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A PRELIMINARY STUDY ON THE OPTIMAL CHOICE OF AN IMPLANT AND ITS ORIENTATION IN VENTRAL HERNIA REPAIR

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This paper addresses the problem of ventral hernia repair. The main goals are to find an optimal surgical mesh for hernia repair and to define its optimal orientation in the abdominal wall to minimise the maximum force at the tissue-implant juncture. The optimal mesh is chosen from a set of orthotropic meshes with different stiffness ratios for typical hernia placement in the abdominal area. The implant is subjected to an anisotropic displacement field, different for the selected hernia placements. The assumed displacement fields correspond to regular human activity. Proper implantation of the mesh may determine the success of hernia repair and/or the postoperative comfort of patients. The proposed solution is based on FEM simulations of different surgical meshes behaviour. In typical hernia placements, the optimal orientation of the stiffer direction of the implant is perpendicular to the spine. However, the presented results show some cases that an oblique direction may be the optimum one.

Keywords: biomechanics, surgical mesh, finite element modelling, optimisation

1. Introduction

Ventral hernia is a common medical problem researched by surgeons and engineers for many years, but question about the main factors influencing hernia repair efficiency still remains open (Muysoms *et al.*, 2013). This problem refers to primary hernias as well as to incisional ones. It is estimated that there is a 12% chance of incisional ventral hernia occurrence after abdominal surgery and a 3.2% chance after laparoscopic operation (Bensley *et al.*, 2013). Laparoscopic ventral hernia repair is believed to be superior to an open operation (Qadri *et al.*, 2010), however the best treating scheme is not specified for the time being, and such problems as recurrences or chronic pain happen (Sommer and Friis-Andersen, 2013). It is believed that the success of ventral hernia repair depends mainly on selection of an appropriate implant and its fixation (Muysoms *et al.*, 2013). In the authors' opinion, mathematical modelling and simulations can provide information about the best course of the treatment, and then, a combination of medical and mechanical knowledge may lead to an increase in hernia treatment efficiency.

This paper refers to laparoscopic repairs. The principle that the properties of surgical meshes should match the properties of the abdominal wall and that implants should be oriented in the human body in accordance with the mechanics of the abdominal wall has been reported in the literature since 2001 (Junge *et al.*, 2001). This issue was discussed e.g., by Kirilova *et al.* (2012), Hernández-Gascón *et al.* (2013), Anurov *et al.* (2012). All these studies are limited to just one position of hernia orifice and two perpendicular orientations of implants. As the abdominal wall is subjected to various strains during human activity, both in magnitudes and in orientations in different locations (Szymczak *et al.*, 2012), it is reasonable to find the best orientation of the implant for different hernia locations in the abdominal wall. This problem was already addressed in (Lubowiecka *et al.*, 2014).

The main goal of this study is to investigate the influence of implants orientation on forces in fasteners. The value of this force determines the success of hernia repair since its increase can lead to the junction failure which is a common cause of the illness recurrence.The maximum force on a fastener affixing an implant should be smaller than the allowable tearing force for a selected tack (Tomaszewska *et al.*, 2013). The proposed solutions are derived from structural mechanics and optimisation methodology. In order to analyse the behaviour of the surgical mesh, a mathematical model of the tissue-implant system, which is created during laparoscopic hernia operation, is applied. The modelling of implant-tissue systems began with the cable model (Szymczak *et al.*, 2010). Next, two-dimensional finite element (FE) membrane models with various boundary conditions were defined (Lubowiecka *et al.*, 2010; Lubowiecka, 2015; Tomaszewska *et al.*, 2013). An FE model of the implant-hernia system was also proposed by Guérin and Turquier (2013) and Hernández-Gascón *et al.* (2013). Some mechanical properties of surgical meshes were recognized for their application in different material models including an orthotropic linear or bilinear elastic material model (Lubowiecka *et al.*, 2014) or a dense net material model (Lubowiecka, 2015), a hyperelastic constitutive model (Hernández-Gascón *et al.*, 2013) and a beam model reflecting the implant material structure (Hernández-Gascón *et al.*, 2012).

