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PATIENT-SPECIFIC MODELS OF HUMAN RESECTED STOMACH AFTER LAPAROSCOPIC SLEEVE GASTRECTOMY: EXPERIMENTAL AND COMPUTATIONAL RESULTS

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Abstract. The conspicuous increase in obesity rate occurring in the last decades in industrialized countries, often accompanied by high morbidity and high mortality rate, have been made obesity a global health concern. Bariatric surgery is the most effective treatment for severe obesity. However, there are still many issues related to surgical procedures not yet been overcome. The importance of experimenting with a new rational approach based on bioengineering methods could strongly improve surgical approach by avoiding drawbacks and complications. The aim of this work is the construction of patient-specific computational models of the resected stomachs after laparoscopic sleeve gastrectomy able to interpret the structural mechanical behavior of human gastric tissues. A coupled experimental-computational approach was performed. Experimental insufflation tests were performed on nine resected stomachs from laparoscopic sleeve gastrectomy. Through a reverse engineering approach, nine specific-patient computational models were developed, aiming at simulating the experimental activities. A double-layered fiber-reinforced anisotropic hyperelastic material formulation was chosen. The experimental evidences provided the pressure-volume behavior of the resected stomachs. The comparison between experimental and computational results permitted to identify the set of the constitutive parameters. The stress-strain distribution described the region and the layer mainly solicited. An engineering approach allows us to characterize the mechanical behavior of the human gastric tissues. Reliable computational models will be used in understanding the biomechanics of the human stomach and will provide a clinical tool to help medical staff in optimizing bariatric procedures.

Key words: bariatric surgery, computational modelling, human gastric tissues.

INTRODUCTION

Nowadays, overweight and obesity are established as global health problems and ones of the most spread non-communicable diseases worldwide. The BMI (Body Mass Index) defines the obese condition and it consists in the ratio between an individual's weight and the square of his height (kg/m^2) [15]. The overweight is defined by a BMI greater than 25 kg/m^2, while a BMI of 30 kg/m^2, or more, identifies an obese condition, which is classified as severe when overcomes 40 kg/m^2 [15]. Every year the WHO (World Health Organization) draws up a report concerning the health conditions of the world population and the rapid spread of the disease has been underlined. Globally, 1.9 billion people have an overweight condition and 650 million

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suffer from obesity [24]. Obesity prevention is the best strategy for dealing with this health emergency: many countries have adopted policies to prevent the spread of obesity, such as awareness campaigns, training of healthcare professionals, advertising regulation, taxation and restrictions on the sale of high calorie food and drink [9, 25].

Bariatric surgery is the most effective treatment for people affected by severe obesity [17]. It involves resection of the gastrointestinal distinct with the aim to induce short-term weight loss and its long-term maintenance, reducing the risk of new pathologies and mortality rate associated with excessive weight, therefore, an improvement in the quality of life [28]. Bariatric surgery operations mainly vary from restrictive to malabsorptive procedures; the former focus on the reduction of the amount of food introduced into the stomach, such as the adjustable gastric banding and the laparoscopic sleeve gastrectomy (Fig. 1, *a*), while the latter change the physiological path of the bolus by modifying the anatomy of the gastrointestinal tract, reducing the absorption of certain nutrients, as biliopancreatic diversion. There are operations that combine the two procedures, gastric by-pass [18].

International federation for the surgery of obesity and metabolic disorders produces annual reports of the bariatric surgery procedures performed in 51 different countries. The total number of bariatric interventions amounts to 394431 in 2018: 87467 laparoscopic sleeve gastrectomy operations (46.0 %), 72645 gastric by-pass operations (38.2 %), 9534 adjustable gastric banding operations (5.0 %) and others (10.8 %) [27]. Although indisputable efficacy of bariatric surgery, concerns about the long-term durability of comorbidity control and complications after bariatric procedures are still present [8] and mortality rate can occur in 0.64 % of cases [7]. Moreover, bariatric field has been related to an empiric approach performed by surgeons from the beginning [1]. However, a more rational approach consisting in more rigorous guidelines on surgeon’s indications and choice of procedures is necessary to reduce risks and improve success rates. In this sense, the strengths and the potential of computational tools can be used to rationally provide the not-measurable or difficult-to-measure in vivo quantities in order to highlight how changes among the bariatric procedures and face with the main drawbacks, quantitively.

Computational models of the stomach could be very useful to investigate the mechanical solicitations, as stress and strain distributions, affecting the gastric wall after food intake, both before and after bariatric procedures [4, 10, 26]. The use of stomach models could be a step forward to understand the mechanism involved in satiety: gastric mechano-receptors mediate the inputs from gastric wall solicitation to stimulate the regions of brain involved in satiety and satiation thanks to a complex nervous path [6 ,13]. Nowadays, the measures of tension and deformation on gastric wall are mainly performed on animal model [16, 19, 21] with invasive equipment, a technique not extendable to human beings for research purposes. Moreover, in-silico models permit to recreate vast surgical scenario and new possible configurations without proceeding with a clinical investigation. However, the reliability of the models is strongly related to geometrical features and material formulation of biological tissues and a coupled experimental and computational approach is necessary.

