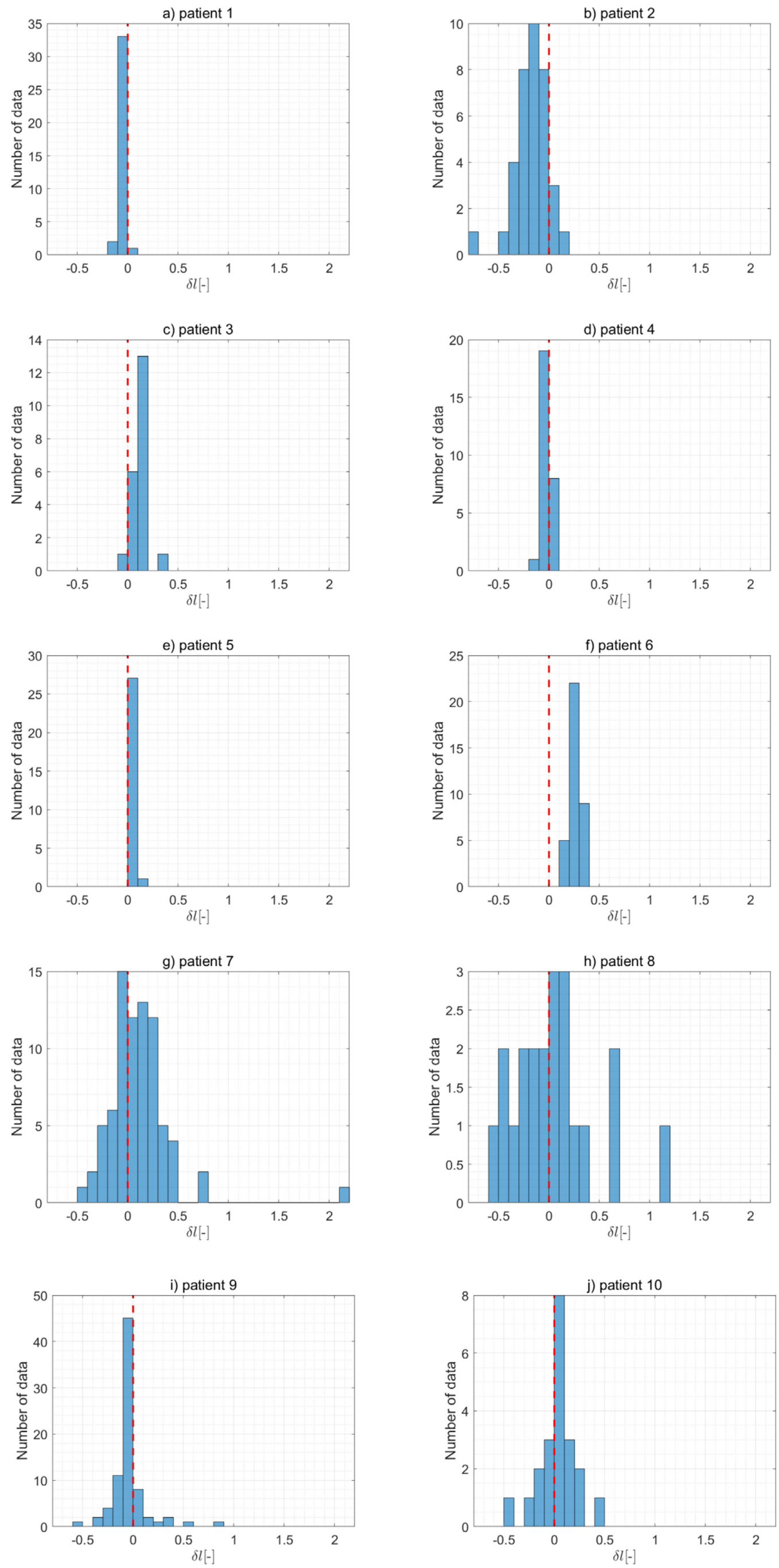


Fig. 4. Histograms of relative elongation (δl) on the internal surface of the abdominal wall with incorporated surgical mesh caused by side bending of the body; the results obtained for each patient.

Table 1
Information on the patients, statistics of obtained positive values of relative elongation (δl) and the relative area change (δA).

Patient No	Gender	Number of visible tacks	Range of most frequent δl	Maximum δl [−]	Medianδl [−]	Median δl on the pentagonal circuit [−]	Median δl on the mesh inside the pentagonal circuit [−]	Relative area change δA[−]
1	F	9	< 0.1	0.024	0.024	0.0241	No positive values	−0.119
2	F	9	< 0.1	0.105	0.051	0.1052	0.0402	−0.332
3	M	7	0.1–0.2	0.312	0.108	0.1171	0.1065	0.215
4	M	8	< 0.1	0.034	0.011	0.0084	0.0136	−0.038
5	M	8	< 0.1	0.130	0.065	0.0492	0.0651	0.126
6	F	9	0.2–0.3	0.340	0.258	0.2659	0.2575	0.613
7	M	13	0.1–0.2	2.170	0.199	0.2817	0.1985	0.136
8	M	7	< 0.2	1.149	0.198	0.2533	0.198	0.020
9	F	13	< 0.1	0.804	0.100	0.1905	0.0685	−0.101
10	M	7	< 0.1	0.440	0.091	0.1337	0.0331	−0.003
Median				0.396	0.091	0.326	0.0685	0.125
Interquartile range				0.538	0.102	0.699	0.160	0.2041