The novel approach presented in this paper is formulating and solving the optimisation problem, which results in the selection of the optimal orthotropic implant and its best orientation in the anisotropic abdominal wall. We consider five possible hernia placements, where implants are imposed to different fields of displacements caused by deformation of abdominal wall during daily activities. The optimisation criterion is minimising the maximum forces on tissue-implant junctures resulting from the patient's body movements.

2. Materials and methods

2.1. Formulation of the optimisation problem

The force acting on a single fastener of a given type of mesh implant depends on the implant mechanical properties, its orientation relative to the direction of the spine, and the layout of the fasteners. In this model, a circular layout of point fasteners is assumed. To find the optimal orientation for an implant, the minimisation of the force $F(i,\alpha,s)$ is defined as an objective function

$$\min_{i\in I,\ 0\leqslant\alpha\leqslant 2\pi,\ s\subset S}\max F(i,\alpha,s) \tag{2.1}$$

where i denotes the number of fasteners indicating their position, I stands for the fastener set, α is the angle between the implant primary axis and the spine, and s indicates the implant number from the set of implants S considered.

A three-stage process of minimising objective function (2.1) is proposed herein. During the first stage, the maximum force $F_{max}(i,\alpha,s)$ in the fastener is sought for a chosen implant s and the implant angle of orientation as a solution of the sub-problem (according to Eq. (2.2). The outcome of this step is the number i_0 that indicates the fastener at which F_{max} occurs

$$\max_{i\in I} F(i,\alpha,s) \tag{2.2}$$

In the second stage, the angle specifying the implant orientation in relation to the spine is sought. The problem is formulated as a minimisation of the maximum force obtained in the first stage with respect to the angle α

$$\min_{0\leqslant\alpha\leqslant 2\pi} F_{max}(i_0,\alpha,s) \tag{2.3}$$

The minimisation procedure is conducted in a discrete manner; the implant orientation angle α changes by the assumed increment $\Delta\alpha$. Thus the orientation angle of the implant α_0 for which the minimal force in tack i_0 (selected in the first step), is identified.

In the last stage, steps one and two are repeated for each implant s from the considered set of implants S

$$\min_{s\subset S} F_{max}(i_0,\alpha_0,s) \tag{2.4}$$

Finally, the implant s_0, its orientation α_0 and the corresponding fastener number i_0 are determined to solve the objective function. This finalises the optimisation procedure.

2.2. Modelling and simulation of the implanted surogical mesh

Four popular synthetic implants used in ventral hernia repair are considered in this study, Proceed™ Surgical Mesh (Ethicon Endo-Surgery, Inc., USA), Parietex™ Composite (Covidien, USA), DynaMesh®-IPOM (FEG Textiltechnik mbH, Germany) and Gore® Dualmesh® Biomaterial (W.L. Gore & Associates, Inc., USA). They are knitted structures made of polypropylene and cellulose, polyester, polypropylene and polyvinylidene fluoride treads, respectively. The latter material is in form of a smooth membrane made of expanded polytetrafluoroethylene. A suggestion concerning proper orientation of the implant in the abdominal wall can be found only in specification of DynaMesh®. The manufacturer recommends a craniocaudal orientation of the mesh, but does not distinguish different hernia locations. The analysis refers to practical cases concerning the first few weeks following the operation, when the implant is not yet encapsulated by a fibrous capsule and when most hernia recurrences occur. The correct mesh orientation decreases the risk of possible postoperative fixation failure even when the mechanical properties of the implant are changed due to tissue overgrowth (Oettinger *et al.*, 2013).

Hernia with an orifice diameter of 5 cm is considered in this study. A standard clinical case is taken into account, in which the implant is affixed to the tissue with point fasteners in a circular order. The least favourable situation is applied with 4 cm spacing between fasteners. The circle of joints has a diameter of 13 cm, and then a radial distance of 4 cm between the hernia orifice edge and joints is preserved according to medical standards. There are 10 fasteners in such a layout.

The mesh is modelled with a polygonal membrane structure (Fig. 1a), supported in 10 points. The numerical model of the implant is defined within the Finite Element Method using the MSC.Marc® commercial system. Eight-node membrane elements QUAD(8) with 3 translational degrees of freedom at each node are used. The model is discretised by 960 finite elements with mesh refinement around the tissue-implant joints (Fig. 1b).