In literature, studies which proposed stomach models in the framework of solid mechanics are present but they considered or a very simple description both in geometry and material formulation [12] or they utilized an average geometry and constitutive parameters obtained from animal tissues [4 ,10].

In this work, the experimental campaign included nine resected stomach after laparoscopic sleeve gastrectomy and the corresponding patient-specific models, ensuring that the computational scenario mimicked the experimental one. Moreover, the step-by-step procedure able to generate a patient-specific virtual solid model of a resected stomach starting from a photo dataset was proposed. A double-layered, fiber-reinforced, visco-hyperelastic anisotropic material formulation was considered. The final purpose was to tune the parameters of a previous work [10] based on swine gastric tissues in order to be able to describe the mechanical behavior of human gastric tissues.

MATERIALS AND METHODS

The samples consisted in nine resected stomachs from laparoscopic sleeve gastrectomy of different patients affected by obesity with an average weight of 121 kg and aged between 19 and 66 years. The samples were provided by U.O.S.D. Week Surgery of the Padua Hospital (Fig. 1, *b*). The resected stomach was tested immediately after extraction, so no conservation operations were necessary. First, a series of photographs were taken, at different heights and with different orientations, to obtain a complete sequence of 360° sample images. Subsequently, the thicknesses of fundus and distal and proximal corpus were measured by means of a digital thickness gauge (Fig. 1, *c*) (resolution of 0.01mm and 5mm of full scale). Given the compressible nature of the gastric tissue, the measurements were always carried out by the same operator, paying attention to correctly measure the thickness without compressing the gastric wall (fundus: 2.4612 ± 0.6814 mm, corpus: 2.6474 ± 0.3408 mm).

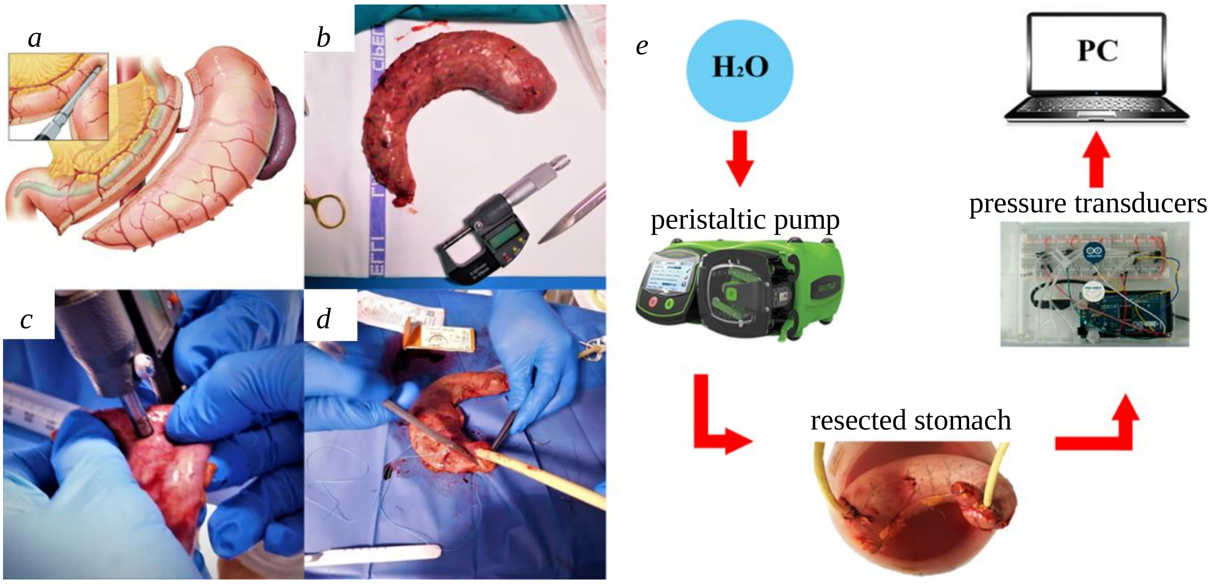


Fig. 1. Laparoscopic sleeve gastrectomy surgical procedure [21] (*a*). Resected stomach obtained from laparoscopic sleeve gastrectomy (*b*). Thickness measurement by digital thickness gauge (*c*). Connection of the tubes through stitches (*d*). Schematic representation of the experimental setup (*e*)

The experimental activities followed the test protocol already presented in literature [3, 10]. The instrumentation consisted of a peristaltic pump (*VerderFlex Vantage 5000, Verder Ltd, UK*) and a pressure transducer (*142 pc 01d, Honeywell, USA*), connected to the sample by means of Verderprene tubes (Fig.1, *d*). From the pump, the 6.4 mm diameter tube was fixed to the proximal part of the stomach, while the one connected to the transducer, 3.2 mm in diameter, was attached to the distal one. The transducer interfaced with a personal computer via a microcontroller *(Arduino MEGA 2560, Arduino LLC)* and a Matlab application (*The MathWorks Inc., Natick, MA, US)* (Fig. 1, *e*). The sampling of the data was carried out at a frequency of 7 Hz. Before the start, the stomach was immersed in saline solution to prevent gravity effects. The pump set up to inflate 200 ml of saline solution at each step, with a flow rate of 25 ml/s. The test terminated when an intragastric pressure of about 5 kPa was reached. To permit the development of the relaxation processes, 10-minute rest period was set among steps [5].

