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Cyclic pulse loads pave the road to the GRIP concept in abdominal wall reconstruction

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Abstract

Aim: Durable reconstruction of the abdominal wall needs to be assessed in a lifelike experimental setting and consider the reconstructed abdominal wall as a coherent compound. Our aim was to evaluate broader possibilities in preclinical testing and to deepen the understanding of the biomechanical influences.

Methods: We developed a test bench that allows studying a compound under cyclic, repetitive loads. Pulse loads transmit energy to the abdominal wall repeatedly. The amount of energy is related to the load characteristics. We used porcine bellies with a round central (5 cm) defect. They were bridged in a sublay position with Cicat Dynamesh®. Further defects, located in an additional incision, were sutured in a standardized small-bite technique. We varied the number of loads, the maximum peak pressure, the pressure plateau length, and the impact area size.

Results: Increasing the peak pressure by 30 mmHg lowers the durability by about 20 %. Prolonging the plateau phase led to a significant durability decrease. During the first 100 dynamic intermittent strain (DIS) impacts, the major tissue deformation and the majority of failures occur. Beyond the 425th DIS impact, about 10 % more failures occur. Increasing elongation and deformation of the tissue raise the likelihood of failure.

Conclusion: If the compound does not establish a strain-stable condition during the period of plastic deformation, failure occurs. The outcome does not only depend on the reconstruction technique but also on the external influences acting on the abdominal wall compound. Considering the biomechanical reality is important for open and minimally invasive abdominal wall reconstruction.

Keywords: Incisional hernia, biomechanical repair, abdominal wall reconstruction, multiaxial tissue assessment, low cyclic fatigue (LCF) testing

INTRODUCTION

A durable repair of the abdominal wall must be assessed in a lifelike setting. The human abdominal wall gets stressed by repetitive intraabdominal pressure peaks every day[1]. The tissue and the repair materials get loaded in unison[2]. Our assessments follow modern biomechanics. We must consider all components of a repaired abdominal wall as a coherent compound. For this purpose, we developed a test bench [Figure 1]. It allows the study of such a compound under cyclic, repetitive loads[3,4]. Repetitive high peak pressures occur during daily activities, such as coughing or sports (DIS = dynamic intermittent strain). Pressures of more than 200 mmHg can develop for less than 1 s[2,5]. These inevitable loads increase the risk of a failed reconstruction[6].

The repaired abdominal wall can be considered as a layered polymer. It consists of the tissue with a textile mesh and fixation. Pulse loads repeatedly transmit energy to the abdominal wall. The amount of transmitted energy is related to the pressure peak, the impact area, and the duration of the cyclic pulse, which may differ during activities such as coughing, weight-lifting, or similar movements. The dissipation of this energy within the compound depends on the temperature and material properties of a component. The load transmission happens at the component interfaces. Currently, there is no unifying theory considering the shakedown of Elastoplast polymers. However, recent experiments have verified the validity of the stability limit analysis model of a multilayer structure[7].

A cyclic load bench test can factorize the influences named above independently. Based on the mesh-defect area ratio, it is possible to relate the clinical and experimental results to a mathematical formula[3,8]. A stable repair needs to reach a critical resistance toward impacts related to pressure (CRIP)[9]. Any repair gains resistance toward impacts related to pressure (GRIP). Once the acquired GRIP surpasses the necessary CRIP, the repair seems durable[10]. The design of a repair has to consider the area of the unstable abdominal wall and its distention. The GRIP/CRIP concept is applicable to open and minimally invasive/robotic abdominal wall repair. We gain deeper insights into these topics through technology. Segmentation and AI analysis can process data from CT scans. We use abdominal scans at rest and during the Valsalva maneuver [Figure 2][9].

Suture failure begins early after closure[11,12]. The interplay of the biomechanical properties determines the long-term durability of a repair. These properties include the dynamic stiction of the materials, the closure technique, the tissue behavior of the individual, and, importantly, the type of loads applied[9,13]. The size of an incisional hernia increases over time and with the intensity of the loading[14]. A larger hernia requires higher GRIP. The neglect of the biomechanical reality results in a more comple × repair and raised costs to society[15]. The US spends over $ 7 billion every year on repeated incisional hernia repair, sick leave, and early retirement[16]. In Germany, the costs amount to at least € 1.8 billion. Using the GRIP concept, more than 99 % of the patients are pain-free and have no recurrence after one year[3,10].

This article describes the state-of-the-art of cyclic load bench test design and requirements for the future. It illustrates the complexity and the broad range of influencing factors when considering cyclic impact loads.