The model is subjected to kinematic extortions related to displacements of the abdominal wall when the patient moves. The range of extortions can be derived from a map of possible strains of the external layer of the abdominal wall, which was discussed by Szymczak *et al.* (2012). A summary of those results is presented in Fig. 2a. However, the strains on the internal surface of the abdominal wall are 2.6-fold smaller than on the external surface (Podwojewski *et al.*, 2013). Thus the reduction factor of 2.6 is applied to the results described by Szymczak *et al.* (2012). The values and directions of maximal strains of the abdominal wall are different in its various regions, so the implant is subjected to various extortions when placed in different parts

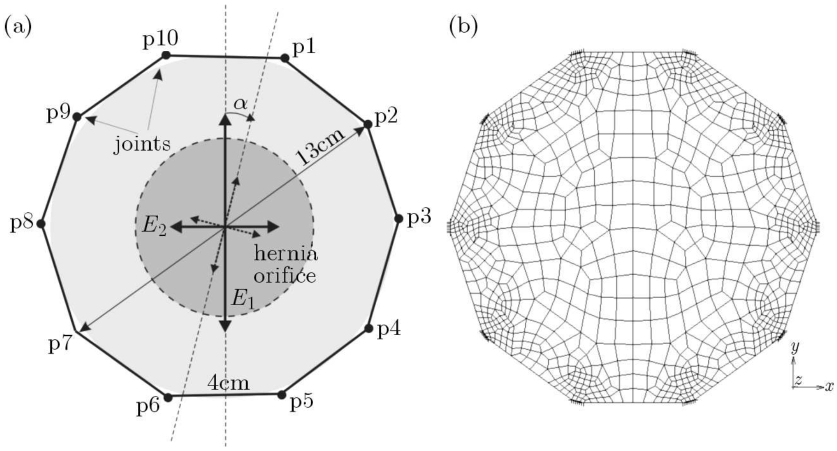

Fig. 1. (a) Scheme model of the implanted surgical mesh; b) Finite Element mesh

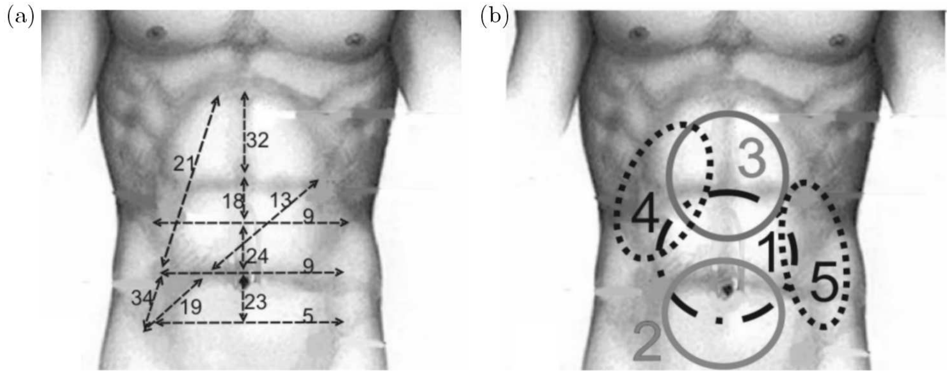

Fig. 2. (a) Directions and values (in %) of strains on the external abdominal surface in different sections, according to Szymczak *et al.* (2012); (b) considered hernia cases

Table 1. Reduced abdominal strains in the radial direction at the fastener imposed in the model supports [%]

[%]	p1	p2	p3	p4	p5	p6	p7	p8	p9	p10
Case 1	9	3	3	6	7	7	6	3	3	9
Case 2	9	3	2	6	7	7	6	2	3	9
Case 3	12	4	3	7	9	9	7	3	4	12
Case 4	9	6	3	5	13	13	5	3	0	0
Case 5	9	5	3	7	13	13	7	3	5	9

of the abdomen. Thus, five hernia locations are considered as marked in Fig. 2b. For each case, the extortions are estimated basing on the abdominal strains presented in Fig. 2a, scaled by a factor of 2.6 and they are applied to the supporting points of the model (p1 to p10, see Fig. 1a). The final values of the extortions applied to each supporting point are included in Table 1.