Photogrammetry can be defined as the methodology that allows obtaining three-dimensional metric information of an object starting from the analysis of frames (films, slides) or digital images of the same acquired from different points of view. 3D modelling starts from the acquisition of the metric data and ends with a virtual model (Fig.). There are several types of approach with which this issue can be addressed. In this paper, the reconstruction of the three-dimensional model of the stomach was carried out using the image-based method: from images, the process obtains 3D coordinates using the collinearity equation or the DLT [22]. *Colmap* 3.6 (*ETH Zurich and UNC Chapel Hill, 2018*) was adopted to create the point cloud. A point-cloud file (ply) was imported in CloudCompare 2.10.2 (*Zephyrus, 2018*) which permitted to generate a coarse volumetric solid. Subsequently, *FreeCAD* 0.18 was used to improve the overall object and to generate a free-form surface of the resected stomach. The models were customized even for what concern the thickness, in fact the thickness of the fundus and proximal and distal corpus were set on the basis of the experimental measurements by means of Solidworks program (*Dassault Systemes, 2018*). Finally, two holes with a diameter of 10 mm were made in the distal and proximal of the structure in order to simulate what happened in experimental tests. The photogrammetric reconstructions led to nine patient-specific models of resected stomach, highlighting the inter-sample variability in terms of dimensions and shapes. The virtual solid models are reported in Appendix A. Proposing customized model in computational simulations is important because the geometry (dimension, shape, thickness) influences the results, and a set of parameters have to be applicable to any configuration entailing reliable results.

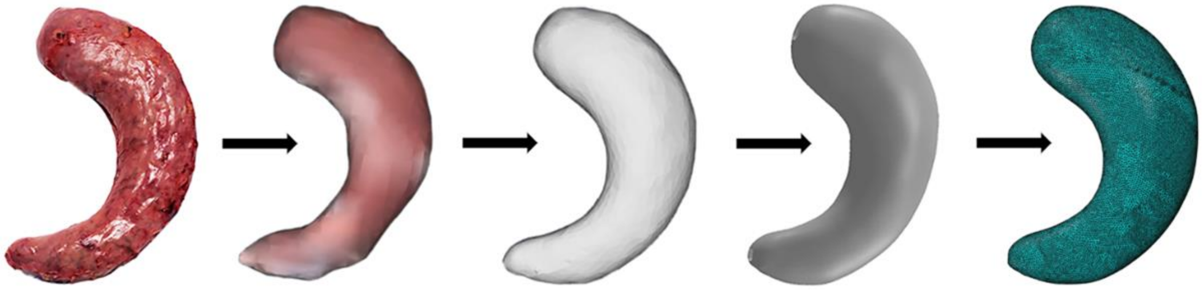


Fig. 2. Reconstruction of a 3*D* model of the stomach using the image-based method. From left to right there are: photograph of the resected stomach, creation of a mesh element from a point cloud, surface generation from the mesh, final virtual solid model, finite element method example (136,664 nodes, 672,184 elements)

The virtual solid models obtained from photogrammetric reconstruction were imported in the general-purpose finite element software Abaqus 2018 (*Dassault Systèmes Simulia Corp., Providence, RI*). The simulations were set to reproduce the experimental inflation process. The stomach brings were kept fixed while a fluid cavity and pressure ramp reaching 10 kPa were imposed, as reported in Fontanella et al. [10]. To identify the optimal set of parameters for the gastric tissues, tuning tests were performed changing the constitutive parameters in order to obtain computational curves as close as possible to the experimental ones and a good agreement between the statistical distribution bands. For the characterization of the gastric tissue a fiber-reinforced anisotropic material formed by two fiber components with viscoelasticity and non-linearity characteristics was considered and the formulation is described in Appendix B.

The preliminary numerical analysis was done with the set of constitutive parameters of the swine gastric tissue. Then, the parameters C_1, C_4, C_6 responsible for the initial stiffness of the ground matrix and of the two families of fibres, were increased. As final tuning, also the α-parameters, responsible of the slope of the exponential growth, was modified.

The finite element discretization led to models having an average number of nodes and tetrahedral elements of 102000 and 485000 respectively. All the simulations were performed by means of a High-Performance Computing Server Fujitsu Primergy RX4770 equipped with two Intel Xeon E7 8890 v4 processors. The mean time of execution of a simulation was about 24 hours running on 20 threads

The experimental data processing followed the protocol already implemented by Carniel et al. [3, 4]. The post-processing was based on the pressure-time and volume-time curves (Fig. 3). In experimental activities, the red points identified the peaks due to the sudden introduction of saline while the green ones corresponded to the pressure after the development of relaxation processes. For post processing, an exponential increasing pressure-volume model was formulated, with different parameters (a_0, b_0) identified for each stomach residue, which best approximates the experimental data identified by the instants of equilibrium (green points in Fig. 3) in correspondence with the relative volume:

$$p = a_0\{\exp(b_0 v) - 1\}, \quad (1)$$

where p is the pressure, v is the volume. The post-processing of the experimental results allowed to characterize the structural behavior of the stomach.