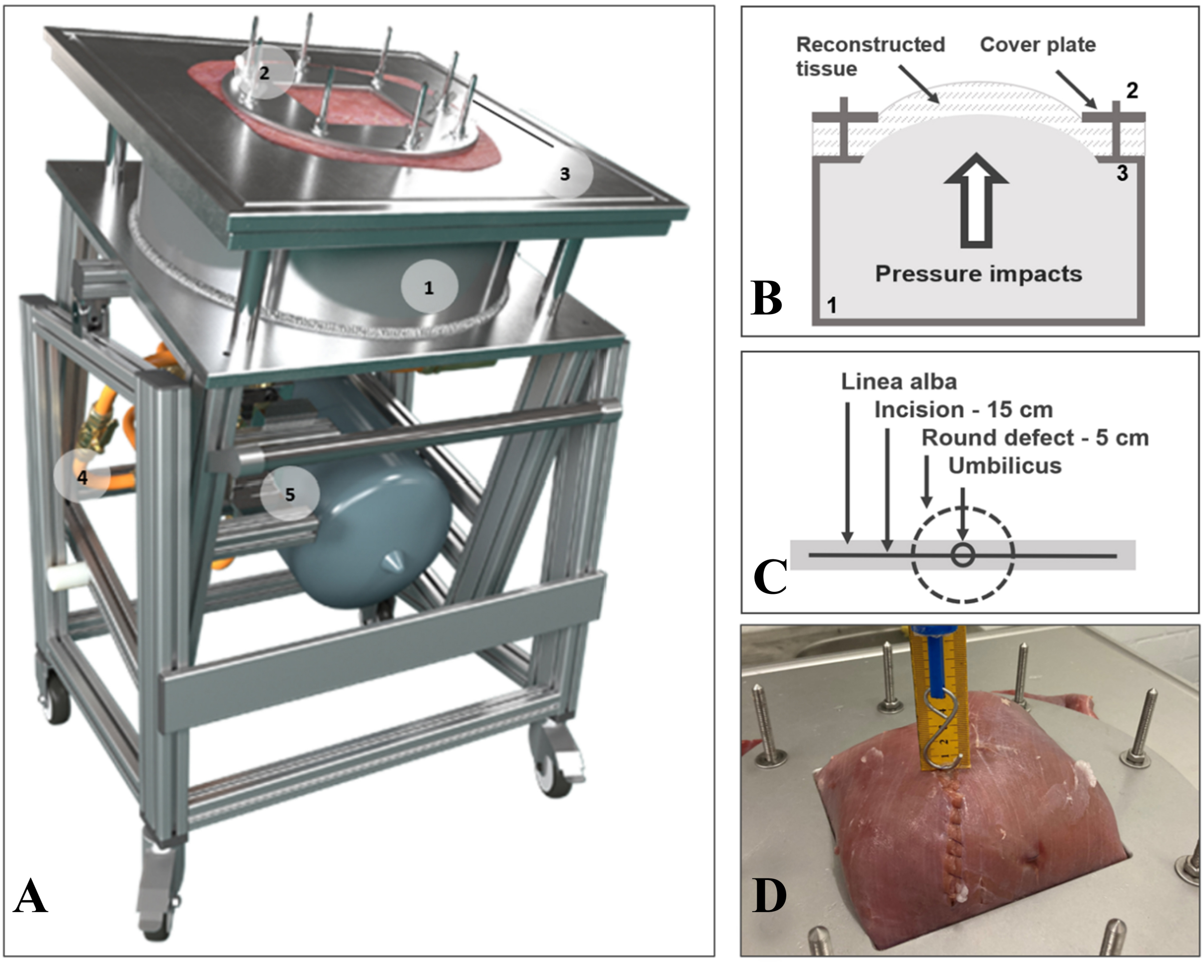

Figure 1. (A) Outline of the test bench and its components; 1 - water reservoir, 2 - cover plate for tissue fixation, 3 - top plate with opening for hydraulic pressure impact, 4 - inlet and outlet pipes and valves, 5 - pressure accumulator. (B) Schematic, labeled illustration of the function of the bench test. (C) Outline of the prepped defects**.** (D) Reconstructed tissue during pressure impact with measurement of the suture tension.

Experimental analysis of the stress limit of the compound of the abdominal wall and reconstruction materials will provide crucial insights. It can pave the road for successful surgical repair of herniated abdominal walls. In analogy to current material sciences for solids, it will be possible to measure cyclic load, strain, and stress in the future for abdominal wall repair.

METHODS

Consideration of influences on the abdominal wall and hernia repair

Various variables influence the simulation of an abdominal wall load. Table 1 points out these variables. A lifelike test requires a multiaxial pressure load. It represents coughing, lifting, or a Valsalva maneuver. These three activities differ in the progression of the load on the abdominal wall. They must be distinguished from lower, chronic pressure elevations[17-19].