Mechanical properties of the meshes selected for the analysis differ significantly. Orthotropic or isotropic, linear or bilinear elastic constitutive models have been identified for them, basing on Biot stress and Biot strain experimentally measured in one-dimensional tensile tests. The experiments are presented in (Tomaszewska *et al.*, 2013). As one can notice, basing on the data summarised in Table 1, in each hernia case the meshes are subjected to strains smaller than 0.3. Thus, constitutive models of the meshes have been specified for the strain range 0-0.3. The least squares method applied in the Marquardt-Levenberg algorithm is used for parameters identification. Finally, the obtained parameters of the constitutive models applied for each kind of the implant are presented in Table 2. It has been observed that Dualmesh® is a nearly isotropic material. The rest of the meshes considered here is distinctly orthotropic, but with different orthotropy ratios calculated as E_1/E_2. E_1 and E_2 are the elastic moduli of the implants derived for two perpendicular directions wherein $E_1 > E_2$. The directions of orthotropy, indicated by E_1 and E_2, for the considered meshes are marked in Fig. 3.

Table 2. Parameters of linear or bilinear elastic orthotropic material models of the implants for the strain range 0-0.3

<table>
<tr><th rowspan="2">Mesh</th><th rowspan="2">$\mathcal{A}$</th><th rowspan="2">Limit stress [N/mm]</th><th colspan="2">E [N/mm]</th><th colspan="2">E_1/E_2</th><th rowspan="2">ε_l [–]</th><th rowspan="2">Poisson's ratio ν_{21} [–]</th></tr>
<tr><th>for $\varepsilon < \varepsilon_l$</th><th>for $\varepsilon > \varepsilon_l$</th><th>for $\varepsilon < \varepsilon_l$</th><th>for $\varepsilon > \varepsilon_l$</th></tr>
<tr><td rowspan="2">Dualmesh</td><td>(2.1)</td><td>8.4</td><td colspan="2">28</td><td colspan="2" rowspan="2">1.1</td><td rowspan="2">N/A</td><td rowspan="2">0.3</td></tr>
<tr><td>(2.2)</td><td>6.1</td><td colspan="2">26</td></tr>
<tr><td rowspan="2">DynaMesh</td><td>(2.1)</td><td>4.5</td><td>6.4</td><td>14</td><td rowspan="2">18</td><td rowspan="2">39</td><td>0.15</td><td rowspan="2">0.3</td></tr>
<tr><td>(2.2)</td><td>1.7</td><td colspan="2">0.36</td><td>N/A</td></tr>
<tr><td rowspan="2">Parietex</td><td>(2.1)</td><td>3.7</td><td>1.6</td><td>21</td><td rowspan="2">1.8</td><td rowspan="2">10</td><td rowspan="2">0.15</td><td rowspan="2">0.3</td></tr>
<tr><td>(2.2)</td><td>2.0</td><td>0.87</td><td>2.1</td></tr>
<tr><td rowspan="2">Proceed</td><td>(2.1)</td><td>4.2</td><td colspan="2">40</td><td colspan="2" rowspan="2">5.3</td><td rowspan="2">N/A</td><td rowspan="2">0.3</td></tr>
<tr><td>(2.2)</td><td>4.1</td><td colspan="2">7.6</td></tr>
</table>