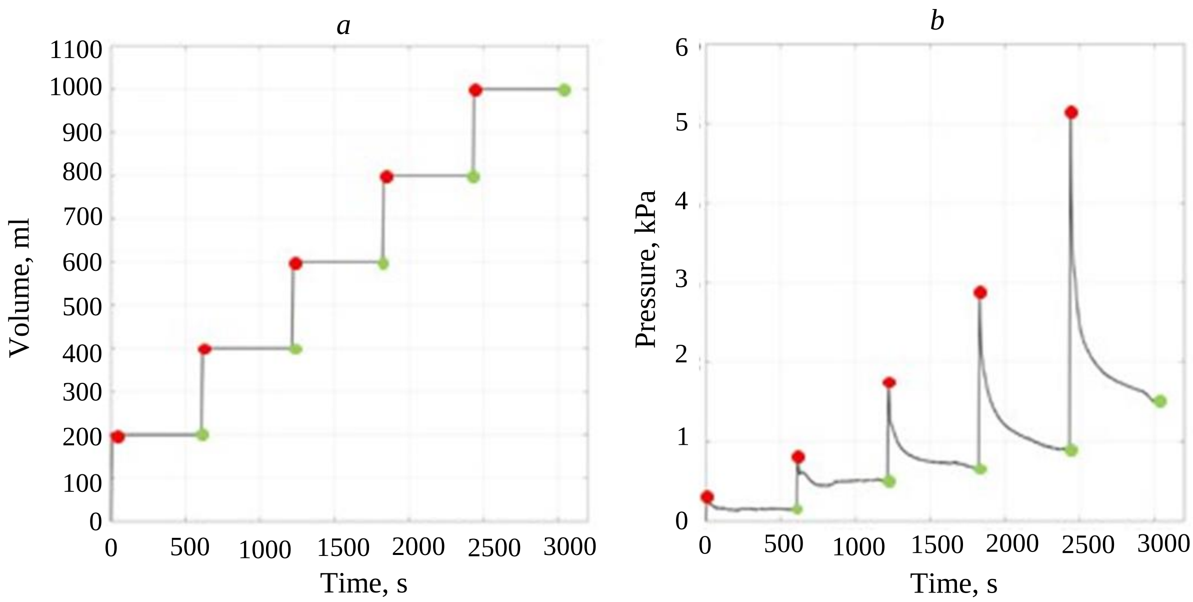
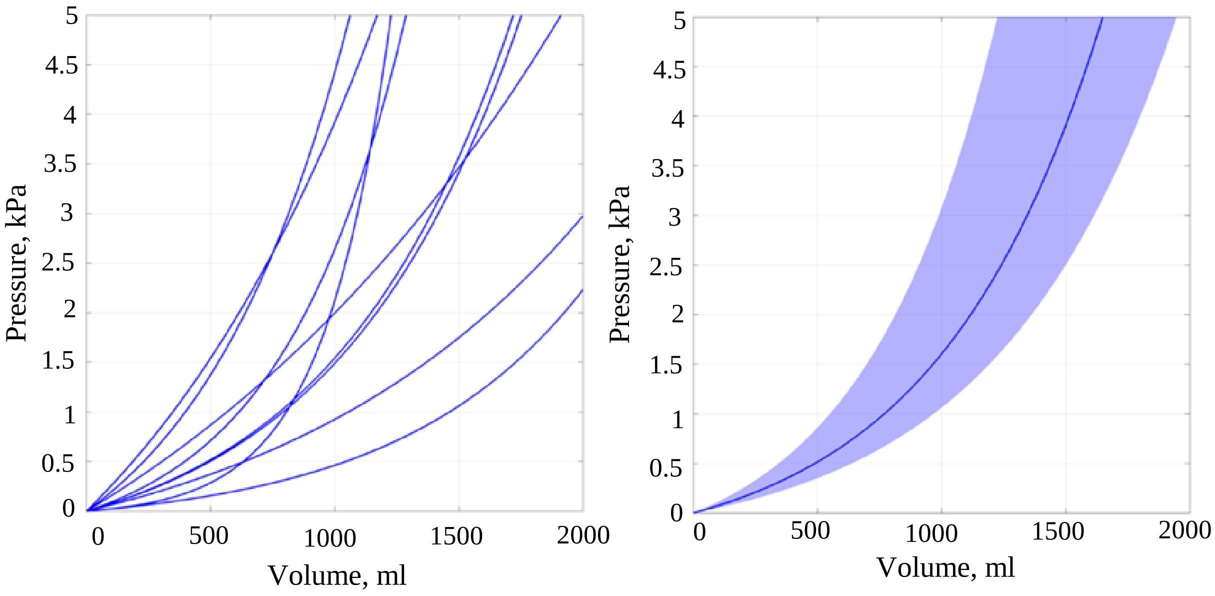


Fig. 3. Experimental data: volume–time relationship (*a*), pressure–time relationship (*b*)

Results

In Fig. 4, the experimental pressure–volume behavior is shown. The collection of pressure and volume data led to pressure–volume curves of the resected stomachs and statistical scatter band (confidential interval 50 %). The results showed the typical non-linear behavior for geometry and material, characteristic of soft biological tissues. There was a first low-tension zone due to the fibers alignment phase, subsequently the high-tension zone was given by the action of the intrafibrillary bonds [3 ,11]. The statistical distribution band was not narrowed due to the high intersample variability.