Force can be applied either longitudinally, perpendicularly, or multiaxially. Each load mode can be described mathematically. Likewise, we must consider the tested compound materials. This paper examines the potential for different loads and their influence on the loaded structures. We apply the results to our

Table 1. Variable influences on an abdominal wall load

	Peak	Plateau	Continuous	
			Low level	High level
Mode of load	Cough	Dynamic lift	IPAP/ICU	Valsalva
Amount of impacts	425[1]	Few	Continuous	Once
Impact area	Normal/perpendicular strain	variable	Shear strain	
Tensile load	Youngs elastic modulus	Poisson's ratio	Shear modulus	
	Interrelated and not to be derived from each other due to anisotropy			
Materials to be tested	any	any	any	
Impact area	Small or large	Small or large	large	
Conditions	Wet	Wet	Wet	
Temperature	Room or body	Room or body	Room or body	

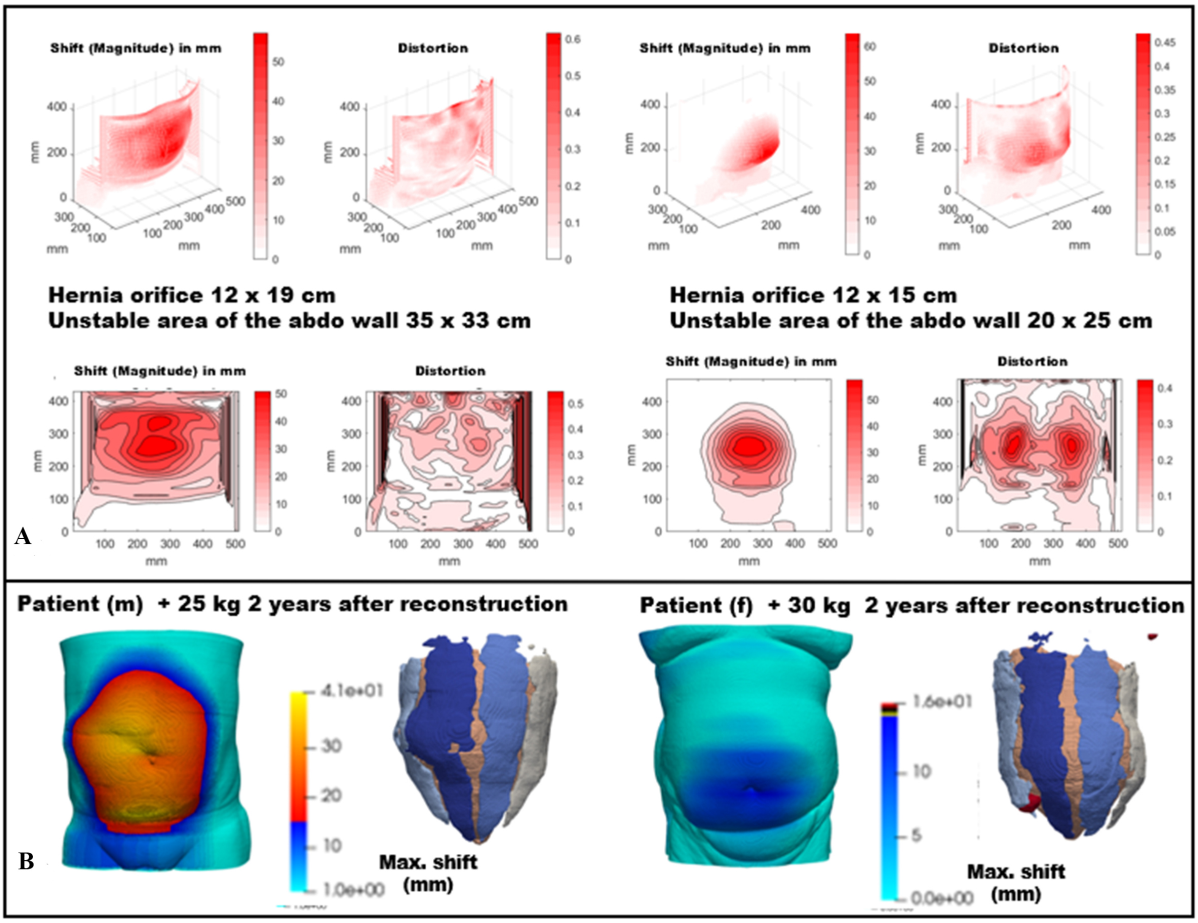

Figure 2. (A) Analysis of assessment of the abdominal walls of a patient with computed tomography (CT) at rest and during the Valsalva maneuver (CTAV) in two herniated patient cases (left and right picture group). The panel shows the shift and the distortion in red shades. The area of greatest movement is shown in bright red, fading with the amount of movement. (B) CT scans of the abdomen during the Valsalva maneuver of non-herniated patients. Right**:** a female patient with a weight gain of 30 kg presented with mild pain two years after reconstruction with a slight distension on the left-hand side and a circumscript detection of protrusion on the right-hand side by analysis with artificial intelligence (right middle picture) with a shift of the ventral abdominal wall of maximally 16 mm (far right picture) Left: a male patient with a weight gain of 25 kg presenting with pain after playing soccer two years after the reconstruction (L-shaped incision for liver transplantation) with a bulge in the right lateral extension of the L-shaped incision without a reherniation (far left picture) and a shift of the ventral abdominal wall of 41 mm as a maximum (left middle picture).

current installation of the bench test design. The bench test can assess a variety of reconstruction techniques and materials. It allows examining commercially available materials by factorizing their properties.