$\mathcal{A}$ – Direction of bigger (2.1) or smaller (2.2) stiffness of the mesh

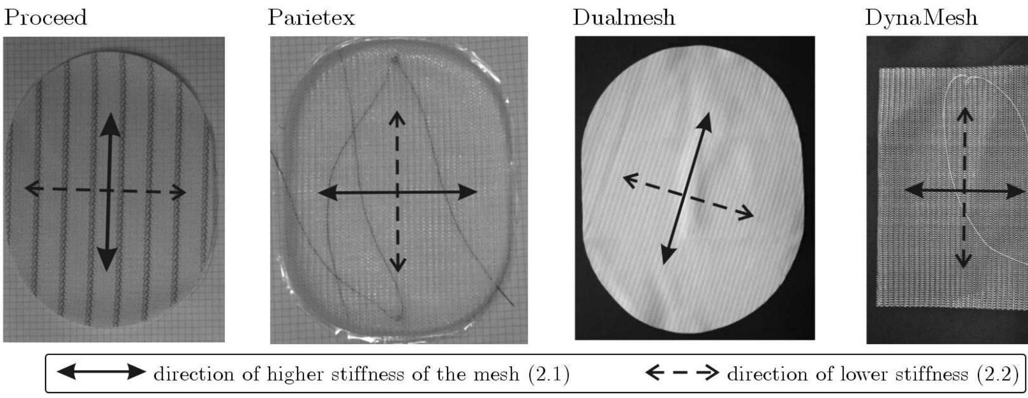

Fig. 3. Directions of the higher and lower stiffness of the considered meshes

The accuracy of the implant model with a proposed polygonal shape has been successfully verified against experiments on a physical model of the system subjected to impact loads resulting from postoperative cough (Lubowiecka, 2015). The h-convergence analysis has been performed within simulations.

According to the optimisation procedure described in Section 2.1, for each implant placed in each hernia case, the reaction forces in the supporting points are calculated (stage 1). Nonlinear static analysis in the range of large strains is performed. Twelve orientations of each implant in each simulated hernia location are considered (α = 0-180 degrees with 15 degree intervals). The angle $\alpha = 0$ stands for the craniocaudal orientation of E_1 direction of the considered implant as marked in Fig. 1a.

The influence of the implant orientation on reaction forces is expressed by the value of the coefficient $D = (F_{max} - F_{min})/F_m \cdot 100\%$, where F_{max} is the maximum reaction obtained for the orientation α_{max}, F_{min} is the maximum reaction obtained for the orientation α_0 (stage 2 of the optimisation). The smallest maximum reaction occurs for the optimal orientation α_0 of the implant and α_{max} is the orientation corresponding to the largest maximum reaction that occurs in the supporting points of the mesh. α_{max} is the least appropriate orientation. The larger the value of the D coefficient, the greater is the effect of the implant orientation on the reaction force. In the final step of the optimisation problem, the optimal solution described by the implant type along with its optimal orientation is found (implant type along with its optimal orientation).

3. Results

The calculated values of the angles α_0 and α_{max} along with D coefficients are presented in Table 3. For almost isotropic Dualmesh®, D value does not exceed 5% in any area, but for other meshes it is visibly higher. The largest values of D are obtained for DynaMesh® (36%-55%) and for Proceed™ (35%-53%). D value of Parietex™ is in the range of 26%-34%.

Table 3. The best and the worst orientations of implants

Case	DynaMesh			Parietex			Proceed			Dualmesh		
	α_{max} [deg]	α_0 [deg]	D [%]	α_{max} [deg]	α_0 [deg]	D [%]	α_{max} [deg]	α_0 [deg]	D [%]	α_{max} [deg]	α_0 [deg]	D [%]
1	15	75	36	15	90	28	30	90	36	15	75	4
2	15	75	42	15	90	26	30	90	35	15	75	5
3	15	75	47	30	90	29	15	90	47	15	90	4
4	165	75	55	90	60	34	0	75	53	165	75	3
5	15	90	48	15	90	33	15	90	50	15	90	4