For the elaboration of the numerical data the same procedure adopted for the experimental data processing was used [4], and comparable results were obtained. The preliminary computational analysis conducted with the set of constituent parameters relating to the swine stomach tissue, reported in Fontanella et al. [10] and the results showed a largely underestimation of gastric stiffness respect to experimental evidences. Various results were



a *b*

Fig. 4. Experimental results: pressure–volume relationship of the nine resected stomach (*a*), experimental statistical distribution (median curve and 50 % scatter band) (*b*)

foreseeable as the numerical analysis mainly depends on the geometry and thickness, moreover the human model consisted in a resected stomach including fundus and corpus regions, while swine model included the whole stomach and, so, also the antrum region. To obtain great agreement between experimental evidences and computational results, simulations were carried out using multiples of the constitutive parameters of the swine gastric tissue. Initially, only the parameters C_1, C_4, C_6 were modified relating to the overall stiffness of the matrix and the fibers. By observing the results obtained, multiplying the C parameters by a factor of 10 underestimated the stiffness of the gastric tissue, instead using a factor of 100 it was overestimated. Following numerous tests with parameters between these two values, a multiplication factor of 80 was chosen because it minimized the error between experimental and computational results. From the results obtained using the parameters relating to the gastric swine tissue, computational evidences showed that the curves did not follow the experimental trend. It led to an increase of parameters α_1, α_4, α_6. The α parameters multiplied by a factor of 1.3 gave the best agreement between experimental and computational results. The final set of constitutive parameters are shown in Table 1. Fig. 5, *a* shows the numerical results of the nine resected stomachs and the Fig. 5, *b* reports the computational scatter band (confidential interval 50 %). Fig. 6 shows the comparison between the experimental data and the computational results. In particular, the curves obtained in the post-processing of the data of resected stomachs are reported in Fig. 6, *a* and the experimental and computational statistical bands with the relative median curves are reported in Fig. 6, *b*.

The dispersion of the computational curves agreed with the experimental results and it established the goodness of the results obtained. The correlation between statistical distributions showed similar trend both as regards the 50 % scatter band and the median curves. Fig. 7 and 8 showed the computational results, in particular the stress-strain distributions of the internal and external layer of the nine resected stomachs. From the results obtained (Figs. 7 and 8), the fundus region presented a maximum principal logarithmic deformation greater than the corpus in all models, while in Fig. 8, the maximum principal stress developed in the corpus was higher than the fundus region. The sharp discontinues between the two regions were due to the choice of constitutive parameters characterizing the fundus and corpus regions which led to a different mechanical response.

Table 1

Optimal set of parameters. *C*-parameters define the initial stiffness of the ground matrix and the fibers, *α*-parameters regulate the variation of stiffness with stretch

Layer	Parameter					
	C_1, kPa	α_1	C_4, kPa	α_4	C_6, kPa	α_6
Corpus connective	1.432	2.112	0.096	4.491	0.056	4.151
Corpus muscular	1.432	2.112	0.056	2.907	0.040	2.413
Fundus connective	1.432	2.112	0.088	1.559	0.032	1.662
Fundus muscular	1.432	2.112	0.080	0.787	0.040	0.815

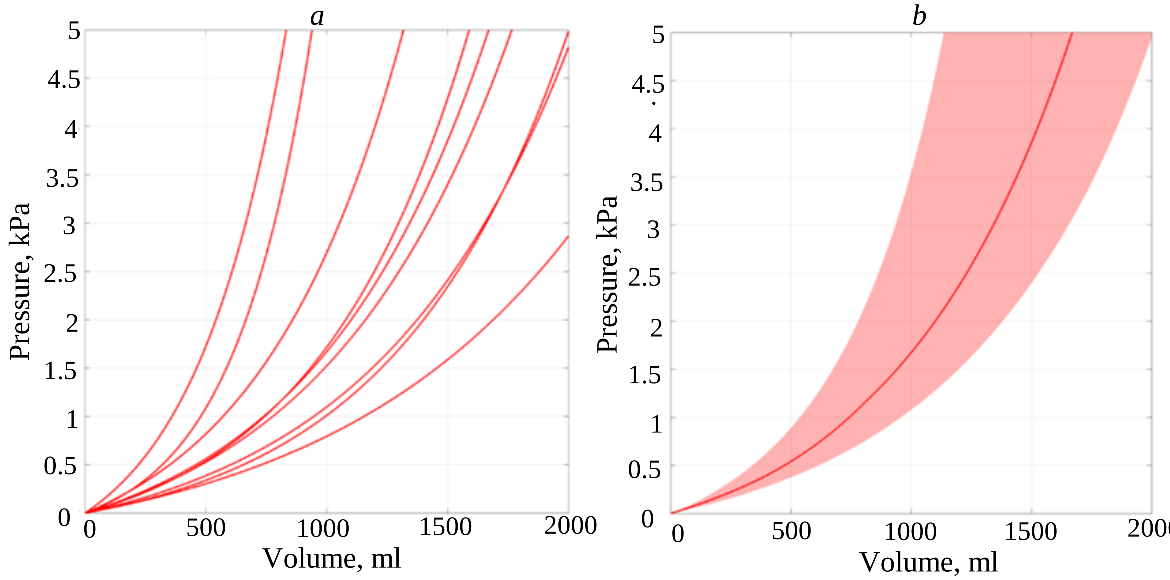


Fig. 5. Computational results: pressure–volume relationship of virtual solid models (*a*), computational statistical distribution (median curve and 50% scatter band) (*b*)