In general, porcine abdominal walls or bovine flanks are suitable model tissues. The porcine tissues consist of all abdominal wall layers that have similar characteristics to the human abdominal wall. The bovine tissues are thinner and include only the oblique abdominal muscles. The two tissues differ in their elastic properties and have distinct median elasticities[20]. That allows mapping the elastic bandwidth of the abdomens of patients. Human abdomens show up to 18-fold variability in tissue extensibility. The variation is lower in porcine and bovine tissues with a ratio of 1:4 but covers 95% of the variation in 123 patients[10]. Thereby, the extensibility behavior of human, porcine, and bovine tissues is comparable with a median of 20%. A variety of defects differing in form (incision, circular, rhomboid, or elliptic), size, and direction (median, lateral, transverse, horizontal) can be applied. The defects can be reconstructed with sutures and meshes in all techniques. This is our standard for the evaluation of coefficients for meshes, fixation elements, and techniques. An EPDM® plate is used to limit the impact area. The area can be adjusted between 20 cm^2 to 496 cm^2. Peak pressure values can be varied between 50 and 350 mmHg. Basal pressures can be adjusted from zero up to 80 mmHg. It is usually kept between 4 and 10 mmHg. Pressure plateau values are held at a minimum of 100 msec but can be increased if needed.

For the purpose of the experiments reported here [Table 2], we used porcine bellies with a 5 cm large round central defect [Figure 1, right]. These defects (ES 1-13) were bridged in a sublay position with a 15 × 15 cm large Cicat Dynamesh®. In series 14-16, the defects were located in an additional 15 cm incision to simulate an incisional hernia. We sutured them in a standardized small-stitch-small-bite technique. We used a 2-0 PDS® suture with a suture-to-wound-length over 4:1. Then we mounted the tissues on the test bench [Figure 1, left]. A third of our patients cough more than 400 times in the first 24 h postoperatively[1]. Accordingly, we loaded the reconstructed tissues 425 times with cyclic pressure impacts. One series was conducted with 1,000 impacts, simulating a worst-case postoperative scenario. We varied the maximum pressure peaks to 120, 150, 180, 210, and 240 mmHg. The length of the maximum pressure plateau was 0.1, 0.2, or 0.4 seconds. We conducted two series with a higher basal pressure (set off) of 40 or 80 mmHg. Two different cover plates for the test bench were used. One had a square 16 cm (256 cm^2) large opening. The second one had a circular 25 cm (490 cm^2) large opening. The experiment was finished when the mesh dislocated or the suture reopened, revealing the plastic sack beneath. Table 2 contains a detailed overview of the conducted experiments and the individual setup.

Application of biomechanical parameters to patient care

Figure 2 shows the analysis of the abdominal wall CT scans of two patients. The shift and distortions were assessed in mm while resting or during the Valsalvas maneuver (CTAV).

The bench test mimics these lifelike conditions. It assesses the behavior of the abdominal wall and an existing defect during stress. The knowledge from our experiments and the preoperative CT scans [Figure 2] enables the application of biomechanical parameters to patient care [Figure 3], as already published[2,7,8].

RESULTS

Influence of the test bench parameters on the abdominal wall and hernia repair

Our test bench provides a suitable assessment method by examining compounds under lifelike circumstances[4]. Experimental series (ES) 1-13 studied the tissue behavior under varying maximum pressure and varying pressure plateau lengths.

Table 2. Top: Overview of the 16 experimental series presented here, with ten valid experiments in each series, totaling 160 experiments, with the experimental boundary conditions and the likelihood of a secure closure (LOSC) Bottom: Explanation of the abbreviations in the title of the experimental series (ES)

Series	Title	Tissue	Defect shape	Defect size (cm)	Mesh size (cm)	Suture USP	SSSB / LSLB suture	Standardization	Amount of stitches (n)	S:W-L-Ratio	LOSC (%)
ES 1	240-0.1sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	30
ES 2	210-0.1sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	50
ES 3	180-0.1sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	70
ES 4	150-0.1sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	40
ES 5	120-0.1sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	90
ES 6	210-0.1sP-DC5-DMesh-40off	bovine	circular	5	15 × 15	-	-	-	-	-	20
ES 7	210-0.1sP-DC5-DMesh-80off	bovine	circular	5	15 × 15	-	-	-	-	-	-
ES 8	150-0.1sP-DC5-DMesh-1000DIS	bovine	circular	5	15 × 15	-	-	-	-	-	70
ES 9	210-0.2sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	40
ES 10	180-0.2sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	30
ES 11	150-0.2sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	40
ES 12	210-0.4sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	0
ES 13	180-0.4sP-DC5-DMesh	bovine	circular	5	15 × 15	-	-	-	-	-	20
ES 14	210-0.1sP-INDC5-PDS20-SBs	porcine	incision+circular	15 + 5	-	2-0	SSSB	yes	21	4.1	100
ES 15	210-0.1sP-INDC5-MM20-SBs-cO	porcine	incision+circular	15 + 5	-	2-0	SSSB	yes	27	4.5	90
ES 16	210-0.1sP-INDC5-PDS20-SBs-cO	porcine	incision+circular	15 + 5	-	2-0	SSSB	yes	23.5	4.3	40