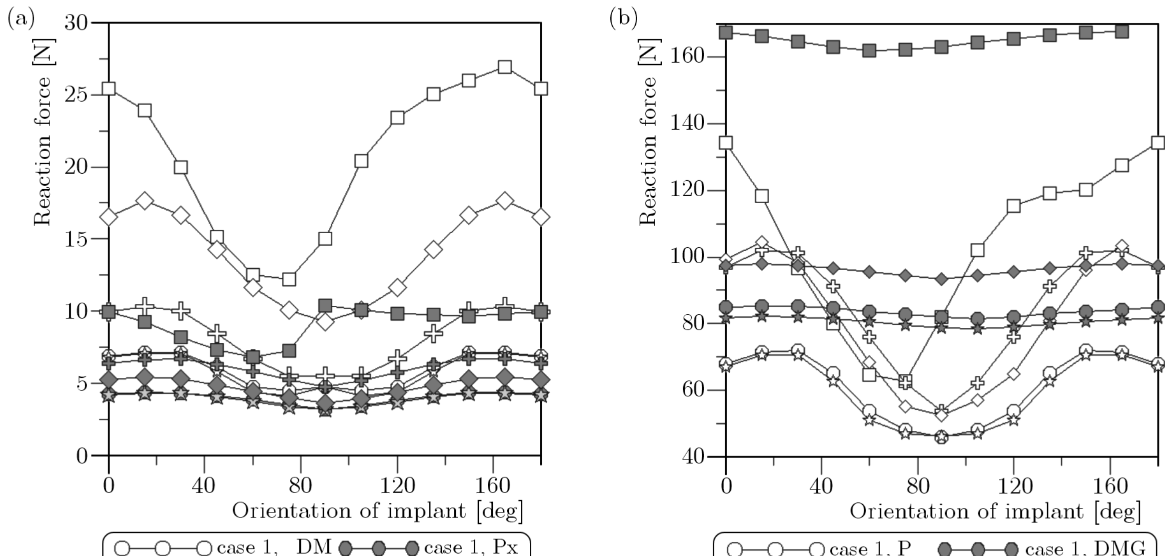

Fig. 4. Maximum reactions F_{max} in meshes depending on the orientation angle α for the following implants: DynaMesh (DM), Parietex (Px), Proceed (P) and Dualmesh (DMG)

The values of all maximum reaction forces obtained in this study are presented in Fig. 4. The distribution of all reactions in the worst and best orientation case is shown in Fig. 5. Finally, the identified optimal orientations of three considered anisotropic implants for each hernia location considered here are shown in Fig. 6. Dualmesh® is the only mesh investigated in this study that