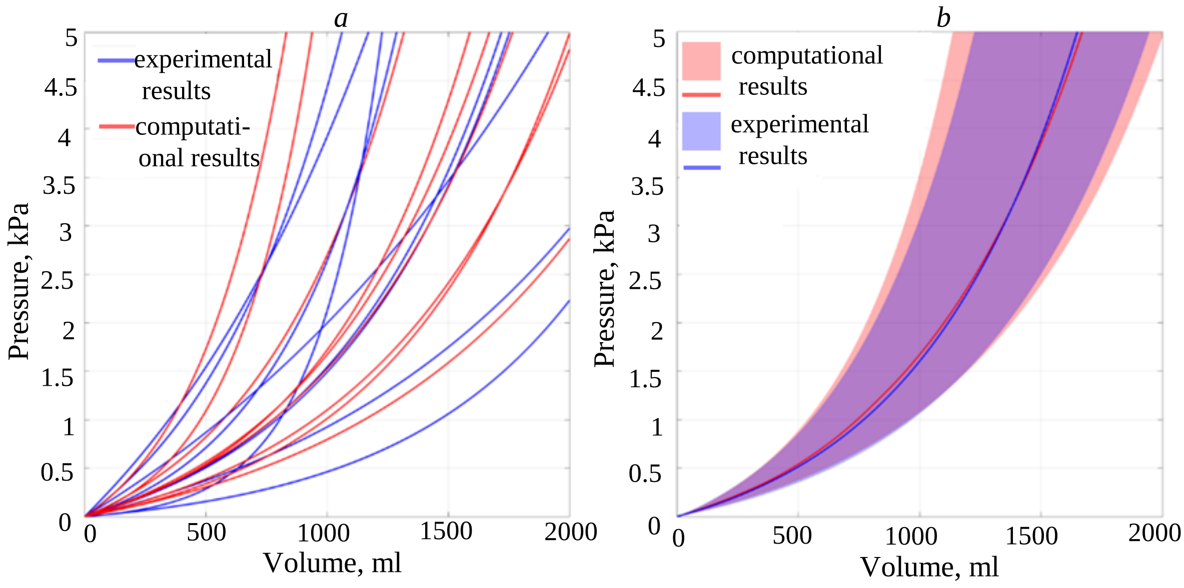


Fig. 6. Comparison of experimental and computational results: experimental pressure-volume curves of resected stomach and computational pressure-volume curves of virtual solid models (*a*), comparison statistical distribution (median curve and 50% scatter band) (*b*)

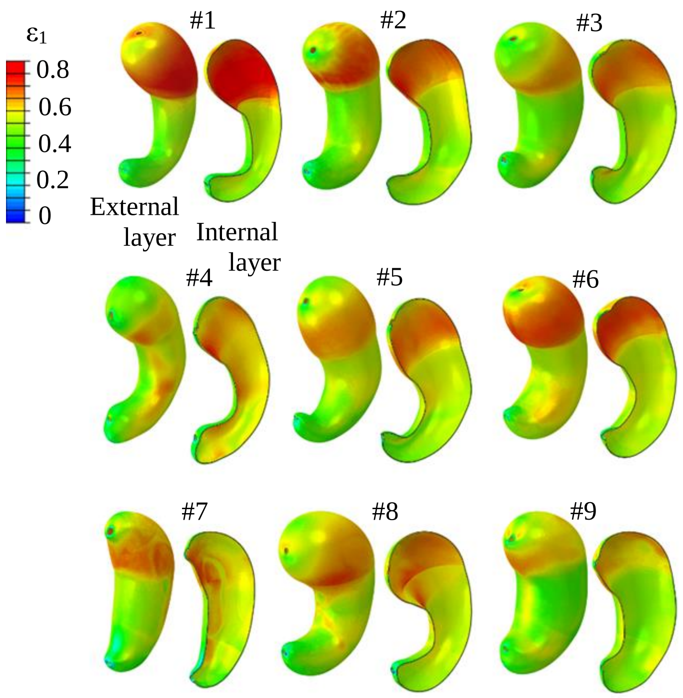


Fig. 7. Results from computational analysis. Logarithmic deformation of the external and internal layer of the nine resected stomach. Results are reported at 5kPa internal pressure