240/210/180/150/120	Peak pressure (mmHg)	PDS20 / MM20	USP 2-0 suture PDS® or MonoMax®
0.1/0.2/0.4 sP	Length of pressure plateau (s)	cO	Circular opening of fixation plate (A = 490 cm²)
DC5	Defect circular 5 cm	40/80 off	40 or 80 mmHg offset pressure
INDC5	Incision 15 cm + defect circular 5 cm	1000 DIS	1000 DIS were conducted
Dmesh	DynaMesh Cicat® 15 ×15 cm		

The likelihood of a secure closure measures how many out of ten reconstructions (in %) withstood the number of impacts (n) given on the x-axis.

Figure 3 shows that, in this case, an exclusively bridged 5 cm round defect with a sublay mesh is an unstable reconstruction. Only low peak pressures, such as 120 mmHg or 150 mmHg, can be withstood with failure rates lower than 20 % (circle and square graph). The mesh dislocates in up to 70 % of the cases when the peak pressure rises to 240 mmHg (rhombic graph). When lowering the peak pressure by 30 mmHg, the

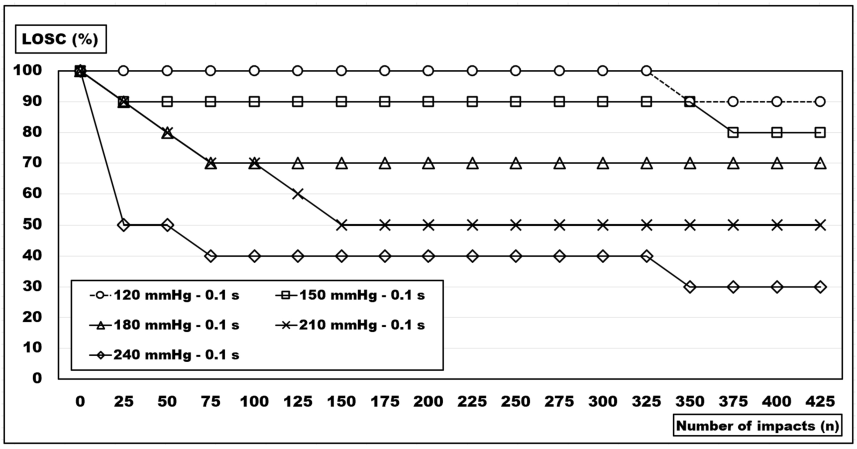

Figure 3. Likelihood of a secure closure (LOSC) until dislocation of the sublay mesh bridging a 5 cm round defect in bovine tissue as a function of the number of DIS impacts, with peak pressures between 120 and 240 mmHg applied for 0.1 s.

LOSC rises by about 20 %.

These experiments resulted in the definition of load limit curves [Figure 4]. The curve illustrates the significantly lower durability for higher maximum pressures (240 *vs.* 120 mmHg $P = 0.0155$). The prolongation of the pressure plateau length showed the same effect (210 mmHg peak with a plateau length of 0.4 s *vs.* 0.1 s $P = 0.0078$). The load limits for shorter pressure plateaus result in a similar correlation with the LOSC. The graphs tend to run parallel.

A worst-case scenario with up to 1000 pressure peaks, respectively, postoperative coughs, is illustrated in Figure 4.

Beyond the 425th DIS impact, about 10 % more failures occur. After the 500th impact up to the 1000th impact, the durability remains stable [Figure 5].

When using the cover plate with the larger, round (ES 15 + 16) instead of the smaller, square opening (ES 14 + all other ES), significantly higher failure rates occur ($P = 0.00016$). This is accompanied by a significantly greater elongation (about 4 cm) and deformation of the tissue ($P = 0.0357$) when using the larger opening. The results support the logical deduction that the greater elongation and deformation of the tissue increases the likelihood of failure.

The incision elongates with the number of cyclic loads applied. The most deformation, so-called plastic deformation, occurs during the first 100 DIS impacts. After that, only slight deformation of the tissue takes place. A steady state of tissue deformation is reached after 100 DIS impacts.

Figure 6 illustrates that the major plastic deformation takes place during the first 100 DIS impacts. This is also the period when most failures (72 %) occur [Figure 7]. After that, only 11%-18 % of the failures occur every 100 impacts.