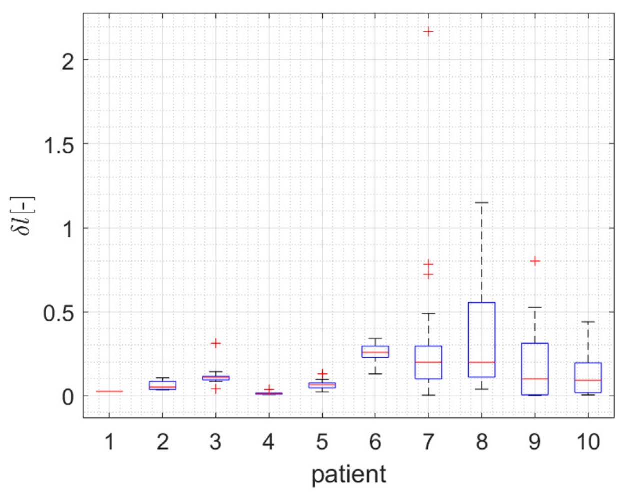


Fig. 5. Boxplot showing the distributions of positive relative elongation (δl) for each patient, where the central line is the median, the bottom and top edges of the boxes show the 25th and 75th percentiles, respectively, and '+' indicates outliers.

the mesh alone. In the human body, mesh is subjected to complex, multiaxial deformation, where elongation in a given direction can be supplemented by shortening in other directions and by shear deformations. The obtained results indicate that under such conditions, despite tissue incorporation, elongations of the mesh higher than those in the simple mechanical test may occur. On the other hand, in laparoscopic procedures, the surgical mesh is connected to the abdominal wall after high pressure is introduced in the abdominal cavity, and then the pressure is released; thus, the surgical mesh becomes less tense and may wrinkle. Therefore, at the first stage of some loading (such as an increase in intraabdominal pressure or extensions due to body movement), the mesh may first straighten before real stretching of the implant begins.

Although strain values in the internal layer of the abdominal wall imposed by movements of the torso have not been reported to date, comparing these results with outcomes obtained for other loadings and other boundary conditions can still be interesting. The median elongation observed here is higher than the mean value of strain reported by Podwojewski et al. (2014) in an *ex vivo* study on the abdominal wall. In that article, the authors applied a pressure of 50 mmHg, and as a result, strains of 3.7 ± 1.0% in the longitudinal direction and 2.6 ± 0.9% in the transverse direction were found on the internal surface of the intact abdominal wall. Kirilova et al. (2011) performed *ex vivo* uniaxial tensile tests on the umbilical and transversalis fasciae, which is a key tissue in this context. The median of the median relative elongations obtained in the current study are lower than the median of the maximum stress of the fasciae (0.15, 0.25, 0.15, and 0.36 in the longitudinal and transverse directions of the transversalis fascia and the longitudinal and transverse directions of the umbilical fascia, respectively). However, the median of the maximum relative elongations obtained in the current study exceeds the values at the maximum stress but is lower than the median of the maximum strains in the fascia (0.71, 1.04, 0.77, and 0.91 in longitudinal and transverse directions of the transversalis fascia and longitudinal and transverse directions of the umbilical fascia, respectively).

The relative elongations of the internal layer of the abdominal wall with incorporated implants observed in the X-ray images are relatively large, implying that the deformation caused by body movement should be considered in analyses of the mechanical behaviors of implants and the abdominal wall with an implant. Additionally, this phenomenon should be considered in the optimization procedure while searching for an optimal implant due to the minimum forces in the joints and the minimum effect of mesh bulging. This phenomenon has also been partially reflected by the numerical analysis outcomes presented by Szymczak et al. (2017). In that study, an optimal implant was selected based on a two-criteria approach. A computational membrane model of a surgical mesh was used, and forced displacement of the tacks due to abdomen deformation was imposed. The deformations were caused by body movements. The forces caused by body movements were higher than the forces in the model under intraabdominal pressure. However, this analysis was based on the strain values at the external surface of the human abdomen reported in (Szymczak et al., 2012). The current *in vivo* study confirms that relatively large values of relative elongations also occur in the internal layer during human body movement.

5. Conclusions

This article shows the elongations in IPOM meshes caused by body movement after incorporation with clinical materials in living humans using long-term follow-ups for the first time. In our opinion, the observations and analyses represent important contributions to understanding the mechanical behavior of the implant-abdominal wall system.

This study shows that body movement causes nonnegligible deformation of the implant-abdominal wall system. Thus, body movement should be considered a factor that influences implant elongation. Notably, although the median of the maximum relative elongation was 39.6%, the relative elongation in some patients reached over 100%. Such elongations cause an increase in the forces in joints, which may even exceed the capacity of tacks, reflecting a potential factor in mesh-fascia rupture that leads to hernia recurrence. Therefore, body movement should be considered in analyses of the mechanical behavior of implanted meshes and in the design of proper implants and plans for efficient hernia repair.

The presented outcomes can be used for computational modeling towards optimization of ventral hernia repair parameters, *e.g.*, the properties of the mesh and its fixation to the abdominal wall. The results can also be used as an input for analyses of local models of implants providing data regarding potential displacements imposed on fixations. Moreover, the results can serve as validation or calibration of numerical models and *in silico* analyses of a system containing the abdominal wall and an implant.

Different ranges of strain on the external layer of the abdominal wall have already been identified and reported in the literature. This study refers to the internal layer of the abdominal wall. The results indicate the need for further investigation of the *in vivo* deformation of a surgical mesh and the internal layers of the living human abdominal wall caused by daily movements. This kind of investigation can be useful when formulating recommendations for surgeries in different hernia locations.

Declaration of Competing Interest

None.

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