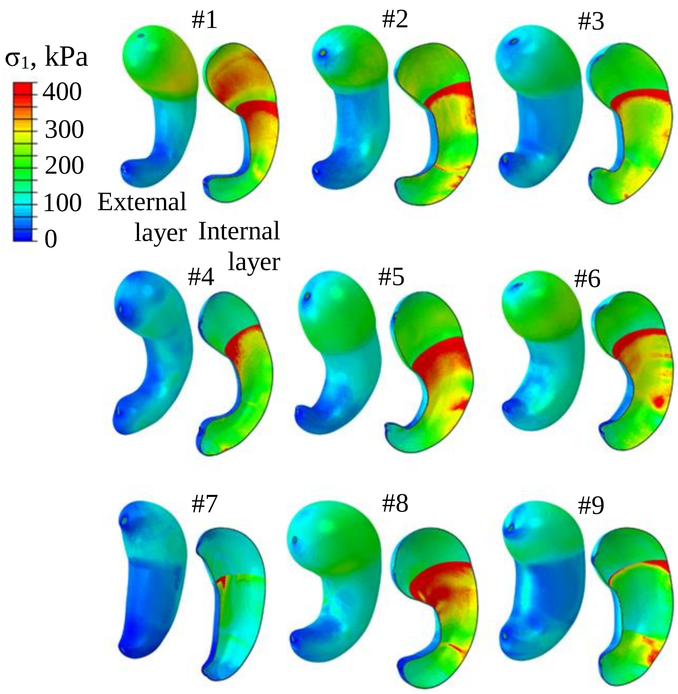


Fig. 8. Results from computational analysis. σ_1 of the external and internal layer of the nine resected stomach. Results are reported at 5kPa internal pressure

Conclusions

Obesity is a global problem, whose social and economic costs are continuously increasing. Bariatric surgery is the most effective procedure for the treatment of obesity, however it is mostly defined because of clinical experience only, while more rational methods are advocated.

The aim of the paper is to characterize the structural behavior of the human resected stomach identifying a set of constitute parameters of the anisotropic fiber-reinforced hyperelastic formulation by comparing experimental and computational results.

An experimental protocol already validated in literature was performed to evaluate and identify the structural mechanical behavior of the resected stomach after laparoscopic sleeve gastrectomy [3, 4]. Gastric mechanical response provided as the pressure–volume relationship was assessed, confirming the typical behavior of biological tissues [11]. The strength of the study pertained to the photogrammetric reconstruction, in fact the virtual solid models are patient-specific in terms of shape, dimension and thickness. This aspect stressed the reliability of numerical analysis whose mechanical quantities, such stress-strain pattern, strongly depend on geometrical features.

The experimental campaign showed a stiffer mechanical response in human samples than in animal ones, leading to an increase in constitutive parameters values. Moreover, the parameters of the corpus region were assumed to be greater than the fundus ones, in according to the studies which considered the fundus more compliant with a reservoir function [14].

The results showed the potential that a computational analysis can assume in the field of surgery and biomechanics, making possible an investigation that experimental methods cannot do. In fact, the numerical approach allows to identify the stress and strain distribution and to carry out, once the model is strongly validated, simulations of new and innovative surgical techniques without performing an experimental activity. In the field of bariatric surgery, the stress and strain distributions are powerful information because they vehicle the activation of receptors, mainly mechano-receptors, whose actions affect the satiety signals and, consequently, weight loss and weight loss maintenance, very important aspects in patients suffering from obesity [2, 20].

The main limitation of the study constated in the small number of samples, as well as the no quantification of the error that the photogrammetric reconstruction process made. Moreover, the stomachs were extracted from patients with obesity, and they could be affected by altered conditions in terms of dimension and thickness respect to normal weight subjects. This work is a starting point for further studies, which are to be considered essential for a more comprehensive and accurate analysis of the mechanical behavior of the human gastric district. Subsequent studies should focus on characterizing the structural behavior of the human stomach considering the whole stomach. However, the reported results are part of an activity under development in the field of bariatric surgery at the University of Padova.

Acknowledgements

The authors warrant that the article is the authors' original work, hasn't received prior publication and isn't under consideration for publication elsewhere. This study has been supported by University of Padova, BIRD 2018, Project n° BIRD183013 titled SMARTBAR: SMART Tools for the effectiveness assessment and the optimization of bariatric surgery.

Appendix A

Fig. 9 proposed the nine resected stomachs, in particular the photos of the samples and the corresponding virtual solid models obtained from the photogrammetric reconstruction used in the computational activity are presented. The intersample variability in terms of shape and dimension was the aspect the authors wanted to introduce in this work because geometrical features affect largely computational results.