DISCUSSION

Cyclic loading as a new concept in abdominal wall reconstruction

Studies on tendons show that not the suture material but the tissue is the predominant weak point[21]. The

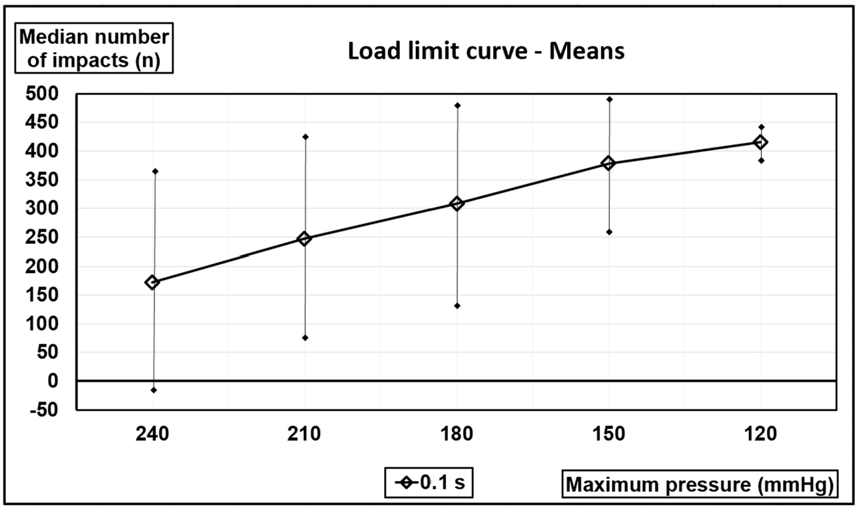

Figure 4. The load limit curve plots the mean number of withstood impacts with their standard deviation at different peak pressure maxima with 0.1 seconds pressure plateau lengths.

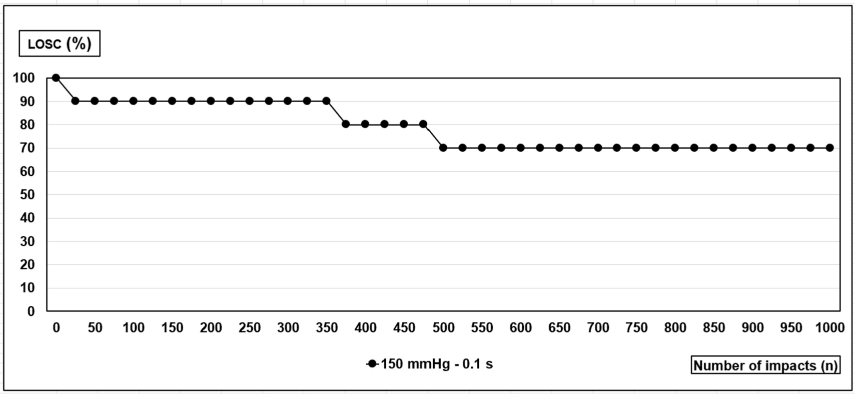

Figure 5. Likelihood of a secure closure (LOSC) until dislocation of a 15 × 15 cm mesh under a 5 cm large round defect under exposure to 1000 DIS impacts with 150 mmHg pressure peaks for 0.1 s each.

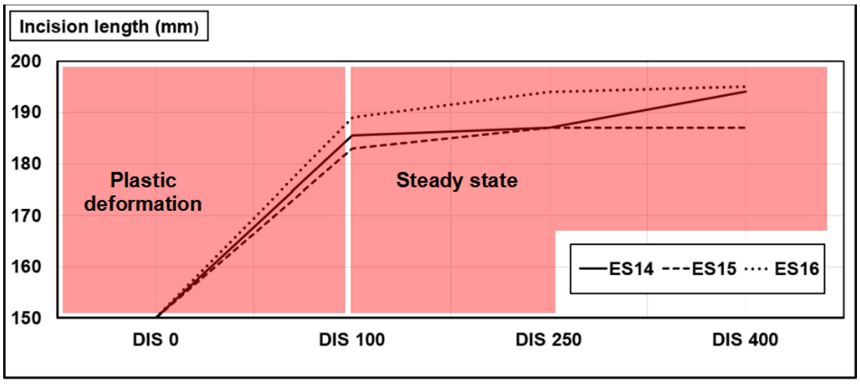

Figure 6. Measured median length of the sutured incision in ES 14 – 16 before cyclic loading and after 100, 250, and 400 DIS impacts.