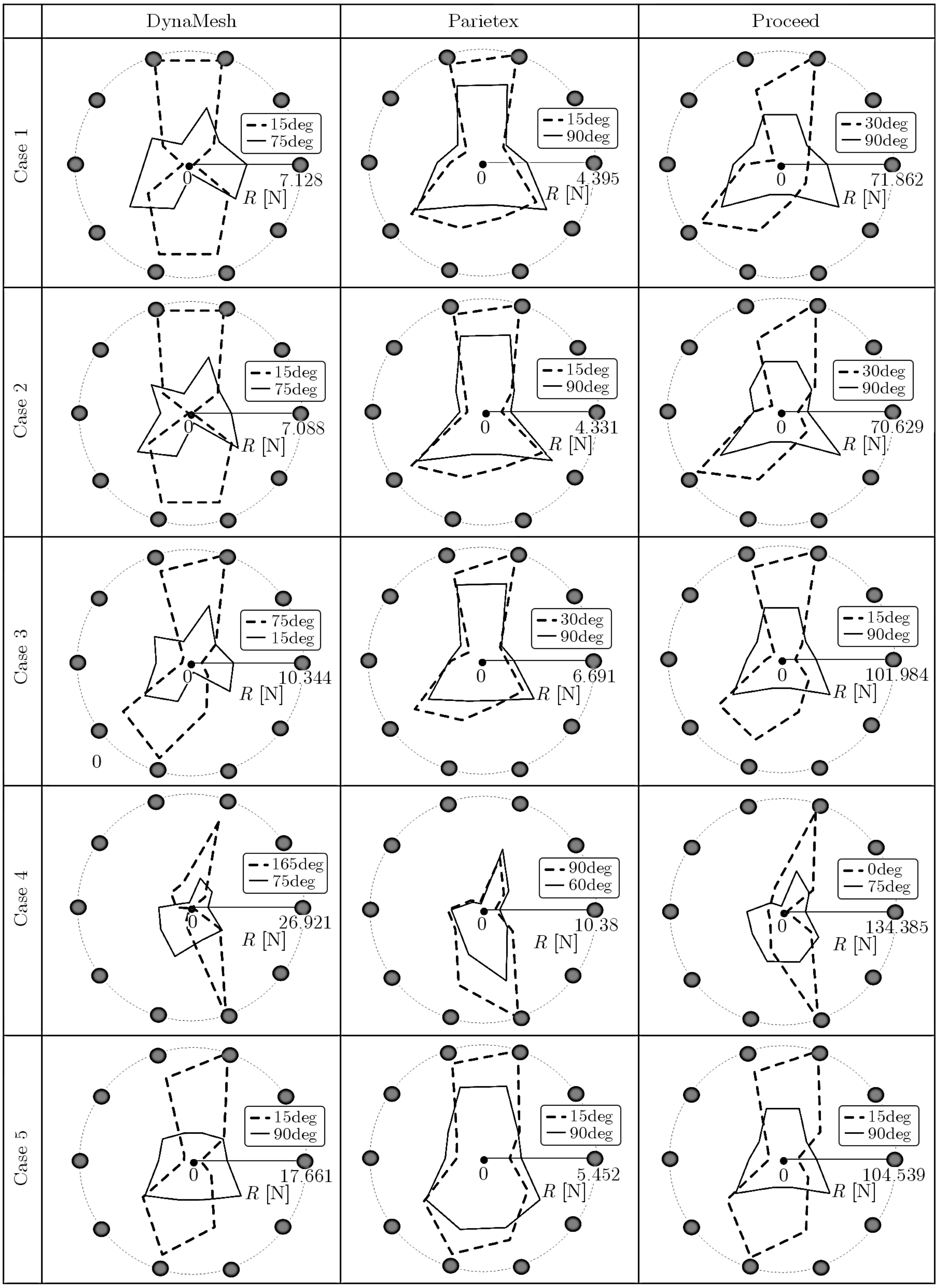

Fig. 5. Reactions F obtained in each support for all investigated orientations of the implant, the solid line is for the best orientation, the dashed line is for the worst orientation of the mesh

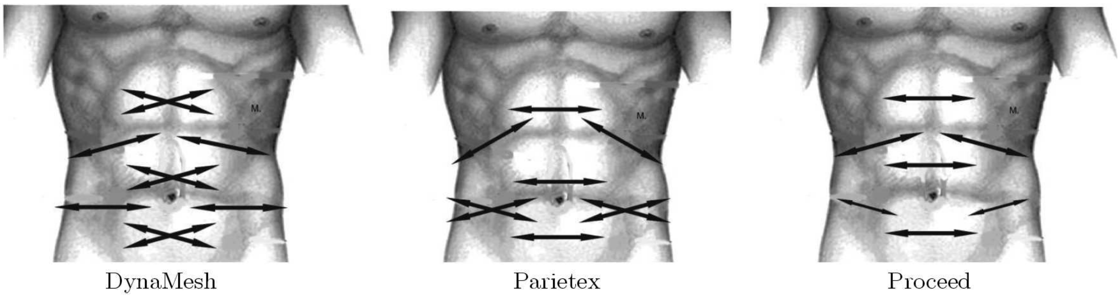

Fig. 6. Optimal orientation angles α_0 (orientation of the direction of E_1)

does not have distinct anisotropic properties. A single optimal orientation does not exist in such a case, any orientation is acceptable.

4. Discussion

Figures 4-6 describe the effects of the implant material orientation on the reaction forces that occur at the supporting points in the tissue-implant interface. These forces cannot exceed the capacity of the tissue-implant juncture, otherwise the junction damage and recurrence of the sickness occurs. The larger the range of junction forces between the most and least appropriate orientations of the implant, the greater is the influence of the implant orientation on the forces in the supporting tacks. This range is measured by D coefficient presented in Table 3. D values of Dualmesh® are relatively small (3%-5%), so any orientation of this mesh can be applied in practice. The largest D values are obtained for DynaMesh® (33%-55%) and for Proceed™ (36%-53%), which means that surgeons should pay special attention to the proper orientations of those implants. Values of D for Parietex™ are in the range of 28%-34%. Those results relate to the orthotropy ratio of each mesh (Table 2). The largest forces for each implant can be found in zone 4 (see Fig. 4). Also the influence of orientation (represented by D value) is the highest in that zone. The results presented in Fig. 4 prove that the lowest maximal reactions are observed for Parietex™ in each hernia case.