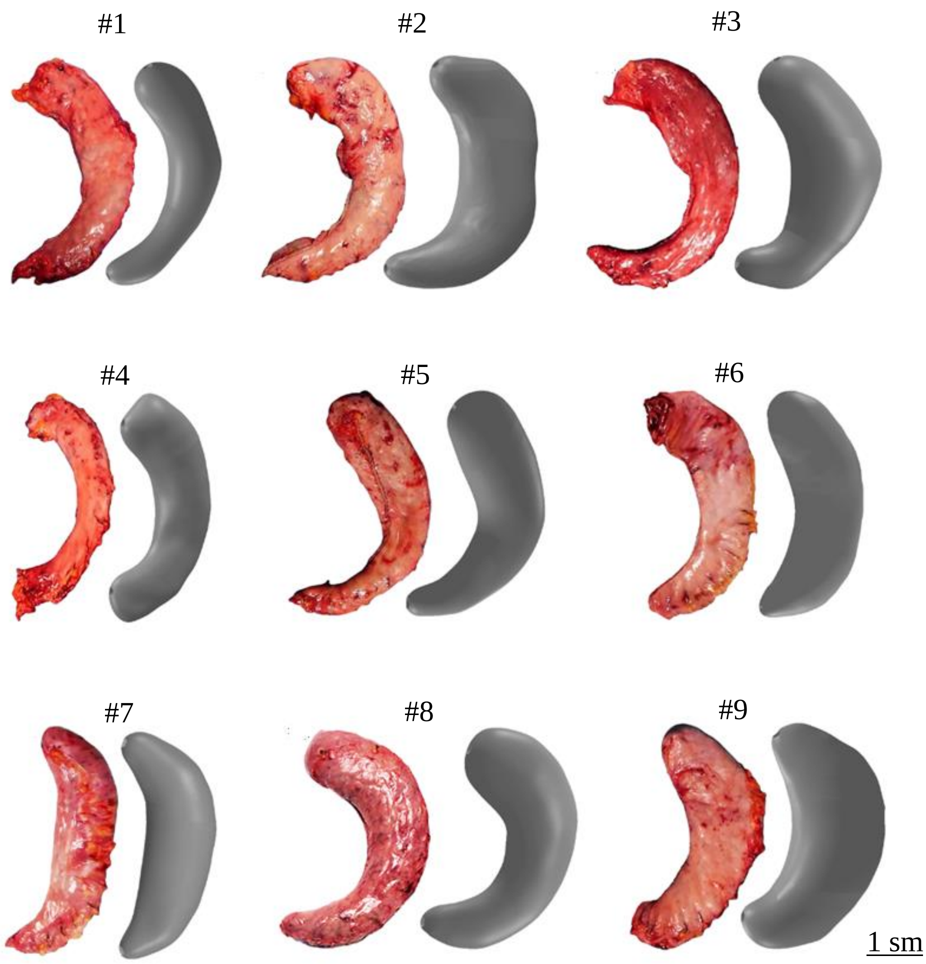


Fig. 9. Photogrammetric reconstruction of nine resected stomachs. On the left the sample obtained from laparoscopic sleeve gastrectomy and on the right the virtual solid model

APPENDIX B

An anisotropic visco-hyperelastic formulation was exploited to characterize the mechanical behavior of stomach tissues, as fully reported in literature [10, 26]. The model was based on the following relationship between the first Piola–Kirchhoff stress tensor *P*, the right Cauchy–Green strain tensor *C* and viscous variables q^i:

$$P\left(C,q^i\right)=2F\,\frac{W^0\left(C\right)}{C}-\sum_{i=1}^{n}q^i, \qquad (1)$$

where W^0 is an hyperelastic potential that specifies the instantaneous response of the tissue, while *F* is the deformation gradient. The evolution of viscous variables q^i was specified by standard differential equations:

$$\dot{q}^i+\frac{1}{\tau^i}q^i=\frac{\gamma^i}{\tau^i}P^0. \qquad (2)$$

Relaxation time τ^i evaluates the time the i^{th} viscous process requiring to develop. Relative stiffness parameter γ^i specifies the contribution of the i^{th} viscous process to the stress drop the material undergoes because of relaxation phenomena.

The fiber-reinforced configuration of both connective stratum and muscularis externa suggested to define the strain energy function by means of contributions from an isotropic ground matrix, as W_m^0, and from fibers, as $W_f{}^0$:

$$W^0(C) = W_m^0(C) + W_f{}^0(C, a_0, b_0), \tag{3}$$

$$W_m^0(C) = -p\left(I_3^{1/2} - 1\right) + \left[C_1/\alpha_1\right]\left\{\exp\left[\alpha_1\left(I_1 - 3\right)\right] - 1\right\}, \tag{4}$$

$$\begin{gathered} W_f^0(C, a_0, b_0) = \frac{C_4}{\alpha_4{}^2}\left\{\exp\left[\alpha_4\left(I_4 - 1\right)\right] - \alpha_4\left(I_4 - 1\right) - 1\right\} + \\ + \frac{C_6}{\alpha_6{}^2}\left\{\exp\left[\alpha_6\left(I_6 - 1\right)\right] - \alpha_6\left(I_6 - 1\right) - 1\right\}, \end{gathered} \tag{5}$$

where I_1 and I_3 are the first and the third invariants of the right Cauchy–Green strain tensor, a_0 and b_0 define the orientation of collagen (within the connective stratum) or muscular (within the muscularis externa) fibers, while I_4 and I_6 are structural invariants that specify the square of tissue stretch along directions a_0 and b_0, respectively. The term p is a Lagrange multiplier that ensures the incompressibility constraint. Constitutive parameter C_1 specifies the tissue initial shear stiffness, while parameter α_1 regulates the nonlinearity of the shear response. Parameters C_4 and C_6 are constants that define the fibers initial stiffness, while α_4 and α_6 depend on fibers stiffening with stretch.

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