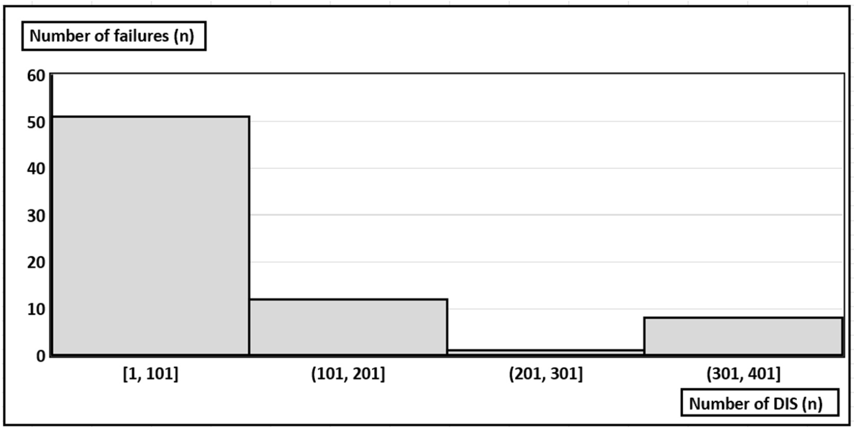

Figure 7. Number of failures in 140 experiments grouped by the time of their occurrence, accumulating to 72 failures in total. The occurrence of failure is divided into four groups of 100 DIS impacts each, comprising the observed failures. ES 7 and ES 14 are missing since no failure was observed in these experiments.

tensile strength of the reconstruction materials is greater than that of the tissues. This is a requirement for market certification. Thus, destructive examination of the reconstruction materials after market approval is not decisive. The examination for fatigue of the entire compound under cyclic loading is necessary[22].

ASTM E606 is a standard test method working with uniaxial forces. It measures the fatigue properties of homogenous materials due to strain[23]. ASTM E606 needs to be expanded for organic polymers. Tissues repaired with textile meshes require testing for destructive and healing processes[24]. There are little data for biological systems. Debonding and ligament fracture are also likely to occur in a biological matri × as well[25]. Non-crosslinked collagen elongates to weak fiber sheets without adequate retention force[26]. Overstrained repairs will not heal. A dehiscence occurs early, and incisional hernias develop as a consequence[27].

Our bench test enables low cyclic fatigue (LCF) testing. Testing of abdominal wall closures ideally needs to be performed repetitively almost 500 times. This ensures a realistic assessment of durability in the patient under everyday conditions [Figure 3]. Considering other test designs (e.g., the AbdoMan[28]), our test bench is the only one that allows this necessary repetitive assessment. The biomechanical influences acting on an abdominal wall repair determine its outcome. The higher the applied peak pressure, the more energy is transmitted to the mesh-tissue compound. More failures occur [cf. Figure 4]. For clinical practice, it is relevant to keep intraabdominal pressure low after surgery. This can be achieved by avoiding stress or by supporting the abdominal wall in stress distribution.

Our results show that an increase in intraabdominal pressure and variations in the biomechanical circumstances have a clear impact on the outcome of the reconstruction. Therefore, in clinical practice, two intervention options emerge for the stabilization of the abdominal wall reconstruction. One option is to minimize the load through measures such as a resting period. Also, optimal coordination with the anaesthesiologist regarding extubation and postoperative cough relief are viable options[29]. Alternatively, a reconstruction of the abdominal wall that reliably withstands the biomechanical stresses can be considered. The GRIP/CRIP concept with CTAV allows a biomechanically calculated repair that remains stable after three years of follow-up, with recurrence rates under 1 %[30].

In addition, force absorption and distribution by the abdominal wall could be supported by an abdominal binder. Whether a simple abdominal binder provides a significant benefit is currently undetermined[31].

The concept of cyclic load over time is vitally important but often underappreciated by hernia surgeons. Surgeons must be aware of the biomechanical conditions within the abdomen, highlighting the need for continuous education and research. Biomechanical considerations form part of the hernia base camp endorsed by the European Hernia Society[32].

Plastic shakedown as a requirement for healing - options for the behavior of reconstructed tissue

Figure 8 illustrates the biomechanical behavior patterns of reconstructed tissues under cyclic loading. Before the start of the experiment, no deformation is visible [Figure 8A]. The compound deforms within the first few cycles [Figure 8B]. Two scenarios can develop from this point. Firstly, the first cycles exceed the yield limit through the total amount of subliminal impacts. The compound is not able to withstand the cyclic load. It deforms in each individual cycle [Figure 8C]. Deformation can be visible as elongation or slackening, which forms an intermediate state and can progress to complete failure, a hernia. Secondly, after a certain number of load cycles, the deformation changes from plastic to elastic behavior [Figure 8D]. The original state is no longer restored, but failure does not occur either. This is called a plastic shakedown. If the cycles are below the failure limit within the loading period allowing a steady state, the compound bears the load successfully[33,34].

The goal of abdominal wall closures is to achieve a "strain stable condition" without failure of the reconstruction. The strain-stable condition is considered to be achieved when the compound has survived 425 impacts. If 425 impacts are not achieved, failure of the compound occurs in a smooth transition. Suture failure mostly begins early after surgery[9,27], such as major tissue deformation [Figure 6]. A resulting fascial dehiscence that can lead to the tearing of the suture line[35] is mostly invisible[11,12]. Herniation usually follows fascial dehiscence that expands to more than 11 mm in four weeks[36].