Variability of reaction forces in all fixation points for certain mesh orientations is shown in Fig. 5. These results prove that in the optimal orientation, the reactions are relatively low and they are the most evenly distributed on the supporting points comparing to other orientations. It is visible that in the case of Parietex, which initially has a small orthotropy ratio, the change of orientation from the worst to the optimal one causes reduction of the reaction forces but does not change significantly the shape of the reaction distribution graph. Whereas for strongly orthotropic meshes, like DynaMesh® and Proceed™ in their optimal orientations, the distribution of forces is more even. Such even force distribution justifies regularly spaced fixing joints. For an orientation different than the optimal, more joints (or stronger ones) should be used in places where larger reaction forces occur than in places with smaller reaction forces.

In the majority of cases considered in this study, the optimal orientation of the stiffer direction of an implant is the transverse direction (90 deg) of the abdominal wall (Table 3 and Fig. 6). This observation corresponds to the results obtained experimentally by Anurov *et al.* (2012) and numerically by Hernández-Gascón *et al.* (2013), who investigated only two orientations of a surgical mesh in the central area of the abdominal wall. However, also a frequent solution of our optimisation scheme is 75 deg especially for hernia located in zone 4. In this case when operating with Parietex™, the optimal orientation of its stiffer direction is 60 deg.

The study emphasises the importance of the proper orientation of surgical mesh when imposed to kinematic extortions related to abdominal wall movements. Thus we do not include constrains on the implant deflection related to bulging in the optimisation procedure. Bulging is related to intraabdominal pressure load and does not take place when the implant undergoes only kinematic extortions. However, in a more general procedure of finding an optimal implant, additional constraints upon the maximum displacements could be included to avoid excessive bulging of the implant.

5. Conclusions

This paper presents an investigation on the influence of orthotropic implant orientation on forces on tissue-implant junctures caused by deformation of the anisotropic abdominal wall. Moreover, it gives a study on the optimal choice of surgical orthotropic meshes and their orientation in ventral hernia repair. Surgeons may consider these results when choosing an implant and when determining its position in different areas of the abdominal wall, particularly when no manufacturer's recommendation exists. The most important findings are presented below.

- The implant Parietex™ best minimises reaction forces. Hence, according to our optimisation procedure, application of this mesh gives the optimal solution. However DynaMesh® has a better orthotropy ratio giving more even distribution of forces on all supporting points.
- For optimal orientations of implants in the abdominal wall, forces acting on different supporting points have the most similar values. Then, a regular distribution of supporting points is the most justified. When the implant orientation is far from the optimal one, then the reaction forces are very different in various fixation points, and there is no mechanical justification for the regular joint distribution around the hernia orifice, and some fixation regions should be strengthened.
- In zone 4, in the upper lateral part of the abdominal wall, the supporting points face the largest forces (see Fig. 4) and the implant orientation has the greatest influence on those forces.
- The orientation of orthotropic implants (DynaMesh®, Parietex™ and Proceed™) strongly influences the forces on the supporting points (up to 55%, 34% and 53%, respectively).
- Placing the implant in the optimal orientation, as shown in Fig. 6, greatly reduces the forces on the supporting points, which may determine the success of hernia repair or postoperative comfort of patients. Although significant influence of the orientation of an orthotropic implant in the anisotropic abdominal wall on hernia repair persistence seems to be expected from the mechanical point of view, this fact is still underestimated in surgical practice as confirmed by the newest medical conference reports and scientific papers, see e.g., Oettinger *et al.* (2013), Li *et al.* (2014).
- Our results show not only an optimal mesh placement but also results for other orientations (Fig. 4). On the basis of that, safer and less safe range of orientations can be established. Information about this range can be useful in clinical practice. Surgeons should pay attention to the orientation of the implant, which currently is not a common practice, and try to avoid orientations which may highly increase reactions in fasteners and, in consequence, increase the risk of exceeding the capacity of tack and cause hernia relapse.
- Displacement of the fasteners during regular activity influences the level of junction forces. As a result, the displacement of fasteners should be considered when analysing and designing the fixation of implants. These results may serve as a basis for the formulation of a relationship between the optimisation of mesh implantation and the recurrence rate of hernias as well as they can be applied in the process of individualisation of the treatment of abdominal hernias.

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