During the first 100 impacts, the highest rate of failures occurs. This matches our finding that the major plastic deformation takes place during the first impacts [Figure 6]. When using a cover plate with a larger opening, greater elongation and deformation of the tissue are visible. This is accompanied by significantly higher failure rates. Both findings show the same result. The greater the deformation of the tissue appears, the higher the likelihood of failure. If the compound is unable to establish a strain-stable condition called plastic shakedown, failure occurs.

In conclusion, realistic repetitive cyclic loading is required for us to assess the abdominal wall properties and the durability of a reconstruction. A lifelike evaluation of the reconstruction durability can only be provided by our bench test protocol. Pulse loads transmit energy to the abdominal wall repeatedly. The amount of energy is related to the peak pressure, the impact area, and the duration of the cyclic pulse. The higher the applied peak pressure, the more energy is transferred to the mesh-tissue compound, leading to more failures. In most cases, increasing the peak pressure by 30 mmHg lowers the durability by 20 %. The elongation of the plateau phase led to a significant decrease of the durability. Simulating a worst-case scenario with 1000 DIS impacts, about 10 % more failures occur beyond the 425th DIS impact. However, after the 500th impact up to the 1000th impact, the durability remains stable.

During the first 100 DIS impacts, the major part of the tissue deformation takes place. Also, a major number of failures occurs during that period. Using a cover plate with a larger opening leads to greater tissue deformation. This results in significantly higher failure rates. The greater the deformation of the tissue

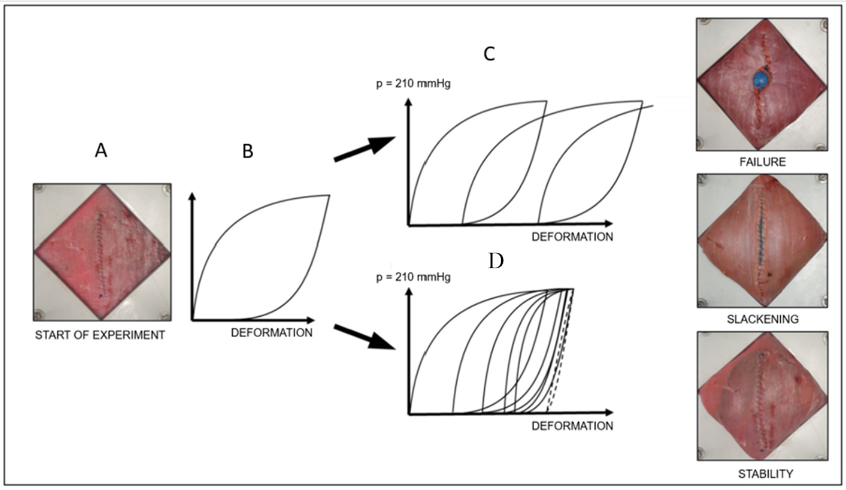

Figure 8. Possible behaviors and outcomes of a compound under repetitive cyclic loading.

appears, the higher the likelihood of failure. A strain-stable state of the compound needs to be achieved. This allows a durable repair. The strain-stable condition is achieved when the compound has survived 425 impacts. If the compound is unable to establish the strain-stable condition called plastic shakedown, failure occurs.

Preoperative CT Scans with Valsalva visualize the importance of lifelike bench test assessment. The behavior of the abdominal wall, the hernia, and additional unstable zones are visible. According to our findings, high intraabdominal pressures should be avoided postoperatively. It increases the failure rates significantly. The early period seems to be the most vulnerable for deformation and failure.

DECLARATIONS

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Authors' Contributions
Performed the data analysis and wrote the article: Lesch C
Performed the experiments: Kugel F, Ludwig Y
Provided crucial thoughts and content for the discussion of tissue behavior and plastic shakedown: Uhr K
Leads the construction of the bench test as well as its maintenance: Vollmer M
Contributed important thoughts and discussions for the construction of the experiments and the paper: Nessel R
Closely guided the execution of the experiments, designed parts of the experiments, and continuously supervised the paper: Kallinowski F

Availability of data and materials
The raw data supporting the conclusions of this article will be made available by the authors without reservation.

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Conflicts of interest

FK received financial and material support by Baxter, Becton Dickinson, Corza Medical, Dahlhausen, Ethicon, FEG, GEM, Medtronic, Olympus and pfm medical based on a Third-Party-Funding-Agreement with the Heidelberg University and / or with Asklepios proresearch. The other authors declare no conflict of interest.

Ethical approval and consent to participate

The research was conducted after building a bench test for low cyclic loading of tissues. Human material was not used. Accordingly, no informed consent from patients was required. The ethical approval to use animal tissues was given by local authorities according to European law with the permission DE 08 221 1018. Figure 2 requires courtesy of Samuel Voss, who provided the pictures. The studies for computed tomography at rest and during the Valsalva maneuver were reviewed and approved by the Ethics Committee of the Heidelberg University vote S-522/2020.

Consent for publication

Not applicable.

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